Canadian Food Inspection Agency
Agence canadienne d'inspection des aliments

Fish Inspection Program

FACILITIES INSPECTION MANUAL

Canada

FOREWORD

There are many important factors involved in the production of a safe, wholesome and good quality product. Processing facilities must be designed, constructed and operated in such a way that acceptable quality, safety and wholesomeness of the product are maintained throughout the process. In order to assist in communicating the needs associated with the production of a safe wholesome product which conforms to all requirements of the Canadian Food Inspection Agency, the "minimum" requirements have been interpreted from the *Fish Inspection Regulations* and compiled in this manual.

Working jointly with the fishing industry of Canada, to protect and enhance Canada's reputation as a supplier of safe and good quality fish products to world markets, this manual will assist companies in complying with the *Fish Inspection Regulations*.

Bulletin

TO: All Holders of the Facilities Inspection Manual

SUBJECT: Guidance for Acceptable HACCP Controls for Live Molluscan Shellfish Processing Establishments

The purpose of this bulletin is to inform manual holders of the minimum expected HACCP controls for live molluscan shellfish processing establishments. This guidance document was developed to provide clear HACCP policies for all molluscan shellfish processing establishments, and to introduce new requirements for establishments that source shellfish from areas adjacent to wastewater treatment plants that are classified as conditional.

It is expected that improvements to this document will be forthcoming as a result of experience gained during implementation of conditional management in several key areas in Canada. Please note that this policy will be adjusted as necessary and finalized in 2009, when it will published as appendix H of this manual.

1. Introduction

This bulletin establishes the criteria for the development and implementation of an acceptable HACCP plan to control any health and safety hazards related to the processing of live molluscan shellfish. The criteria in this document serve to assist in the determination of compliance with the requirements of the Quality Management Program (QMP) Reference Standard, Section 5: The Hazard Analysis Critical Control Point (HACCP) Plan. Processors must review their HACCP controls and make changes necessary to ensure compliance with these criteria.

2. Scope

This bulletin is applicable to all registered fish processing establishments that process live molluscan shellfish.

3. Requirements For HACCP Controls For The Processing Of Live Molluscan Shellfish

The Canadian Shellfish Sanitation Program (as administered by the Canadian Food Inspection Agency, Environment Canada and Fisheries and Oceans Canada) provides the basis for determining which areas are acceptable for shellfish

harvesting. It is the responsibility of each registered shellfish processing establishment to use this information and any other control measures deemed necessary to ensure shellfish are safe for consumption. Any control measures developed must be clearly documented in each establishment's QMP.

As required by the Fish Inspection Regulations, an acceptable HACCP plan requires the appropriate application of the seven principles of HACCP by the operator of the fish processing establishment. In addition to the requirements listed in Section 5 of the QMP Reference Standard, a HACCP plan for live molluscan shellfish shall comply with the following requirements.

Product Description

In order to conduct a hazard analysis and a determination of critical control points, the product description must identify all product attributes that influence the safety and acceptability of live molluscan shellfish. Product descriptions shall indicate:

- the CSSP classification of all harvest waters where the shellfish are sourced from.
- if the harvesting is subject to a conditional management plan or a decontamination plan.
- all culturing, harvesting, holding and transportation practices that may influence safety and acceptability.

Note: More detailed guidelines and references for the development of an acceptable product description can be found in Appendix A of the QMP Reference Standard.

3.1 Conduct a hazard analysis (Principle 1)

The hazard analysis shall identify the following as a significant hazards:

a) the presence of microbiological pathogens in harvest waters. Shellfish can be contaminated with these pathogens from sources of human sewage or animal feces in harvest waters. These waters can be:

   - subject to decontamination fisheries
   - subject to conditional management plans
   - subject to natural events (e.g. herring spawning activities)
   - subject to a technology used to grow shellfish that could create or attract significant potential sources of contamination (e.g. floating bags where large numbers of birds could perch)
   - closed to harvesting (emergency closures or sanitary closures)

b) the presence of naturally occurring pathogenic microorganisms hazard where applicable. *Vibrio parahaemolyticus* (Vp)is considered a significant hazard in shellfish harvested in Pacific Northwest waters during the warmer months. Specific HACCP controls for this hazard are detailed in the document "HACCP Controls to Prevent the Growth of *Vibrio parahaemolyticus* to Unacceptable Levels in Live Oysters Destined for Raw Consumption".*

c) the presence of marine biotoxins in all harvest waters.

3.2 Determine the critical control points (Principle 2)

For each significant hazard, a critical control point must be identified where appropriate control measures are applied to prevent or eliminate or reduce the hazard to an acceptable level.

For situations where it is possible for shellfish to be received by the processor before an area was closed to harvesting, a critical control point must be identified for the application of control measures involving monitoring of the harvest area status. Such situations include:

- Shellfish sourced from harvest waters subject to a conditional management plan for waste water treatment plant operation and which are inside the response line as identified on the classification map for that area.

3.3 Establish critical limits (Principle 3)

A critical limit is a maximum or minimum value to which a hazard must be controlled at a critical control point. Critical limits shall be designed to:

a) confirm that the safe harvest conditions were in place at time of harvest in conditionally classified areas. The conditional management plan (CMP) will define the required conditions and can be a source of validation of this critical limit.

   - Critical limits for a CMP for waste water treatment plant (WWTP) operation shall be designed to confirm acceptable WWTP operation at the time of harvest.

b) confirm that shellfish are harvested from classified areas(except prohibited)and are in the open status.

c) confirm that the terms of the relay or depuration as described in the decontamination plan have been achieved. The decontamination plan will serve as validation of the critical limits.

d) ensure shellfish are not exposed to sources of contamination or conditions allowing microbiological pathogens to grow to unacceptable levels during harvesting, holding, and transporting from the harvest area to the processing establishment.

3.4 Establish a system to monitor control of the CCP (Principle 4)

At each CCP, the processor shall establish monitoring procedures to determine that the system is operating within the critical limits identified.

a) For CCPs identified for shellfish harvested under a CMP, monitoring procedures must be in place to check that the conditions described in the CMP were in place at time of harvest.

- Where the CMP is for the operation of a WWTP, monitoring procedures must take into account the time required for processors to become aware that the WWTP is not operating normally as described in the CMP. Acceptable monitoring procedures, for every lot of shellfish received, may involve:

  * Checking the status of the harvest area only after the response time identified in the CMP has elapsed.
  * Establishing direct communication systems with the operator of the WWTP to check that the conditions of the CMP were in place at time of harvest or equivalent monitoring procedures.

b) For CCPs identified to prevent the processing of illegally harvested shellfish from closed areas (emergency closures, sanitary closures and marine biotoxin closures), monitoring procedures must be able to demonstrate that all harvesters are licensed and that all lots of shellfish correctly identify the harvest location. Examples of acceptable monitoring procedures may include but are not limited to:

- Maintaining lists of licensed commercial harvesters that the processor will only accept shellfish from
- Checking tags or questioning harvesters at receipt to identify the harvest location
- Buying at the harvest location
- Having a representative of the processor at the harvest area to observe harvesting practices (master harvester)
- Establishing harvest plans that identify, in advance, the harvesters and location of harvest
- Establishing supplier quality assurance agreements (SQAs) with lease holders

- Checking the area status for emergency closures, sanitary closures and biotoxin closures on Fisheries and Oceans Canada websites or by other means of communication with DFO

c) For CCPs identified for shellfish harvested under a MCFR licence, monitoring procedures must be able to demonstrate that the terms of the relay or depuration, as described in the decontamination plan, have been achieved. Examples of acceptable monitoring procedures may include but are not limited to:

- Monitoring shellfish tracking records to ensure all lots of shellfish are relayed or for the appropriate amount of time (i.e., 14 days).
- Monitoring shellfish tracking records to ensure all lots of shellfish are depurated for the appropriate amount of time (i.e., 48 or 72 hours) and other key depuration parameters such as:
  - tank flow rates
  - loading capacity of tanks and trays
  - faecal coliform levels
  - spacing of trays within tanks
  - water quality parameters such as temperature, salinity, dissolved oxygen, turbidity, ammonia, etc.
- Establishing supplier quality assurance agreements (SQAs) with holders of the MCFR licence

d) For CCPs identified for the conditions during the holding and transport of shellfish from the harvest site to the processor, monitoring procedures must be able to demonstrate that shellfish are not exposed to sources of contamination or conditions allowing microbiological pathogens to grow to unacceptable levels. Examples of acceptable monitoring procedures may include but are not limited to:

- Establishing supplier quality assurance agreements (SQAs) with suppliers.
- Requiring suppliers to document harvest and transport conditions.

3.5 Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control (Principle 5)

a) Corrective action procedures must address the segregation of affected product and the culling, reworking and/or disposition of affected product.

- Unless otherwise specified in the CMP, shellfish

received by the processor that was harvested when the conditions (such as the normal operation of the WWTP) described in the CMP were not in place, must be returned to the original harvest area or disposed
- Corrective action procedures must identify that when the safety of shellfish is in question, it will be returned to the harvest area or disposed.

b) Corrective action procedures must prevent or reduce the likelihood of reoccurrence of the problem

- by investigating how the problem developed
- by reviewing the QMP Plan to determine where changes are required to prevent re-occurrence of the problem
- by implementing the changes

c) Unacceptable shellfish sample results can be an indication that existing CCPs are not effective in ensuring that shellfish received for processing originated from the identified harvest waters. In response to unacceptable lab results, the processor is required to re-evaluate their HACCP plan and make modifications as required.

- Where the investigation determines that problem is related to the misrepresentation of the harvesting area then the processor shall modify the controls for assuring that shellfish labels accurately identify the harvest location
- Where the investigation determines that the problem is linked to the harvest area then the processor shall consider modifying controls to ensure that harvest practices are adjusted to take into account any potential sources of contamination

d) In response to any other information questioning the effectiveness of HACCP controls, the processor shall re-evaluate their HACCP plan and make modifications as required.

Additional guidance for implementing acceptable corrective actions, applicable to the processing of all fish and seafood products, is contained in Appendix I of the Reference Standard (to be issued at a later date).

3.6 Establish procedures for verification to confirm that the HACCP system is working effectively (Principle 6)

The HACCP plan must identify the verification activities designed to demonstrate that the HACCP controls are implemented effectively. Processors are required to have two types of ongoing verification procedures:

a) Records of the monitoring actions for CCP critical limits and corrective actions taken must be verified at an established frequency to confirm that they are occurring as described in the QMP plan.

b) Independent checks must be completed to verify that the control measures implemented at each CCP are adequate and effective.

- For shellfish harvested under a CMP, the processor shall review the results of the verification activities described in the CMP annual report.
- For shellfish that is delivered to registered establishments by harvesters, procedures must be in place to verify that harvest area information on tags and/or harvester verbal or paper declarations are accurate.
- microbiological analysis, at specified frequencies, is required for incoming shellfish, shellfish before and after depuration, and for shellfish after relay if the relay period is less than 21 days.

Additional guidance for the development of acceptable QMP Verification and Maintenance activities applicable to the processing of all fish and seafood products is contained in Appendix G of the Reference Standard.

3.7 Establish documentation concerning all procedures and records appropriate to these principles and their application (Principle 7)

a) For shellfish harvested under a Conditional Management Plan, a copy of the plan must be included in the QMP plan documentation.

b) For shellfish harvested under a MCFR licence, a copy of the decontamination plan must be included in the QMP plan documentation.

c) EC classification maps showing where shellfish can be harvested from must be readily accessible.

d) Current DFO shellfish prohibition orders which delineate what areas are closed to shellfish harvesting must be readily accessible.

e) Supplier Quality Assurance (SQA) agreements that are used as a control measure as well as a record of verification of the SQA.

f) Records shall be kept for all testing, measurements, and monitoring at CCPs.

g) Records shall be kept for corrective actions when the critical limits are exceeded.

h) Records shall be kept of all verification activities.

i) Records shall be kept of any changes made to the QMP plan.

TO: All Holders of the Facilities Inspection Manual

SUBJECT: Changes to Compliance Verification Policy

This Bulletin supersedes and replaces Bulletin numbers 21 and 23. Please remove these Bulletins from your manual.

This Bulletin is intended to guide inspectors and managers in the scheduling and planning of compliance verifications. The Compliance Verification Policy is adjusted, as indicated within this bulletin, to increase the frequency of CFIA contact with industry, to emphasise the significance of the QMP Reference Standard, and to support improved planning and delivery of the CFIA's Quality Management Program.

The following policy directives are in effect:

The compliance verification (CV) is the primary tool for verification of regulatory compliance at federally registered establishments. The CV assesses the QMP Plan implementation and effectiveness against the requirements set out in the QMP Reference Standard, and by association, the Fish Inspection Regulations.

Compliance verifications are conducted during an establishment's operating season according to the following schedule:

Newly Registered Establishments

1. For an establishment with a new certificate of registration, a CV should be scheduled directly following the issuance of the registration certificate. For new registrations, the scope of a CV should address all seven elements of the QMP Reference Standard.

Previously Registered Establishments

2. For an establishment with a pre-existing certificate of registration, the scope of a CV normally will address less than seven elements of the QMP Reference Standard. Exceptions to this may include a CV conducted at an establishment in a remote location or with a very short operating season, a CV conducted in response to a food

safety emergency, and/or when a wide-scale loss of QMP controls is suspect.

QMP with a HACCP Plan

3. For establishments with a HACCP Plan, a CV should be conducted at least once every four months of operation. For establishments operating less than four months per year, a CV should be conducted at least once per year. A 2-year planning cycle should be used and during this period all seven elements of the QMP Reference Standard must be verified at least once.

QMP without a HACCP Plan

4. For establishments without a HACCP Plan, a CV should be conducted at least once every six months of operation. For establishments operating less than six months per year, a CV should be conducted at least once per year. A 3-year planning cycle should be used and during this period all seven elements of the QMP Reference Standard must be verified at least once.

CV Scope

The CV team will develop the CV scope in consideration of all of the following objectives:

- to assess each of the seven elements of the QMP Reference Standard at least once over the appropriate two- or three-year cycles;
- to assess health and safety controls with priority;
- to verify the implementation and effectiveness of corrective action plans developed during previous compliance verifications;
- to assess an area of a suspect non-compliance based on establishment history or an emerging issue.

To assist the CV team in developing the scope of the CV, the Inspection Manager (or designate) should establish a target for total direct time to conduct a CV. The CV team should allocate approximately 30% of direct time to planning and preparation, 60% to execution, and 10% to meetings with industry and CAP assessment.

Closing the CV

The CV is closed when the corrective action plan (CAP) has been accepted by the CV team. The development and submission of an acceptable CAP should be a priority for the registered establishment personnel.

CAP

Normally, CFIA personnel will verify the implementation and effectiveness of the CAP at a subsequent CV. Objective evidence pertaining to CAP implementation and effectiveness can be gathered at any time following the acceptance of the CAP. However, if health, safety or product compliance is at issue, the CFIA personnel should schedule the CAP to be verified promptly after implementation. The objective evidence collected is applied to a subsequent CV.

Time Utilisation

Advance planning for CV scheduling, CV team assignments, and the development of a CV checklist is advantageous and appropriate.

- It is not necessary to perform a compliance verification over a continuous period of time; the CV may be planned to be performed in stages and in many cases this is recommended. For example, this would apply in the case of establishments which operate for pulse fisheries, with short operating seasons, or for those whose export certification requests require CFIA contact. For such cases and where possible, the CV scope and checklist should be prepared well in advance so that inspection personnel are ready to conduct CV activities whenever an opportunity arises.

- Efforts should be made to consolidate regulatory verification activities whenever possible. For example, CVs for establishments which require ICSSL certification inspections should be scheduled to be conducted within 120 days of the ICSSL expiry date. This would enable the CV results to be applied to the ICSSL facility inspection requirements.

CV Team

The size of the CV team may be related to the plant size and/or complexity of the QMP Plan. In general, better results may be obtained using a team size of two persons. However, a 1-person execution of the on-site component of the audit, is acceptable when a 2nd team member (such as a supervisor) participates through deliberations and /or discussion during the planning, execution and CAP assessment phases. As in larger teams, one member of the team should be a "team leader". Rotation of inspection staff auditing individual establishments is encouraged.

Richard Zurbrigg
Director
Fish, Seafood and Production Division

TO: All Holders of the Facilities Inspection Manual

Subject: Inspection and Certification of Fish landed by Vessels of Canadian and Foreign Origin

N.B. This bulletin supersedes and replaces Bulletin nos. 4 and 14. Please remove these Bulletins from your manual.

This bulletin is intended to guide inspectors in the inspection, product certification and use of the "Product of Canada" designation for fish landed in Canada by Canadian and foreign vessels.

1. General

1.1 All Canadian vessels used for fishing or for transporting fresh round or dressed unfrozen, frozen, salted or pickled fish intended for further processing at Canadian federally registered processing establishments and/or for export shall meet the requirements of Schedule III of the Fish Inspection Regulations (FIR).

1.2 Fishing vessels shall be inspected in accordance with the frequencies prescribed in the local workplan to ascertain compliance with the FIR.

1.3 In accordance with section 14(1.1) of the FIR, all shellfish and crustaceans, excluding live lobster and live crab, landed by fishers must be processed in Canadian federally registered processing establishments if destined for export. Federally registered establishments may include enclosed processing facilities onboard Canadian-flagged freezer-factory ships or shore-based processing facilities.

2. Landings of Live or Fresh Fish Meeting Requirements of Schedule III only

The following criteria apply to fresh round or dressed unfrozen fish, live shellfish and crustaceans, including landings of shucked scallops:

2.1 Canadian Vessels

Landings by a Canadian fishing vessel are:

a) subject to inspection, may be exported directly, or may be destined for further processing in federally registered fish-processing establishments in accordance with Section 14 of the FIR;

b) eligible for "Product of Canada" designation; and

c) eligible for product certification.

2.2 Foreign Vessels

a) Foreign vessels importing, processing or otherwise handling live molluscan shellfish must comply with the provisions of the National Shellfish Shippers Program and must appear on the approved list of establishments contained in the Interstate Certified Shellfish Shippers List (ICSSL).

b) Landings by foreign vessels intended for further processing at registered fish-processing establishments or for direct sale to consumers are to be considered imports.

c) Fish inspectors shall deal with these imports in accordance with FIR import requirements and charge appropriate fees.

d) To be eligible for certification and designation as either "Product of Canada", or "Made in canada from Imported ingredients" / "Made in Canada from domestic and imported ingredients", the lots of fish landed by foreign vessels must have undergone substantial transformation during processing in federally registered fish processing establishments.

e) Compliance and certification of lots for export is to be in accordance with QMP procedures.

3. Landings of Frozen Whole, Dressed or Headed and Gutted Fish or Salted or Pickled Fish

The following criteria apply to the harvesting of fish, other than shellfish or crustaceans, which is frozen-at-sea in a whole or dressed form, or is salted or pickled:

3.1 Canadian Vessels

a) all landings requiring certification must be delivered to Canadian federally registered fish-processing establishments, and all fish must be treated as

"Incoming Fish" under the establishment's QMP;

b) compliance and certification of these lots of fish is to be evaluated in accordance with QMP procedures; and

c) all fish is eligible for a "Product of Canada" designation.

3.2 Foreign Vessels

Foreign vessel landings of sea-frozen fish, salted fish or pickled fish shall be dealt in accordance with section 2.2 of this Bulletin.

4. Fish Including Cooked and Frozen Shrimp and Other Crustaceans or Shellfish Harvested and Processed by Canadian Registered Freezer-Factory vessels

4.1 Canadian Vessels

The following criteria apply to processing on-board Canadian freezer-factory vessels, including all freezer-factory vessels which process raw material to final product form, without recourse to further processing in shore-based establishments:

a) the vessel must be registered as per Section 15 of the FIR, have a QMP and pay applicable fees;

b) certification of lots will only be considered when the lots are made readily available to the inspector and where suitable inspection facilities exist;

c) owners and operators or captains of processing vessels shall permit CFIA to station designated fish inspectors onboard for such periods of time to adequately and properly conduct at-sea inspections of factory processes and products, and shall provide suitable "officer level" food and accommodations, unrestricted radio room access, and when reasonable, facilitate mid-sea transfers of Inspection personnel to inbound or outgoing vessels;

d) certification of lots is to be conducted in accordance with QMP procedures, or upon a lot-by-lot inspection performed by a fish inspector, and where the fish is found to meet the requirements of the FIR; and

e) all landings are eligible for a "Product of Canada" designation.

4.2 Foreign Vessels

4.2.1 Foreign vessel landings of fish including cooked, sea-frozen shrimp and other crustaceans or shellfish shall be dealt with in accordance with section 2.2 of this Bulletin.

4.2.2 Notwithstanding section 4.2.1 above, CFIA may register foreign factory-freezer vessels as Canadian fish processing establishments provided that they meet all requirements of section 4.1 of this Bulletin.

Terence McRae
Director
Fish, Seafood and Production Division

TO: All Holders of the Facilities Inspection Manual

SUBJECT: RE-ENGINEERED QUALITY MANAGEMENT PROGRAM
TRANSITION DOCUMENT - REGULATORY VERIFICATION POLICIES & PROCEDURES

The purpose of this Bulletin is to provide Manual holders with the attached document which details the policies and procedures to be followed during the transition period for implementing the re-engineered Quality Managment Program (QMP).

David Rideout
Director General
Inspection Directorate

TRANSITION DOCUMENT

QMP Regulatory Verification Policies & Procedures

Scope This document outlines the policies and procedures that will be followed during the transition period, December 8, 1997 to October 1, 1998, for implementing the re-engineered Quality Management Program (QMP) in federally registered fish processing plants.

Authorities Fish Inspection Act
Fish Inspection Regulations

Definitions

QMP Regulatory Verification	A combination of inspection and audit activities carried out by CFIA Inspectors to verify that a fish processing operation's QMP Plan meets the requirements set out in the QMP Reference Standard.
Industry Self-Verification	A review of the written QMP Plan by the processor to ensure that all elements of the QMP Reference Standard are addressed.
Systems Verification	An audit of the company's documented QMP Plan against the QMP Reference Standard.
Compliance Verification	An audit of the operating QMP to verify the industry is implementing the QMP as designed and that the system is effective in meeting the requirements as set out in the QMP Reference Standard.
Non-conformity	A deficiency in the processor's QMP by virtue of a deviation from the QMP Plan, the QMP Reference Standard, or the applicable regulations.
Minor non-conformity	Those deficiencies where procedures specified in the processor's QMP are not followed, but there is no violation of specific product or process regulations.
Major non-conformity	Those deficiencies that violate the QMP Reference Standard but do not present a health or safety risk.
Critical non-conformity	Those deficiencies in the processor's QMP that may or have resulted in unsafe or fraudulent product.
Objective evidence	The qualitative or quantitative information, records, or statement of fact pertaining to the implementation of a quality management program, which is based on observation, measurement or test.

I. Policy

INDUSTRY SELF-VERIFICATION

1. As of December 8, 1997, all processors operating federally registered plants must have begun to re-engineer their QMP and submitted a self-verification package of the re-engineered QMP to the CFIA. If the self-verification package is not complete, then the processor must provide a preliminary self-verification using the checklist to indicate their progress to date.

2. Those operators of federally registered fish plants that are not currently processing on December 8, 1997, must begin to re-engineer their QMP and submit a self-verification package prior to commencing operation. If the self-verification package is not complete, then the processor must provide a preliminary self-verification using the checklist to indicate their progress to date prior to commencing operations.

3. As of October 1, 1998, all operators of federally registered fish plants must have completed the re-engineering of their QMP and submitted a completed self-verification package to the CFIA.

4. CFIA will review the processor's self-verification package, and if complete, may allow the processor to operate under the re-engineered QMP.

5. CFIA also has the flexibility to advise a processor to start to operate under a partially completed re-engineered QMP based upon the Prerequisite, Regulatory Action Point and HACCP Plans.

6. Until a processor begins to operate under the re-engineered QMP, the operation will be assessed under the original QMP.

7. CFIA will schedule a Systems Verification of the documented QMP once it has been determined through the review of the self-verification package that the processing plant has completed the re-engineering of the QMP.

REGULATORY VERIFICATION

1. Upon receipt of a complete industry self-verification package, CFIA will initiate regulatory verification. This verification will be conducted in two phases, the systems verification and the compliance verification.

2. Regulatory Verification activities will be performed by persons designated as Inspectors under the Fish Inspection Act and meeting the qualifications set out in Appendix A.

3. The CFIA reserves the right to conduct unannounced inspections to verify compliance with health and safety, schedule I and II

(FIR), and product regulatory requirements during the transition period.

4. Industry has the right to an appeal process and they may request a review of a regulatory verification decision. Appeals must be made in writing to the Regional Director of Inspection within 30 days of the decision that is being appealed. The written appeal should state the reason(s) why the decision should be given further consideration. This is applicable for all verification decisions excepting prosecution.

SYSTEMS VERIFICATION

1. CFIA will schedule the systems verification based on operating season, risk and markets.

2. For new operations, or those where the efficacy of the HACCP Plan is in question, CFIA will advise the processor to refrain from implementing the re-engineered QMP until the systems verification is conducted by the CFIA.

3. The processor will be required to make available to CFIA a copy of the re-engineered QMP Plan.

4. Except when impractical, the systems verification will be performed at a CFIA office.

5. All information contained in the QMP Plan is confidential.

6. The systems verification will be based on the QMP Reference Standard.

7. The results of the verification shall be recorded in a report and provided to the processor.

8. When indicated on the report, the processor will be required to take action to correct, revise, or amend the QMP Plan.

9. The systems verification will be closed once the QMP Plan has been determined to meet the requirements of the QMP Reference Standard.

10. Upon closure of the systems verification, the CFIA will inform the processor that the re-engineered QMP is satisfactory and the operation will be assessed under the regulatory verification system.

11. Upon closure of the systems verification, the CFIA will schedule a compliance verification.

COMPLIANCE VERIFICATION

1. During the transition period, all compliance verifications will include verification of the Prerequisite Plan, the Regulatory Action Point Plan, and where applicable, the HACCP Plan.

2. The CFIA will extend the privilege of announced compliance verifications to establishments which have demonstrated their commitment to the re-engineered QMP through a history of compliance and cooperation.

3. Non-conformities identified by the CFIA during the course of a compliance verification will be documented and supported with objective evidence.

4. The results of the verification shall be documented in a report and provided to the processor.

5. The processor will be required to provide a Corrective Action Plan addressing all non-conformities indicated on the Compliance Verification Report.

6. The processor must take immediate corrective action on critical non-conformities. For major and minor non-conformities, the company is responsible for initiating and implementing corrective actions to correct the non-conformity and the cause of the non-conformity. Corrective actions should be implemented as soon as practicable.

7. The compliance verification will be closed when all corrective actions have been implemented by the processor and verified by the CFIA.

II. Procedures

INDUSTRY SELF-VERIFICATION

1. After December 8, 1997, all federally registered fish processing plants must have submitted to CFIA a self-verification package of the re-engineered QMP Plan prior to commencing operations.

2. If the self-verification package is not complete, then a preliminary self-verification using the checklist must be submitted indicating the progress made to date and the scheduled date for completion of the package.

3. Processors are required to verify their written QMP plan, by operation, using the self-verification checklist (Appendix C) to demonstrate all of the elements outlined in the QMP Reference Standard (Appendix B) are addressed.

4. The self-verification package must include the:

a) self-verification checklist;
b) operation(s) and product(s) included under the re-engineered QMP Plan; and
c) HACCP plan, where applicable.

5. The CFIA will review the self-verification package for completeness.

6. If review of the self-verification package indicates the re-engineering of the QMP is not complete, the CFIA will advise the processor to re-submit the self-verification package.

7. If the self-verification package indicates the re-engineering of the QMP is complete, CFIA will schedule the systems verification and advise the processor.

8. If, after December 8, 1997, a processor operates without submitting a self-verification package, the following actions will be taken:

   a) the Inspector will determine if the QMP re-engineering process has begun;

   b) if the Inspector determines that the processor has not taken steps to re-engineer the QMP, the Inspector will request an immediate commitment, in writing, to do so;

   c) if the processor refuses to make the commitment in writing, or fails to act upon the commitment, CFIA may remove the processor's export privileges.

SYSTEMS VERIFICATION

1. CFIA will schedule the systems verification based on the:

   a) date of submission of the completed self verification package;
   b) operating season of the facility;
   c) market requirements of the exporter; and
   d) product risk.

2. CFIA will advise the processor of the scheduled date of the systems verification and obtain a copy of the re-engineered QMP Plan.

3. During the initial stages of the systems verification, the CFIA will advise the processor of the objectives of the verification and answer any questions from the processor.

4. Except when impractical, the systems verification will be performed at a CFIA office. When the systems verification is conducted at a processing facility, the processor must make space and support equipment available for the team to work.

5. The Systems Verification Report (Appendix D) will be used to evaluate the QMP Plan against the QMP Reference Standard.

6. Where required, an on-site validation of the QMP Plan may be conducted to determine if the plant floor and process flow diagrams are accurately described in the QMP Plan.

7. At the conclusion of the systems verification, an exit meeting will be held with the processor and the Systems Verification Report will be provided and explained.

8. During the exit meeting, the processor will have the opportunity to respond to the non-conformities identified in the Systems Verification Report. Where information provided by the processor impacts on CFIA findings, the Systems Verification Report will be amended before the verification is closed.

9. The processor will be required to take action to correct, revise, or amend the QMP Plan to address the findings identified in the Systems Verification Report by a specified date.

10. The systems verification will be closed by CFIA once all amendments have been completed by the processor and verified by the CFIA.

11. The processor will be advised when the system verification is closed by copy of the final report.

COMPLIANCE VERIFICATION

Preparatory work

1. The CFIA will schedule a compliance verification when the systems verification is closed.

2. The CFIA will inform the processor in advance of the compliance verification at the discretion of the Regional Director of Fish Inspection, or according to the following procedures:

    a) After an establishment receives three (3) consecutive Acceptable compliance verifications, the establishment may be eligible for "announced" audit status. The Area Inspection Chief, in consultation with the District Supervisor, will assess the documented plant compliance and management commitment in order to award this status. Plant management will be advised of the decision of this assessment and substantiating reasons during the 3rd consecutive Acceptable exit interview.

    b) After an establishment receives "announced" audit status, the Inspector will inform the plant management in advance of the scheduled compliance verification. To verify the

effectiveness of announced audits, the CFIA will perform an unannounced audit at a frequency of 25% of the compliance verifications.

3. The CFIA will prepare for the compliance verification by reviewing the QMP Plan and, using Appendices E and F, develop the verification scope and activities tailored to the processing operation.

4. Except when impractical, the preparatory work will be performed at a CFIA office. Consequently, it will be necessary for the processing plant to provide CFIA with a copy of the QMP Plan.

Opening meeting with plant management

5. The compliance verification will begin with an opening meeting with the management of the processing plant to explain the compliance verification scope and objectives. The meeting will also permit the processor to pose any questions regarding the compliance verification.

6. The management of the processing plant will be given the option of providing a person to accompany the CFIA Inspector(s) during the compliance verification.

Conducting the in-plant verification activities

7. The CFIA will conduct the compliance verification as per the developed checklist.

8. Non-conformities will be based on objective evidence and recorded on a Non-conformity Report (Appendix G).

9. If, during the compliance verification, the CFIA identifies any critical non-conformities, the processing plant will be required to correct the non-conformity immediately or stop production until it can be adequately addressed.

10. For each day the compliance verification continues, the plant management will be informed of the verification progress.

Exit meeting with plant management

11. At the completion of the compliance verification, the Non-Conformity Report(s) (Appendix G) and the Compliance Verification Summary Report (Appendix H) will be prepared for presentation to the processing plant management.

12. An exit meeting will be scheduled with the management of the processing plant.

13. During the exit meeting, the processor will have the opportunity to respond to any of the non-conformities identified. Where information provided by the processor impacts on CFIA findings, the report(s) will be amended before the verification is closed.

14. At the exit interview, the processor will be requested to prepare a Corrective Action Plan for each non-conformity within a specified time.

Compliance Verification Closure

15. The Inspector will verify that the Corrective Action Plan describes:

    a) a short-term action which will address the immediate non-conformity;
    b) a longer-term action which will prevent a re-occurrence of the non-conformity;
    c) persons responsible for implementing the corrective action; and
    d) a reasonable time frame for implementation of the corrective action.

16. When an Inspector is unable to reach agreement with the processor on the Corrective Action Plan, the Inspector will forward the Non-Conformity Report(s) and the Compliance Verification Summary Report to their immediate supervisor for action.

17. The CFIA will verify corrective actions by review of the QMP Plan amendments or by observation, measurement, inspection, or other verification activities suitable to the specific non-conformity.

18. If, during verification of a corrective action, the Inspector identifies an additional non-conformity, that non-conformity will be documented and included in the current compliance verification.

19. When long term corrective action is planned for plant construction or equipment non-conformities, the processor will be required to implement interim operational procedures to control any risk arising from the non-conformity. The CFIA will verify these corrective actions based on observation, measurement, inspection, or other suitable verification activities.

20. The compliance verification will be closed when all corrective actions have been implemented by the processor and verified by the CFIA.

III. Compliance Strategy

1. If, during the transition period, the CFIA identifies an absence of control for health and safety hazards, the CFIA will rate the operation as Fail and the enforcement procedures as specified in the "Facilities Inspection Manual" will be applied.

2. If, during the transition period, the CFIA requests a voluntary closure and the processor refuses to voluntarily

cease operation, the Certificate of Registration shall be cancelled under the direction of the Regional Director of Fish Inspection.

3. During the transition period, federally registered processing plants which are operating and fail to cooperate with the CFIA in meeting the regulatory requirements will risk cancellation of federal registration .

4. During the transition period, federally registered processing plants which are operating and fail to begin to re-engineer their QMP risk loss of export privileges.

IV. Roles and Responsibilities

1. Regulatory verification will be conducted using a team approach.

2. The team will be comprised of the principal contact Inspector, the lead Inspector, and other CFIA personnel as required to perform the verification activity.

3. The District Supervisor will coordinate the regulatory verification activities in each jurisdiction.

4. The principal contact Inspector and lead Inspector will determine the needs for the regulatory verification activity and involve other CFIA personnel, including additional inspectors as required, to ensure the team has the necessary knowledge and skills to conduct the verification.

5. CFIA personnel may undertake multiple roles in the delivery of the program during the transition period.

6. The responsibilities of the principal contact Inspector will include, but not necessarily be limited to:

   a) acting as liaison to the federally registered processing plant;

   b) initiating the regulatory verification process with the plant;

   c) reviewing the Industry self-verification package for completeness;

   d) participating in the systems verification and meeting with the processor to explain the results of the systems verification;

   e) preparing the compliance verification scope and checklist;

   f) conducting the compliance verification, including preparation of all reports and review of the processor’s

Corrective Action Plan.

7. The responsibilities of the lead Inspector will include, but not necessarily be limited to:

   a) conducting systems verification, directing other team members in systems verification activities, reviewing the findings of the systems verification team, preparing the Systems Verification Report and, where required, meeting with the processor to explain the results of the systems verification;

   b) reviewing the compliance verification scope and checklist prepared by the principal contact Inspector;

   c) reviewing the results of the compliance verification and providing guidance on the drafting of the Compliance Verification Summary Report.

8. Each Region will be responsible for providing the support and training to ensure that regulatory verification activities are performed by personnel with the necessary skills and knowledge (Appendix A).

V. Frequency of Compliance Verifications

1. During the transition period, at least one compliance verification will be conducted on each processing operation of federally registered fish processing establishments.

2. Additional compliance verifications will be conducted as practicable based upon plant compliance history and product risk.

3. If at any time the Inspector identifies a non-conformity while in a fish processing establishment and a compliance verification is not in process, the Inspector may issue a Non-conformity Report and require a Corrective Action Plan from the processor. If the processor refuses to take action, a compliance verification may be initiated after consultation with the District Supervisor.

VI. Assessment of QMP Operations

Under regulatory verification, the QMP Operation will be assessed by the CFIA as either Acceptable or Unacceptable.

1. Operations will be assessed as Acceptable under the following condition:

   a) the compliance verification has been closed by the CFIA.

2. Operations will be assessed as Unacceptable under the following conditions:

a) the processor has failed to meet the terms of the Corrective Action Plan and reach closure of the compliance verification within the determined time frame; and

b) the CFIA identification of a Critical non-conformity during a compliance verification until such time as the non-conformity is actioned by the processor and verified by the CFIA.

VII. Product Certification Inspection Frequency

During the transition period, product inspection for export certification will occur as follows:

1. For establishments (by operation type) which are in compliance, product inspections will be conducted at a rate of 1 in 10 requests (or 10% by volume).

2. For establishments (by operation type) which are rated as Fail or assessed as Unacceptable, each lot for which a request for certification is made must be inspected in accordance with the Fish Products Inspection Manual.

3. When a product inspection for certification finds the product to be unacceptable, a regulatory verification will be initiated at the establishment, and

   a) if the product is found to be unacceptable for reasons other than those outlined in item b), the next four (4) certification requests will be subject to mandatory inspection. Four consecutive inspections must be found to be acceptable before the inspection rate reverts to that applicable for plants in compliance.

   b) if product is found to be unacceptable for reasons relating to labelling, weight, or grade standard, the next two (2) certification requests will be subject to mandatory inspection. Two consecutive inspections must be found to be acceptable before the inspection rate reverts to that applicable for plants in compliance.

VIII. Use of the Canada Inspected Logo

1. Any "Canada Inspected" logo designation in effect prior to the transition period will remain in effect during the transition period.

2. New requests for use of the "Canada Inspected" logo will be evaluated on a case-by-case basis using the principles set out in Chapter 3, Subject 1, of the Facilities Inspection Manual.

3. Withdrawal of approval to use the "Canada Inspected" logo will be at the discretion of the Regional Director of Fish Inspection.

LIST OF APPENDICES

1. Appendix A - Inspector Qualifications for Regulatory Verification
2. Appendix B - The QMP Reference Standard
3. Appendix C - Industry Self-Verification Checklist
4. Appendix D - QMP Systems Verification Report
5. Appendix E - Instructions and Example for Preparing a Compliance Verification Activities Report
6. Appendix F - QMP Compliance Verification Activities Report
7. Appendix G - QMP Non-conformity Report
8. Appendix H - QMP Compliance Verification Summary Report

Appendix A

Qualifications for Regulatory Verification

INDUSTRY SELF-VERIFICATION REVIEW

Inspectors reviewing the Industry self-verification packages will have knowledge and understanding of the:

- information contained in *How to Re-engineer your Quality Management Program Plan: A Manual For Fish Processors*
- Regulatory Verification policies and procedures

SYSTEMS VERIFICATION

In general, Inspectors conducting systems verification will have skills and abilities which include:

- the ability to effectively communicate those principles, policies, and procedures which relate to the implementation of the re-engineered QMP
- the ability to write effective reports to document QMP regulatory verification activities

Inspectors conducting systems verification on the Prerequisite Plan and Regulatory Action Point Plan will have knowledge and understanding of:

- the QMP Reference Standard
- the Schedule I and II requirements (FIR and Handbook of Compliance)
- the Fish Inspection Regulations, for product standards, ingredient and packaging standards, and labelling requirements
- the applicable sections of the Food and Drug Act and Regulations, for input materials requirements
- pest control systems
- sanitation systems
- the recall system requirements
- the Regulatory Verification policies and procedures

Inspectors conducting systems verification on the HACCP Plan will have knowledge and understanding of the:

- example HACCP Plans
- QMP Reference Standard
- principles of HACCP
- process of conducting a hazard analysis
- process of CCP determination
- hazards associated with the specific fish product/process under scrutiny
- process of validating critical limits

COMPLIANCE VERIFICATION

In general, Inspectors conducting compliance verification will have skills and abilities which include:

- the ability to effectively communicate those principles, policies, and procedures which relate to the implementation of the re-engineered QMP
- the ability to write effective reports to document QMP regulatory verification activities
- the ability to use audit techniques practically to conduct a compliance verification
- the ability to apply learned knowledge purposefully in a working environment

Inspectors conducting compliance verification of the Prerequisite Plan and Regulatory Action Point Plan will have knowledge and understanding of:

- the QMP Reference Standard
- the Schedule I and II requirements (FIR and Handbook of Compliance)
- the Fish Inspection Regulations, for product standards, ingredient and packaging standards, and labelling requirements
- the applicable sections of the Food and Drug Act and Regulations, for input materials requirements
- pest control systems
- sanitation systems
- the recall system requirements
- the Regulatory Verification policies and procedures

Inspectors conducting compliance verification of the HACCP Plan will have knowledge and understanding of the:

- QMP Reference Standard
- Fish Inspection Regulations and applicable sections of the Food and Drug Act and Regulations, for health and safety requirements
- principles of HACCP
- hazards associated with the specific fish product and process under scrutiny
- Regulatory Verification policies and procedures

Appendix B

The QMP Reference Standard

I. THE SCOPE:

This document sets out the requirements for the documentation and application of a processor's Quality Management Plan. The standard is based on the Fish Inspection Regulations.

II. FIELD OF APPLICATION:

Each federally registered fish processing establishment must develop, document and apply a specific QMP Plan for the products and processes carried out in the establishment. The QMP Plan must be based on the requirements set out in this standard. The standard will be used as the foundation of the regulatory verifications performed by government inspectors to verify that a specific QMP plan of a fish processing operation is meeting the standard and the requirements of the regulations.

III. DEFINITIONS:

Critical Control Point (CCP) : A step at which control can be applied (and is essential) to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Critical Limit: A criterion which separates acceptability from unacceptability.

HACCP (Hazard Analysis Critical Control Point) : A system which identifies, evaluates and controls hazards which are significant for food safety.

HACCP Plan: A document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety in the segment of the food chain under consideration.

Hazard: A biological, chemical or physical agent or factor with the potential to cause an adverse health affect.

Prerequisite Plan: Programs that control the plant environment elements and recall procedures to ensure compliance with the Fish Inspection Regulations.

QMP Plan: A document prepared by a fish processor in accordance with the QMP Standard which outlines the controls implemented to ensure that the fish products were processed under sanitary conditions and resulted in a safe, acceptable, and fairly traded fish product.

Regulatory Action Point Plan: Are controls established at a processing step(s) to ensure regulatory compliance. They focus on 3 elements of fish processing:

-minimum acceptable fish product standards
-input materials
-labelling of final product

Regulatory Verifications: Activities carried out by Government Inspectors to verify that a fish processing operation's QMP Plan meets the requirements set out in the QMP Reference Standard and the Fish Inspection Regulations. The Regulatory Verification activities will include: verifying the documented QMP Plan, verifying the application of the QMP plan, inspecting plant conditions and product, investigating corrective actions and performing appropriate tests.

IV. THE COMPONENTS OF THE QMP STANDARD:

The QMP consists of the following sections:

1. Management Roles and Responsibilities (recommended),
2. Background Product and Process Information,
3. The Prerequisite Plan,
4. The Regulatory Action Points Plan, and
5. The HACCP Plan.

The Three Control Components of QMP

QMP		
Prerequisite Plan	Regulatory Action Points Plan	HACCP Plan
I. Plant Environment **II. Recall**	**I. Minimum Acceptable Fish Product Standards** **II. Input Materials** **III. Labelling**	**CCPs - Determined through the application of HACCP principles**

1. MANAGEMENT ROLES AND RESPONSIBILITIES

It is recommended the processors describe how the re-engineered QMP was developed, how it will be implemented, and identify the position responsible for the maintenance of the QMP Plan.

2. THE PRODUCT AND PROCESS INFORMATION

Processors are required to identify product and process information in the form of a Product Description, Process Flow Diagram and a Plant Floor Plan where necessary.

a) The Product Description must identify those product attributes and characteristics that are important in ensuring a safe and acceptable fish product.

b) The Process Flow diagram must outline all of the production steps and assists in identifying those steps that are important in processing a safe fish product meeting all regulatory requirements.

c) The Plant Floor Plan identifies cases where hazards are controlled through the application of sanitary or restricted access zones.

3. THE PREREQUISITE PLAN

a) Processors are required to identify the in-plant controls that provide assurances that:

   i) the physical plant facilities are designed, constructed and maintained in a condition to allow for the sanitary production of food,

   ii) all potential sources of significant contamination are controlled, and

   iii) product can be rapidly recalled from first shipping destinations.

b) The Prerequisite Plan is divided into two components:

   i) Plant Environment Program. As part of the Plant Environment Program processors are required to identify:

      A) the plant environment standard that is applied in the facility *(as a minimum the standard must meet the requirements of the Fish Inspection Regulations)*,

      B) the actions that are taken by the processor to

ensure the standard is met,

C) the record keeping system to record corrective actions when problems are identified[1],

D) the corrective action system in place to address deficiencies when they are identified.

ii) Recall Procedures

A) For the purposes of carrying out a product recall processors are required to have a product identification and distribution system that allows for the rapid identification of the 1st shipping destination.

B) As part of the Recall controls the processor is also required to notify the CFIA of any valid health and safety complaints.

[1] - *Under the Plant Environment Program, processors are not required to record the results of monitoring unless there is a problem identified. In these cases the processor must record the problem and the corrective action that was initiated.*

4. THE REGULATORY ACTION POINT (RAP) PLAN

Processors are required to establish, document and apply controls that ensure the final product meets the requirements of the Fish Inspection Regulations.

a) The Regulatory Action Point Plan must describe the controls to ensure that:

i) the fish is handled properly during processing and results in a final product that is not tainted, decomposed or unwholesome and meets all applicable sections of the Fish Inspection Regulations;

ii) any ingredients added to the fish product or packaging material used are acceptable for food and meets all regulatory requirements as specified in the Fish Inspection Regulations and the Food and Drug Act and Regulations; and

ii) the labelling and coding of all fish products meet the requirements of the Fish Inspection Regulations and are not false, misleading or deceptive.

b) As part of the RAP Plan the processor must identify:

i) the fish product standard(s) and the ingredient and packaging requirements (pertaining to the acceptability for use in food processing) that they are processing to *(the minimum fish product standards that must be met are set out in the DFO*

Fish Products Standard & Methods Manual),

ii) the actions that are implemented in production to ensure the standards and requirements are met,

iii) the record keeping system to record corrective actions when problems are identified[2] .

iv) the corrective action system in place to address deficiencies when they are identified.

[2] - Under the Regulatory Action Points, processors are not required to record the results of monitoring unless there is problem identified. In these cases the processor must record the problem and the corrective action that was initiated.

5. THE HAZARD ANALYSIS CRITICAL CONTROL POINT (HACCP) PLAN

Processors must develop, document and implement a HACCP Plan to address any health and safety hazards related to the product or process. The processor must apply the principles of HACCP[3] to identify any significant hazards and for those significant hazards identified, develop a HACCP plan to prevent, eliminate or reduce the hazard to an acceptable level.

a) The HACCP Plan must include the following:

i) Hazard Analysis,
ii) Critical Control Points (CCPs),
iii) Critical Limits,
iv) Monitoring Procedures,
v) Corrective Action System,
vi) Verification Procedures, and
vii) Record Keeping System.

[3] - Consistency with the CODEX Food Hygiene Committee document, Alinorm 97/13 and the Hazard Analysis and Critical Control Point System by the National Advisory Committee on the Microbiological Criteria for Foods, 1992.

6. VERIFICATION REQUIREMENTS

Processors will be required to perform the following verification activities to ensure that their QMP Plan is functioning correctly:

a) Before implementation the processor will be required to:

i) validate the critical limits of CCPs, where appropriate; and

ii) verify the QMP Plan to ensure that all of the necessary controls are in place and that it meets the requirements of the QMP Standard.

b) Once the QMP Plan is implemented the processor is required to:

i) perform routine verification of the HACCP Plan to ensure it is functioning effectively (e.g., Record reviews, Corrective Action reviews, review of calibration of equipment);

ii) verify or validate any changes to QMP controls or CCP critical limits that may occur in the ongoing development of the QMP Plan; and

iii) verify the QMP Plan at least once per calendar year.

7. RECORD KEEPING REQUIREMENTS

The record keeping requirements for the QMP Plan are:

a) Record keeping requirements for the Prerequisite Plan and the Regulatory Action Point Plan (RAPs) will be "records by exception". Records will only be required when a deficiency is identified during the monitoring procedures. In these cases the processor is required to record the deficiency and document the corrective action that was taken.

b) Record keeping requirements for the HACCP Plan require that all testing, measurements, and monitoring procedures at CCPs are recorded and corrective actions are recorded when the critical limits are exceeded.

c) Records must be maintained of all verification actions.

d) To ensure that the QMP Plan is accurately documented, processors are also required to maintain records of the amendments to the QMP Plan.

Appendix C

Industry Self-Verification Checklist

Industry Self-Verification Checklist		
Plant Name	Registration Number	
Mailing Address	Telephone	Fax
Plant Manager	Quality Management Coordinator	
Verifier	Date of Verification	

Comments

Operations Included in this Self-verification: _____

Products Included in this Self-verification: _____

Signature Of Verifier: _____

Component	**Yes**	**No**	**Comments**
1. Management Roles and Responsibilities			
Development of QMP described			
QMP manager identified			
Organization chart completed			
2. Process and Product Description			
Product description completed for each			
Process flow diagram completed			
Plant floor diagram completed			

Industry Self-Verification Checklist (continued)			
Component	**Yes**	**No**	**Comments**
3. Prerequisite Plan			
! Plant Environment Program			
Standard identified			
Documented sanitation program complete			
Documented pest control program complete			
Hygiene and employee behaviour training complete			
Controls and monitoring procedures complete			
Corrective action system complete			
Record-keeping system (forms) developed			
! Recall Procedures			
4. Regulatory Action Point Plan			
! Minimum acceptability standard controls			
Product standard identified			
Controls and monitoring procedures complete			
Corrective action system complete			
Record-keeping system (forms) developed			
! Input materials controls			
Packaging and ingredients identified and acceptable			
Controls and monitoring procedures complete			
Corrective action system complete			
Record-keeping system (forms) developed			
! Labelling			
Labelling standard identified (Fish Inspection Regulations)			
Controls and monitoring procedures complete			
Corrective action system complete			
Record-keeping system (forms) developed			
RAPs added to process flow diagram			
5. HACCP Plan			
Hazard analysis complete and accurate			
Significant hazards identified			
Control measures for significant hazards developed			
Critical limits identified			
Critical limits validated			
Monitoring procedures complete			
Corrective action system complete			
Record-keeping system (forms) developed			
HACCP Plan documented			
Supporting Standard Operating Procedures complete			
CCPs added to the process flow diagram			
Verification procedures identified			

Appendix D

QMP Systems Verification Report

INSTRUCTIONS:

The Systems Verification Report is used by the Inspector in the assessment of a QMP Plan against the requirements of the QMP Reference Standard. The systems verification is done on the initial QMP Plan submission and on amendments made by the company.

Using the Systems Verification Report and the QMP Plan provided by the processor, the Inspector will record objective evidence to describe what is missing, incorrect, or requires additional information. This information will be provided to the company to assist in the corrective action to the QMP Plan. The Inspector will also record information to benchmark the QMP Plan at the systems verification that will be useful in future verification activities.

All sections of this report applicable to the QMP Plan should be completed by the systems verification team. Where the QMP Plan requires revision, amendment or correction, the Inspector will summarize these items. The processor will receive a copy of the QMP Status Summary page (first page) and, where applicable, the Summary of Items Requiring Corrective Action page(s).

The processor representative must complete the Corrective Action Plan section on the QMP Status Summary page. When all items requiring corrective action have been corrected by the processor and verified by an Inspector, the Inspector will record this on the QMP Status Summary page and indicate the systems verification is closed.

Where significant revisions are required to the QMP Plan, the Inspector has the flexibility to use additional systems verification report(s) in assessing each revision. Use of multiple reports should be indicated in the corrective action plan verification box on the QMP Status Summary page.

QMP SYSTEMS VERIFICATION REPORT

Plant name:
Registration No:

QMP Plan Date:
Operation(s) included:
Products included:

Plant QMP contact:
Telephone/Facsimile:

QMP Status Summary

Section	Complete	Requires Revision	N/A
A. Management Roles & Responsibilities	( )	( )	( )
B. Process and Product Description	( )	( )	( )
C. Prerequisite Plan	( )	( )	( )
D. Regulatory Action Point Plan	( )	( )	( )
E. HACCP Plan	( )	( )	( )

Result (Indicate acceptable or requires corrective action):

Corrective Action Plan (To be completed by the Processor Representative)

_____
Representative Signature

Corrective Action Plan Verification (to be completed by the Inspector)

_____ _____
Inspector Signature **Systems Verification Closure Date**

Summary of Items Requiring Corrective Action

Inspector

Date

A. Management Roles & Responsibilities

Criteria: None (optional section)

Criteria Compliance Questions:

Where this section is included, comment on

1. How the processor developed the QMP Plan?
2. What positions are responsible for implementing the QMP?
3. How will the QMP will be maintained?
4. What responsible manager(s) have a role in the maintenance of the QMP?

Findings:

Inspector _____ Date _____

B. Process and Product Description

Criteria: Product description is completed for each type of product
Process flow diagram is completed
For processors which use controlled access, restricted access, or sanitary zones as a means of controlling or preventing hazards, a plant floor diagram is completed

Process & Product Benchmark Information:

List the following product information as described in the QMP Plan and note any potential health or safety implications to be assessed in the Prerequisite, Regulatory Action Point, or HACCP Plan sections of the QMP Plan:

1. Product name:

2. Source of raw materials:

3. Final product characteristics:

4. Other ingredients:

5. Packaging description:

6. Intended manner of consumer preparation:

7. Shelf-life (where applicable):

8. Intended product market/consumer group:

9. Labelling instructions for safe storage and preparation:

10. Distribution control requirements:

Additional Comments:

_____ _____

Inspector Date

Process Flow

Criteria Compliance Questions:

1. Are all RAPs and CCPs indicated on the process flow diagram?

2. Have all sources of raw materials input been included on the diagram?

3. Does the diagram include all plant areas?

4. Does the diagram accurately represent the actual production process flow including all processing steps? (This may require an on-site verification.)

Findings:

Inspector Date

Plant Layout diagram

Criteria Compliance Questions

1. Are all controlled access, restricted access, and/or sanitary zones indicated on the diagram?

2. Are all raw material inputs shown on the diagram?

3. Is in-process product flow shown on the diagram?

4. Is employee traffic flow shown on the diagram?

5. Does the diagram accurately represent the actual production plant layout? (This may require an on-site verification.)

Findings:

_____ _____

Inspector Date

C. Prerequisite Plan

Criteria: Standard identified
Documented Sanitation Program is completed
Documented Pest Control Program is completed
Control and monitoring procedures are established
Corrective Action system is completed
Record keeping system is developed

Prerequisite Plan Benchmark Information:

1. List the standards identified:

2. List the Standard Operating Procedures (SOP):

3. List the forms identified:

Criteria Compliance Questions:

Plant Construction & Equipment

1. Do the QMP Plan standards for plant construction & equipment meet the minimum requirements as specified in the Fish Inspection Regulations?

2. What control measures are established for plant construction & equipment?

3. Are the control measures sufficient to maintain adherence to the standard?

Criteria Compliance Questions:

Plant Construction & Equipment continued

4. Are monitoring procedures described for each control measure which specify what is being monitored, how it is being monitored, at what frequency, and by whom?

5. Is the frequency of monitoring sufficient?

6. Are corrective action procedures developed which address correction of the identified non-conformity and review of the non-conformity to establish measures to prevent a re-occurrence?

7. Is a report established to record the identification of non-conformities and the corrective action plan ?

8. Do SOP's, where used, describe complete and effective operating procedures?

Findings:

_____ _____

Inspector Date

Criteria Compliance Questions:

Plant Sanitation & Employee Hygiene

1. Do the QMP Plan standards for plant sanitation and employee hygiene and pest control meet the minimum requirements as specified in the Fish Inspection Regulations?

2. What control measures are established for plant sanitation and employee hygiene and pest control?

3. Are the control measures sufficient to maintain adherence to the standard?

4. Are monitoring procedures described for each control measure which specify what is being monitored, how it is being monitored, at what frequency, and by whom?

5. Is the frequency of monitoring sufficient?

6. Are corrective action procedures developed which address correction of the identified non-conformity and review of the non-conformity to establish measures to prevent a re-occurrence?

7. Is a report established to record the identification of non-conformities and the corrective action plan ?

8. Do SOP's describe complete and effective operating procedures?

_____ _____

Inspector Date

Plant Sanitation & Employee Hygiene continued

Findings:

Inspector Date

Criteria Compliance Questions:

Plant Recall System

1. How does the processor's Recall System ensure a timely & accurate recall of all products from the first shipping destination?

2. How does the processor's Recall System ensure the CFIA is notified of any valid health and safety complaints?

Findings:

Inspector Date

D. Regulatory Action Point Plan

Criteria: Minimum acceptable product quality control RAP is completed
Input material control RAP is completed
Labelling control RAP is completed

Regulatory Action Point Plan Benchmark Information:

1. List the standards identified:

2. List the Standard Operating Procedures (SOP):

3. List the forms identified:

Criteria Compliance Questions:

Minimum Acceptable Product Quality RAP

1. Do the QMP Plan standards for this RAP meet the minimum requirements as specified in the Fish Inspection Regulations?

2. What control measures are established at this RAP?

3. Are the control measures sufficient to maintain adherence to the standard?

4. Are monitoring procedures described for each control measure which specify what is being monitored, how it is being monitored, at what frequency, and by whom?

Minimum Acceptable Product Quality RAP continued

5. Is the frequency of monitoring sufficient?

6. Are corrective action procedures developed which address correction of the identified non-conformity and review of the non-conformity to establish measures to prevent a re-occurrence?

7. Is a report established to record the identification of non-conformities and the corrective action plan ?

8. Do SOP's describe complete and effective operating procedures?

Findings:

Inspector Date

Criteria Compliance Questions:

Input Material Control RAP

1. Do the QMP Plan standards for this RAP meet the minimum requirements as specified in the regulations?

2. What control measures are established at this RAP?

3. Are the control measures sufficient to maintain adherence to the standard?

4. Are monitoring procedures described for each control measure which specify what is being monitored, how it is being monitored, at what frequency, and by whom?

5. Is the frequency of monitoring sufficient?

6. Are corrective action procedures developed which address correction of the identified non-conformity and review of the non-conformity to establish measures to prevent a re-occurrence?

7. Is a report established to record the identification of non-conformities and the corrective action plan ?

8. Do SOP's describe complete and effective operating procedures?

_____ _____

Inspector Date

Input Material Control RAP continued

Findings:

Inspector

Date

Criteria Compliance Questions:

Labelling Control RAP

1. Do the QMP Plan standards for this RAP meet the minimum requirements as specified in the Fish Inspection Regulations?

2. What control measures are established at this RAP?

3. Are the control measures sufficient to maintain adherence to the standard?

4. Are monitoring procedures described for each control measure which specify what is being monitored, how it is being monitored, at what frequency, and by whom?

5. Is the frequency of monitoring sufficient?

6. Are corrective action procedures developed which address correction of the identified non-conformity and review of the non-conformity to establish measures to prevent a re-occurrence?

7. Is a report established to record the identification of non-conformities and the corrective action plan ?

8. Do SOP's describe complete and effective operating procedures?

_____ _____

Inspector Date

Labelling Control RAP continued

Findings:

Inspector

Date

E. HACCP Plan

Criteria: Hazard analysis is complete and accurate
Significant hazards are identified
Justification for inclusion or exclusion of significant hazards is provided
Control measures for significant hazards are identified
Critical limits are identified
Critical limits are validated
Monitoring procedures are complete
Corrective action system is complete
Record keeping system (forms) is developed
HACCP Plan is documented
Supporting Standard Operating Procedures are complete
Verification Procedures are identified

Hazard Analysis Benchmark Information

List the significant hazards determined:

a. biological -

b. chemical -

c. physical -

_____ _____

Inspector Date

Hazard Analysis

Criteria Compliance Questions:

1. How was the hazard analysis conducted?

2. Does the hazard analysis correspond with each step on the process flow diagram?

3. Does the hazard analysis includes all sources of incoming materials and incoming ingredients?

4. Are there any hazards generally associated with this process or product which have not been identified?

5. Does the hazard analysis include an accurate justification for including (or excluding) the hazard?

6. Are control measures identified for the significant hazards?

Findings:

_____ _____

Inspector Date

CCP Determination Benchmark Information

List the Critical Control Points determined:

CCP Determination

Criteria Compliance Questions:

1. Does the CCP determination include all significant hazards identified in the hazard analysis?

2. Is the determination of CCP's accurate?

3. Are all CCPs correctly identified on the process flow diagram?

Findings:

Inspector _____ Date _____

HACCP Plan Benchmark Information (For CCP _____):
Use one page per CCP

1. List CCP #

2. List the specific hazard:

3. List processing step:

4. List the control measures identified:

5. List the Standard Operating Procedures (SOPs):

6. List the forms identified:

Findings:

_____ _____
Inspector Date

Criteria Compliance Questions (For CCP _____):
Use one page per CCP

1. Are the control measures sufficient to maintain adherence to the standard?

2. Are critical limits established for each control measure?

3. Describe how the critical limits were validated?

4. Does the processor use operational limits where feasible?

5. Are monitoring procedures described for each control measure which specify what is being monitored, how it is being monitored, at what frequency, and by whom?

6. Is the frequency of monitoring sufficient?

7. Are corrective action procedures developed which address correction of the identified non-conformity and review of the non-conformity to establish measures to prevent a re-occurrence?

8. Do SOPs, where used, describe complete and effective operating procedures?

9. Are verification activities adequate to confirm that the control measures, monitoring procedures, reporting, and corrective action specified at the CCP are being followed?

10. Is the frequency of verification activities adequate?

11. Is a report system established to record the results of the monitoring, verification, and the identification of non-conformities and corrective action?

_____ _____
Inspector Date

Findings (For CCP _____):

_____ _____

Inspector Date

Appendix E

Instructions and Example For Preparing the Compliance Verification Activity Report

INSTRUCTIONS:

The Compliance Verification Activities Report (the "checklist") gives direction to the Inspector in performing the compliance verification. A properly developed checklist achieves two goals: first, it establishes the minimum criteria of investigation and conformance in the course of the compliance verification; and second, it establishes consistency amongst Inspectors and between compliance verifications.

The compliance verification checklist should be prepared during a pre-audit review of the QMP and in advance of the compliance verification. The checklist may be expanded during the course of the compliance verification if required in order to determine compliance to the reference standard.

Checklist questions should be devised to determine if the section criteria are met. The Inspector will verify that criteria are met by using a combination of activities which may include inspection, interview, observation, measurement, sampling for laboratory analyses, and document review. The Inspector is responsible for collecting objective evidence in support of the inquiry and recording the findings accordingly.

EXAMPLE:

This is an example of some sections of a Compliance Verification Activity Report.

Since each compliance verification activity report will be developed using a particular QMP Plan, each report will be different, reflecting the controls and procedures established by the processor.

Section 2 - Process and Product Description
Compliance Criteria:

- Product(s) observed in the plant is described in the QMP Plan.
- Process flow observed in the plant is described in the QMP Plan.
- Controlled access, restricted access, or sanitary zones observed are described in the QMP Plan.

Example Compliance Verification Activities Used to Verify the Compliance Criteria:

Observe
Observe process flow, employee traffic, and input material sources in the plant to determine if the actual process flow matches that described in the QMP Plan.
Observe controlled access, restricted access, and/or sanitary zones to determine if the zone(s) matches what is described in the QMP Plan.

Inspect
Inspect random lots of final product before shipping to determine if the product description information is accurate.

Section 3a - Prerequisite Plan - Plant Construction & Equipment

Compliance Criteria:

- Plant and equipment design, construction, and maintenance is satisfactory for the sanitary production of food.
- Control measures in use match those described in the QMP Plan.
- Control measures in use are effective in achieving compliance with Schedule I.
- Monitoring procedures used in the plant match those described in the QMP Plan.
- Monitoring procedures used in the plant are effective to check adherence to control measures.
- Corrective action records are made to document non-conformities.
- Corrective actions are effective and appropriate to correct the non-conformity and to prevent re-occurrence.

Example Compliance Verification Activities Used to Verify the Compliance Criteria:

Inspect
- Inspect plant and equipment design, construction, and maintenance using checklist and compliance manual. Is the plant in compliance with Schedule I? Do any deficiencies represent a health or safety risk to the consumer?

Observe
- Is the plant in compliance with Schedule I? Do any deficiencies represent a health or safety risk to the consumer?
- Observe employees using Standard Operating Procedures (SOPs) - are SOPs being implemented as described in the QMP Plan?
- Are the SOPs effective?

Interview
- Is the responsible person knowledgeable of the plant standard (schedule I requirements)?
- Does the responsible person monitor the plant conditions as specified in QMP plan?
- Does the responsible person have the authority to effectively deal with non-conformities?
- Are corrective actions effective and appropriate to correct the non-conformity?
- Is the root cause of a non-conformity found and the system corrected to prevent a re-occurrence?
- Does the responsible person verify the Corrective Actions?

Example questions:

Are you the person who normally does this job?
What type of training or experience do you have for doing this job?
Can you show me the written standard that you use to evaluate your plant against?
Can you tell me what actions you take to ensure that the plant is in compliance with the standard?
Can you tell me the reasoning your plant used to come up with the procedures you are following?
Can we go into the plant and can you show me what you actually do to check the plant for compliance with the standard?
If you find something not right, can you show me what you do after that?

Paper Review
- Are corrective action records being made to record non-conformities?
- Do corrective action plans document the immediate corrective action and longer term actions to prevent a re-occurrence?
- Identify any SOP's referenced for control of plant construction & equipment.
- Do the SOP's identify and describe complete and acceptable operating procedures in reference to the specified control measure?

Section 3b - Prerequisite Plan - Plant Sanitation & Hygiene
Compliance Criteria:

- ♦ Plant sanitation, employee hygiene, and pest control program is satisfactory for the sanitary production of food.
- ♦ Control measures in use match those described in the QMP Plan.
- ♦ Control measures in use are effective in achieving compliance with Schedule I.
- ♦ Monitoring procedures used in the plant match those described in the QMP Plan.
- ♦ Monitoring procedures used in the plant are effective to check adherence to control measures.
- ♦ Corrective action records are made to document non-conformities.
- ♦ Corrective actions are effective and appropriate to correct the non-conformity and to prevent re-occurrence.

Example Compliance Verification Activities Used to Verify the Compliance Criteria:

Inspect

- Inspect plant sanitation and hygiene condition using checklist and compliance manual.
- Inspect cleaners, sanitizers & lubricants. Are they properly stored? Are they properly labeled for identification?
- Verify effectiveness of the plant sanitation by test methods. Is the bacterial load at acceptable levels?
- Inspect premises for indications or evidence of pest infestation (insects, rodents, birds, etc.).
- Is the plant in compliance with Schedule II? Do any non-conformities represent a health or safety risk to consumers?
- Observe adherence to SOP in sanitary zones? Do employees follow the SOP?

Observe

- Observe plant employees adherence to employee hygiene SOP. Are employees following the SOP? Is the SOP effective?
- Observe plant cleanup and sanitation. Does the cleanup crew follow the Sanitation SOP? Is the SOP effective?
- Does the cleanup crew have adequate equipment?

Interview

- Is the responsible person knowledgeable of the plant sanitation & hygiene standard (schedule II requirements)?
- Is the responsible person knowledgeable of the sanitation SOP?
- Does the responsible person monitor the plant conditions as specified in the QMP plan?
- Does the responsible person have the authority to effectively deal with non-conformities?
- Are corrective actions effective & appropriate to correct the non-conformity?
- Is the root cause of non-conformity being analyzed and the system corrected to prevent re-occurrence?

- Does the responsible person verify the Corrective Actions?
- Does the cleanup crew understand the sanitation SOP?
- Does the cleanup crew use the sanitation SOP?

Suggested questions:

Are you the person who normally does this job?
What type of training or experience do you have for doing this job?
Can you show me the written standard that you use to evaluate plant sanitation & hygiene?
Can you tell me what actions you take to ensure that the plant meets the standard?
Can you tell me the reasoning your plant used to come up with the procedures you are following?
Can we go into the plant and can you show me what you actually do to check the plant for sanitation & hygiene?
If you find something not right, can you show me what you do after that?
What would you do to fix the cause of the problem?
Can you tell me the steps you would perform to clean this piece of equipment?
How much of this cleaner would you put in the pail?

Paper Review

- Are corrective action records being made to record non-conformities?
- Do corrective action plans document the immediate corrective action and longer term actions to prevent a re-occurrence?
- Review records for cleaners, sanitizers & lubricants. Are they all approved?
- Identify any SOPs referenced for control of plant sanitation & hygiene.

Section 3c - Prerequisite Plan - Recall Procedures
Compliance Criteria:

- ♦ The product identification and distribution system permits rapid recall of product up to the first shipping destination.
- ♦ Notify the CFIA of any valid health & safety complaints.

Example Compliance Verification Activities Used to Verify the Compliance Criteria:

Interview

- Interview the person responsible for recording product distribution information. Does the responsible person understand the system and record the information as described in the QMP plan?
- Interview the person responsible for the recall system. Is the person knowledgeable of the recall system?
- Is there a system in place to notify the CFIA of any valid health & safety complaints?

Suggested questions:

Are you the person who normally does this job?
What type of training or experience do you have for doing this job?
Can you show me how you record product distribution information?
If I give you a lot number, can you tell me the first shipping destination?
When would you notify the CFIA of a consumer compliant?

Test the Recall System

- Give the responsible person a lot number of product which is likely to have been distributed. Is the recall system capable of identifying the first shipping location of this product?

Paper Review

- Review the product distribution records. Are they maintained in a systematic manner and as described in the QMP plan?

Section 4a - Regulatory Action Point Plan - Product Quality

Compliance Criteria:

- ♦ Processing practices are satisfactory to ensure final product is not tainted, decomposed or unwholesome, and meets all applicable sections of the Fish Inspection Regulations.
- ♦ Control measures in use match those described in the QMP Plan.
- ♦ Control measures in use are effective to ensure no TDU fish.
- ♦ Monitoring procedures used in the plant match those described in the QMP Plan.
- ♦ Monitoring procedures used in the plant are effective to check adherence to control measures.
- ♦ Corrective action records are made to document non-conformities.
- ♦ Corrective actions are effective and appropriate to correct the deficiency and to prevent re-occurrence.

Example Compliance Verification Activities Used to Verify the Compliance Criteria:

Inspect

- Inspect 2 lots of final product to determine compliance to the standard.

Interview

- Interview the person(s) responsible for product quality. Do the responsible persons understand the quality requirements as described in QMP plan?
  - Do you know what the requirements for fish product quality are?
  - How do you ensure these requirements are met on a day-to-day basis?
  - What type of training or experience do you have for doing this job (product quality)?

Observe

- Is product quality monitored as specified in the QMP plan?
- Is the level of monitoring effective in maintaining control of product quality?
- Does the responsible person have the authority to effectively deal with unacceptable product?
- Is unacceptable product segregated from acceptable product?
- Are corrective actions effective and appropriate to correct the non-conformity?
- Is the root cause of a non-conformity found and the system corrected to prevent a re-occurrence?
- Does the responsible person verify the Corrective Actions?

Paper Review

- Are corrective action records being made to record non-conformities ?
- Do corrective action plans document the immediate corrective action and longer term actions to prevent a re-occurrence?

Appendix F

QMP Compliance Verification Activity Report

Compliance Verification Activity Report Page 1 of ___

Establishment Name: Establishment Number:
Operation: Location:

Section 1 - Management Roles and Responsibilities

(Insert Regulatory reference here)

Compliance Criteria:

- The management roles and responsibilities stated in the QMP Plan are implemented in the operation.

Compliance Verification Activities:

Findings:

Inspector: Date:

Section 2 - Process and Product Description

(Insert Regulatory reference here)

Compliance Criteria:

- Product(s) observed in the plant are described in the QMP Plan.
- Process flow observed in the plant is described in the QMP Plan.
- Controlled access, restricted access, or sanitary zones observed are described in the QMP Plan.

Compliance Verification Activities:

Findings:

Inspector: Date:

Section 3a - Prerequisite Plan - Plant Construction & Equipment
(Insert Regulatory reference here)

Compliance Criteria:

- Plant and equipment design, construction, and maintenance is satisfactory for the sanitary production of food.
- Control measures in use match those described in the QMP Plan.
- Control measures in use are effective in achieving compliance with Schedule I.
- Monitoring procedures used in the plant match those described in the QMP Plan.
- Monitoring procedures used in the plant are effective to check adherence to control measures.
- Corrective action records are made to document non-conformities.
- Corrective actions are effective and appropriate to correct the deficiency and to prevent re-occurrence.

Compliance Verification Activities:

Findings:

Inspector: Date:

Section 3b - Prerequisite Plan - Plant Sanitation & Hygiene
(Insert Regulatory reference here)

Compliance Criteria:

- Plant sanitation, employee hygiene, and pest control program is satisfactory for the sanitary production of food.
- Control measures in use match those described in the QMP Plan.
- Control measures in use are effective in achieving compliance with Schedule II.
- Monitoring procedures used in the plant match those described in the QMP Plan.
- Monitoring procedures used in the plant are effective to check adherence to control measures.
- Corrective action records are made to document non-conformities.
- Corrective actions are effective and appropriate to correct the deficiency and to prevent re-occurrence.

Compliance Verification Activities:

Findings:

Inspector: Date:

Section 3c - Prerequisite Plan - Recall Procedures

(Insert Regulatory reference here)

Compliance Criteria:

- The product identification and distribution system permits rapid recall of product up to the first shipping destination.
- The processor provides CFIA with notification of valid health and safety complaints.

Compliance Verification Activities:

Findings:

Inspector: Date:

Section 4a - Regulatory Action Point Plan - Product Quality
(Insert Regulatory reference here)

Compliance Criteria:

- Processing practices are satisfactory to ensure final product is not tainted, decomposed or unwholesome, and meets all applicable sections of the Fish Inspection Regulations.
- Control measures in use match those described in the QMP Plan.
- Control measures in use are effective in to ensure no TDU fish.
- Monitoring procedures used in the plant match those described in the QMP Plan.
- Monitoring procedures used in the plant are effective to check adherence to control measures.
- Corrective action records are made to document non-conformities.
- Corrective actions are effective and appropriate to correct the deficiency and to prevent re-occurrence.

Compliance Verification Activities:

Findings:

Inspector: Date:

Section 4b - Regulatory Action Point Plan - Input Materials
(Insert Regulatory reference here)

Compliance Criteria:

- Ingredients added to the fish product or packaging materials used are acceptable for food and meet all regulatory requirements as specified in the Fish Inspection Regulation and the Food and Drug Act.
- Control measures in use match those described in the QMP Plan.
- Control measures in use are effective to ensure ingredients and packaging material meet regulatory requirements.
- Monitoring procedures used in the plant match those described in the QMP Plan.
- Monitoring procedures used in the plant are effective to check adherence to control measures.
- Corrective action records are made to document non-conformities.
- Corrective actions are effective and appropriate to correct the deficiency and to prevent re-occurrence.

Compliance Verification Activities:

Findings:

Inspector: Date:

Section 4c - Regulatory Action Point Plan - Labelling
(Insert Regulatory reference here)

Compliance Criteria:

- Labelling and coding of fish products meet the Fish Inspection Regulations requirements and are not false, misleading or deceptive.
- Control measures in use match those described in the QMP Plan.
- Control measures in use are effective to ensure labelling and coding of fish products meet the FIR requirements.
- Monitoring procedures used in the plant match those described in the QMP Plan.
- Monitoring procedures used in the plant are effective to check adherence to control measures.
- Corrective action records are made to document non-conformities.
- Corrective actions are effective and appropriate to correct the deficiency and to prevent re-occurrence.

Compliance Verification Activities:

Findings:

Inspector: Date:

Section 5 - Hazard Analysis Critical Control Point Plan

(Insert Regulatory reference here)

Compliance Criteria:

- A hazard analysis was conducted including all potential hazards.
- When significant hazards are identified, the QMP Plan contains an acceptable HACCP Plan.
- Control measures in use match those described in the QMP Plan.
- Control measures in use are effective to ensure the production remains within the critical limits.
- Monitoring procedures used in the plant match those described in the QMP Plan.
- Monitoring procedures used in the plant are effective to ensure the critical limits are not being exceeded and the standard is met.
- Corrective action is taken when monitoring indicates the process is outside of the defined critical limits.
- Corrective actions are effective and appropriate to control affected product, correct the deficiency and to prevent re-occurrence of the deficiency.
- Verification procedures in use match those described in the QMP Plan.
- Verification procedures used in the plant are satisfactory to ensure the HACCP Plan is effective.
- Records in use match those described in the QMP Plan.
- Records are maintained for all CCP monitoring, verification, and corrective activities.
- Records are completed with all pertinent information.

Compliance Verification Activities:

Findings:

Inspector: Date:

Section 6 - QMP Plan Verification & Maintenance

(Insert Regulatory reference here)

Compliance Criteria:

- At least annually, the processor will verify:
  - the QMP Plan is still effective and is being implemented correctly
  - all CCP controls and their implementation
  - any amendments to the processing line have been documented in the QMP.
- Verification procedures in use match those described in the QMP Plan.
- Verification procedures used in the plant are satisfactory to ensure the HACCP Plan is effective.
- Records in use match those described in the QMP Plan.
- Records are maintained for QMP Plan verification activities.
- Records are kept to log when amendments or changes are made to the QMP Plan documentation.
- Records include what changes were made to the QMP Plan and by whom.

Compliance Verification Activities:

Findings:

Inspector: Date:

APPENDIX G

QMP Non-Conformity Report

Regulatory Verification **Non-Conformity Report** Page of	
Company Name: Location:	Reg./License No. **QMP** ☐ _____ **QMP Importer** ☐ _____ **Other**_____ ☐ _____
Inspector:_____ Regulatory Verification # _____	**Category** **Critical** ☐ **Major** ☐ **Minor** ☐
Non-conformity Findings for the QMP Element: _____	
Actual: Required: Inspector Signature: Acknowledged by :	
Corrective Action Plan (to be completed by Processor Representative):	
Corrective Action by Date: Acknowledged by:	
Follow-up Verification:	
_____ _____ Date Inspector	

APPENDIX H

QMP Compliance Verification Summary Report

Compliance Verification Summary Report	Page ____ of ____

Company Name:	Date:
Location:	

The contents of this report are confidential to the Company as named above. As such, distribution to persons not under the employ of both parties must be agreed by both parties prior to circulation.

The signature(s) below of the Company's representative(s) indicates their acknowledgment and understanding of the non-conformities that are the subject of this report.

General Comments - Inspector(s):

Compliance Verification Conclusions, Follow-up Actions, and Assessment

Compliance Verification Assessment: **Date Closed:**

Exit Meeting

CFIA Inspectors	*Company Representative(s)*
Signed _____	Signed _____
Signed _____	Signed _____
Signed _____	
Signed _____	

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* - To be issued at a later date

DEFINITIONS

Note: Several of the following definitions have been taken from the "Fish Inspection Regulations". Others have been added for the purpose of assisting in the interpretation of the Facilities Manual. Additional definitions may be found in the "Fish Inspection Act", "Fish Inspection Regulations", and the "Fish Products Inspection Manual".

Certificate of registration
A certificate issued in accordance with subsection 15(6) of the *Fish Inspection Regulations*. *(certificat d'agrément)*

Compliance Verification (CV)
Activities carried out by CFIA Inspectors to verify that a federally registered fish processing establishment has implemented its Quality Management Program plan as designed and that it meets the requirements set out in the *Fish Inspection Regulations* and the QMP Reference Standard. This includes a combination of audit and inspection activities. *(vérification de la conformité)*

CV checklist
A worksheet used during a Compliance Verification. The elements of a checklist include: the standard or requirement to be met; a task list of questions and actions to be completed; and areas to record objective evidence and findings. *(liste de contrôle de la VC*)

CV objective
A statement outlining the purpose of a Compliance Verification and what the CV is to accomplish. The purpose of each CV will be to determine if the processing establishment's QMP plan is being implemented as planned, and if it is effective in ensuring compliance with the *Fish Inspection Regulations. (objectif de la VC)*

CV plan
A guide developed by a CV team leader, to assist in carrying out a Compliance Verification in a systematic manner. *(plan de la VC)*

CV scope
A statement outlining the boundaries or limits of activities planned for the Compliance Verification. *(portée de la VC)*

Control measure (also known as preventative measure)
An action performed to maintain adherence to a standard or to eliminate a hazard or reduce it to an acceptable level. *(mesure de contrôle)*

Corrective action
The procedure that is to be followed whenever a deviation from a critical limit in a HACCP plan occurs or whenever the results of monitoring procedures in respect of a prerequisite program plan, a regulatory action point plan or a quality management program for the importing of fish show that there is non-compliance with the *Fish Inspection Regulations*. *(mesures correctives*)

Corrective Action Plan (CAP)
A documented plan of corrective actions required, including time frames, persons responsible for implementing the plan and the processor's verification that the corrective action is working. A Corrective Action Plan is prepared in response to a compliance verification or inspection report, and must be reviewed and accepted by the CFIA. *(plan de mesures correctives)*

Critical Control Point (CCP)
A point in a process operation at which control is to be applied in order to prevent or eliminate a hazard or reduce it to an acceptable level. *(point de contrôle critique*)

Critical limit
The maximum or minimum value to which a hazard must be controlled at a critical control point. *(limite critique*)

Critical non-conformity
A failure of a processing establishment's QMP system that may result, or has already resulted, in the production of an unsafe or fraudulent product. *(non-conformité critique)*

Facilities Manual
The *Facilities Inspection Manual*, published by the Department of Fisheries and Oceans in 1988, as amended from time to time. *(Manuel des installations)*

Finding
A conclusion drawn with respect to conditions or activities observed, based on analysis of the objective evidence gathered during a Compliance Verification. *(constatation)*

Fish import licence
A licence issued in accordance with subsection 6.1 (1) of the *Fish Inspection Regulations*. *(permis d'importation de poisson)*

Fraud
A deliberate act or practice conducted in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding the character, value, quantity, composition, merit or safety of a fish product. *(fraude)*

Fraudulent Product
Product that has been intentionally produced, packaged or labelled in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety. *(produits frauduleux)*

Hazard
A biological, chemical or physical agent or factor that has the potential to cause illness or injury to humans in the absence of its control. *(danger*)

Hazard Analysis Critical Control Point (HACCP)
A system which identifies, evaluates and controls hazards which are significant for food safety. HACCP is an internationally recognized approach to food safety management. *(Analyse des dangers et maîtrise des points critiques)*

High-risk products
Products that, if not properly prepared or processed, may pose a serious risk to human health and safety. *(produit à haut risque*)

Inspection Manual
The *Fish Products Inspection Manual,* published by the Department of Fisheries and Oceans in 1988, as amended from time to time. *(Manuel d'inspection)*

Monitoring procedure
A planned observation or measurement of a parameter, at a specified point or time, which is then compared to a target (i.e., a standard, an operational limit, a critical limit). *(procédure de surveillance)*

Non-conformity
A deviation from a processing establishment's QMP system that results in the establishment not following its QMP plan or not complying with the *Fish Inspection Regulations*. *(non-conformité)*

Objective evidence
Qualitative or quantitative information, facts, or records obtained through observations, measurements, tests, inspections, or interviews made during a Compliance Verification, which can be independently confirmed. *(preuve tangible)*

Person
An individual, partnership, corporation, cooperative, association or organization. *(personne)*

Quality Management Program (QMP)
A fish inspection and control system, that includes procedures, inspections and records, for the purpose of verifying and

documenting the processing of fish and the safety and quality of fish processed in, exported from or imported into Canada. See Chapter 3, Subject 1 for more information. *(Programme de gestion de la qualité)*

Quality Management Program Import Licence
A licence issued in accordance with subsection 6.1(1.1) of the *Fish Inspection Regulations. (Permis d'importation avec programme de gestion de la qualité)*

QMP Plan
A document describing controls applied in a fish processing establishment to meet requirements under the *Fish Inspection Regulations*. *(plan de PGQ)*

QMP Reference Standard
The standard that sets out the requirements for the documentation and application of a fish processing establishment's Quality Management Program. The Reference Standard is based on the *Fish Inspection Regulations*. See Chapter 3, subject 4 for more information. *(Norme de référence du PGQ)*

QMP System
The practical administration in a federally registered fish processing establishment of the controls described in its QMP Plan. *(Système de PGQ)*

Regulated party
Any person subject to the requirements of the *Fish Inspection Act, Fish Inspection Regulations* and other applicable legislation. *(partie réglementée)*

Regulatory Verification
Activities carried out by CFIA Inspectors to verify that a federally registered fish processing establishment's Quality Management Program meets the requirements set out in the *Fish Inspection Regulations* and the QMP Reference Standard. Regulatory Verification consists of two components: Systems Verification and Compliance Verification. See Chapter 3, subject 1 for more information. *(vérification réglementaire)*

Registered establishment
A freezer-factory vessel, barge, onshore plant, building or premise where fish are processed or stored for export and that is registered pursuant to subsection 15(6) of the *Fish Inspection Regulations*. *(établissement agréé)*

Restricted access zone
That part of a processing area where personnel movements are restricted and employee hygiene and sanitation procedures are in

place to control potential contamination or cross-contamination, but which does not meet the specific requirements of a Sanitary Zone. *(zone d'accès limité)*

Revocation
A certificate of registration, licence or permit issued pursuant to the *Fish Inspection Regulations* is cancelled and withdrawn for violations of the *Fish Inspection Regulations* and that all privileges with respect to the certificate of registration, licence or permit are removed. *(révocation)*

Sanitary zone
That part of a processing area, for sensitive processing steps or high risk products, for which a set of controls, meeting specified criteria, have been established to control all vectors of potential contamination or cross contamination including air movement, employee hygiene and sanitation procedures. *(zone sanitaire)*

Standard Operating Procedures (SOPs)
A detailed set of instructions which describes how to carry out a task, function or product formulation. *(Procédure normalisée d'exploitation)*

Suspension
A certificate of registration, licence or permit issued pursuant to the *Fish Inspection Regulations* is temporarily withdrawn for the specific period of time noted in the notice of suspension and that all privileges with respect to the certificate of registration, licence or permit are temporarily removed. *(suspension)*

Systems Verification
An evaluation of a federally registered fish processing establishment's documented Quality Management Program plan against the QMP Reference Standard to verify that it contains all the necessary components and has the necessary controls to ensure compliance with the *Fish Inspection Regulations*. *(Vérification des systèmes)*

Validation
Supportive evidence or documentation to confirm that the values of the critical limits for each Critical Control Point (CCP) are sufficient to prevent, eliminate or reduce to an acceptable level, food safety hazards in the final product. *(validation)*

Verification
A review of a control system or its records performed on a regular basis to determine whether the controls are working as intended and are functioning effectively to control the relevant hazards. Verification activities may include conducting records checks, reviewing procedures, conducting operational simulations (such as

mock recalls), internal audits, tests or measurements (independent of monitoring controls), and product sampling (including microbiological & chemical). *(vérification)*

Amend.no.4 93/01/28

CHAPTER 1

INTRODUCTION

1. APPLICATION AND PURPOSE OF THE MANUAL

The purpose of the Facilities Inspection Manual is to provide Canadian Food Inspection Agency (CFIA) inspectors and industry personnel with the policies and procedures necessary to determine compliance with the *Fish Inspection Regulations* and to ensure uniformity of interpretation and consistency in application of the regulations.

As new information is developed, this manual will be updated. All inquiries, suggestions or comments from within Canada are to be directed to the closest CFIA regional office. Inquiries, suggestions or comments from outside Canada are to be sent to:

Fish, Seafood and Production Division
Canadian Food Inspection Agency
59 Camelot Drive
Ottawa, Ontario, Canada
K1A 0Y9

When an addition or amendment to the manual is required, the change will originate from Fish, Seafood and Production Division in Ottawa, Canada.

2. MANUAL STRUCTURE AND TEXT FORMAT

The structure of this manual is similar to that of others produced by Fish, Seafood and Production, for the purpose of explaining regulatory criteria and compliance requirements.

The reason for a specific regulation is usually self-evident; however, a brief explanation as given in Chapters 5 and 6, is usually helpful to understand the requirements for compliance with the regulations.

The Compliance statements identified in Chapters 5 and 6 for Construction and Equipment, and Operating requirements respectively, are based on requirements which have been found necessary and proven practical in their application by industry and government. Deficiency statements applied to each section of Chapters 5 and 6 clearly identify and score conditions that do not satisfy the minimum requirements of

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the regulations.

GMPs

Although the requirements in this manual are based on the *Fish Inspection Regulations* currently in place, it is appropriate to mention Good Manufacturing Practices (GMPs).

The requirements in this manual for construction, equipment and operations are "minimum" requirements. For some products, such as ready-to-eat foods which are consumed without further cooking and extra care has to be taken to ensure the safety of the food, GMPs have been prepared for voluntary use by the industry. GMPs for many items have been developed for this purpose and are available under separate cover.

CHAPTER 2, SUBJECT 1
CERTIFICATES OF REGISTRATION

1. SCOPE

This subject outlines the policies and procedures governing the registration of fish processing establishments that are under the jurisdiction of the *Fish Inspection Act* and *Fish Inspection Regulations*.

2. AUTHORITIES

Fish Inspection Act, R.S. 1985, c. F-12
Fish Inspection Regulations, C.R.C., c. 802
Canadian Food Inspection Agency Fees Notice

3. POLICY

3.1 General

3.1.1 Any establishment, including a fishing vessel, where fish and fish products are processed for export (which includes shipment from one province to another) must have a certificate of registration issued in accordance with the *Fish Inspection Regulations* (FIR). Establishments where fish and fish products are processed for export will hereafter be referred to as registered establishments.

There are a number of exceptions to the requirement to process or to store fish for export in a registered establishment. These exceptions are set out in subsections 14(2) and 14(3) of the FIR and include, but are not limited to, the following:

- Persons licenced to catch fish under the *Fisheries Act* may process their catch as whole or dressed unfrozen fish or as salted or pickled fish (fisher-packers). Fisher-packers may not process fish roe for export. Processing may occur on board their vessel or on shore at a location that is owned or leased by the fisher-packer. When processing occurs on shore, a person that did not participate in catching the fish must not assist with processing the fish. Fish must not be processed when there is a condition that may lead to serious contamination or to product that is tainted, decomposed or unwholesome.

- Fish imported into Canada by a person holding a valid

import licence that is exported for direct sale to the consumer without further processing.

- Final products processed by a registered establishment may be stored in an unregistered cold-storage or other unregistered locations prior to marketing provided that the fish is not further processed in any manner at the unregistered establishment.

- Live fish, including live lobsters and crabs, and fresh whole or dressed fish, may be washed, iced or boxed at an unregistered establishment. Exceptions to this includes:

  - shellfish;
  - scallop adductor muscle after unloading from catch vessel;
  - echinoderms;
  - fish raised in an aquaculture operation; and
  - crustaceans, other than noted above;

  which must all be processed, which includes washing, boxing and icing, at a registered establishment. Note that an unregistered establishment cannot dress or grade fish unless the dressing or grading is needed to preserve product quality and safety before delivery to a registered establishment.

- Fishing vessels that are not registered may freeze whole or dressed fish, other than shellfish, echinoderms or crustaceans provided that the fish are destined for further processing at a registered establishment. Shrimp are excluded from the types of crustaceans identified above and may be frozen by an unregistered vessel provided they are then delivered to a registered establishment for further processing.

- Fishing vessels that are not registered may remove the adductor muscles from scallops with or without the roe attached.

- Initial actions taken by a fisher or an unregistered establishment to preserve the safety and quality of fish before delivery to a registered establishment for further processing before export. These actions would be limited to those that are considered necessary to preserve the quality and safety of the fish, and would include freezing, dressing or icing as long as they were performed in compliance with the FIR.

Federal registration is available to all Canadian fish

processing establishments where the operator of the establishment is willing and able to comply with the requirements of the FIR (see Section 3.5).

3.1.2 An establishment's certificate of registration includes all buildings that are found at a single location and that are used together as part of its operation(s) (see Chapter 2, Subject 3 of this manual).

3.1.3 An establishment located in Canada that processes fish, and sells that fish via the Internet or mail order sales to a person located outside of the province where the establishment is located, would be subject to the requirements of the FIR and must be registered. These cases should be carefully evaluated to determine whether or not there is intent to export fish as companies that advertise fish via the Internet or via mail order catalogues for only intra-provincial sale would not be subject to the requirements of the FIR and therefore do not require registration.

3.1.4 When actions taken to export fish are performed entirely by the consumer of the fish without assistance from any other person, then those actions are exempt from the inspection requirements of the FIR, since the fish is being exported by a person for their own personal consumption. Examples include cases where a person purchases fish from an establishment, and then transports it across a border for that person's own consumption, or processes the fish and then transports the fish across a border for his or her own personal consumption. In this example, the establishment from which the fish was exported need not be registered.

3.1.5 All fish processing and fish products in a registered plant must be identified and included in the QMP Plan. Although fish products for intra-provincial sale are not subject to the FIR, it is not possible to leave them out of the Quality Management Program (QMP) Plan.

Once a fish plant is federally registered, all of its facilities, equipment and processing operations are subject to regulatory requirements at all times, regardless of whether the fish products produced in it are for export or intra-provincial trade.

A person may request the operator of a registered establishment to custom process fish for that individual's own personal consumption. Such cases could include the custom processing of sport caught fish. The registered establishment must include the controls they will

implement for that service in their QMP Plan.

3.2 Administration of Certificates of Registration

3.2.1 The authority to issue and to take other actions with respect to an establishment's certificate of registration rests with the President of the CFIA or delegate. Regional Directors have been identified as delegates to the President for these activities.

3.2.2 Regional Directors will establish a process to issue, renew, suspend, revoke, reinstate, amend, inactivate, or reactivate a certificate of registration in their region in accordance with these policies and procedures. The process should include maintenance of adequate records of all registered establishments, including all relevant information and documents in cases where an application for a new or renewed certificate of registration or a request for reinstatement, inactivation, reactivation, or amendment is refused. Records should include the reason(s) for the refusal. The procedures should identify the appropriate personnel who will be involved in the different steps of the process. The identity of appropriate personnel to perform these tasks will be based on factors such as their job descriptions, designation as an inspector under the authorities of the Fish Inspection Act, and appropriate training and experience.

3.3 Certificates of Registration for New Establishments

3.3.1 Upon accepting an application with all required information and payment of fees, the CFIA will issue a certificate of registration for a new establishment provided that it meets the requirements of Schedules I and II of the FIR, it is free from serious contamination, and it has an acceptable QMP Plan. The process to evaluate the application and verify that the applicant will meet the conditions of registration should be determined by personnel with appropriate training and experience to verify compliance with the FIR.

A newly registered establishment must meet all requirements of Schedule I of the FIR, including those that apply to establishments constructed after they came into force in April, 1999.

The CFIA will work co-operatively with applicants to provide them with adequate information on all regulatory

requirements. The applicant must take appropriate corrective actions when they do not meet these requirements before the certificate of registration will be issued.

A certificate of registration will not be issued for an establishment when the Regional Director has determined that there are reasonable grounds to believe that the applicant will not comply with the FIR.

3.3.2 An establishment will be considered a "new" establishment for the purposes of an application for a certificate of registration when:

a) it has not been previously federally registered under the FIR; or

b) it had previously been registered, and a sufficient period of time has elapsed after the registration expired such that the establishment, and/or any previously developed QMP Plan, may not comply with the requirements of the FIR, and in the opinion of the Regional Director or delegate, a Systems Verification and/or a Schedule I and II inspection must be performed to verify compliance; or

c) it is currently registered under the Meat Inspection Act or the Canada Agricultural Products Act but has not yet been registered under the Fish Inspection Act and Regulations; or

d) in the case of a currently registered establishment, the processing facilities are moved from either:

i) one building to another at the location identified on its Certificate of Registration; or

ii) the location identified on its Certificate of Registration to any other location.

3.4 Renewal of Certificates of Registration for Existing Establishments

3.4.1 Upon receiving an application, the CFIA will renew a certificate of registration for an existing establishment that is currently registered, provided that it meets the requirements of the FIR.

3.4.2 The process to renew a certificate of registration will include a review of the information in the application, and a review of the status of the establishment and its

QMP Plan. When there has been no opportunity to conduct any Compliance Verification activities at an establishment during the past year, an inspector should verify compliance with Schedule I before renewing the certificate of registration.

3.4.3 The establishment is responsible to apply for renewal of their certificate of registration before it expires. No fish may be processed for export at an establishment with an expired certificate of registration.

3.5 Refusal to Issue or Renew a Certificate of Registration

3.5.1 A certificate of registration will not be withheld from an establishment when the operator of the establishment is willing and/or able to comply with the FIR through co-operation with the CFIA.

The Regional Director's decision to refuse to issue or to renew a certificate of registration will be the result of the operator of the establishment showing a willful, reckless, or negligent disregard for complying with the conditions of the certificate as prescribed by the FIR. Examples of when a Regional Director will refuse to issue or renew a certificate of registration for an establishment include, but are not limited to, the following:

a) there are reasonable grounds to believe that the applicant or the operator of the establishment has provided false information to the CFIA for the purpose of obtaining a certificate;

b) the establishment is not free from serious contamination;

c) the establishment is not operated in accordance with its QMP Plan;

d) the operator has not taken actions in response to a complaint that suggests that the fish processed at the establishment may present a risk to the health of consumers, or has not informed the CFIA when their actions indicate that the complaint was valid and the health of consumers is at risk; or

e) the operator of the establishment otherwise fails to comply with the FIR or a condition of the certificate of registration.

3.5.2 A certificate of registration will not be renewed if the

establishment has unpaid fish inspection fees (see Chapter 2, Subject 3 of this manual).

3.6 Expiry of a Certificate of Registration

3.6.1 A certificate of registration expires one year after the date of issue. In the case of a certificate of registration that is renewed before expiry, this will be one year from the date which is identified upon the existing certificate of registration.

3.6.2 Once a certificate of registration has expired, no processing of fish or fish products for export may take place at that establishment. The certificate may be renewed at a later date. The expiry date for the certificate of registration will be one year following the date of issue.

3.7 Certificates of Registration Not Assignable or Transferable

3.7.1 A certificate of registration is issued to the applicant in respect of the establishment identified upon the certificate. A certificate of registration is not assignable or transferrable to any other person, nor is it assignable or transferrable to any other establishment.

3.7.2 The owner of an establishment cannot transfer the certificate of registration to another person or company during a change of ownership of that establishment. A change in ownership of an establishment will be considered to have occurred when the owner, (e.g., person, partner(s) or company) identified in the application for the certificate of registration has (have) transferred the controlling interest of the establishment to another person(s) or company.

This does not include a change in shareholder status, or the transfer of ownership of a parent company, provided that the immediate ownership of the registered establishment remains the same (see Section 3.8 below).

3.8 Amendment of a Certificate of Registration

3.8.1 The holder of a valid certificate of registration may request its amendment. An amendment would be required in situations where there are changes in:

- an officer of the company named in the application for the certificate provided that person was not the sole or part owner of the establishment;

- the legal name of the establishment;
- the size of the processing area; or
- the types of fish processing operations conducted at the establishment.

3.8.2 Upon written request by the holder of a certificate of registration, the CFIA will amend the certificate, provided that all the necessary information has been supplied and the establishment meets the requirements of the FIR.

When the amendment concerns a change in the size of the processing area, the establishment may require inspection to verify compliance with the requirements of Schedule I as a result of any renovations.

When the amendment concerns a change in processing operations, a systems verification of the amendments to the QMP Plan should be conducted to verify that adequate controls have been implemented.

3.8.3 The certificate of registration will not be amended if the establishment has unpaid fees (see Chapter 2, Subject 3 of this manual).

3.9 Certificate of Registration Becomes Void

3.9.1 A certificate of registration becomes void in any one of the following situations:

a) there is a change in the ownership of the registered establishment identified on the certificate of registration (see section 3.7);

b) the establishment is subject to receivership, or the owner has made an assignment in bankruptcy with regards to the registered establishment (see section 3.11 below regarding a temporary certificate of registration);

c) the owner of the establishment permanently ceases to operate it as a fish processing business (see section 3.10 below regarding inactivation of the certificate when the owner of the establishment plans to temporarily cease fish processing activities);

d) the operator of the establishment surrenders the certificate of registration to the CFIA; or

e) the registered establishment and/or the equipment or conveyances contained in it are destroyed or damaged to the extent that it is not possible to conduct fish processing or storage operations in compliance with the FIR.

3.9.2 Once a certificate of registration for an establishment becomes void, no fish or fish products may be processed for export at the establishment until a new certificate of registration has been issued for the establishment.

3.10 Inactivation of Certificate of Registration

3.10.1 A certificate of registration may be temporarily inactivated upon written request by the operator of a registered establishment. Inactivation is a status of the registration that allows the operator of an establishment to maintain the certificate of registration for the establishment during a period when no processing of fish and fish products for export is taking place.

There are a number of situations in which the operator of an establishment may inactivate the certificate of registration. These include:

- the establishment operates on a seasonal or intermittent basis, and is now closed;
- fish or fish products continue to be processed in the establishment, but not for export;
- the establishment will temporarily be used for another commercial activity; or
- the establishment operators decide to cease operations in order to make changes to the QMP Plan or the establishment.

3.10.2 The Regional Director will make the decision with respect to the acceptability of the request to inactivate the registration following a review of the information provided by the operator. Inactivation will not be granted if the establishment has unpaid fees (see Chapter 2, Subject 3 of this manual), or the inactivation is requested for fraudulent purposes or to bypass the operator's responsibilities to comply with the conditions of registration.

3.10.3 During the period while an establishment's Certificate of Registration is inactivated, the establishment must comply with the conditions applicable to the status of

inactivation. No regulatory verification activities will be undertaken in the establishment by the CFIA during this time.

3.10.4 There must be no processing of fish or fish products for export in an establishment once its certificate of registration has been inactivated.

3.10.5 The period of inactivation cannot extend beyond the expiry date of the current certificate of registration.

3.10.6 A holder of a certificate of registration that has been inactivated may request that it be reactivated. Upon written request by the holder of the inactivated certificate, the CFIA will reactivate the certificate of registration following verification that the establishment complies with all conditions of registration prescribed by the FIR to operate the establishment to process fish for export.

3.11 Temporary Certificate of Registration

3.11.1 When the certificate of registration for an establishment becomes void because of receivership or bankruptcy as described in section 3.9, the receiver or trustee in bankruptcy may wish to continue operating the establishment while its future is being determined. The receiver, or the trustee in bankruptcy, may apply for a temporary certificate of registration, which allows the establishment to continue producing and exporting fish and fish products.

3.11.2 Upon receiving an application, the CFIA will issue a temporary certificate of registration to an establishment provided that it meets the requirements of the FIR.

3.11.3 The maximum period of time for a temporary certificate of registration to be valid is 240 days from the date of issue.

3.11.4 A temporary certificate of registration is not assignable or transferrable.

3.12 Suspension of a Certificate of Registration

3.12.1 A Regional Director may suspend an establishment's certificate of registration in situations where the operator of the establishment is unable or unwilling to comply with the FIR. Actions leading to the suspension of an establishment's certificate of registration will be conducted in accordance with the Fish Inspection Program

Compliance Management Process.

The following situations provide examples of when the CFIA will take actions leading to the suspension of an establishment's certificate of registration:

- the operator of the establishment has not taken actions to respond to information questioning the safety of fish that was processed or stored in the establishment, or has not informed the CFIA when their actions indicate that the fish is a hazard to the public; or

- a compliance verification identifies non-conformities and the operator of the establishment is unwilling or unable to address the non-conformities through the development and implementation of an acceptable Corrective Action Plan.

3.12.2 A CFIA Regional Director may, upon request by the holder of the certificate, reinstate a certificate of registration which has been suspended once it has been verified that all instances of non-compliance have been corrected and the requirements of the FIR have been met. The request to reinstate the certificate must be provided in writing within 30 days of the suspension. Assessment criteria used to determine if the certificate of registration should be reinstated will include:

- an evaluation of the written submission;

- if applicable, on site verification of any corrective actions; and/or

- interviews with management and operators through a formal hearing and/or on site visits.

3.13 Revocation of a Certificate of Registration

3.13.1 A Regional Director may revoke an establishment's certificate of registration. Enforcement actions that lead to the revocation of an establishment's certificate of registration will be conducted in accordance with the Fish Inspection Program Compliance Management Process.

Revocation of the certificate of registration will occur following its suspension when the request to reinstate the certificate was denied.

A certificate of registration may also be revoked in situations where there are reasonable grounds to believe

that the operator of the establishment has provided false information for the purposes of obtaining a certificate.

3.13.2 A CFIA Regional Director may, upon request by the holder of the certificate, reinstate a certificate of registration which has been revoked once it has been verified that all instances of non-compliance have been corrected and the requirements of the FIR have been met. The request to reinstate the certificate must be provided in writing within 30 days of the revocation. Assessment criteria used to determine if the certificate of registration should be reinstated will include:

- an evaluation of the written submission;
- if applicable, on site verification of any corrective actions; and/or
- interviews with management and operators through a formal hearing and/or on site visits.

3.13.3 A CFIA Regional Director may revoke a certificate of registration when an inspector is unable to contact the operator of the establishment for a period of 90 days. This action will not be taken for seasonal operations or establishments with an inactive certificate of registration.

4. PROCEDURES

4.1 General

4.1.1 An establishment will be issued one certificate of registration that will include all of the processing operations conducted within the establishment as requested by the applicant.

Establishments that wish to export shellfish to the United States must be listed on the Interstate Certified Shellfish Shippers List (ICSSL). Refer to Chapter 1 of the Canadian Shellfish Sanitation Program - Manual of Operations for more information on ICSSL listings (to be issued at a later date).

4.1.2 A certificate of registration for an establishment must identify all of the types of processing operations that may be conducted within the establishment (see Appendix B of Chapter 2, Subject 3 of this manual for guidelines on operation types). No processing operation can take place unless the establishment is registered for that type of

operation as identified on the certificate.

4.1.3 Each certificate of registration will be assigned a unique registration number.

Refer to Chapter 1 of the Canadian Shellfish Sanitation Program - Manual of Operations for more information concerning the registration number of an establishment that is listed on the ICSSL (to be issued at a later date).

4.1.4 An establishment receiving a new certificate of registration will normally be given a registration number that has not previously been used.

However, where there is a transfer of ownership of a currently registered establishment, the Regional Director may, upon request, issue a certificate of registration to the new owner which bears the same registration number and/or establishment name as the original certificate of registration. This will require verification that the use of the same registration number will not create difficulties in tracing product origin.

4.1.5 CFIA Regional Directors will designate personnel to maintain and update information related to the registered fish processing establishment in the appropriate CFIA databases, including its current regulatory status.

Personnel should take the necessary steps to verify that the names of establishments with new or renewed certificates are added to, or maintained on, the appropriate lists of registered establishments maintained by the CFIA.

4.1.6 The name of the establishment will be removed from any export list of registered establishments maintained by the CFIA when a certificate of registration expires, is suspended, revoked or declared void. The CFIA will notify the establishment that their name will be removed from the lists prior to taking this action. Upon written request, the CFIA may allow an establishment to remain on an export list for a specified period of time (depending on the nature of the product and the volume of inventory) when the following conditions are met:

- the establishment has product in storage that was processed when it had a valid registration;
- the product is in compliance with the FIR;

- the operator of the establishment can demonstrate sufficient controls on their inventory such that they will only export product that was processed when the registration was valid;

- there are no reasonable grounds based on objective observations and/or past performance of regulatory compliance, to believe that the owner intends to conduct fraudulent activities; and

- the arrangement between Canada and the foreign country concerning the administration of the export list allows for establishments to remain on the list after their registration has expired.

4.1.7 All records concerning the administration of an establishment's certificate of registration will be maintained in accordance with the CFIA's *Recorded Information Management Policy*.

4.2 Issuing a New Certificate of Registration

4.2.1 Any person wishing to obtain a certificate of registration for a new fish processing establishment must submit a properly completed "Application for Registration of Fish Processing Establishments" form (see Appendix A) to the designated office in their region. The applicant should be the operator of the establishment (this can be the owner of the establishment, one of the partners owning it, a key officer of the company owning it, or the manager of the establishment when it is operated on behalf of an owner or company).

The following information must be included with the application:

- the full business name, business address and business telephone number of the applicant and, if applicable, the full names of partners or officers of the company. This section should include a description of the ownership of the establishment indicating whether it is privately owned by an individual or a partnership, or owned by a corporation. In addition, where the establishment is operated by a partnership or a corporation, the full names of all partners, or officers of the corporation;

- a description of the types of process operations intended to be conducted. See Appendix B of Chapter 2, Subject 3 for guidelines on process operations;

- the types of fish products intended to be produced, stored or exported;
- a product description of each type of fish product intended to be produced, stored or exported;
- a process flow diagram that identifies each step in the process operation for each type of fish product; and
- a detailed diagram of the establishment with dimensions of the processing area.

Details described above that are not included in the application form may be included in the applicant's QMP Plan. The QMP Plan is a document outlining the Quality Management Program (QMP) that will be implemented in the establishment, and should accompany the application.

The application should include a self-verification of the QMP Plan by the operator of the establishment. This is a document signed by the applicant that attests that they have validated the critical limits of the CCP's and verified that the QMP plan meets the criteria of the Reference Standard (see Section 6.0 of the QMP Reference Standard). A self verification checklist may be used by the applicant and is included as Appendix C of this Chapter.

The application for a certificate of registration for a new establishment must be accompanied by full payment of the appropriate fee. See Chapter 2, Subject 3 for more details on the calculation of the appropriate registration fees.

4.2.2 Personnel with appropriate training and experience will evaluate each application for a certificate of registration for a new establishment. This evaluation will include, but is not limited to, the following:

a) a review of the information submitted for the purposes of identifying the applicant and the establishment (i.e., name, address, telephone number, etc. and, if applicable, the names of partners or officers of the corporation operating the establishment) and verification that the information is complete and accurate;

b) a review of the self-verification of the QMP;

c) a Systems Verification of the QMP Plan to verify that

it meets the requirements of the QMP Reference Standard (see Chapter 3, Subject 2 and Chapter 3, Subject 4, of this manual); and

d) an on-site inspection of the establishment to determine its compliance with criteria prescribed by the FIR, including activities to verify:

- the requirements set out in Schedules I and II (see Appendix E);
- freedom from serious contamination; and
- the relevant elements of the QMP Plan (such as process flow diagram and plant layout) to identify that it meets the criteria of the QMP Reference Standard.

The applicant may be provided with the registration number upon submitting their application and full payment, prior to completion of the above steps. This may be done in order to allow the applicant to take appropriate steps to design packaging materials or to apply for inclusion on export lists such as the EU List. If the applicant expresses an interest in exporting to the EU, and an inspector has verified that they will comply with the requirements of Schedules I and II of the FIR, then the inspector may take appropriate actions to request an addition to the EU list.

4.2.3 When the evaluation described in subsection 4.2.2 indicates that an applicant has met all the requirements of the FIR, including payment of all fees, and there are no reasonable grounds based on objective observations and/or past performance of regulatory compliance to believe that the applicant will not comply with the FIR, a certificate of registration will be issued and sent to the applicant. This certificate of registration will be signed and dated by the Regional Director. The certificate of registration cover letter (Appendix D) will accompany the signed copy of the certificate of registration that is delivered to the establishment.

Records of the evaluation should be maintained on file that include the following:

- Schedule I and II reports (see Appendix E);
- Self Verification Checklist;
- Systems Verification Report;
- Application Form.

4.2.4 When the evaluation described in subsection 4.2.2 indicates that the applicant has failed to meet the requirements of the FIR, a certificate of registration will not be issued. The CFIA will contact the applicant to inform them of the requirements that have not been met.

4.2.5 To facilitate ongoing processing operations during the transfer of ownership of an establishment, the new certificate of registration may be issued to coincide with the date the transfer of ownership takes place.

4.2.6 Compliance verification of a newly registered establishment will be performed as described in Chapter 3, Subject 3 of this manual.

4.3 Renewal of a Certificate of Registration

4.3.1 The CFIA will send the holder of a certificate of registration a notice of renewal, at least 60 days before its expiry, to advise them that their certificate will expire. The notice of renewal should include:

a) a bilingual cover letter, stating that the certificate of registration will expire, identifying the date when it will expire, explaining the requirements for renewal, and advising that no fish may be processed for export once the certificate has expired. This letter must also identify the complete CFIA address where the client is to return their application with full payment, in addition to a contact location (see sample letter in Appendix B);

b) a registration application form (Appendix A).

4.3.2 Prior to expiration of the establishment's certificate of registration, the CFIA may contact the person to remind them that their certificate will expire and to determine the person's intent with regard to renewal of the establishment's certificate of registration.

4.3.3 Processing of fish with the intent to export must cease following the expiration of a certificate of registration.

4.3.4 When renewing their certificate of registration, the operator of a registered establishment should submit a properly completed Application For Registration form.

A person applying to renew an existing certificate of registration does not need to provide the following information as long as it has been previously submitted and there have been no changes:

- the types of fish products intended to be produced, stored or exported;
- a product description of each type of fish product intended to be produced, stored or exported;
- a process flow diagram that identifies each step in the process operation for each type of fish product; and
- a detailed diagram of the establishment.

When there have been changes to this information, the person applying to renew their existing certificate of registration should indicate that there has been a change in the appropriate section of the Application for Registration form. Details about the change should not accompany the form, since this information should be included as part of the establishment's QMP Plan. The CFIA will verify that the establishment's QMP Plan is accurate, and reflects the current processing conditions during the next scheduled Compliance Verification.

4.3.5 The CFIA will review the information submitted by the applicant to renew their certificate of registration and the status of the establishment and its QMP Plan before renewal. For establishments that have not had a compliance verification conducted in the past year, an inspector will verify its compliance with Schedule I requirements and the status of the QMP Plan (see Appendix E).

4.3.6 The certificate of registration will be recommended for renewal when the review of the application indicates that:

- the information provided by the applicant is complete and accurate;
- the establishment is in compliance with the FIR; and
- payment for all applicable fees is included and establishment has no unpaid fees (see Chapter 2, Subject 3 of this manual).

The certificate of registration will be signed and dated by the Regional Director, and forwarded to the applicant. The certificate of registration cover letter (Appendix D) will accompany the signed copy of the certificate of registration that is delivered to the establishment.

4.3.7 When a certificate of registration is renewed, the

certificate issued will have the same registration number as the original Certificate of Registration.

4.3.8 An inactivated certificate of registration will no longer be valid after its expiry date and must be renewed. A request to renew an inactivated certificate will be treated as a request for reactivation unless the holder of the certificate is simultaneously requesting another inactivation. See section 4.9 below for further details.

4.3.9 The CFIA will contact the applicant when the information provided to renew their certificate of registration is not complete and/or accurate. Every effort will be made to obtain the necessary information before the expiry of the certificate to allow the establishment to operate. Efforts to contact the applicant to acquire the necessary information should be documented and kept on file. The Regional Director may use discretion to renew the certificate of registration for an establishment that is willing and able to comply with the FIR but has not been able to provide the necessary information before the expiration of the certificate.

4.3.10 If an establishment chooses to allow its certificate of registration to expire for a short period of time because of seasonal availability of products, or other factors, the establishment may renew its certificate at a later date, provided that all fees have been paid and the establishment meets all other requirements of the FIR. The date of issue displayed on the certificate of registration will correspond to the date that it became effective, and will not be back dated to correspond with the expiry date of the old certificate.

It may not be necessary to remove an establishment from an export list if it's certificate of registration expired and it plans to renew its certificate at a later date provided the establishment can demonstrate product compliance and the necessary controls described above. See Section 4.1.6 above.

4.4 Refusal to Renew A Certificate Of Registration

4.4.1 The Regional Director may refuse to renew a certificate of registration when:

- the applicant has provided false or misleading information;
- the review of the status of the establishment and its QMP Plan indicates that the operator is unwilling or

unable to comply with the conditions of registration based on objective observations and/or past performance of regulatory compliance; or

- the establishment has unpaid fees (see Chapter 2, Subject 3).

Documents justifying the refusal to renew the certificate of registration should be kept on file. The Regional Director will notify the applicant in writing and provide an explanation of the reasons why the certificate of registration will not be renewed.

4.4.2 If the applicant is able to take corrective actions to demonstrate compliance with the conditions of registration and/or reinstate their credit privileges, the Regional Director may renew their certificate of registration.

4.5 Suspension or Revocation of a Certificate of Registration

4.5.1 The Regional Director will provide the operator of an establishment whose certificate of registration is suspended or revoked with a written notice of the suspension or revocation. The notice should be delivered by hand or by registered mail to the operator as appropriate.

4.5.2 A certificate of registration will be revoked following a suspension if the operator has not requested a reinstatement within 30 days following the initial notice of suspension. The Regional Director will provide the operator of an establishment whose certificate of registration is revoked with a written notice of the revocation. The notice should be delivered by hand or by registered mail to the operator as appropriate.

4.5.3 A certificate of registration will be revoked if an inspector is unable to contact the operator of an active establishment for a period of 90 days. The inspector must document and keep records of each attempt to contact the establishment. The Regional Director will provide the operator of an establishment whose certificate of registration is revoked with a written notice of the revocation. The notice should be delivered by registered mail to the mailing address provided by the operator on their application for registration.

4.6 Reinstatement of a Certificate of Registration

4.6.1 The holder of a certificate of registration which has been suspended or revoked may apply for reinstatement of the

certificate by writing to the CFIA Regional Director within 30 days of the date of the suspension or revocation. The request for reinstatement may be in the form of an appeal of the suspension or revocation or as a written Corrective Action Plan describing how compliance will be achieved.

The operator of the establishment must not process fish for export until the certificate of registration is reinstated.

4.6.2 After receiving an establishment's request for reinstatement, the CFIA will evaluate the request and verify the establishment's compliance with the FIR. This will include a review of the circumstances which led to the suspension or revocation being taken, and a review of the Corrective Action Plan submitted. Other possible actions include:

- an on-site inspection of the establishment to verify its compliance with the FIR;
- a formal hearing with the operator of the establishment; and
- any other actions deemed to be appropriate.

If required, this review may take longer than the thirty days provided for the operator to request reinstatement of the certificate.

4.6.3 Cost recovery fees, as set out in Chapter 2, subject 3 of this manual, must be paid in full before the reinstatement of a certificate of registration.

4.6.4 The decision to reinstate the certificate of registration will be based on factors such as:

- an evaluation of the corrective actions to verify that they result in compliance with the FIR;
- the ability of the operators of the establishment to demonstrate a clear understanding of their responsibilities to develop and maintain a QMP Plan that meets the requirements of the Reference Standard, and their commitment to its implementation;
- the ability of the operators of the establishment to take the necessary actions to control any non-compliant products that where implicated in the suspension or revocation of the certificate of

registration.

The Regional Director will notify the operator of the establishment of the reinstatement by means of a letter sent by registered mail or other suitable means. This letter will state the effective date of reinstatement of the certificate of registration.

The reinstated certificate of registration will carry the same expiry date as the original certificate.

4.6.5 When the operator of the establishment has failed to submit an acceptable Corrective Action Plan or implement actions to comply with the FIR, the request for reinstatement of the certificate of registration will be denied. The Regional Director will inform the applicant of this decision by means of a letter sent by registered mail or other suitable means. This letter will explain the reason(s) for denial of the application and will advise the applicant of the instances where regulatory requirements have not been met.

4.6.6 The Regional Director may reinstate a certificate of registration of an establishment that was revoked when an inspector was unable to contact the operator following a period of 90 days when the operator is able to provide the reasons why nobody could be contacted and a corrective action plan that provides a suitable contact person for the establishment.

4.6.7 The decision of the Regional Director not to reinstate a certificate of registration that has been revoked is final and is not subject to further appeal.

4.6.8 A subsequent request for a certificate of registration for an establishment where the original certificate was revoked, and the request to reinstate the revoked certificate was denied, will be treated as a request for a new establishment.

4.7 Amendment of a Certificate of Registration

4.7.1 An operator of a registered establishment who wishes to amend its certificate of registration should submit a completed Application for Registration form to the CFIA Regional Director in their region. This form is attached to this subject as Appendix A.

When the amendment requested involves a change in the operations that are conducted at the establishment, the QMP Plan must be amended to reflect these changes. The

operator should review and amend their plan in order that all the necessary controls are implemented to address the new operations to ensure they are performed in compliance with the FIR. A self-verification of the amended QMP Plan must also be conducted by the operator of the establishment to validate the critical limits of the CCP's and to verify that the QMP plan meets the criteria of the Reference Standard (see Section 6.0 of the QMP Reference Standard). The amended QMP Plan, and the self-verification, should be submitted at the same time as the application for amendment.

4.7.2 The CFIA will review each application for amendment of a certificate of registration. This will include a review of the reason(s) for the request and any supporting documents. Where applicable, the review of the request for amendment will include the following:

- a review of the self-verification submitted;
- an review of the amended QMP Plan submitted in relation to the application for amendment;
- an on-site verification of the establishment to determine its compliance with the FIR; and/or
- any other actions deemed necessary to verify that the establishment is, and will remain, in compliance with the FIR.

If the request for amendment of a certificate of registration is missing essential information such as the amended QMP plan, or a self-verification, then the CFIA will contact the applicant and request that these documents are made available before taking further actions.

4.7.3 When the review described in subsection 4.7.2 indicates that the application is complete and all requirements of the FIR have been met (including the payment of any associated fees, as identified in Chapter 2, Subject 3 of this manual), an amended certificate of registration will be issued to the applicant. This certificate of registration will be signed and dated by the Regional Director.

4.7.4 An amended certificate of registration will carry the same expiry date as the original certificate, and will be modified to reflect all the changes which have been approved by the Regional Director.

4.7.5 The certificate of registration will not be amended when the review described in subsection 4.7.2 indicates that the application for amendment is: 1) not complete and the applicant is unable or unwilling to provide the appropriate documents; or 2) does not meet the requirements of the FIR. The Regional Director will notify the applicant by means of a letter sent by registered mail or other suitable means. This letter will explain the reason(s) for the denial of the application, and advise the applicant of the instances where the regulatory requirements have not been met.

4.7.6 When the request for amendment is refused, the case should be reviewed to determine if the further actions are required.

4.8 Change of Ownership of an Establishment

4.8.1 A change of ownership of an establishment will require the new owners of the establishment to apply for a certificate of registration.

The certificate of registration will remain valid if the holder of the certificate ceases to be in control of the registered establishment when the holder is an officer of a corporation, or a manager acting on behalf of an owner of the establishment or a company that owns the establishment. This includes situations where a manager that is identified as the holder of the certificate quits, retires, dies, is incapacitated, demoted or fired. However, the CFIA must be notified by the owner(s) of this change in advance, or immediately after in situations where advance notice is not possible, and the owner(s) must also request an amendment to the certificate.

4.8.2 An inspector should review the conditions related to the change of ownership to determine if a Systems Verification of the QMP Plan is necessary. Systems Verification is necessary when the new owners have made changes that affect the implementation of the original plan such as changes to the plant and/or its operations.

4.8.3 If the establishment continues operation after a change in ownership, there is no need to meet requirements of Schedule I that were applicable after April 1999.

If the establishment has been left dormant for a period of time, which in the opinion of the Regional Director, has resulted in a condition such that the establishment or the QMP Plan no longer comply with the FIR, then the change of ownership should be treated in the same manner as a

request for registration of a new establishment.

4.9 Inactivation of a Certificate of Registration

4.9.1 An operator of a registered establishment who wishes to inactivate its Certificate of Registration should submit a request for inactivation to the CFIA. The request may be made by using the Application for Registration form (Appendix A) or through a written submission containing the required information. The request for inactivation must include the identity of the establishment; the reason(s) for the request; and the period of time for the inactivation. The request must also indicate whether fish processing operations will be continued in the establishment after the inactivation.

4.9.2 The CFIA will review the reason(s) for the request, a review of the compliance history of the establishment, and a verification that all applicable fees have been paid.

4.9.3 If the reason(s) for inactivation is(are) valid (see 3.10 above), all fees have been paid, and there is no cause to suspect that the inactivation has been requested for fraudulent purposes based on objective observations and/or past performance of regulatory compliance, the certificate of registration will be inactivated. The Regional Director will notify the operator of the establishment of the inactivation by means of a letter sent by registered mail or other suitable means.

4.9.4 If the review indicates that the applicable fees have not all been paid, the reason(s) for the request for inactivation is(are) not acceptable, or fraudulent intention is suspected (e.g., fish products will continue to be processed for export at the establishment), the inactivation will not be granted. The Regional Director will inform the operator of the establishment of this decision not to inactivate by means of a letter sent by registered mail or other suitable means.

4.9.5 If the inactivation is granted and the operator of the establishment intends to continue processing fish and fish products for intra-provincial sale, provincial authorities will be contacted so that they may take appropriate actions.

4.9.6 Once an inactivated certificate of registration has expired the operator of the establishment may apply for renewal of the certificate as set out in section 4.3. The operator may also apply for continued inactivation of the certificate at the same time. The application for renewal

of the certificate will be treated as a request for reactivation unless the holder of the certificate simultaneously requests inactivation.

4.9.7 The operator of a registered establishment which has had its certificate of registration inactivated may continue to store and/or export fish and fish products that were produced prior to the inactivation, providing that all of the following conditions are met:

- the product must be stored in a manner that prevents its contamination;
- the product must be clearly identified by means of production dates, or other appropriate markings, to verify that it was processed during the time that the establishment held a valid Certificate of Registration;
- the product must be in final product form, and must be fully packaged;
- the product must be continuously stored under appropriate conditions; and
- the product must meet all other provisions of the FIR.

4.10 Reactivation of a Certificate of Registration

4.10.1 The operator of a registered establishment that has had its registration inactivated may request a reactivation of the Certificate of Registration by applying in writing to the CFIA Regional Director in that region.

4.10.2 The CFIA will evaluate a written request for reactivation of a certificate of registration to verify that the establishment complies with the conditions of operating with an active certificate. This evaluation will include a review of the reason(s) for the inactivation, a review of the compliance history of the establishment and the circumstances under which the inactivation was granted. The inspector should take the necessary actions to verify compliance with the FIR before the certificate is reactivated.

4.10.3 If the inactivation was originally requested, and granted, after a Compliance Verification identified non-conformities in the establishment, the evaluation will include appropriate activities to verify that the establishment has implemented the Corrective Action Plan and is in compliance with the FIR.

4.10.4 When the evaluation described in subsection 4.10.2 indicates that the requirements of the FIR have been met (including the payment of any associated fees, as identified in Chapter 2, Subject 3 of this manual), the certificate of registration will be reactivated.

4.10.5 When the evaluation described in subsection 4.10.2 indicates that the requirements of the FIR have not been met, the certificate of registration will not be reactivated. The Regional Director will notify the applicant by means of a letter sent by registered mail or other suitable means. This letter will explain the reason(s) for the denial of the application, and advise the applicant of the instances where the regulatory requirements have not been met.

4.11 Issuance of a Temporary Certificate of Registration

4.11.1 A receiver or a trustee in bankruptcy for an establishment whose certificate of registration has been voided may apply for a temporary certificate of registration by submitting a properly completed "Application For Registration" form (Appendix A) to a CFIA Regional Director.

4.11.2 The CFIA will evaluate each application for a temporary certificate of registration. This will include a review of the information submitted, a verification that the applicant is the authorised receiver or trustee in bankruptcy, and a review of the recent compliance records of the establishment. Where the review indicates that the information submitted is inadequate, the applicant will be informed that more information is required.

4.11.3 If the review indicates that there are outstanding Corrective Action Plans, or modifications to the establishment or its QMP that could affect the operation of the establishment, an inspector should take the appropriate actions to verify that the establishment and its operations will meet the requirements of the FIR.

4.11.4 When the evaluation indicates that the application is complete and the establishment is in compliance with the FIR, the Regional Director will issue a temporary certificate of registration and forward it to the applicant.

4.11.5 Where the evaluation indicates that the applicant fails to meet the requirements of the FIR, a temporary certificate of registration will not be issued. The Regional Director will inform the applicant of this decision by means of a

letter sent by registered mail or other suitable means. This letter will provide an explanation of the decision not to issue a temporary certificate.

5. FORMS/DOCUMENTS

Appendix A - Application for Registration of Fish Processing Establishments

Appendix B - Notice of Expiry of a Certificate of Registration

Appendix C - Self Verification Checklist

Appendix D - Certificate of Registration Cover Letter

Appendix E - **Certificate of** Registration

APPENDIX A

APPENDIX B

APPENDIX C

SELF VERIFICATION CHECKLIST / LISTE DE CONTRÔLE DE L'AUTOVÉRIFICATION

Plant Name / Nom de l'usine		Registration Number / Numéro d'enregistrement	
Mailing Address / Adresse postale		Telephone: Fax: Téléphone : Télécopieur :	
Plant Manager / Directeur d'usine		Quality Management Coordinator / Coordonnateur de la gestion de la qualité:	
Verifier / Vérificateur		Date of verification / Date de la vérification	
Comments / Commentaires:			
Component / Composante	Yes/Oui	No/Non	Comments/ Commentaires:
1. Management Roles and Responsibilities (Recommended but optional) / **Rôles et responsabilités de la direction** (Recommandé mais facultatif)			
Development of QMP Described / Élaboration du PGQ - décrite			
QMP Manager Identified / Responsable du PGQ - identifié			
Roles and Responsibilities identified / Préparation de l'organigramme - terminée			
2. Background Product and Process Information / Description du procédé et du produit			
Product Description completed for each type of product / Description du procédé pour chaque catégorie de produits - terminée.			
Process flow diagram completed / Diagramme de fabrication - terminé			
Plant floor diagram completed / Schéma des opérations de l'usine - terminé			

3. Prerequisite Plan / Programmes préalables			
Plant Environment Program / Programme environnement de l'usine			
Component / Composante	Yes/Oui	No/Non	Comments/ Commentaires:
Standard identified (Minimum FIR) / Norme - définie (minimum RIP)			
Documented sanitation program complete / Programme d'assainissement - documenté			
Documented pest control program complete/ Programme de lutte contre la vermine - documenté			
Hygiene and employee behaviour training complete / Formation en hygiène et comportement des employés - terminée			
Controls and monitoring procedures complete / Mesures de contrôle et procédure de surveillance - terminées			
Corrective action system complete / Système de mesures correctives - terminé			
Record-keeping system (forms) developed / Système de registres (formulaires) - établi			
Recall and Notification Procedures Developed / Procédures de rappel et notification - établi			
4. Regulatory Action Point Plan / Plan des points d'intervention réglementaire			
Minimum Acceptable Product Quality Control / Normes minimales acceptables de qualité			
Product standard identified / Norme du produit - définie			
Controls and monitoring procedures complete / Mesures de contrôle et procédure de surveillance - terminées			
Corrective action system complete / Système de mesures correctives - terminé			
Record-keeping system (forms) developed / Système de registres (formulaires) - établi			

Input Materials Controls / Matières premières et matériaux d'emballage			
Component / Composante	Yes/Oui	No/Non	Comments/ Commentaires:
Packaging and ingredients identified and acceptable / Matériaux d'emballage et ingrédients - définis et acceptables			
Controls and monitoring procedures complete / Mesures de contrôle et procédure de surveillance - terminées			
Corrective action system complete / Système de mesures correctives - terminé			
Record-keeping system (forms) developed / Système de registres (formulaires) - établi			
Labelling / Étiquetage			
Labelling standard identified (Fish Inspection Regulations) / Normes d'étiquetage - définies (Règlement sur l'inspection du poisson)			
Controls and monitoring procedures complete / Mesure de contrôles et procédure de surveillance - terminées			
Corrective action system complete / Système de mesures correctives - terminé			
Record-keeping system (forms) developed / Système de registres (formulaires) - établi			
RAPs added to process flow diagram / PIR ajoutés au diagramme de fabrication			
5. HACCP Plan / Plan HACCP			
Component / Composante	Yes/Oui	No/Non	Comments/ Commentaires:
Hazard Analysis complete and accurate/ Analyse des dangers - terminée et exacte			
Significant hazards identified / Dangers importants - recensés			
Control measures for significant hazards developed / Mesures de contrôle des dangers importants - établies			
Critical limits identified / Limites critiques - identifiées			
Monitoring procedures complete / Procédure de surveillance - terminée			

Corrective action system complete / Système de mesures correctives - terminé			
Record keeping system (forms) developed / Système de registres (formulaires) - établi			
HACCP Plan documented / Plan HACCP - documenté			
Supporting Standard Operating Procedures complete / Procédures normalisés d'exploitation - établis			
CCPs added to the process flow diagram / CCP ajoutés au diagramme de fabrication			
Verification procedures identified Procédure de vérification - définie			
6. Verification / Vérification			
Critical limits validated / Valider les limites critiques des CCP			
Schedule and methods for annual verification developed / Programme et méthodes pour l'examen annuel développé			
7. Records / Tenue des registres			
Component / Composante	Yes/Oui	No/Non	Comments/ Commentaires:
Method to record changes to QMP plan developed (e.g., QMP Amendment Log) / Méthodes pour tenir un registre des modifications apportées au plan PGQ développés (p.ex. un registre de modifications)			
Signature		Date	

APPENDIX D
CERTIFICATE OF REGISTRATION COVER LETTER

Date

Company name
Address Line 1
Address Line 2
City, Province
Postal Code

Dear (name of applicant)

On behalf of the Canadian Food Inspection Agency (CFIA), I would like to acknowledge the efforts of you and your staff on meeting the requirements of the *Fish Inspection Regulations* (FIR) for the registration of your establishment. Conditions for the registration of your establishment require the development and implementation of a Quality Management Program (QMP) Plan and operating consistent with the principles of HACCP (Hazard Analysis Critical Control Points). In issuing the attached certificate of registration for your establishment, the CFIA is recognising the HACCP-based QMP Plan that was submitted by your establishment. Please note that the certificate of registration is not valid after its expiry date.

The CFIA will conduct regularly scheduled audits of your establishment to verify compliance with the conditions of registration provided by the FIR. Continued compliance with the FIR is essential to maintain your certificate of registration. Establishments with a valid certificate of registration are considered by the CFIA to be in good standing with the requirements of the FIR, allowing the CFIA to provide such assurances to foreign government inspection services.

For example, the CFIA uses the Canadian List of Approved Exporters to the U.S. as certification that the listed establishments are processing in accordance with the requirements of the U.S. Food and Drug Administration's seafood HACCP regulations (21 CFR part 123). This list can be found on the CFIA web site at:

http://www.inspection.gc.ca/english/anima/fispoi/export/exporte.shtml

Please consult with your local CFIA office for more information on the requirements of the FIR or the inclusion of your establishment on an export list.

Sincerely,

Name
Regional Director
Region, Area

APPENDIX E
CERTIFICATE OF REGISTRATION

New 03/10/31

CHAPTER 2, SUBJECT 3
REGISTERED ESTABLISHMENTS - COST RECOVERY

1. SCOPE

This subject outlines the policies and procedures governing the payment of registration fees and fees for the inspection of fish processing establishments.

2. AUTHORITIES

Fish Inspection Act, R.S. 1985, c. F-12
Fish Inspection Regulations, C.R.C., c. 802
Canadian Food Inspection Agency Fees Notice

3. POLICY

3.1 General

3.1.1 Registration fees apply to fish processing establishments registered under the authority of the Fish Inspection Regulations that process or store fish for interprovincial or international trade (see Chapter 2, Subject 1 of this manual for more details concerning the registration of establishments).

No fees are to be charged to a person that holds a fish export licence that allows them to export live aquaculture finfish or to operate a can screening warehouse for the export of canned fish at an unregistered establishment.

3.1.2 An establishment's certificate of registration includes all buildings that are found at a single location and that are used together as part of the operation(s) described in its Quality Management Program (QMP) Plan. Fees for the certificate of registration will depend on the total processing area of the building(s) and types of processes occurring at this location in accordance with these policies.

When a company processes fish at separate and distinct locations, these locations will be considered as separate establishments and will each be assigned their own certificate of registration.

3.1.3 The Canadian Food Inspection Agency (CFIA) shall charge and

collect all applicable fees for establishment registration identified in the Fish Inspection Regulations and the Canadian Food Inspection Agency Fees Notice. This includes those establishments that are registered with the CFIA for processing a commodity other than fish.

3.1.4 Fees for an establishment's certificate of registration, inspection services required to reinstate the certificate, or other inspection services concerning the establishment or its QMP, must be paid in full before the certificate will be issued or the other inspection services will be provided.

3.1.5 A certificate of registration will be issued, renewed, amended, inactivated, re-activated or re-instated only when the applicant has no unpaid fees owing to the CFIA (see section 4.5).

3.1.6 An establishment's certificate of registration is not assignable and expires one year after the date it was issued.

3.2 Application for a Certificate of Registration

3.2.1 Following the receipt of a completed application, a certificate of registration shall be issued in accordance with the policies and procedures outlined in Chapter 2, Subject 1 of this manual.

Full payment of all applicable registration fees must accompany the application for an establishment's certificate of registration.

3.2.2 Where the operator of the establishment has not paid fees owing to the CFIA for product certification, or for other cost-recoverable services for the inspection of fish, the certificate of registration will not be renewed until all fees owing to the Agency have been paid in full.

3.3 Establishment Size and Operations

3.3.1 The person submitting the "Application for Registration" form (see Appendix C), shall provide complete information and shall calculate the applicable fee in accordance with the size of the facility and the type of process operation.

3.3.2 In determining the size of the establishment's processing area for "registration" purposes, all areas within the perimeter of the building(s) identified under the

establishment's QMP Plan for processing or storing fish are to be included. This does not include other areas where fish is not processed such as:

- offices;
- lunch rooms;
- changing rooms;
- toilet facilities;
- laboratories;
- maintenance shops;

3.3.3 A description of process operation types is provided in Appendix B.

3.3.4 The application must include full payment of all fees relative to the size of the establishment's processing area and types of process operations.

3.4 Depuration Establishment

3.4.1 The initial fees for shellfish depuration establishments are dependent on the size of the establishment and are listed in Table 3 of Appendix A. These fees are one-time only and are applied when the establishment provides their initial application to conduct depuration operations. These fees are additional to all fees for the certificate of registration. The initial fees for depuration establishments include the costs associated with signing the Memorandum of Agreement as described in Chapter 10 of the Canadian Shellfish Sanitation Program Manual of Operations. After the initial year, the fees to renew the certificate of registration are the same as for any other establishment, as listed in Tables 1 and 2 of Appendix A.

Prior to the signing of the Memorandum of Agreement, the process of reviewing and approving the application may be halted at the request of the applicant and no additional start-up fees will be required when the process is reactivated. This is on the condition that the application is for the same depuration facility and is reactivated within a period of time that is acceptable to the Regional Director.

Note: For existing depuration facilities, the system can be modified at no charge, if verification of the modifications are undertaken by the establishment and subsequently approved by CFIA.

3.4.2 If the applicant includes other operation types (e.g., salt

fish at a separate building situated at the same location), additional fees payable shall be as identified in Tables 1 and 2 of Appendix A, as applicable.

3.5 Amendment of a Certificate of Registration

3.5.1 A person requesting an amendment of a certificate of registration will notify the CFIA of the request by completing a "registration application form".

3.5.2 When the amendment involves the addition of a process operation, an additional fee is:

a) not applicable if the process area of the establishment is 300 m^2 or less; or

b) applicable if the process area of the establishment is over 300 m^2 (with the amount corresponding to the fee for that operation type payable at the time of the request).

3.5.3 When the size of the processing area of an establishment is changed after a certificate of registration is issued and during the period for which that certificate is valid, no fees shall be:

a) refunded if the size is decreased from greater than 300 m^2 to 300 m^2 or less; or

b) charged if the size is increased from 300 m^2 or less to greater than 300 m^2, provided that no additional process operations are added to the existing certificates of registration.

Fees may be amended based on these modifications, as applicable, when a certificate of registration is renewed.

When the size of processing area of an establishment is increased from 300 m^2 or less, to greater than 300 m^2, and a request for any additional process operation(s) (including payment of fees), is made during the period for which a certificate of registration is valid, the certificate may be amended in accordance with the policies and procedures described in Chapter 2, Subject 1 of this manual.

3.6 Inactivation of a Certificate of Registration

3.6.1 A person may request the inactivation of the certificate of registration of their establishment provided that the

establishment has no unpaid fees. Policies and procedures describing the inactivation of a certificate of registration are described in Chapter 2, Subject 1 of this manual.

3.6.2 An establishment that renews its certificate of registration that has been assigned an inactivated status must pay all applicable fees depending on the size of the establishment, and the processing operations that will be conducted when the certificate is reactivated. All applicable fees must be paid even if the establishment applies to maintain its certificate of registration in an inactivated status.

3.7 Reinstatement of a Certificate of Registration/Fish Export Licence

3.7.1 When a certificate of registration, or a fish export licence has been suspended or revoked, an inspection fee of $1000 (plus applicable sales tax) must be paid to evaluate the corrective actions before the certificate can be reinstated. In the case where a certificate of registration or a fish export licence was suspended or revoked because of unpaid fees, the reinstatement fee will not be charged provided the only action required to reinstate the certificate of registration was the payment of the unpaid fees.

3.8 Requested Establishment Inspections

3.8.1 A person may request an inspection to either verify compliance of an establishment with the requirements of Schedule I of the FIR or to verify compliance of the establishment's QMP Plan with the requirements of the FIR.

This type of inspection does not apply to an inspection request made for the purpose of reinstating a certificate of registration, as described in Section 3.7 above.

The cost of a requested inspection of an establishment is $500 (plus applicable sales tax).

3.8.2 A report prepared as a result of the requested on-site inspection or the QMP Plan review represents the findings at the time of assessment.

3.8.3 A "requested establishment inspection" is complete when the inspector delivers a completed inspection report or completed verification report to the owner or operator of

the establishment.

3.9 Revenue Administration

CFIA Cost Recovery Policies and Procedures will be followed to address issues such as refunds and the collection of unpaid fees.

4. PROCEDURES

4.1 General

4.1.1 The process to issue certificates of registration is described in Chapter 2, Subject 1 of this manual, and should include steps to verify that:

a) "application forms" received are complete and accurately describe the name of the company and applicant;

b) full payment is received; and

c) the establishment and its QMP meet the requirements of the Fish Inspection Regulations.

4.1.2 The procedure to issue, renew, amend, reactivate or reinstate a certificate of registration or a fish export licence should include a review of information available from the CFIA Accounts Receivable Service Centre regarding any unpaid fees owed to the Agency. See section 4.5, Revenue Administration, for more details.

4.2 Fees for Certificate of Registration

4.2.1 The process implemented by Regional Directors to issue certificates of registration should include steps to verify that the contents of completed registration application forms are accurate, and that fee payment calculations are correct. An inspector may inspect an establishment to determine the size of the processing area, FIR compliance and/or to verify the information submitted.

4.2.2 The diagram of the establishment that is included for a new certificate of registration should include the dimensions of the processing area to assist with the calculation of the appropriate fee. A new diagram must be provided by the applicant at the time of renewal when any changes are made to the processing area of the establishment.

4.2.3 Full payment of the fees for the certificate of registration should accompany the completed application form and should be sent directly to the designated CFIA fish registration office specified in the renewal letter.

Payment can be made via cheque, money order or credit card. Cheques and money orders should be in Canadian funds and payable to "The Receiver General For Canada". The person applying must ensure company names and/or registration numbers are noted on cheques or money orders. Payment of registration fees by installments (e.g., post-dated cheques) is not acceptable.

Visa, Mastercard and American Express credit cards are accepted. Essential information to be included **by the person applying** on the application forms include;

1. Name of card holder
2. Card number
3. Expiry Date
4. Signature of card holder

4.3 Certificate of Registration Renewal

4.3.1 The CFIA will contact the holder of a certificate of registration at least 60 days prior to the expiry date of the existing certificate. Procedures for the renewal of an establishment's certificate of registration are found in Chapter 2, Subject 1, Section 4.3 of this manual.

4.3.2 As indicated in Chapter 2, Subject 1 of this manual, the CFIA will not refuse to issue a certificate of registration to an establishment as long as the establishment demonstrates that it is willing and able to comply with the requirements of the regulations. If an establishment's certificate of registration expires during the renewal process because of administrative activities (i.e., waiting for confirmation of payment) the Regional Director should be consulted. The circumstances should be evaluated to verify that the establishment is willing and able to comply with the regulations and that the reasons for the delay are purely administrative. If this is the case, the Regional Director may renew the establishment's certificate of registration when it expires, even though all steps in the process to renew the certificate have not been completed.

In the event that a certificate of registration expires, and the establishment has not paid all fees or has shown that it is not willing or able to comply with the FIR in

any other way (e.g., enforcement actions have been taken), then the certificate should not be renewed until the outstanding issues have been addressed. This will be treated as an enforcement action and appropriate policies and procedures for enforcement (Compliance Management Process) and suspension and revocation of the certificate of registration (Chapter 2, Subject 1 of this manual) should be followed.

4.3.3 An establishment with an expired certificate of registration may remain on export lists upon written request. See Chapter 2, Subject 1 for further details concerning the removal of an establishment from export lists.

4.4 Fees for Inspection of Establishments

4.4.1 When an inspection is necessary to reinstate a fish export licence or an establishment's certificate of registration after it has been suspended or revoked, a fee of $1000 (plus applicable sales tax) must accompany the form "Request for an Inspection of a Fish Processing Facility" (Appendix E), where the item "Suspended/Revoked Registration Facility Inspection" is selected. The inspection will not be performed until payment is confirmed.

This fee is applicable to the inspection of the corrective action plan and any other inspection activities that were necessary to verify that the establishment is in compliance with the regulations. This fee includes the evaluation of any amendments necessary for the development of an acceptable corrective action plan related to the reasons for the suspension or revocation of the certificate of registration.

4.4.2 A person may request an inspection of an establishment or a QMP Plan by completing the form "Request For an Inspection of a Fish Processing Facility" (Appendix E), and including a payment of $500 (plus applicable sales tax). The inspection will not be performed until payment is confirmed. This service is optional and does not form any part of the process that is followed to verify regulatory compliance for newly registered establishments or those that are currently registered.

This fee is not refundable and is not included in any of the fees necessary to issue a certificate of registration.

Note: There is no provision for blueprint review, either as a service or for regulatory approval. While the FIR requires an applicant to provide a detailed diagram of the establishment (e.g., blueprints), this is used by the inspector to view the layout of the establishment during the systems verification. Blueprints may be used to illustrate the "process flow diagram" and the "detailed diagram of the establishment" referred to in paragraphs 15.(1) (e) and (f) of the Regulations. No regulatory actions will be taken based solely on the nature or contents of blueprints. Therefore, the CFIA will not inspect or approve blueprints of an establishment.

4.5 Revenue Administration

4.5.1 Revenue administration is the responsibility of the Office of the Vice-President, Corporate Services of the Canadian Food Inspection Agency. The National Centre for Accounts Receivable has the lead role in the collection of all fees payable.

4.5.2 The National Centre for Accounts Receivable should be consulted in matters concerning any reimbursement of fees to the client.

4.5.3 Proof of full payment of registration fees and of any other previously invoiced fees is a condition of registration. Prior to issuing a certificate of registration and/or conducting other inspections of the facilities which are subject to fees, confirmation is required from the National Centre for Accounts Receivable that the payment has been processed (i.e., the applicants's cheque has been cashed or the credit card transaction has been processed) and has been accepted. This principle applies in the case of a registration renewal, an amendment to a registration or for a new registration.

4.5.4 The National Centre for Accounts Receivable (Accounts Receivable) will provide reports to Regional personnel that identify establishments and licence holders with unpaid fees. These reports should be reviewed prior to issuing, renewing, amending, inactivating, reactivating or reinstating a certificate of registration or a fish export licence. Should the name of the establishment or licence holder appear on the list, Regional personnel should contact Accounts Receivable for further information before proceeding. If the client has not taken steps to resolve the issue of unpaid fees, no further steps should be taken to issue, renew, amend, reactivate or reinstate a

certificate of registration or a fish export licence until all fees have been paid.

5. FORMS/DOCUMENTS

Appendix A - Fees for Registration of Establishments

Appendix B - Categories of Process Operation Types

Appendix C - Application for Registration of a Fish Processing Establishment

Appendix D - Certificate of Registration

Appendix E - Request For an Inspection of a Fish Processing Facility

New 03/10/31

APPENDIX A
FEES FOR REGISTRATION OF ESTABLISHMENTS

Table 1

Item	Total Size of Processing Areas in Establishment	Fee ($)
1	300 m2 or less	1000
2	More than 300 m2	1500

Table 2

Fees for process operations for registered establishments with processing areas of a total size greater than 300 m2

Item	Process Operation	Fee ($)
1	Canning fish	1000
2	Processing ready-to-eat fish	1000
3	Processing shellfish	1000
4	Pickling, spicing or marinating fish	500
5	Salting or drying fish	500
6	Processing fresh or frozen fish or semi-preserves	500
7	Any other type of process operation	1000

Table 3

Initial fees for shellfish process operations conducted by depuration

Item	Total Size of Processing Areas in Establishment	Fee ($)
1	300 m2 or less	6000
2	More than 300 m2	7500

Table 4

Fees for Establishment Inspections

Item	**FIR section**	**Fee ($)**
Inspection for registration reinstatement	17.(3)	1000
Facility or QMP inspection	17.1	500

Table 5

Facilities-related services identified in the FIR for which there are no fees

Item	**FIR section**	**Fee ($)**
Issue a fish export licence	15.1(1)	0
Reinstatement of fish export licence	17.(3)	0
Issuance of temporary certificate of registration	16.4(3)	0

APPENDIX B
CATEGORIES OF PROCESS OPERATION TYPES

The impact of a process operation categorisation is limited to the cost recovery fees charged and has no bearing on the processor's QMP or the CFIA regulatory verification of the establishment's controls.

Note: Where a product is applicable to more than one category, the following rule of precedence is applied:

- Cannery before Shellfish before RTE before PSM or Salted before F/FR/SP
- For example, a canned clam operation is cost recovered as a cannery (cannery before shellfish); an imported frozen cooked shelled shrimp re-packing operation is cost recovered as a RTE operation (RTE before F/FR).

1. **Canning Fish:** Means processing where the fish product is sealed in a container and is sterilised.

   Product Examples:
   - Canned salmon
   - Fish in retort pouches

2. **Processing Ready-to-Eat Fish:** Means processing where the fish (other than canned fish or live molluscan shellfish) product does not require preparation except thawing or reheating before consumption.

   Ready-to-eat products are typically:

   a) presented as "ready-to-eat", i.e., no preparation required;

   b) labelled to indicate that cooking is not required; or

   c) cooked or not cooked by the processor and are customarily consumed without cooking by the end user.

   Product Examples:
   - Cooked and frozen crustaceans with the shell removed or separated (e.g., crab sections, lobster tails, peeled shrimp). Note: Cooked and frozen whole and in-the-shell are considered fresh/frozen products.
   - Hot-smoked fish product
   - Cold-smoked fish product

- Cooked lobster meat and cooked crab meat
- Pâté, mousse, shrimp cocktail, kamaboko

3. **Processing Shellfish:** Means processing any edible species of bivalve molluscs of the class *Bivalvia* and all marine, carnivorous species of the class *Gastropoda*, either shucked or in the shell, in whole or part, excluding the adductor muscles of scallops and the meat of geoducks.

   Examples:
   - Clams, oysters, mussels, quahogs, geoducks
   - Whelks
   - Whole and roe-on scallops.

   Note: Squid, octopus, and other cephalopods are not included

4. **Pickling, Spicing or Marinating Fish:** Means processing where fish is preserved by pickling in brine, with or without the addition of vinegar and/or spices, is not frozen, and where the product has an expected shelf life in excess of 90 days. Pickled, spiced, and marinated fish is sold in barrels or containers in its own brine or curing ingredients.

   Examples:
   - Pickled split turbot
   - Pickled split summer mackerel

5. **Salting or Drying Fish:** Means processing where fish is salted, and where the final product is intended to have a moisture content of less than 54%.

   Salting includes the processing of fish to be sold in the green salted state to other processors or retailers for final drying and preparation before sale.

   Saltfish are either pickle or kench cured, removed from pickle tanks or kench stacks, press piled and typically dried before transport and/or sale to consumers.

   Examples:
   - Light salted cod
   - Gaspé cure slack-salted fish
   - Dried squid

6. **Processing Fresh or Frozen Fish or Semi-preserves:** Means processing where the fish products are:
   - live (excluding molluscan shellfish); or
   - presented for sale in their natural, unprocessed, unfrozen state, as at the time of capture, such that further preparation by consumers such as heading,

dressing, cleaning, skinning, or filleting is required prior to consumption; or
- washed, split, headed, dressed, cleaned, skinned, or filleted and/or refrigerated or frozen to preserve quality; or,
- partially cooked, and requiring further cooking prior to consumption, (have cooking instructions on the label); or,
- semi-preserved, that is fish prepared by salting or pickling in brine, vinegar, sugar, spices or any combination thereof and packed so that it may be kept fit for human consumption for a minimum of six months by means of refrigeration without freezing.

Examples:
- Whole and dressed fish and fish fillets
- Scallop meats
- Smoked herring, mackerel, capelin, or groundfish which requires cooking prior to consumption.
- Fish sticks and seafood dinners which are labelled with cooking instructions (i.e., are partially cooked and require further cooking prior to consumption).
- Frozen cooked crustaceans, when they are marketed whole still in the shell, can be considered fresh/frozen products, (whole frozen cooked lobster and shrimp). Note: When the shell is removed or separated (e.g., crab sections, lobster tails, peeled shrimp), they are considered RTE products.
- Canned anchovies, marinated mussels

7. Any other type of process operation - means any processing of fish not included in the above-noted process operation types.

Example:
- Fish oil extraction

2	3	C-1
New		03/10/31

APPENDIX C

2	3	C-2
New		03/10/31

New 03/10/31

APPENDIX D

2	3	E-1
New		03/10/31

APPENDIX E

CHAPTER 2, SUBJECT 4
REGULATION OF CANADIAN ESTABLISHMENTS PROCESSING FISH BY-PRODUCTS

1. SCOPE

This policy provides for the appropriate regulation of Canadian fish processing establishments registered under the Fish Inspection Regulations (FIR) (registered establishments) that process fish by-products for export. It addresses the regulation of fish by-products that are imported for further processing by registered establishments. This policy refers to the regulation of fish by-products that are prepared for human consumption either by themselves, or as a food ingredient, or as a Natural Health Product (see definition below). This policy does not apply to fish by-products that are prepared for use in drugs, cosmetics or in products not consumed by human beings.

2. DEFINITIONS

The following definitions are included to provide clarity on issues specifically related to this document.

"cosmetic" includes any substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth, and includes deodorants and perfumes. (Food and Drugs Act)

"drug" includes any substance or mixture of substances manufactured, sold or represented for use in

a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,

b) restoring, correcting or modifying organic functions in human beings or animals, or

c) disinfection in premises in which food is manufactured, prepared or kept. (Food and Drugs Act)

"export" means to ship from Canada to any other country, or from any province to any other province. (Fish Inspection Regulations)

"fish" means any fish, including shellfish and crustaceans, and marine animals, and any parts, products or by-products thereof. (Fish Inspection Act)

"fish by-products" refers to commodities that are manufactured from fish, including shellfish, crustaceans, and marine animals in a form that is different than conventional foods and which are intended for human consumption (either directly or as a food ingredient). Fish by-products include, but are not limited to:

a) by-products derived from marine mammals (e.g., seal oil);

b) by-products derived from fish, including fish cartilage, fish oils, and fish proteins; and

c) by-products derived from the carapaces of crustaceans; but

do not include marine plants or marine plant products.

"Natural Health Product" - see Natural Health Products Regulations, SOR/2003-196. (Health Canada)

"processing" includes cleaning, filleting, icing, packing, canning, freezing, smoking, salting, cooking, pickling, drying or preparing fish for market in any other manner.(Fish Inspection Act)

3. ESTABLISHMENT REGISTRATION

Establishments that process fish by-products for the production of drugs, cosmetics, or other substances that are not intended for human consumption, (e.g., fish meal used for the production of animal feeds) will not require a certificate of registration. Note that these activities may be subject to requirements administered by other CFIA programs (see note below).

Establishments that process for export fish by-products intended for human consumption (including fish by-products used as food ingredients) must be registered in accordance with the policies and procedures described in Chapter 2, Subject 1 of this Manual.

The CFIA will not require registration of an establishment when fish by-products are used to manufacture Natural

Health Products and/or drugs that are subject to the controls specified by a licence issued to the establishment by Health Canada.

An establishment not regulated by Health Canada that processes fish by-products for export to an establishment that manufactures Natural Health Products and/or drugs, must be registered under the FIR.

Note: Fish by-product renderers producing fish meal or fish oil products from inedible offal, fish or fish by-products from fish processing plants, or other sources, are subject to the *Feeds Regulations* and the *Health of Animals Regulations*, and must meet the requirements identified in said regulations.

4. QUALITY MANAGEMENT PROGRAM

The registered establishment must develop a Quality Management Program (QMP) Plan that meets the requirements described by the QMP Reference Standard (Chapter 3, Subject 4 of this manual). The hazard analysis will be performed as described in the QMP Reference Standard based on known hazards.

In a situation where an inspector needs to determine if a hazard exists, the inspector will forward an inquiry through the Program Network to the National Manager, Quality Management Programs, Fish Seafood and Production Division. Once the hazard has been identified, and has been deemed significant, critical limits must be determined and mechanisms for control implemented at the processing level. In lieu of a standard, critical limits will be determined through a case-by-case risk assessment. The results of the risk assessment will establish the critical limits for the product being produced by that particular establishment. The results of the risk assessment **may not be used** to establish critical limits for other establishments processing similar products.

5. FISH EXPORT CERTIFICATES

A fish export certificate will be issued for fish by-products when the products are in compliance with the Fish Inspection Regulations and were processed at a registered establishment. Export certificates will be issued following the policies and procedures described in Chapter

10 of the Fish Products Inspection Manual.

6. FISH BY-PRODUCTS IMPORTED FOR FURTHER PROCESSING

All importers of fish by-products destined for further processing at a registered establishment must hold a Fish Import Licence or a Quality Management Program Import Licence. Fish by-products that are imported for further processing as products destined for human consumption (including fish by-products used as ingredients) by a registered establishment, will be inspected in accordance with the policies and procedures described in Chapter 3 of the Fish Products Inspection Manual.

Product of Canada designation and the application of policy pertaining to "substantial transformation", shall be granted as described in the policies and procedures found in Chapters 3 and 10 of the Fish Products Inspection Manual.

CHAPTER 3, SUBJECT 1

QUALITY MANAGEMENT PROGRAM

1. SCOPE

This subject provides an introduction to the Quality Management Program (QMP) and Regulatory Verification. The definitions of terms used in this Chapter are included under "Definitions" at the beginning of this manual. Subjects 2, 3 and 4 of this chapter outline the policies and procedures governing the QMP and Regulatory Verification activities carried out by the Canadian Food Inspection Agency (CFIA).

2. AUTHORITIES

Fish Inspection Act, R.S., c. F-12
Fish Inspection Regulations, C.R.C., c 802

Food and Drugs Act, R.S., c. F-27
Food and Drug Regulations, C.R.C., c. 870

Consumer Packaging and Labelling Act, R.S., c. 38
Consumer Packaging and Labelling Regulations, C.R.C., c. 417

3. THE QUALITY MANAGEMENT PROGRAM

3.1 Introduction

The Quality Management Program is a fish inspection and control system that includes procedures, inspections and records, for the purpose of verifying and documenting the processing of fish and the safety and quality of fish processed in and exported from Canada. All federally registered fish processing establishments in Canada are legally required under the *Fish Inspection Regulations* to adhere to the QMP.

Note: The term "Quality Management Program" refers both to the overall program operated by the CFIA, and the individual program operated in a fish processing establishment. An individual establishment's documented program is usually referred to as a QMP plan.

A QMP Plan is a document prepared by a registered fish

establishment, in accordance with the Facilities Inspection Manual, that outlines the controls implemented to ensure that fish products are processed under sanitary conditions and that the result is a safe fish product that complies with federal regulations.

3.2 Objective of the Quality Management Program

The CFIA's objective for the QMP is to promote the production of safe and wholesome fish and seafood products, protect consumers of Canadian fish and seafood, meet international trade requirements and maintain open access to international markets.

3.3 History of the QMP

The Quality Management Program, developed as a result of co-operation between the Government of Canada and the fish processing industry, became mandatory for all federally registered fish processing establishments in 1992. At the time, federal fish inspection was under the authority of the Department of Fisheries and Oceans (DFO). QMP was originally based on 5 out of 7 principles of HACCP (Hazard Analysis Critical Control Point), an internationally recognised system for ensuring safe food production.

By 1996, several reviews of the QMP had been conducted, by the processing industry, the federal government and an international panel. A QMP re-engineering project was begun in June, 1996, to assess and implement many of the recommendations of these reviews, including adopting all seven HACCP principles.

The re-engineering process continued when federal fish inspection was transferred to the new Canadian Food Inspection Agency, created on April 1, 1997. The re-engineered QMP model (described below in section 3.6) was produced in 1998, after extensive consultation with the fish processing industry. Implementation then began on a voluntary basis, and the program became mandatory in April, 1999.

3.4 Roles and Responsibilities of Government

3.4.1 The CFIA is responsible for developing, in consultation with the fish processing industry, regulations, standards, policies and procedures which set out the requirements for industry compliance with federal legislation. The CFIA is also responsible for verifying that the fish processing

industry operates within regulatory requirements.

3.4.2 The CFIA assesses the fish processing industry's compliance through regulatory verification. Regulatory verification focuses on assessing the adequacy of an establishment's QMP plan and verifying that the establishment applies the system as described and that it is effective in maintaining compliance with the regulatory requirements.

3.4.3 The CFIA is responsible for taking the appropriate enforcement action, as necessary, to ensure compliance with regulations.

3.5 Roles and Responsibilities of Industry

3.5.1 Each federally-registered fish processing establishment is responsible for designing and implementing an appropriate QMP plan to ensure compliance with the applicable legislation and regulations.

3.5.2 Fish processing establishments are responsible for ensuring that they have the personnel, on staff or under contract, with the necessary knowledge and skills required to develop, implement and maintain their QMP plans and to ensure that their operation is in compliance with all applicable legislation and regulations.

3.5.3 Fish processing establishments are solely responsible and liable for the fish products they produce, sell and/or import.

3.6 The QMP Model

There are three basic control components to a QMP plan: the Prerequisite Plan, the Regulatory Action Point (RAP) Plan, and the HACCP (Hazard Analysis Critical Control Point) Plan.

The Three Control Components of the QMP Model		
Prerequisite Plan	**Regulatory Action Point Plan**	**HACCP Plan**
I Plant Construction & Equipment	**I** Minimum Acceptable Fish Product Standards	Critical Control Points (CCP's) - determined through the application of HACCP principles
II Plant Sanitation & Hygiene	**II** Input Materials	
III Recall	**III** Labelling	

3.6.1 **Prerequisite Plan**: This section of the QMP plan consists of programs that ensure compliance with the *Fish Inspection Regulations,* and an acceptable environment for food processing, through controls for construction & equipment, sanitation & hygiene and an effective recall system. The Prerequisite Plan is an essential foundation for a HACCP plan, since it includes aspects of plant operations, necessary to the production of safe food, that must be in place before processing begins.

Plant Construction and Equipment Program
Describes how the physical plant facilities are designed, constructed and maintained in a condition to allow for the sanitary production of food.

Plant Sanitation and Employee Hygiene Program
Describes the control of all sources of contamination, and includes written Sanitation, Personnel Hygiene and Pest Control Programs.

Recall Program
Describes the procedures used to allow the processing establishment to rapidly identify the first shipping destination of any food product.

3.6.2 **Regulatory Action Points (RAP) plan**: This section deals with controls established to ensure compliance with the *Fish Inspection Regulations* and other relevant regulations. These controls are targeted at three elements of fish processing:

- minimum acceptable fish product quality;
- input materials; and
- labelling.

3.6.3 **HACCP Plan:** This section consists of a plan prepared in accordance with the seven principles of the HACCP system to ensure that any significant health and safety hazards identified are controlled during the processing of fish.

3.7 The QMP Reference Standard

The QMP Reference Standard sets out the requirements for the documentation and application of a fish processing establishment's QMP plan. The standard is based on the *Fish Inspection Regulations*. For a description of the Reference Standard, and Interpretive Guidelines explaining the requirements of the standard, refer to Subject 4 of this Chapter.

4. REGULATORY VERIFICATION

Regulatory Verification encompasses the activities carried out by CFIA Inspectors to verify that a federally registered fish processing establishment's QMP meets the requirements set out in the *Fish Inspection Regulations*.

Regulatory Verification is intended to answer two fundamental questions about an establishment's QMP:

1. Is the QMP plan adequate for the products that are being processed in the registered establishment?

2. Is the registered establishment complying with its own QMP plan as written?

4.1 Elements of Regulatory Verification

4.1.1 Regulatory Verification includes a combination of audit and inspection activities. Audit activities will be carried out in accordance with recognised audit principles.

4.1.2 Regulatory Verification activities include verifying the documented QMP Plan, verifying the application of the QMP plan in the registered establishment, inspecting plant conditions and product, taking samples, investigating corrective actions, and performing tests.

4.1.3 Regulatory Verification is divided into the following components:

<u>Systems Verification (SV)</u>
Systems Verification is an evaluation of a federally

registered fish processing establishment's documented QMP plan against the QMP Reference Standard to verify that it contains all the necessary components and has the necessary controls to ensure compliance with the *Fish Inspection Regulations*. The emphasis is on verifying documentation. For a description of CFIA policies and procedures governing Systems Verification, refer to Subject 2 of this Chapter.

Compliance Verification (CV)

Compliance Verification consists of activities carried out by CFIA Inspectors to verify that a federally registered fish processing establishment has implemented its QMP plan as written and that it meets the requirements set out in the *Fish Inspection Regulations* and the QMP Reference Standard. These activities may include: verifying the operation of the QMP; inspecting plant conditions and product; taking samples; investigating corrective actions; and performing tests. The emphasis is on verifying implementation. For a description of CFIA policies and procedures governing Compliance Verification, refer to Subject 3 of this Chapter.

CHAPTER 3, SUBJECT 3

COMPLIANCE VERIFICATION POLICIES AND PROCEDURES FOR REGISTERED ESTABLISHMENTS

1. SCOPE

This subject outlines the policy and procedures governing the Compliance Verification activities to be conducted in federally registered fish processing establishments. Subject 1 of this Chapter contains an introduction to Regulatory Verification. The definitions of the terms used in Compliance Verifications are included in "Definitions" at the front of the manual.

2. POLICY

2.1 Guiding Principles

2.1.1 All registered establishments shall be evaluated for compliance with regulatory requirements through Compliance Verifications, performed as prescribed by these policies and procedures. The CFIA will usually commence scheduling Compliance Verifications for a registered establishment when the Systems Verification of its documented QMP plan is completed.

2.1.2 The Compliance Verification approach is based on working co-operatively with establishments as they implement and make incremental changes to their QMP plan to meet the QMP Reference Standard and comply with the *Fish Inspection Regulations*. The Fish Inspection Program Compliance Management Process is intended to deal with those establishments that are unwilling or unable to implement or maintain an effective QMP.

2.1.3 Compliance Verifications will be conducted using internationally recognised principles and methods of auditing.

2.1.4 Compliance Verifications are intended to evaluate an establishment's QMP as a whole, not just individual operations or operation types. However, a single CV will not involve an assessment of every process or activity in an establishment's QMP.

2.1.5 The scope of a Compliance Verification outlines the

boundaries or limits of activities planned for the CV, i.e., what parts of the QMP will be investigated. The scope of a CV on an establishment may cover the implementation of all elements of the establishment's QMP (i.e., Prerequisite plan, RAP plan, and HACCP plan). However, the scope of some CVs will be more focussed and will not cover all elements.

2.1.6 Where a Compliance Verification identifies non-conformities, the processor will be required to develop a Corrective Action Plan (CAP) acceptable to the CFIA that outlines a schedule for addressing the non-conformities.

2.1.7 In keeping with the co-operative approach outlined in 2.1.2, if a CV team leader and a processor are unable to reach agreement on the findings of a CV or the resulting Corrective Action Plan, the CV team leader should inform the processor that further clarification or guidance may be sought from the Operational supervisor/manager.

2.2 Organisation and Scheduling of CVs

2.2.1 A Compliance Verification includes:

- pre-notification of the CV to the processor;
- identification of a CV team leader and team members;
- a CV plan, schedule and time frames;
- a review of establishment background information, including previous CVs;
- development of CV checklists specific to the establishment;
- an evaluation of the establishment conducted on-site in the processing facility;
- completion of Non-conformity Reports if required, and a Compliance Verification Exit Report; and
- follow-up activities, where necessary, to confirm that corrective actions have been completed.

2.2.2 CFIA will normally inform the processing establishment in advance of the date on which a Compliance Verification will be carried out. However, CFIA inspectors retain the right to perform inspection activities at federally registered fish processing establishments at any time, as authorized by the *Fish Inspection Act*.

2.2.3 The selection of appropriate CV team leaders and team members will be at the discretion of individual CFIA Operations Managers and Supervisors.

2.2.4 To conduct Compliance Verifications, CFIA inspectors must have successfully completed all applicable training courses. Inspectors must also be participating in, or have completed, the QMP Mentorship Program.

Mentorship is a supportive on-the-job training, coaching and assessment process, in which a more experienced inspector shares their knowledge and experience with a less experienced inspector, with the goal of achieving consistent application of CV policy and procedures.

2.2.5 As stated in 2.1.4 above, a single Compliance Verification will not assess every process or activity in an establishment's QMP. Instead, for each CV a representative sample or "slice" of the QMP will be chosen. Within the boundaries of the CV scope, the "slice" will outline the specific processes or activities that will be examined. For each "slice" chosen:

- the significant points for health & safety or regulatory compliance are selected;
- a thorough, focussed evaluation is completed to confirm that the system controls are in place and that they adhere to the QMP plan; and
- once evidence is gathered and a conclusion is reached, the CV team member moves on to the next element in the CV.

2.2.6 Each Compliance Verification of an establishment (except for the initial CV) will take previous results into account, so that the CV can examine products and processes that were not previously evaluated and, if necessary, concentrate on progress made on long-term corrective actions and areas of concern previously identified. With the goal of developing and maintaining a "Continuous Record", the results of CVs conducted over time will flow together to form a "compliance picture" of the establishment.

2.2.7 CV teams will conduct Follow-up activities to verify that Corrective Action Plans have been followed. When the short-term corrective actions have been completed, and the plans for long-term corrective actions have been found to be acceptable, this will lead to closure of the Compliance Verification.

2.2.8 The scheduling of Compliance Verifications will be based on

Establishment CV Priorities, determined as described in section 3.2.

2.2.9 CFIA Operations Managers and Supervisors will be responsible for developing overall Compliance Verification plans for their respective areas of responsibility. These plans will be based on the target CV frequencies set out in section 3.3. From these plans, individual CVs can then be scheduled for each processing facility within the area of responsibility.

2.3 Product Action

Where the acceptability of fish products is brought into question through the identification of a non-conformity during a CV, and the establishment cannot resolve the problem as part of a Corrective Action Plan, inspectors are to take appropriate product action. Detention or seizure may be necessary to control fish products that are tainted, decomposed or unwholesome, fraudulently presented or otherwise fail to meet the requirements of the *Fish Inspection Act*, *Fish Inspection Regulations* or other applicable legislation.

3. PROCEDURES

3.1 The "Slice" Approach

3.1.1 For each Compliance Verification, a representative sample or "slice" approach will be taken. This means that each CV will focus on one or a limited number of products and/or processes.

To illustrate the "slice" approach, consider a ready-to-eat plant processing shrimp and crab as an example. Using the "slice" approach, an example of a typical CV in this processing plant would:

- look at the shrimp operation, but not the crab;
- for plant sanitation, look at the state of cleanliness, the effectiveness of the clean-up procedures, and the training instructions for the cleanup crew working in the shrimp processing room;
- for employee hygiene, look at the controls, practices, level of knowledge and understanding of personnel working in the shrimp processing room;
- look at a proportional number of SOPs (that would not be covered under the HACCP plan) and/or control

measures associated with the safety of the product as an example, or areas of poor compliance based on establishment history; and
- ♦ if there are eight ingredients used in the process, look at three of these ingredients.

3.1.2 When the HACCP element is included in the Scope of the CV and that element includes CCPs, then all CCPs related to the product being produced within the scope of the CV are to be fully assessed, along with any associated SOPs.

3.2 Establishment CV Priorities

3.2.1 Establishment CV Priorities are determined using establishments' compliance profiles and product profiles.

3.2.2 An establishment's **compliance profile** is assessed as either High (i.e., good) or Low, based on its overall ability to maintain controls within its operations and maintain compliance with regulatory requirements.

This ability is evident from the quality and level of resources, including buildings and equipment, and the levels of staff training, knowledge, expertise and competence available for the specific operation. In addition, an establishment's ability to maintain controls and meet regulatory requirements relates to its commitment to its QMP. Commitment is demonstrated by the establishment's historical and current compliance records.

3.2.3 **Product profiles** will be assessed as either High or Low based on:

- ♦ the level of health and safety risk for the product (i.e., inherent microbiological, chemical and marine toxin risks); and

- ♦ the economic factors related to trade and marketing (e.g., large volumes to single source export markets, speciality products to niche markets).

3.2.4 Where there is a mixture of both high and low levels for each assessment criteria, the assessment will reflect the highest product profile and lowest compliance level. For example, if an establishment has a good historical compliance for canned products, but has a poor compliance for fresh/frozen products, the compliance profile would be rated as low.

3.2.5 An establishment's CV Priority will be set at either 1, 2 or 3 based on its Establishment Compliance Profile and Product Profile as shown in the following table:

ESTABLISHMENT COMPLIANCE PROFILE	PRODUCT PROFILE	ESTABLISHMENT CV PRIORITY
Low	High	1
Low	Low	2
High	High	2
High	Low	3

3.3 Compliance Verification Frequency

Compliance Verifications will be conducted at different frequencies on different establishments, based on Establishment CV Priorities, with a minimum frequency of once per year. The following table is a guide to target scheduling frequencies for CVs, based on Establishment CV Priorities:

ESTABLISHMENT CV PRIORITY	CV FREQUENCY
1	Once every 3 months or 45 operating days
2	Once every 4 months or 60 operating days
3	Once every 6 months or 90 operating days

If an establishment operates on a full-time, continuous basis, the frequency should be based on the number of months of operation. For example, if a processing plant with a CV Priority of 2 operated full-time for five months each year, two CVs would be scheduled, since its operating period exceeds four months.

If an establishment is not operating continuously, operating days can be used. For example, a seasonal processing plant (with a CV Priority of 1) operating for 15 days in the spring and 20 days in the fall would be evaluated once a year, as its total number of operating days is less than 45.

These frequencies will be subject to review on a continuing basis.

3.4 Conducting a Compliance Verification

3.4.1 A Compliance Verification is comprised of three separate phases:

1. Planning and preparation

2. Conducting the in-plant evaluation & report writing

3. Follow-up verification of the Corrective Action Plan

3.4.2 The planning phase is considered a critical component to ensuring a successful CV. As a general guideline, the time allocations for a typical CV would be 40 per cent for planning, 50 per cent for conducting the in-plant activities, and 10 per cent for follow-up.

3.5 The Planning Phase

3.5.1 The Planning Phase of the Compliance Verification includes the following:

- the selection of the CV team leader and team members;
- identifying the CV scope;
- determination of date and time frames;
- completion of a CV plan to assign responsibilities & schedule activities;
- a review of background information (this could include inspection or sampling activities before the in-plant phase of the CV); and
- development of a checklist of activities to be conducted in the processing plant.

In planning for the CV, the CV Plan Pre-verification tasklist section should, as a minimum, identify the responsible team member(s) for each element (e.g., pre-requisite) and section (e.g., pest control) of the QMP Reference Standard identified in the scope and also identify activities, and responsible inspector, such as:

- product and water sample collection, analysis and submission;
- product inspections;
- retrieval of up-to-date QMP plan; and
- review of past non-conformities.

3.5.2 The CV team size and composition will be determined by the scope of the CV, the size and complexity of the processing establishment and its operations, the need for specialised

personnel, and the geographic location and resources available.

Normally, the number of persons involved full time throughout the CV should not exceed three (i.e., the team leader and two team members). The team may include specialists such as microbiologists, process specialists or persons providing language interpretation, who may join the team to perform specific functions or provide additional support but may not be present for the entire CV.

3.5.3 The Team Leader's role is to co-ordinate and lead the Compliance Verification, and to be responsible for:

- ♦ determining the objective and scope of the CV;
- ♦ acting as the principal contact with the plant management;
- ♦ assigning tasks to individual team members;
- ♦ convening and chairing team meetings to review the individual checklists;
- ♦ ensuring the task assignments are complete, to avoid overlap or omissions;
- ♦ developing a CV plan as a schedule or checklist to avoid duplication or omissions (see Appendix A of this Chapter for the CV Plan form). When completed, the CV Plan forms a part of the final CV file;
- ♦ leading the opening meeting and exit meeting with the plant management;
- ♦ extending an invitation to plant management to meet at the end of each day of the CV to review issues encountered during the day;
- ♦ reviewing results and findings of team members;
- ♦ guiding and directing the preparation of the CV report;
- ♦ facilitating team decisions on non-conformities and contentious issues;
- ♦ final editing and preparation of reports;
- ♦ co-ordinating Follow-up activities; and
- ♦ closing the CV, or recommending enforcement action, as appropriate.

3.5.4 In the assignment of tasks, the team leader should exercise flexibility in order to achieve the most efficient completion of the Compliance Verification. For instance, it may be more efficient to assign each team member a section of the facility, or a specific portion of the process, etc., rather then assigning an element of the QMP reference standard (prerequisite, RAP, etc.). Where overlap might occur as a result, (e.g., evaluating a prerequisite program), a clear separation of team member's tasks is

required to avoid duplication.

3.5.5 Team Members are responsible for completing the following activities:

- ♦ reviewing all relevant background information about the establishment. This entails reviewing the establishment's QMP plan (with updates), Systems Verification report file, previous CV reports, and historical data (product and certification results, recall information, consumer complaints, previous corrective action reports) in order to determine the best approach to assess the QMP;
- ♦ preparing individual checklists of questions to ask and activities to complete;
- ♦ for new processing methods, ensuring that they are knowledgeable about the critical food processing issues involved, in order to develop appropriate activities or questions for the checklist;
- ♦ assembling the necessary technical equipment required to carry out tests or measurements;
- ♦ undertaking inspections as directed by the team leader; and
- ♦ having copies of the necessary standards and reference materials available.

3.5.6 Sampling and testing of products, water or ice during a CV is an appropriate tool to verify that the controls in place are effective in meeting the requirements of the *Fish Inspection Regulations*. Samples may be taken before or during the in-plant portion of the CV. As part of the CV plan, the team should identify which items will be sampled during the CV.

A guide to suggested targets for sampling and testing is included as Appendix L of this Subject.

Samples may also be withdrawn and analysed to verify the following parameters:

a) content - examination to evaluate conformity with all weight declarations (e.g., net and/or drained weight, as appropriate), and to evaluate conformity with all other content declarations such as style, count, composition, etc.;

b) sensory - examination to evaluate compliance with sensory standards for taint, decomposition, and unwholesomeness; and

c) container integrity - to determine compliance with standards.

All analyses must be performed according to appropriate methods and procedures described in the applicable manuals (e.g., Fish Products Inspection Manual, Fish Products Standards and Methods Manual).

3.6 The CV Checklist

CV team members will use their individual checklists, prepared using the CV Checklist form, as their main worksheet when carrying out their assigned tasks (the CV Checklist form is included in this Chapter as Appendix C). The checklist provides a structure that allows team members to approach their tasks in a logical and systematic way. The development of a good checklist takes time and is a crucial step to ensure a successful CV.

3.6.1 CV Checklists will contain the following elements:

1) **QMP Requirement** - entries in the QMP requirement section are to be separated into the following two sub-sections.

QMP Reference Standard: For the Reference Standard or regulations statement, precise terminology is to be used. A reference tool (copy-n-paste Reference Standard summary for CV checklist) is available for this purpose.

QMP Plan: The section in the establishment's QMP plan which references the standard or regulation to be met. If the option of choosing key points is used, the inspector shall identify this by including the word summarized and adding a title "Summary of the company's QMP plan";

2) **Task List** - includes the questions to be asked, procedures to be monitored, processes to be verified, samples to be taken, things to be measured or tested, people to be interviewed, records to be reviewed, and inspections to be undertaken;

3) **Objective Evidence** - the factual information collected as a result of completing the task list; and

4) **Findings** - conclusions that are determined as a result of the objective evidence obtained. A number of pieces

of objective evidence may be needed in order to arrive at a single finding.

3.6.2 The tasks prepared in the checklist must permit a thorough, in-depth evaluation of the processor's implementation of their QMP plan, within a limited time frame. The "slice" approach (outlined in Section 3.1) is the key to achieving this objective.

3.6.3 The establishment's QMP plan determines how the system controls are evaluated. The checklist tasks will determine if:

- the control measures are implemented and effective in achieving compliance with the requirements of the *Fish Inspection Regulations*;
- the monitoring procedures are being conducted as outlined in the plan, and the frequency of monitoring is sufficient to ensure compliance;
- corrective action procedures are initiated consistently each time monitoring indicates a deviation;
- the corrective action taken results in control over the process being maintained and products remaining in compliance; and
- the corrective action records are complete and accurate.

3.6.4 The tasks outlined in the checklist will collect objective evidence from:

- observation (e.g., watching the cleanup crew at work)
- inspection (e.g., evaluating equipment cleaning, product quality)
- testing (e.g., sampling for laboratory analysis)
- measuring (e.g., chlorine levels or cold storage temperatures)
- interviewing/questioning (e.g., talking to Quality Control supervisor)
- reviewing documents (e.g., review of procedures available to staff)

3.6.5 The checklist must contain sufficient detail, and be complete enough, that it can be used by the team member as an effective guide for the assigned areas to be evaluated during the CV. The information on each team member's checklist will be different, reflecting the specific elements of the QMP plan they have been assigned to evaluate.

3.6.6 The checklist is considered a tool for the team member to use in conducting the CV. While it may be shown to the processor on request, it is not intended to be part of the summary report given to the establishment. When completed, however, the checklist forms part of the CFIA file record of the CV.

Further guidance on developing a CV checklist may be found in Appendix M of this Subject.

3.7 Conducting the In-plant Portion of the Compliance Verification

3.7.1 *Opening meeting*

At the opening meeting with plant management, the CV team leader will introduce the team members to plant representatives, explain the purpose of the meeting, outline the scope and objective of the CV, and explain the mechanics of the CV process to ensure that there are no "surprises", including outlining the specific areas that will be covered in the slice chosen for the CV (see Appendix B of this Chapter for the Opening Meeting Checklist form).

Topics to be discussed during the opening meeting include the need to ask questions of employees in the plant (emphasising that this will be done in a way that minimises interruption); an invitation to have plant representatives accompany team members; a tentative CV schedule; the confidentiality of the CV and its documents; applicable plant safety or hygiene standards to follow; room for the team to meet in the establishment; and any significant changes to the QMP plan; and getting copies of them.

In consultation with the plant management, the team leader will determine the appropriate processing plant personnel to be interviewed, or to accompany the team members, and with whom the team may discuss results, issues, etc. at the end of each day.

3.7.2 Normally, a CV's scope would not change. However, there may be situations where a team leader would find it necessary to revise the scope. One example would be when a Critical non-conformity is determined that has implications beyond the original scope of the CV.

If a situation develops that makes it necessary to revise the CV scope, the team leader will advise the plant

management and outline the reasons for this decision. Revisions to the CV scope should be limited, to permit adequate examination of other areas of the establishment's system where a team member notices, or has evidence of, a lack of controls.

3.8 Gathering Objective Evidence during the Compliance Verification

3.8.1 Using the task list outlined on their checklist, each team member will conduct their assessment, collecting objective evidence to determine whether the procedures outlined in the QMP plan are being followed. Where discrepancies between QMP procedures and observed activities are noted, the team member will try to answer the following questions:

- are the differences significant in relation to the establishment's overall system and its controls?
- do the discrepancies impact on regulatory requirements or affect health and safety?

Following the slice approach, when enough evidence has been gathered to answer these questions, the investigation should conclude and the team member move on to the next point. If these questions cannot be answered, deeper investigation is needed. There may be instances where objective evidence is obtained that suggests a problem is present, but a conclusion cannot be reached. In these situations, it is useful to review the information with other members of the CV team. There may be a relationship to other portions of the establishment's system, and a pattern may develop that will steer the investigation until a conclusion can be reached.

3.8.2 Records will be examined for completeness and accuracy, and to find any anomalies. It is not necessary to examine all the documentation that is available; a sample of the records produced since the last assessment of this section shall be taken for review.

3.8.3 Notes made during the CV must be clear, concise and accurately reflect the condition observed or the answer to a question. As the completed checklist forms part of the Compliance Verification file, subjective comments, personal opinions, etc. are inappropriate.

3.8.4 Where language comprehension is a concern, team members should ask for someone in the plant to interpret or obtain the services of an interpreter to complete the activity.

3.9 Determining Non-Conformities from Information Found During a CV

3.9.1 Before a decision on a non-conformity can be made, the findings must be linked back to the QMP requirement. The following questions should be asked to confirm whether the findings indicate a non-conformity:

1) Do the findings relate to the QMP system controls? QMP systems may have insufficient controls when:

- controls are not complete,
- controls are not being followed, and/or
- controls are not effective.

If system controls are significantly affected, then the findings would result in the conclusion that there are non-conformities.

2) Do the findings relate to regulatory requirements or the QMP Reference Standard?
If the findings relate to regulatory requirements or the QMP Reference Standard, then the findings would result in the conclusion that there are non-conformities.

3.9.2 Processors are accountable for all aspects of their QMP plans. However, these plans may include requirements that exceed those in the *Fish Inspection Regulations*. While the processor is responsible for applying the QMP plan as it is written, CV team members will exercise discretion in ensuring that non-conformities are related to system problems and violations of regulatory requirements.

Over time, processors are expected to develop their QMP plans to be practical, realistic and focussed on the important areas for compliance with regulatory requirements.

3.9.3 All team members will evaluate CV findings, and the team leader will coordinate the process of reaching decisions regarding non-conformities.

3.9.4 There may be situations where there are a number of findings all related to a single, system-related problem. Wherever possible, these findings should be summarized together into a single Non-conformity Report.

3.10 Identification of a Critical Non-Conformity during a Compliance Verification

3.10.1 A Critical non-conformity is a failure of the QMP system that could result, or has already resulted, in the production of unsafe or fraudulent product.

When a critical non-conformity is identified, the Team Leader will prepare a Non-conformity Report with the classification identified as "Critical". The report will detail the Findings and Objective Evidence that led to the issuing a Critical Non-conformity. The report must be issued to the facility as soon as possible. Hand written non-conformity reports are acceptable in cases where data entry in CFIA systems is impractical in short time frames.

The identification of a Critical non-conformity will require the processor to:

1) initiate corrective actions to eliminate the non-conformity and bring the process back under control.

   These actions may include, but are not limited to:

   - ♦ correcting the immediate problem(s);
   - ♦ voluntarily closing the plant or halting processing;
   - ♦ identifying and segregating all affected product for culling, reworking, or disposal;
   - ♦ investigating why the problem occurred; and
   - ♦ making the necessary system or control changes to eliminate or prevent a recurrence.

2) immediately develop a Corrective Action Plan

3.10.2 The Corrective Action Plan developed must be acceptable to the team leader, and the results of the corrective actions must be verified by the CV team, before the Critical non-conformity will be considered to have been satisfactorily dealt with. Since a Critical non-conformity is **system related**, team members must conduct a thorough investigation across the entire QMP plan to ensure that all aspects of the Critical non-conformity have been addressed.

The CV Team Leader is required to respond to the facility in writing as to the decision reached by the team with respect to the acceptability of the Corrective Action Plan.

In circumstances where geographical location or other factors prevent the Inspector from accessing appropriate

forms and presenting a formal written reply to the facility, a verbal response may be provided until such time as a formal reply is drafted and presented.

3.10.3 Activities of the Compliance Verification may be suspended if the Critical non-conformity is not dealt with satisfactorily.

3.10.4 The team leader should consult the Fish Inspection Program Compliance Management Process and initiate any other action that may be appropriate to ensure that the Critical non-conformity has been addressed.

3.10.5 Failure to develop an acceptable Corrective Action Plan or to meet the terms of a Corrective Action Plan to correct a Critical non-conformity will result in enforcement action being taken as per the Compliance Management Process.

3.10.6 Any product action initiated by the CFIA as a result of a Critical Non-conformity will be documented in the appropriate section of the CFIA data systems.

3.11 Completing a Non-conformity Report (Appendix D)

3.11.1 The Non-conformity Report consists of the following elements:

1) **Non-conformity identified** - outlines the non-conformity, which is linked back to a systemic problem with the QMP requirement;

2) **Classification** of the non-conformity as Critical or not;

3) **QMP element** - the section in the processor's QMP which references the standard or regulation to be met; and

4) **Objective Evidence** - the factual evidence collected in support of the finding of a non-conformity.

3.11.2 In writing a Non-conformity Report, CV team members will use wording which reflects the objective nature of the evidence used to arrive at the decision. Subjective terms such as "unacceptable" or "inadequate" should be avoided.

3.12 Exit Meeting

3.12.1 The purpose of the exit meeting is to:

- present the results of the CV to the plant management and ensure that they are clearly understood;
- discuss the non-conformities found;
- respond to any concerns expressed by plant management;
- establish a time frame for submitting a Corrective Action Plan (CAP); and
- explain the follow-up procedures that will occur to assess the CAP and close the CV.

3.12.2 The following procedures will be followed during the exit meeting (see Appendix G of this Chapter for the Exit Meeting Checklist form):

- the meeting is chaired by the CV team leader;
- a copy of the CV report should be made available for the management representatives present;
- the team leader restates the CV objective and indicates whether or not the objective was met;
- the team leader restates the CV scope and, if the scope changed during the CV, gives the reasons for changing the scope;
- the team leader describes the components of the slice chosen for the CV;
- the CV team leader presents the results of the Compliance Verification, clearly identifying each non-conformity;
- team members should also report on any positive and commendable features that they have observed during the CV;
- for each non-conformity, team members outline the objective evidence gathered to support the conclusion;
- the team leader explains to the management representatives that **all non-conformities must be corrected**;
- the team allows the management representatives the opportunity to give their perspective on the results and express any concerns they may have;
- the team addresses any questions or concerns that plant management has;
- the team negotiates a reasonable time frame for the establishment to submit a CAP to the CFIA. This date is entered in the QMP CV Exit Report;
- the team leader explains the Follow-up procedures that will occur to assess the CAP;
- the management representatives are asked to sign the QMP Compliance Verification Exit Report; and
- the CV team keeps the original report and copies are given to the establishment.

3.12.3 The Compliance Verification documentation presented to the establishment will consist of the Non-conformity Report page(s) and the QMP Compliance Verification Exit Report.

The comment section of the CV Exit Report may be used to convey information not provided in the Non-conformity Report.

If applicable, the general comments section of the CV Exit Report may be used to identify the following:

- information related to the verification of implementation of corrective actions from a previous CV;
- indicate the right to appeal, as per Section 5 of this subject;
- if applicable, provide positive reinforcement to company personnel in their efforts to implement their QMP.

3.12.4 It is not required for the processor to have corrective actions or CAPs completed for the exit meeting. In most cases, time is needed to develop long-term solutions. In situations where the non-conformity has a straightforward solution, the processor may wish to present a completed corrective action at the exit interview. This is acceptable, but it is at the discretion of the team leader as to when the verification assessment of the corrective action takes place.

3.12.5 When the CV team leader is unable to reach an agreement with the processor on a time frame for completing a Corrective Action Plan, the CV cannot be closed. The team leader will take action as described in section 3.16, Assessment of the QMP.

3.13 Evaluating a Corrective Action Plan

3.13.1 A written Corrective Action Plan will be considered acceptable when, for each non-conformity identified, the plan describes:

- actions to be taken that will correct the problem that gave rise to the non-conformity, including, when product is involved:
  - identification and segregation of all affected product,
  - evaluation, analysis and/or testing of all affected

product, and
- appropriate actions to deal with any non-compliant product (e.g. culling, reworking, re-labelling, destroying, etc.);

- ♦ the system changes to be made to prevent a recurrence of the non-conformity;
- ♦ where an action involves long-term construction changes or equipment replacement, interim procedures that are to be put in place to control any risk arising from the problem, with monitoring procedures that are sufficient to ensure continuing compliance with the regulations;
- ♦ the person(s) or position(s) responsible for implementing the corrective actions;
- ♦ a section for the processor to acknowledge that the corrective action was implemented and the date the action was taken; and
- ♦ a reasonable time frame for implementation of the corrective actions. The processor must ensure that the CAP addresses the non-conformities promptly to ensure they do not lead to the production of unsafe product.

3.13.2 Each corrective action will be assessed for adequacy prior to acceptance of the Corrective Action Plan. If the corrective action(s) is (are) not found to be acceptable, they must be returned to the processor with a description of what is not acceptable and a request for the necessary changes. This process may occur a number of times until the CAP is found to be acceptable.

3.13.3 The QMP Compliance Verification - Corrective Action Assessment form (see Appendix H) is to be used when the submitted Corrective Action Plan has been assessed as unacceptable. Every unacceptable CAP assessment must be documented using this form. The Assessment Comment section within the form must be identical to those in CFIA data systems.

3.13.4 The processor is responsible for investigating each non-conformity to resolve the system-related problem. As a result of their investigation, the processor may conclude that the corrective action to be taken does not require a change to the QMP. In following up, the CV team member will investigate to confirm that the processor's rationale for their conclusion is sound, and that all parameters were taken into consideration and all reasonable options were explored.

3.13.5 Where it is not possible to reach agreement with the

processor on the adequacy of the proposed Corrective Action Plan or a reasonable time frame for corrective actions, the CV cannot be closed. The CV team leader will take action as described in section 3.16, Assessment of the QMP.

3.13.6 Where the processor fails to develop an acceptable Corrective Action Plan within a reasonable period of time, the CV cannot be closed. The CV Team Leader will take action as described in section 3.16, Assessment of the QMP.

3.14 Follow-up and Verification of the Corrective Action Plan

3.14.1 Once the Corrective Action Plan has been evaluated and accepted by the CFIA, the Follow-up phase of Compliance Verification will be scheduled for sometime after the completion date for the short-term corrective actions (see Appendix K for the Follow-up Checklist form). The purpose of the Follow-up phase is to:

- verify that the agreed-upon corrective actions have been completed and are effective, which will lead to closure of the compliance verification; or
- recommend the appropriate enforcement action, in cases where the processor has failed to meet the terms of the Corrective Action Plan.

3.14.2 The Follow-up should be carried out as soon as possible after the planned completion date of the short-term corrective actions to determine if the action was timely.

3.14.3 The CV team leader is responsible for co-ordinating Follow-up activities, and the Follow-up will normally be conducted by members of the CV team. In some cases it will not be possible or practical for all members of the CV team to participate in the Follow-up.

3.14.4 The participating CV team member(s) will gather objective evidence, using CV techniques, to confirm the changes made to the QMP (i.e., to procedures, control measures, standards, repairs, etc.) to complete the corrective action(s). Specific activities could include:

- reviewing the problem areas and/or revised procedures;
- reviewing new or revised documentation submitted as part of the corrective action; and
- sampling of fish products, ice or water.

3.14.5 Long-term corrective actions, which have longer time-frames for implementation (e.g., next operating season), may be

evaluated for completeness and effectiveness at subsequent Compliance Verifications.

3.14.6 If at any time during the Follow-up, a Critical non-conformity is discovered, the CV team leader will ensure that the processor initiates action under Section 3.10 of these procedures.

3.14.7 When an establishment can demonstrate that actions have been taken, and the terms of the Corrective Action Plan have not been reached (or will not be reached) through circumstances beyond the establishment's control or because of time deadlines that have proven to be unrealistic, then the establishment may continue operating with new time frames for completion of the Corrective Action Plan, if the non-conformities are not likely to result in unsafe or fraudulent product.

3.14.8 Where an establishment has failed to meet the terms of the Corrective Action Plan, with the exception of the circumstances described in 3.14.7, the CV cannot be closed. The CV Team Leader will take action as described in section 3.16, Assessment of the QMP.

3.15 Compliance Verification Closure

3.15.1 The Compliance Verification is closed when the following occurs:

- there are no non-conformities identified as a result of the Compliance Verification; or
- in the Follow-up phase, the CV team verifies that the short-term corrective actions have been completed and any interim measures have been implemented, and for any elements of the corrective actions having long-term implementation time-frames, the Corrective Action Plan is found to be acceptable.

3.16 Assessment of the Quality Management Program

3.16.1 The establishment's QMP will be assessed as Acceptable when the Compliance Verification has been closed by the CFIA.

3.16.2 The establishment's QMP will be assessed as Unacceptable when either of the following conditions applies:

- non-conformities exist, and the processor has failed to develop an acceptable Corrective Action Plan or to meet the terms of a Corrective Action Plan and reach closure

of the Compliance Verification; or
- non-conformities exist, and the establishment has a history of operating without proper controls and is unlikely to initiate an effective Corrective Action Plan.

3.16.3 Where a QMP has been assessed as Unacceptable, the CV team leader will forward the Non-Conformity Report(s), CV Summary Report, and Corrective Action Plan (if one exists) to the appropriate Operational supervisor/manager, and recommend action as per the Fish Inspection Program Compliance Management Process.

4. CFIA COMPLIANCE VERIFICATION FILE

The completed Compliance Verification file retained in the CFIA office will include:

- Copy of CV announcement (on CFIA letterhead)
- CV Plan
- Opening Meeting Checklist
- CV Checklist (as completed by each team member)
- Completed CV Non-conformity Report
- CV Exit Report
- Corrective Action Checklist - follow-up from prior CVs
- Exit Meeting Checklist
- Corrective Action Plan Assessment Form (when CAPs are rejected)
- Documents related to Product Inspection (Fish Inspection Report, LSTS Report of Analysis, MCAP Product Report)
- Enforcement Reports (all associated documents, including INCRs and warning letters)
- CV Closure Letter (on CFIA letterhead)
- Compliance Verification Filing Cover Sheet
- results of the Follow-up to verify completion of the Corrective Action Plan.

5. APPEALS

An appeal process is available to processors, whereby they may request a review of any CV decision. Appeals must be made, in writing, to the appropriate CFIA Regional Director, stating the reason(s) why a decision should be given further consideration. The appeal must be received within 30 days of the decision that is being appealed.

The CFIA will send a written response acknowledging receipt of the appeal as quickly as possible. The CFIA will then investigate the appeal and respond to the processor within 30 days of receiving the appeal. To maintain an objective approach, appeals will be investigated by CFIA staff that were not part of the original team that conducted the CV.

Pending the outcome of the appeal, the original decisions will remain valid.

6. FORMS/DOCUMENTS

The following are the forms to be used during Compliance Verification audits.

Appendix A - Compliance Verification Plan
Appendix B - Opening Meeting Checklist
Appendix C - Compliance Verification Checklist
Appendix D - Compliance Verification Non-conformity Report
Appendix E - Compliance Verification Exit Report
Appendix F - Corrective Action Checklist
Appendix G - Exit Meeting Checklist
Appendix H - Corrective Action Plan Assessment Form
Appendix I - CV Closure Letter - no non-conformities
Appendix J - CV Closure Letter - acceptable CAP
Appendix K - Follow-up Checklist
Appendix L - Guide to Sampling and Testing during a CV
Appendix M - Compliance Verification Checklist (information and examples)

Copies of forms are provided for information/reference only. Individual forms may be available from alternate locations, and may not be exactly as shown here.

APPENDIX A
COMPLIANCE VERIFICATION PLAN

CV Date: _____ **CV Reference # :** _____

Registered Establishment:	**Registration #:**
Establishment Contact:	**Announced CV:** _____ **Letter/Fax sent:** _____
CV Objective:	
CV Scope:	
CV Team Leader: _____ **CV Team Members:** _____ _____ _____	**Opening Meeting:** **Date:** _____ **Exit Meeting:** **Date:** _____
Pre-verification Tasklist / Person Responsible: _____ _____ _____ _____	
Establishment Documentation Required/ To be reviewed by: _____ _____ _____	
CV Plan Comments	

APPENDIX B
OPENING MEETING CHECKLIST

CV Date: **CV Reference #:**

Registered Establishment:

Registration #:

Introduce CFIA Team		**Record meeting attendance**	
Explain objective and scope		**Explain Compliance Verification methods/questioning/sampling**	
Explain schedule		**Define non-conformities/classifications**	
Confirm plant shift and break schedules		**Confirm meeting facilities, etc.**	
Confirm any confidentiality requirements		**Confirm any special safety requirements**	
Confirm plant representatives to accompany team		**Explain nature of reporting & follow-up**	
Agree on tentative time/date for closing meeting		**Invite senior plant management to attend closing meeting**	

Comments/Notes:

_____

_____

_____

_____

_____

_____

_____

_____

Signature of CV team leader:

APPENDIX C
COMPLIANCE VERIFICATION CHECKLIST

CV Date: **CV Reference #:**

Registered Establishment: **Registration #:**

CV Team member(s):

Element: **Product Description:**

Section:

No	QMP Requirement	Task List	Objective Evidence	Findings
1				
2				
3				
4				
5				
6				

APPENDIX D
COMPLIANCE VERIFICATION - NON-CONFORMITY REPORT

Registered Establishment: **CV Reference #:**

Registration #:

Non-conformity #: **Classification:**

QMP Element/Section	Description of the Non-conformity	Objective Evidence

Follow-up Verification Comments

Corrective Action Completed: _____
(Signature of CV team member)

Date:

APPENDIX E
QMP COMPLIANCE VERIFICATION EXIT REPORT

Report Date: **CV Reference #:**

Registration # : **Registered Establishment:**	
Address:	**Exit Meeting Date:**
CV Objective:	
CV Scope:	
Status of Compliance Verification (CV):	
CV Team members:	**(Signatures)**
_____	_____
_____	_____
_____	_____
Corrective Action Plan (To be completed by registered establishment) When required, written Corrective Action Plan to be submitted by (date) _____	
Establishment Representatives **(Print name and title)**	**(Signatures)**
_____	_____
_____	_____
_____	_____
The signature(s) of the establishment's representative(s) above indicates their acknowledgement and understanding of the Compliance Verification and non-conformities (attached as applicable).	
Exit Report General Comments: (Continue on next page where required)	

APPENDIX F
CORRECTIVE ACTION CHECKLIST

CV Date: **CV Reference #:**

Registered Establishment: **Registration #:**

CV Team member(s):

Corrective Action #:

No.	Non-conformity/ Corrective Action	Task List	Follow-up Comments

APPENDIX G
EXIT MEETING CHECKLIST

CV Date: _____ CV Reference # : _____

Registered Establishment:

Registration # :

Chaired by Team Leader		Copies of the CV report for all present	
Restate objective & indicate if it was met		Restate scope & indicate if any changes	
Describe slice chosen for the CV		Review CV results	
Identify non-conformities and outline the objective evidence to support		Identify the category (Non-conformity or Critical non-conformity) for each one	
Explain that all non-conformities must be corrected		Ask for any questions or concerns from plant representatives/management	
Negotiate reasonable time frame for establishment to submit Corrective Action Plan		Explain follow-up procedures to assess Corrective Action Plan	
Plant representatives to sign CV Summary Report		Copies given to establishment	

Comments/Notes:

_____

_____

_____

_____

_____

_____

_____

_____

Signature of CV team leader: _____

APPENDIX H
CORRECTIVE ACTION PLAN ASSESSMENT FORM

CV Reference #:

Registered Establishment:	**Date:**
Address:	**Registration # :**
Establishment Contact for Corrective Action Plan:	

Due Date for Corrective Action Plan:
Corrective Action Plan submitted: (Date)
Corrective Action Plan evaluated: (Date)

Results of evaluation of Corrective Action Plan:

Corrective Action Plan is not accepted and must be resubmitted _____
Corrective Actions must be modified _____
Additional corrective actions required _____
(some non-conformities not addressed)
Time frame for corrective actions is not acceptable _____

Revised Corrective Action Plan must be resubmitted by:

Version Of .

Assessment Comments:

Signature of CV Team Leader

_____ Date:

Instructions for Completion of Corrective Action Plan Assessment Form

The Corrective Action Plan (CAP) Assessment Form is to be used when the submitted CAP has been assessed as unacceptable, and **every** unacceptable CAP must be documented using this form.

A date by which a response is required must be included.

A copy of the completed form is to be provided to the establishment for each unacceptable CAP.

The information in the comment section of the form must be identical to the information captured in CFIA data systems. This may be done using copy and paste functionality.

APPENDIX I
CV CLOSURE LETTER - NO NON-CONFORMITIES

(Print on CFIA Letterhead)

Canadian Food Inspection Agency
Address line 1
Address line 2
Address line 3

Date

Company Name
Address line 1
Address line 2
Address line 3

Attention: Mr. Company Owner

Dear Sir:

The Compliance Verification (CV) conducted at your facility during the period _____ is now complete. Our CV team did not identify any non-conformities during the course of this audit, and this compliance verification file will now be considered "Closed".

Continued compliance with the *Fish Inspection Regulations* is essential to maintain your certificate of registration. You and your staff have demonstrated your company's continued commitment to ensuring regulatory compliance through the on-going implementation of your Quality Management Program (QMP) plan. Please continue to monitor the implementation of your QMP Plan and to make changes as necessary to build on your efforts of working towards continuous improvement of your QMP Plan.

If you have any concerns or questions, please feel free to contact Inspector _____ at XXX-XXX-XXXX.

Regards,

Fish Processing Specialist Inspector

APPENDIX J
CV CLOSURE LETTER - ACCEPTABLE CORRECTIVE ACTION PLAN

(CFIA Letterhead)

Canadian Food Inspection Agency
Address line 1
Address line 2
Address line 3

Date

Company Name
Address line 1
Address line 2
Address line 3

Attention: Mr. Company Owner

Dear sir:

An evaluation has been completed on the Corrective Action Plan that you submitted to the Canadian Food Inspection Agency (CFIA) on_____ subsequent to a Compliance Verification conducted at your facility.

The CFIA has no objection to the implementation of this Corrective Action Plan. This Compliance Verification file will now be considered "Closed".

Continued compliance with the FIR is essential to maintain your certificate of registration. Monitoring the implementation of your Corrective Action Plan to verify that you are preventing the recurrence of non-conformities identified during the Compliance Verificaton is a necessary step to ensuring continued compliance with the FIR. Please continue to verify that all elements of the company's Quality Management Program are effective in maintaining compliance with the FIR.

The implementation of this Corrective Action Plan and its effectiveness in maintaining compliance with the *Fish Inspection Regulations* (FIR) will be verified during future Compliance Verification activities.

If you have any concerns or questions, please feel free to contact Inspector _____.

Regards,

Fish Processing Specialist Inspector

APPENDIX K
FOLLOW-UP CHECKLIST

Carried out promptly after CAP date	
Verification of Corrective Actions - completed satisfactorily and deal adequately with non-conformities	
Evaluate changes to procedures, control measures, standards	
Re-verify deficit areas	
Review new or revised documentation	
Samples taken of product, water or ice as required	
Long-term corrective actions to be evaluated at next Compliance Verification	
All Corrective Actions verified - Compliance Verification closed	
Closure of Compliance Verification pending	
Enforcement Policy enacted	

Comments/Notes:

_____

_____

_____

_____

_____

_____

_____

Signature of team leader: _____

APPENDIX L
GUIDE TO SAMPLING & TESTING DURING A COMPLIANCE VERIFICATION

Sampling objective	Microbiological	Chemical
To verify the effectiveness of a critical control point (CCP) within the HACCP plan: - sample immediately after CCP, **or** - sample the final product	Sample and test: - high risk products including, but not limited to, ready-to-eat products - incoming shellfish - final product shellfish	Analyse products for: - aquaculture drug residues - histamine - pH - water activity - shellfish toxins
To check the effectiveness of regulatory action points (RAPs): - sample fish and non-fish components which are controlled by a RAP	Sample and test: - fish supplied from another registered establishment, where hazard is controlled at the other establishment (e.g., molluscan shellfish to be marinated, salmon to be smoked)	Sample and test fish and/or components for: - quality - additives - species identification - contaminants (e.g., PCB, pesticides) - proximate analysis (e.g., water content)
To verify effectiveness of controls implemented prior to processing: - sample product with SQA, buyer specifications, or other such measures in place to control a hazard	Sample and test: - high-risk ingredients or inputs	Analyse products for: - aquaculture drug residues - toxic elements (e.g., mercury)
To verify the acceptability of non-fish components, especially if these are associated with a hazard: - sample non-fish components	Sample and test high risk ingredients, for example: - pasta - egg noodles - breading - rice	Sample and test ingredients for: - additives
To verify the acceptability of the plant water supply: - sample water and ice	Sample and test: - treated water - untreated water - ice - others, as appropriate	
To verify the effectiveness of the Prerequisite Plan, examine: - sanitation program - products	- Swab surfaces and equipment[1] - Sample and test products with microbiological hazards which are controlled by prerequisite program	Sample and test products with chemical hazards which are controlled by prerequisite program

[1] Policy and procedures to be developed

APPENDIX M
COMPLIANCE VERIFICATION CHECKLIST (information and examples)

CV Date: **CV Reference #:**

Registered Establishment: **Registration #:**

CV Team member(s):

Element: **Product Description:**

Section:

No	QMP Requirement (Reference the QMP plan & relevant regulatory requirements)	Task List (Interview, Observe, Measure, Inspect, Review)	Objective Evidence (Factual information collected as a result of completing the task list)	Findings (Conclusions drawn from Objective Evidence)
1	**The QMP Requirement is linked to the Findings column**	→ → **The Task List is linked to the Objective Evidence column** → →	→ → **For each point in the Task List, objective evidence should be noted here, to demonstrate either compliance with the QMP Plan or a departure from the Plan.**	**The finding is a conclusion drawn about whether or not the QMP requirement is being met based on the objective evidence**

No	**QMP Requirement** (Reference the QMP plan & relevant regulatory requirements)	**Task List** (Interview, Observe, Measure, Inspect, Review)	**Objective Evidence** (Factual information collected as a result of completing the task list)	**Findings** (Conclusions drawn from Objective Evidence)
2	Each QMP Requirement should be arranged as it is organised in the processor's plan & be linked to the Reference Standard and FIR.	The tasks outlined here should reflect the "slice approach".	For each task listed, objective evidence should be noted here to demonstrate either compliance with the QMP plan or a deviation from the QMP plan.	The finding is a conclusion drawn about whether or not the QMP requirement is being met, based on the Objective Evidence.
3	For each section, the requirements to be tested: - control measures - monitoring - corrective actions Are they implemented as planned and effective?	**Examples** Interview the person doing a monitoring activity or the QC supervisor that does the Corrective Action - does the person know the standard? - do they have a copy or access to it? - are they applying it correctly? - is the result effective? Observe If a plan has 16 SOPs, look at the 5 most critical to compliance. Inspect If there are 6 packaging materials, pick 2 that are in direct contact with fish being processed. If there are 8 ingredients used in the plant, look at the 2 being used in the process.		

	EXAMPLE Plant Sanitation, Employee Hygiene and Pest Control Control measures - do they match those described in the QMP plan? - are they effective in achieving compliance? Monitoring procedures - do they match those described in the QMP plan? - are they effective in checking adherence to control measure? Corrective actions - are they effective and appropriate to correct the non-conformity and to prevent recurrence? - do records document non-conformities?	Observe - plant employees' adherence to employee hygiene SOP. Are employees following the SOP? Is the SOP effective? - plant cleanup and sanitation. Does the cleanup crew follow the Sanitation SOP? Is the SOP effective? - Does the cleanup crew have adequate equipment? Inspect - plant sanitation and hygiene condition using guide and compliance manual. - cleaners, sanitizers & lubricants. Are they properly stored? Are they properly labelled for identification? - the premises for indications or evidence of pest infestation (insects, rodents, birds, etc.) - the plant for compliance with Schedule I & II. Do any non-conformities represent a health or safety risk to consumers? Interview (suggested questions) - Are you the person who normally does this job? - What type of training or experience do you have for doing this job? - Can you show me the written standard that you use to evaluate plant sanitation & hygiene? - Can you tell me what actions you take to ensure that the plant meets the standard? - Can you show me what you actually do to check the plant for sanitation & hygiene? If you find something not right, what do you do? - What would you do to fix the cause of the problem? - Can you tell me the steps you would perform to clean this piece of equipment? - How much of this cleaner would you put in the pail? Record Review - Are corrective actions being recorded? - Do the corrective actions outline the immediate corrections and longer term actions to prevent a re-occurrence? - Do the records for cleaners, disinfectants & lubricants match what is in the processing area?		

CHAPTER 3, SUBJECT 4

THE QMP REFERENCE STANDARD AND COMPLIANCE GUIDELINES

SCOPE

This subject sets out the requirements for the documentation and application of a federally registered fish processor's Quality Management Program (QMP) Plan. The QMP Reference Standard, hereafter called the "Reference Standard" is based on the Fish Inspection Regulations.

FIELD OF APPLICATION

Each federally registered fish processing establishment, as a condition of registration, must develop, document and apply a specific QMP Plan for the products and processes carried out in the establishment.

The purpose of the Reference Standard is to guide the development, implementation, and maintenance of a Quality Management Program to assure the production of fish and seafood products which meet the requirements of the Fish Inspection Regulations and to ensure that such processing is conducted in establishments which also meet regulatory requirements.

The Reference Standard is the blueprint for the development of the QMP Plan by a processor: it sets out the requirements for the documentation and application of a fish processing establishment's Quality Management Program. CFIA personnel use the Reference Standard during the systems verification and compliance verification.

This document is organised according to the seven elements of the Reference Standard. For each element, the document identifies:

1. The *Reference Standard Requirements* - these are the mandatory requirements established during the re-engineering of the QMP[1] (1996-1998). Since the element(s), sub-element(s), and sub-sub-element(s) requirements are general in description, this document provides additional guidance for interpretive purposes.

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[1] The QMP Reference Standard was originally published as part of Bulletin 18, February 06, 1998, to the Facilities Inspection Manual.

2. The *Intent Statement* - indicates the primary objective of the Reference Standard Requirement. It is the stated intent of the Reference Standard Requirement which is key for CFIA personnel using this document in an assessment of a QMP Plan.

3. *Compliance Guidelines* - provide acceptable options to meet the intent of the Reference Standard Requirements.

4. For some elements, or parts thereof, *Compliance Notes* provide guidance on specific points.

5. The *Appendices* provide detailed guidance and options for the development of QMP controls to meet the requirements of the Reference Standard and the Fish Inspection Regulations. Additional appendices may be developed as needed.

The controls and methods described in this document are not necessarily the only valid means of achieving the desired results. Alternative strategies to those described in the Compliance section and/or the Appendices, that address the Reference Standard Requirement such that the Intent is satisfied, should be considered when assessing compliance.

A food production facility may be subject to a wide range of applicable legislation at the municipal, provincial and federal level. Quality system controls respecting acts, regulations and/or standards, other than those identified within this document, are not required to be addressed in the QMP Plan. Notwithstanding, processors should ensure that all processing operations and products meet other applicable legislation and market requirements.

CONTENTS

1. MANAGEMENT ROLES AND RESPONSIBILITIES

Reference Standard Requirement:

1.1 The position responsible for the QMP Plan must be identified.

1.2 It is recommended that the processor describe how the QMP was developed and how it will be implemented.

Intent:

Management commitment is critical to the successful development, implementation, and maintenance of the QMP Plan.

Compliance Guidelines:

1. The name, business address, business telephone number and the title of the person responsible for the QMP at the establishment must be identified.

2. It is not mandatory but it is strongly recommended that senior management of the establishment demonstrate their commitment to the QMP in writing.

   Managers can demonstrate commitment by taking on responsibilities under the QMP, supporting training knowledge, and encouraging and motivating establishment personnel in the development, implementation and maintenance of the QMP. Management participation will set a good example, promote quality management, and foster cooperation in the establishment.

   Managers can perform tasks such as explaining the QMP to personnel; allocating equipment, materials, staff and space to QMP activities; and assigning quality management duties.

   The following are some options for demonstrating management roles and responsibilities:

   a) an organisation chart;

   b) a written description of each manager's accountability;

   c) a written description of company dispute-resolution processes, e.g., between production staff and

quality management staff;

d) a vision statement or mission statement that emphasizes quality management;

e) a QMP Plan internal audit schedule, with management roles indicated;

f) documentation of management's role in corrective and preventive actions;

g) a written statement of commitment signed by all management staff;

h) Prerequisite Plan, RAP Plan and HACCP Plan procedure manuals; and/or

i) a signed statement of management commitment to quality management training, accompanied by a list of training opportunities for personnel, broken down by job requirements.

2. BACKGROUND PRODUCT AND PROCESS INFORMATION

Reference Standard Requirements:

2.1 Processors are required to identify product and process information in the form of a Product Description, Process Flow Diagram and where applicable, an Establishment Floor Plan.

2.1.1 The Product Description must identify those product attributes and characteristics that are important in ensuring a safe and acceptable fish product.

2.1.2 The Process Flow Diagram must outline all of the production steps and assists in identifying those steps that are important in processing a safe fish product meeting all regulatory requirements.

2.1.3 The Establishment Floor Plan identifies cases where hazards are controlled through the application of sanitary or restricted access zones.

Intent:

In order to develop the Prerequisite and RAP Plans and to conduct the hazard analysis and determination of critical control points, the establishment's QMP development team will need to identify and assess product/process information and the establishment layout.

The purpose of a product description is to identify and document all product attributes including those process and packaging characteristics which influence the safety and acceptability of the fish product.

The purpose of a process flow diagram is to verify and document the process steps to aid in determining when and where control measures and monitoring procedures should be established.

The purpose of an establishment floor plan is to document where sanitary zones or restricted access areas are being used as control measures for identified hazards.

Compliance Guidelines:

1. Product Description

For each product or groups of products processed in the

establishment, a product description should include:

a) a descriptive product name;

b) the source of raw material used in producing the product;

c) important characteristics of the final product which may affect product safety;

d) all ingredients;

e) product packaging;

f) end product use;

g) product shelf life;

h) market destination;

i) labelling instructions for safe product storage (where applicable);

j) special distribution controls or instructions (where applicable);

Information contained in the product description must be supportable. In particular, physical characteristics, composition, packaging, and/or shelf-life attributes which impact on the risk of a hazard or its likelihood of occurrence must be substantiated. This data is usually found in association with the HACCP Plan.

The development of an accurate and complete product description is essential to the further development of the QMP Plan including the HACCP and RAP Plans. More detailed guidelines and references for the development of an accurate product description can be found in Appendix A of this document.

2. Process Flow Diagram

A process flow diagram must be included in the QMP Plan for each of the products or groups of products that are produced in the establishment. The process flow diagram must outline all the production steps and must be complete and accurate.

Dependant on the nature of the product, product-specific

regulations (e.g., for molluscan shellfish), and the product holding conditions and time before shipping, the final step of "shipping" may or may not be an important process step. Normally this final step would be included, and if this step is excluded, justification should be provided in the hazard analysis documentation.

Note: When the RAP and HACCP Plans are completed, the RAP and Critical Control Points (CCP) should be indicated on the process flow diagram.

3. Establishment Floor Plan

If the application of sanitary zones or restricted access areas has been identified as a control measure during the development of a HACCP Plan, then an establishment floor plan must be included in the QMP Plan. The plan must clearly show the flow of materials, personnel and product within the establishment and outline all sanitary zones and restricted access areas.

The term "sanitary zone" refers to that part of a processing area with sensitive processing steps or high risk products, for which a set of controls meeting specified criteria have been established to control all vectors of potential contamination or cross contamination, including air movement, personnel hygiene and sanitation procedures.

The term "restricted access zone" refers to that part of a processing area where personnel movements are restricted and personnel hygiene and sanitation procedures are in place to control potential contamination or cross contamination, but that does not meet the specific requirements of a sanitary zone.

3. THE PREREQUISITE PLAN

Reference Standard Requirements:

3.1 Establishment Environment Program

Processors are required to identify:

3.1.1 the establishment environment standard that is applied in the facility; as a minimum the standard must meet the requirements of the Fish Inspection Regulations;

3.1.2 the actions that are taken by the processor to ensure the standard is met;

3.1.3 the record keeping system to record corrective actions when problems are identified;

3.1.4 the corrective action system in place to address deficiencies when they are identified.

3.2 Lot Accountability and Notification Program

3.2.1 For the purposes of carrying out a product recall, processors are required to have a product identification and distribution system that allows for the rapid identification of the first shipping destination.

3.2.2. As part of the Lot Accountability and Notification Program the processor is also required to have procedures to notify the CFIA of any valid health and safety complaints.

Intent:

Processors are required to identify controls on establishment design, construction and maintenance in order to provide assurance, that the food will be produced under sanitary conditions, of control of all potential sources of significant contamination, and that will allow the rapid recall of product from first shipping destinations.

Compliance Guidelines:

The Prerequisite Plan has two components: the Establishment Environment Program; and the Lot Accountability and Notification Program

The Establishment Environment Program includes *Construction and Equipment* and *Sanitation and Personnel Hygiene.*

1. The Construction and Equipment section describes the controls to ensure that the establishment facilities and equipment are suitably designed and built and maintained in a state appropriate for safe food processing.

2. The Sanitation and Personnel Hygiene section describes the cleaning and sanitizing procedures, the hygiene procedures for personnel and visitors, as well as pest control measures and procedures.

Each section must include:

a) the standard that is applied in the facility. At a minimum, the standard must meet the requirements of Schedules I and II of the Fish Inspection Regulations as described in the Facilities Manual. A copy of the standard must be included or, where the standard is a part of the laws, regulations or other documents published by the Government of Canada, it may simply be referenced. In either case, the standard must be in the establishment and readily available for review in printed or electronic format.

   Where fresh fish is unloaded, handled, held or transported at a registered establishment, conveyances and equipment must comply with Schedule V of the Fish Inspection Regulations, "Requirements For Conveyances And Equipment Used For Unloading, Handling, Holding And Transporting Fresh Fish".

b) the control measures that are employed to ensure the processing facility is in compliance with the standard.

   For the Construction and Equipment section, the control measures ensure that the processing facility is suitably designed, built, and maintained. Control measures can include: training production personnel on the standard so that they can identify deficiencies; routine inspection of the facility; maintenance schedules; procedures for scheduled equipment maintenance and calibration; controls for a safe water supply.

For the Sanitation and Personnel Hygiene section, the control measures ensure the facility is operated and maintained in compliance with the standard. Control measures must include written sanitation, personnel hygiene, and pest control programs. Guidelines for developing these written programs can be found in the Appendices of this document.

c) The monitoring procedures that are used to ensure that the control measures are being correctly and consistently carried out. The monitoring procedures must clearly specify what is being monitored, how it is being monitored, at what frequency, and by whom. The frequency of each monitoring action must be sufficient to ensure that the standard is being met.

In the Prerequisite Plan, processors are not required to record the results of monitoring unless a problem is identified. In these cases, the processor must record the problem and the corrective action information.

d) The corrective actions to be taken when monitoring identifies a deviation from the standard. The corrective action should include actions to fix the immediate problem and to prevent a recurrence of the problem.

e) The record-keeping system for recording the results of monitoring and corrective actions when problems are identified. The corrective action record should allow for the recording of a description of the deviation, the part of the standard not complied with, the corrective action taken, the person(s) responsible for the action, the date the action was taken, the date it was verified as effective, the person responsible for verifying and, if applicable, any interim preventative measures for long-term corrective actions. A copy of the corrective action record must be included.

3. Lot Accountability and Notification Program

a) Processors must provide a written description of the system used to trace fish to their first shipping destination. For each shipment of fish this must include:

- the name and address of the person to whom each shipment was sent;
- the type of fish;
- the quantity of fish;
- the method of transportation, including manifest and container numbers or other information that is sufficient to identify or trace the location of the fish;
- the date on which the fish was shipped; and
- the date on which the fish was processed.

b) Processors should establish specific procedures to address the requirement for notification of CFIA, within 24 hours, in the event of any valid health and safety complaints. A "valid" complaint means where the initial investigation indicates the health of consumers is at risk.

c) For health and safety complaints the following records must be kept:

- the date and time when the processor received information questioning the safety of fish processed or exported by the registered establishment, and a description of the information;
- in cases where the complaint is confirmed: the date and time it was confirmed; the name, address and telephone number of the informant; the method of investigation and the results obtained; the corrective actions taken; and the date and time when the CFIA was notified.

Compliance Notes

1. Construction Materials

Where the suitability of construction materials is in question, the *Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products* (also called the *Reference Listing)* should be consulted. The Reference Listing may be accessed at:

http://www.inspection.gc.ca/english/ppc/reference/cone.shtml

Construction materials used for construction, renovation, and maintenance should be selected on the basis of chemical and physical suitability of the materials in relation to their intended use.

2. Chemicals

All non-food chemicals are controlled under the Establishment Environment Program. Non-food chemicals include, bleaches, cleaners, deodorizers, desiccants, disinfectants, denaturing agents, floor-drying compounds, industrial antifreeze, inks, lubricants, pesticides, protective oils, refrigerating brine additives, refrigerants (immersion freezing), sanitizers, and water-treatment compounds. These compounds include chemicals which may be acceptable for food contact and those that are not.

Processors must ensure that these chemicals are approved for their intended use and must have controls to ensure that these chemicals are applied according to their intended use and stored to prevent unintentional contact with food products. The acceptability of chemicals for their intended use must be documented in the QMP Plan. Chemical acceptability is substantiated by inclusion in the *Reference Listing.*

Non-food chemicals used outside of the fish processing and support areas need not be substantiated in the *Reference Listing*; however, the processor must have controls in place to ensure these products do not enter into, or contaminate, areas where fish and/or input materials are handled or stored.

Examples of chemicals exempt from the requirement for inclusion on the *Reference Listing* include, pesticide products for outdoor use only, products used in offices or similar non-regulated areas, products used in cafeterias or lunch rooms, products used in heating systems, products used outdoors only for sewage or waste water systems, products used in cooling towers or evaporator condensers, products used for the cleaning or maintenance of the exterior of vehicles, and products for use in the maintenance shop on non-food contact equipment.

3. Ice

When ice is used for processing, as a processing aid or as an ingredient, and that ice is manufactured in the registered facility, the processor will set out control measures under the Establishment Environment Program. Control measures to address requirements for the ice manufacturing equipment, holding, storage, and the

quality of the water source and supply should be considered.

When ice is used for processing, as a processing aid or as an ingredient, and that ice is manufactured outside of the registered processing establishment, the controls under the QMP are two-fold. The processor will set out controls under the Establishment Environment Program for requirements relating to the holding and storage of the ice. Secondly, the processor will establish controls for the transport and the quality of ice under the RAP Plan.

4. Standard Operating Procedure (SOP)

A Standard Operating Procedure (SOP) is an effective means for establishing, documenting, and communicating a control measure associated with the Prerequisite Plan, RAP Plan, or HACCP Plan. A SOP is a detailed set of instructions which describes how to carry out a repetitive task. Trained personnel can use a SOP for a specific task to carry out that task with little further direction.

4. THE REGULATORY ACTION POINTS (RAP) PLAN

Reference Standard Requirements:

4.1 The RAP Plan must describe the controls to ensure that:

fish is handled properly during processing and results in a final product that is not tainted, decomposed or unwholesome and meets all applicable sections of the Fish Inspection Regulations;

any ingredients added to the fish product or packaging material used are acceptable for food and meet all regulatory requirements as specified in the *Fish Inspection Regulations* and the *Food and Drugs Act* and *Regulations*; and

labelling and coding of all fish products meet the requirements of the *Fish Inspection Regulations* and is not false, misleading or deceptive.

As part of the RAP Plan the processor must identify:

4.1.1 The fish product standard(s) and the ingredient and packaging requirements to which they must comply;

4.1.2 The controls that are implemented in production to ensure the standards and requirements are met;

4.1.3 The record keeping system to record corrective actions when problems are identified;

4.1.4 The corrective action system in place to address deficiencies when they are identified.

Intent:

Within the RAP Plan, processors are required to document and apply controls that ensure the fish is handled properly while under the control of the registered establishment and result in a final product that meets all requirements of the applicable sections of the Fish Inspection Regulations. The three areas that must be addressed are minimum acceptable product quality, input materials, and labelling.

Compliance Guidelines:

1. <u>Minimum acceptable product quality</u>

This section of the RAP Plan describes the controls to

ensure that fish will be handled properly while under the control of the registered establishment and will result in final products that meet all applicable sections of the *Fish Inspection Regulations*.

2. Input materials (Ingredients and Packaging Material)

   This section of the RAP Plan describes the controls to ensure that any ingredients added to the fish product and any packaging material used are acceptable for food and meet all regulatory requirements.

3. Labelling and Code Markings

   This section of the RAP Plan describes the controls to ensure that the labelling and code markings of fish products is accurate, legible, and not misleading.

Each section must include:

a) The standard that is applied at the facility. The standard may be the CFIA standard as set out in the Fish Products Standards and Methods Manual, applicable sections of the Regulations, or another standard equivalent or superior to these. The standard must outline the accept/reject criteria which identifies compliance.

   A copy of the standard must be included or, where the standard is a part of the laws, regulations or other documents published by the Government of Canada, it may simply be referenced. In either case, the standard must be in the establishment and readily available for review in printed or electronic format.

   For minimum acceptable product quality, the standard identifies minimum compliance parameters for product safety (tainted, decomposed and unwholesome) and quality, if applicable.

   For input materials (ingredients and packaging material), the standard identifies the minimum compliance parameters for input material acceptability for use in food processing or production and compliance to all applicable regulatory requirements specified in the *Fish Inspection Regulations* and the *Food and Drugs Act* and *Regulations*.

For packaging material, primary considerations include that all packaging materials must be new, clean and sound and approved for food use. Packaging material must not impart any undesirable substance to the food product, either chemically or physically and should protect food sufficiently to avoid contamination. The acceptability of packaging materials for their intended use must be documented in the QMP Plan. For packaging materials which contact (or may contact) food[1], the acceptability is substantiated by inclusion in the *Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products*.

Ingredients must be identified and acceptable for food use. Ingredient acceptability can be substantiated by several methods: a manufacturer's attestation; documentation from a recognised government or non-governmental authority; results of analysis from an accredited laboratory; and ingredients commercially prepared and labelled for food preparation use. Where product additives are used, their identity and concentration is in compliance with the Food and Drug Regulations. Guidance on additives for fish and fish products for sale in Canada can be found on the CFIA Internet site, in the *Guide to Additives Permitted in Fish and Fish Products*.

For labelling and code markings, the standard identifies the minimum compliance parameters to ensure that the labelling and coding of all fish products is accurate, legible, not misleading and meets the requirements of the *Fish Inspection Regulations*. These requirements include any specific species requirements found in the body of the regulations, as well as those set out in Part II - Labelling.

b) The control measures applied to ensure that final product will meet the standard(s) and that any

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[1] As an example: Fresh fish fillets wrapped in polyvinyl bags, inside insulated Styrofoam containers, inside waxed cardboard boxes. The polyvinyl bags have direct food contact, the Styrofoam containers may contact the fish through minor breakage of the Styrofoam material, the waxed cardboard does not contact the fish. The polyvinyl bags and Styrofoam boxes should be made of material substantiated as approved for food contact; the waxed cardboard boxes need not be substantiated.

product not meeting the standard will be removed from production.

Control measures can include inspections, evaluations, sampling, pre-printing label evaluations, pre-use review and final product label and coding inspections. For information on supplier quality assurance (SQA) as a control measure, refer to the Appendices of this document. Sampling plans must be at least equivalent to those used by the CFIA.

c) The monitoring procedures used to ensure that the control measures are being correctly and consistently carried out. The monitoring procedures must clearly specify what is being monitored, how it is being monitored, at what frequency, and by whom. The frequency identified for each monitoring activity must be sufficient to ensure that the standard is being met.

Under the RAP Plan processors are not required to record the results of monitoring unless a problem is identified. In these cases, the processor must record the problem and the corrective action information.

d) The corrective actions to be taken when monitoring identifies a deviation from the standard. These actions must include both fixing the immediate problem and preventing the problem from happening again. This section must describe how all product not meeting the standard is identified and segregated, culled, and reworked or disposed of in an appropriate manner.

e) The record-keeping system for recording the result of monitoring and corrective actions when problems are identified. The corrective action record should allow for the recording of a description of the deviation, the part of the standard not complied with, the corrective action taken, the person(s) responsible for the action, the date the action was taken and the long-term preventative steps (if applicable). A copy of the corrective action record must be included.

Compliance Notes

Note 1. Receipt of incoming fish and other input materials from suppliers

Where the processor receives fish from suppliers, the processor must establish control measures to ensure, protect, and preserve the quality of that fish. An effective type of control measure is the use of a Supplier Quality Assurance (SQA) agreement. A SQA can be an effective control measure to address many types of situations where an understanding between business parties is required. For example, for transport requirements (i.e., transport vehicles are clean, proper care has been taken, and the vehicles have not been used to transport hazardous materials), temperature control requirements, withdrawal from medicated feeds (i.e., for cultured species) as well as many other requirements.

Guidelines for developing a SQA as a control measure are outlined in the Appendices of this document.

Note 2. Standard Operating Procedures

A standard operating procedure (SOP) is an effective means for establishing, documenting and communicating a control measure associated with the Prerequisite Plan, RAP Plan, or HACCP Plan. A SOP is a detailed set of instructions which describes how to carry out a repetitive task. Trained personnel can use a SOP for a specific task to carry out that task with little further direction.

Note 3. Identification of Input Materials (ingredient and packaging materials)

Processors should consider all processing steps to identify ingredients. Some components to the final product may not be immediately recognisable as "an ingredient" because they are added to the product indirectly (i.e., as a processing aid) rather than by formulation. For example, when wood chips or sawdust is used in smoking fish product, the processor must identify and consider the input material (sawdust) which is the precursor to the ingredient, natural wood smoke. Also, when ice used for processing is received from facilities outside of the registered establishment (i.e., the ice is not under the Establishment Environment Program), the processor must identify and consider the input material (ice) which is the precursor to the ingredient, added water or ice.

Packaging material includes cartons, wrapping materials,

films, synthetic casings, netting, trays, pouches, bags and any other material used in the shipping of food products which may come into contact with the food product shipped.

Note 4. Regulatory requirements other than the FIR

Processors are not required to establish controls within the QMP Plan to ensure that regulatory requirements outside of the FIR are met. Nonetheless, processors must ensure all final products are in compliance with all applicable regulations including, *Food and Drug*, *Consumer Packaging and Labelling*, and *Weights and Measures*, and foreign country legislation for exported products

Note 5. Documentation associated with the RAP Plan

Documents must be included in the QMP Plan which substantiate the acceptability of the packaging materials. (e.g., their listing in the *Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products*).

Processors must document any specialised packaging requirements, such as oxygen permeable packaging for ready-to-eat chilled products, set out in the Food and Drug Regulations.

5. THE HAZARD ANALYSIS CRITICAL CONTROL POINT (HACCP) PLAN

Reference Standard Requirement:

5.1 Processors must develop, document and implement a HACCP Plan to control any health and safety hazards related to the product or process. The processor must apply the seven principles of HACCP to identify any significant hazards and for those significant hazards identified, develop a HACCP Plan to prevent, eliminate or reduce the hazard to an acceptable level.

The HACCP system consists of the following seven principles:

5.1.1 Principle 1 - Conduct a hazard analysis.
5.1.2 Principle 2 - Determine the Critical Control Points (CCPs).
5.1.3 Principle 3 - Establish critical limit(s).
5.1.4 Principle 4 - Establish a system to monitor control of the CCP.
5.1.5 Principle 5 - Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.
5.1.6 Principle 6 - Establish procedures for verification to confirm that the HACCP system is working effectively.
5.1.7 Principle 7 - Establish documentation concerning all procedures and records appropriate to these principles and their application.

Intent:

Every processor must analyse their products and processes to determine if any health and safety hazards are present and, where significant hazards are identified, appropriate controls are put in place. The application of the HACCP principles must be consistent with the Recommended International Code of Practice - General Principles of Food Hygiene, CAC/RCP 1-1969, Rev.3 (1997), Amd. (1999).

Compliance Guidelines:

1. <u>Conduct a Hazard Analysis</u>

   a) The hazard analysis and the development of the HACCP Plan is conducted by a HACCP team, including at least one member who has knowledge of HACCP from either formal training or experience.

b) The hazard analysis is conducted at each process step for every product type. Process steps where a significant hazard may be introduced or where a hazard may increase to an unacceptable level must be identified.

c) The hazard analysis includes the identification of all potential hazards (biological, chemical, physical), the determination of the significance of the hazard identified, i.e., consideration of its severity and the likelihood of occurrence and, if applicable, justification for a determination of non-significance of a hazard.

d) The processor demonstrates that they have considered all process steps in conducting their hazard analysis. A Hazard Analysis Worksheet, or equivalent, is used to organise and document the hazard analysis.

e) The processor considers all activities and materials in the establishment, including incoming fish, ingredients, packaging materials, establishment personnel, the establishment itself, product descriptions, the process flow diagram documented in the Background Product and Process Information section, as well as consumer complaint information, and epidemiological and technical literature available when conducting the hazard analysis.

f) For some establishments, the hazard analysis will not identify any significant hazards. The HACCP component of the QMP Plan would therefore only include the hazard analysis and other applicable documentation (examples are given in number 7 below *Establish a Documentation and Record-Keeping System*.) The determination of CCPs and associated controls would not be applicable.

2. Determine Critical Control Points (CCPs)

a) For each significant hazard identified in the first step, there is an appropriate preventive measure in place to prevent or eliminate the hazard or reduce it to an acceptable level.

b) The method and results of the CCP determination are documented and CCPs are indicated on the process flow diagram.

3. Establish Critical Limits

   a) Critical limits are established for each CCP identified. A critical limit means the maximum or minimum value to which a hazard must be controlled at a critical control point. For example, a temperature or time which must be achieved to ensure destruction of a pathogenic bacteria, a specific pH to prevent the growth of bacteria, a level of a preservative, a size of detectable shell pieces, or the presence of acceptable product analysis documentation from a SQA supplier of raw materials.

   b) The critical limits are validated to demonstrate that they are effective and the validation is documented.

4. Establish Monitoring Procedures

   a) At each CCP, the processor has established monitoring procedures to determine that the system is operating within the critical limits identified. It is important to have monitoring procedures which produce immediate measurable results to which action can be initiated since there may be potential food safety implications.

   b) The monitoring procedures include what will be monitored, if applicable how the critical limits and preventive measures will be monitored, how frequently monitoring will be performed, and who will perform the monitoring.

   c) For each monitoring activity, the processor has established that personnel performing the monitoring have the knowledge and ability to conduct the procedure. Where specialised skills are required in order to adequately monitor a process or perform an activity which is critical to ensure product safety, appropriate training requirements, experience, and/or skills are identified. For example, the following positions are recognised as requiring specialised skills: retort operator, can closing machine operator, can screening machine operator, and container integrity inspector. Personnel in these positions require special knowledge and experience.

5. Establish a Corrective Action System

   a) Corrective action procedures are established to be initiated when monitoring indicates that the process is operating outside the defined critical limits. The corrective action procedures are established in advance so the personnel conducting the monitoring will have direction on the steps to take when a deviation is identified.

   b) The corrective action procedures address: the correction of the deficiency that gave rise to the problem; the identification and segregation of all affected product; the culling, re-working, and/or disposition of affected product in an appropriate manner.

   c) The corrective action procedures address: the prevention or reduction in likelihood of reoccurrence of the problem (e.g., by investigating how the problem developed); if a review of the QMP Plan (e.g., to determine where changes of procedures, control measures, standards, etc., are needed) is needed; the implementation of necessary changes; identification of changes in the QMP amendment log.

   d) The corrective action procedures include a record system to document at least the details of the problem, including the date the problem was identified, the corrective action taken, the person(s) responsible for the action, the date the action was taken and the changes needed to eliminate or prevent re-occurrence of the problem.

6. Establish Verification Procedures

   a) Verification activities are an additional level of control and monitoring to ensure the HACCP Plan is operating as it was designed. The verification activities are conducted in addition to the CCP monitoring, but on a less frequent basis, in order to review the implementation of the plan through the records or through additional tests or analysis. For each monitoring activity, the processor must establish and document verification procedures to ensure that the CCP is working as designed.

   b) The verification procedures include what will be

verified, how it will be verified, how frequently verification will be performed, and who will perform the verification.

c) Verification activities are performed by qualified personnel and usually by personnel not associated with monitoring of the CCP.

7. Establish Documentation and Record Keeping

a) Processors keep two types of records associated with HACCP, "documentation" and "records". Documentation refers to those records which are created as a result of the development of the HACCP Plan, and records, which are created as a result of the implementation of the HACCP Plan.

b) Documentation is maintained as a record of HACCP Plan development, recognising the support and input from many individuals and usually over a considerable period of time. During this phase there are numerous decisions taken and authorities referenced. This information is essential to justify, if necessary, to regulatory agencies or customers why certain actions or activities are taken and also to assist in future development and evolution of the plan. Documentation includes the QMP and HACCP Plans as well as component parts such as SOPs. It also includes the hazard analysis, product attribute data, CCP determination, critical limit validation data, personnel training records, and manufacturer specifications for operation and maintenance of specialised equipment.

c) Records are generated by the procedures or activities performed and any corrective actions taken. The processor establishes a record-keeping system that ensures that CCP monitoring records, corrective action records and verification records are complete, accurate, legible, and available for review. These records include all information required in the QMP Plan and are initialled or signed and dated by the person responsible for monitoring and by the person responsible for reviewing to verify the monitoring or corrective actions where this review is identified in the QMP Plan as a verification activity. A copy of each record is included in the HACCP Plan.

Additional guidance on electronic records system can be found in the Appendices of this document.

6. VERIFICATION & MAINTENANCE OF THE QMP PLAN

Reference Standard Requirements:

6.1 Processors are required to perform the following verification activities to ensure that their QMP Plan is functioning correctly.

6.1.1 Before implementation the processor is required to validate the critical limits of CCPs.

6.1.2 Before implementation the processor is required to review the QMP Plan to ensure that all of the necessary controls are in place and that it meets the requirements of the Reference Standard.

6.1.3 Once the QMP Plan is implemented the processor is required to perform routine verification of the HACCP Plan to ensure it is functioning effectively.

6.1.4 Once the QMP Plan is implemented the processor is required to verify or validate any changes to the QMP Plan or to critical limits that may occur in the ongoing development of the QMP Plan.

6.1.5 Once the QMP Plan is implemented the processor is required to review the QMP Plan at least once per year.

6.1.6 To ensure that the QMP Plan is accurately documented, processors are required to maintain a list of amendments of any changes to their QMP Plan.

Intent:

The QMP Plan is a dynamic document and verification is a systematic and comprehensive approach to ensure continuous maintenance and improvement to the QMP Plan in order to confirm that the QMP meets the needs of the fish processor in producing a safe, wholesome, fairly traded product.

Compliance Guidelines:

There are five main activities that a processor is required to perform to verify the QMP Plan.

Before implementation of the QMP Plan, the processor is required to:

1. Validate the critical limits for all identified Critical

Control Points. The processor must obtain supportive evidence or documentation to confirm that the parameters of the critical limit for each CCP are sufficient to prevent, eliminate or reduce to an acceptable level, food safety hazards in the final product. There are two components to this supportive evidence or documentation:

- sound and reliable scientific evidence, standards from an accepted authority, advice from an accepted authority, or a regulatory standard to demonstrate that the process, if operated within the established critical limits, will result in a safe product, and

- sufficient technical data, gathered through testing and measurement of the process in a processing establishment, to demonstrate that the process can operate within the chosen critical limits.

2. Review the QMP Plan to ensure that it complies with the requirements of the Reference Standard. This includes:

   - reviewing the Prerequisite and RAP Plans to confirm that all the necessary controls and documentation are in place. This includes the strategy for monitoring, the taking of records when required, and the implementation of appropriate corrective actions, as outlined in the QMP Plan; and

   - reviewing the HACCP Plan to confirm that all the necessary controls and documentation are in place. This includes the strategy for monitoring and recording at CCP, the implementation of appropriate corrective actions, and the verification of the HACCP Plan to ensure the system is working effectively.

Once the QMP Plan is implemented, the processor is required to:

3. Perform routine verification procedures to confirm that the HACCP system is working effectively (HACCP principle 6). For CCP verification, the processor must complete independent tests, measurements, sampling, review of monitoring procedures and records etc., as necessary and at an appropriate frequency, to verify that the control measures implemented at each CCP are effective and being implemented as described in the plan.

4. Re-validate QMP controls or CCP critical limits as

changes are made to raw materials, products, processes, equipment, or in response to adverse review findings, recurring deviations, new information on hazards or control measures, on-line observations, and/or new distribution or consumer handling practices where potential hazards may be encountered.

5. Review the QMP Plan, at least once per year, including:

   - verifying the HACCP Plan, to confirm that it is complete, accurately reflects current products and processes (product descriptions, process flow, and establishment layout), has effective controls over the significant hazards, and the monitoring of the critical limits is at a frequency sufficient to ensure that products remain in compliance. This verification should include, as appropriate, product sampling and testing, a review of process deviations, corrective actions, audit findings, and consumer complaints. The HACCP Plan is also verified following a system failure or, when there is a significant change in the product or process.

   - conducting a review of the QMP Plan, including Prerequisite and RAP Plans, to confirm that these programs are complete and functioning effectively. Verification activities for the Establishment Environment Program can use a combination of visual observation, record review, surface swabs or other methods of microbiological analysis of surfaces such as contact plates, or ATP (adenosine triphosphate) bioluminescence. Mock recall exercises are effective verification of the traceability system. Verification of the RAP Programs can include product and incoming material testing and label inspection at atypical inspection points or using more stringent sampling regimes.

     This review would confirm that all corrective actions, problems and consumer complaints have been evaluated to ensure the results were effective and that all amendments and other required written changes have been made to the QMP Plan.

     The processor should consider the yearly operating schedule in order to best schedule the annual review of the QMP Plan. Some verification activities require the establishment to be in typical production mode in order to assess (for example,

swab samples for microbiological analysis), whereas some verification activities, such as equipment calibrations may better be scheduled during shutdown periods. All elements of the QMP Plan should be reviewed in the course of each year, however, each element need not be reviewed simultaneously. The QMP Plan should describe the schedule and method by which each element will be reviewed.

7. RECORD KEEPING

Reference Standard Requirements:

7.1 Records must be kept for the QMP Plan as follows:

7.1.1 For all Prerequisite and RAP Plans, record keeping may be "by exception".

7.1.2 For the HACCP Plan, record keeping is mandatory for all testing, measurements, and monitoring at CCPs and for corrective actions when the critical limits are exceeded.

7.1.3 For all verification activities and results, record keeping is mandatory.

7.1.4 For amendments or changes to the QMP Plan, a record must be maintained.

Intent:

Two types of records are components of the QMP Plan, the record of the development and the components of the quality management program, referred to as "documents" or "documentation" and those records taken as a result of the implementation of the quality management program, simply termed "records".

It is important to balance the volume of record keeping with the true needs of the organisation and the resources available to deliver the system. The development, usage and maintenance of documentation and records should be sufficient to provide evidence that the system was developed properly, is being implemented as written, and can demonstrate trends to identify a problem.

Compliance Guidelines:

1. Copies of all of the records (e.g., blank examples) described in the QMP Plan, including monitoring, verification, corrective action and personnel training records, are part of the QMP Plan documentation.

2. When records by exception are permitted, records are only required when a deficiency is identified during the monitoring procedures. In these cases the processor is required to record the deficiency and document it using a Corrective Action Record.

3. When a QMP Plan or any part of its documentation is amended, the date and the changes and the date they are made must be recorded. An accepted practice is to include an amendment log in the QMP Plan. This will ensure that the written QMP Plan continues to reflect the controls that are being applied in the processing operation.

4. The effectiveness of record keeping is improved by ensuring that personnel understand why they are taking records, when, and how to complete the record accurately. The processor should review records periodically to ensure they are current and relevant. Records may contain information outside of the scope of the QMP Plan and processors may combine records to reduce paper load.

5. Records remain current, legible, readily identifiable and retrievable. The location of all files and records in respect of the QMP Plan must be identified. The retention time for records is a very important issue. Records must be retained for at least 36 months and should be retained for a period of time which is relevant to the product shelf life. Records should be stored in a manner which is secure, easily accessible, and which protects the integrity of the record.

6. Consideration can also be given to technology to allow for continuous monitoring or automatic capture of data through computers or remote sensors. When microprocessor technology is used, specific controls must be developed to control the creation and maintenance of electronic records and electronic signatures. Further guidance on this subject is provided in the Appendices of this document.

APPENDICES

APPENDIX A
GUIDELINES FOR THE DEVELOPMENT OF A PRODUCT DESCRIPTION

The importance of the product description, including the intended use, distribution, and consumer information should not be underestimated.

The product description has two major roles:

a) it contains sufficient information regarding the product which is essential to the hazard analysis and the development of safety and regulatory controls in the QMP Plan;

b) to describe the scope of the QMP Plan, i.e., all of the documentation, controls, reports, corrective actions, etc., in the QMP Plan that pertain specifically to the product described in this section.

Information contained in the product description must be supportable. In particular, physical characteristics, composition, packaging, and/or shelf-life attributes which impact on the risk of a hazard or its likelihood of occurrence must be substantiated. This data is usually found in association with the HACCP Plan.

The product description can be developed using the following 3-step approach:

Step 1 - Describing the product in consumer terms

The product should be described in consumer terms, including:

a) the product name

This should use the acceptable common name associated with the species, and the manner of processing or intended preparation.

For example, fresh aquaculture raised Atlantic salmon, canned chinook salmon, salt cod, etc.

The *List of Canadian Acceptable Common Names for Fish and Seafood*, also referred to as the "Fish List", identifies the English and French common names for fish and seafood which are acceptable for use in Canada.

The 'List of Canadian Acceptable Common Names for Fish and Seafood' is available on the CFIA Internet.

b) the type of product packaging

This should describe the packaging of the final product and may include multiple types of packaging.

Key issues associated with food safety are selective barrier films, vacuum packaging, recycled packaging materials, the acceptability of food contact materials, and identification of potential sources of physical contamination (i.e., product packed in glass represents a potential source of contamination from broken glass).

Any characteristics of the packaging which may affect the multiplication of microbial pathogens and/or the formation of toxins should be identified. For example, the potential for growth and toxin production of *Clostridium botulinum* in products packaged in selective barrier (i.e., oxygen permeable) films, and vacuum or modified atmospheric packaging and the potential growth of *Listeria monocytogenes* in products packaged for extended shelf-life.

Step 2 - Describe any factors which may result in the addition of ingredients or other compounds to the product

Consider and identify any sources of intentional and/or unintentional additions to the product which may affect product safety, including:

a) the source of incoming fish where it could affect product safety

Fish, whether migratory or non-migratory may be disposed to naturally occurring or man-made contaminants or other compounds in the environment.

In general, Canadian products should be identified by the waters where the fish was harvested or the location closest to it. However, where a known risk exists, it is important to identify any source(s) that is not acceptable. For example, a fisheries exclusion zone or area closed to harvesting as a food safety precautionary measure.

Bivalve molluscs must be identified by specific harvest

area or areas.

Imported fish must be identified by the country of origin, and where geographic risks apply, by more specific localities.

b) processing steps or processing aids which could affect product safety or regulatory compliance

Any compounds that are added to the product, either directly or indirectly, such that they are part of the product whether or not the component is listed on the label, must be identified.

Fish culture, harvesting, processing, and/or transport operations should be considered. For example, consider the following ingredients, processing aids, or residual compounds that may be added to the product:

- aquaculture therapeutants
- sawdust used to naturally smoke fish
- ice used to pack fresh fish during transport, processing or in the final product
- boiler compounds in steam used to pre-cook fish
- water used to flume or wash fish
- traditional ingredients (salt, sugar, spices, vinegar, etc.) must also be listed.

c) the important characteristics of the final product which are intended to affect product safety or influence the growth of disease-causing pathogens, such as additives, salt concentration, water activity (a_w), or pH.

Step 3 - Describe the conditions of distribution, intended use, and consumers of the food

Consider and identify the factors which impact on product safety and regulatory compliance, including:

a) the product market, i.e., within Canada or outside Canada;

b) special distribution controls or instructions for safe product distribution, e.g., "Keep Refrigerated" or "Keep Frozen";

c) labelling instructions that may be applicable for safe product storage and preparation, e.g., "Keep

Refrigerated";

d) the intended end product use which may effect the product safety.

For example, consider: Will the food be heated by the consumer? Will there likely be leftovers? Is the food intended for the general public? Is the food intended for consumption by a population with increased susceptibility to illness (e.g., infants, the aged, the infirm, immuno-compromised individuals)? Is the food for institutional use or for the home?

e) the product's shelf life.

For example, consider: the potential growth of *Listeria monocytogenes* in extended shelf-life products; the potential effect of shelf life on the integrity of sensitive packaging materials.

APPENDIX B
GUIDELINES FOR THE DEVELOPMENT OF A SANITATION PROGRAM

An effective sanitation program is an essential support for any food safety program. While it is not an integral part of the HACCP Plan, which is restricted to process steps, the sanitation program must be in place before a HACCP Plan can be properly introduced.

Cleaning is the removal of dirt or debris by physical and/or chemical means.

Sanitizing is the process used to rid or reduce the number of microbes (microorganisms) on the surface. Sanitizing cannot be accomplished until surfaces are clean. Sanitizing cannot be effective without a good pest control program as described in Appendix C.

The food processing establishment is a distinctive environment and a sanitation program should be designed to meet the specific needs of that environment to ensure that fish and fish products are prepared under sanitary conditions.

Cleaners and sanitizers should be selected to be effective in the processing conditions found at the establishment. These products are known to have differences in activity relative to ambient temperature, cleaning water characteristics, and the level and type of processing debris present. The method of product use, i.e., the application method, concentration and contact time will affect the performance of cleaning and sanitizing products.

An effective written sanitation program includes the following:

1. Procedures for equipment sanitation which specify step-by-step instructions for equipment to be cleaned and sanitized, including:

   - person(s) or positions responsible;
   - identification of equipment and utensils;
   - disassemble/reassemble instructions when required for cleaning, disinfecting, lubrication, and inspection;
   - methods of cleaning, disinfecting, and rinsing;
   - chemicals and concentrations used;
   - time and temperature requirements for cleaning and disinfecting;
   - lubricants used where applicable; and
   - frequencies for cleaning and sanitizing.

2. Procedures for establishment sanitation which specify step-by-step instructions for premises, processing, and storage areas to be cleaned and sanitized, including:

   - person(s) or position(s) responsible;
   - identification of premises, processing, and storage areas;
   - methods of cleaning, disinfecting, and rinsing;
   - chemicals and concentrations used;
   - time and temperature requirements for cleaning and disinfecting;
   - frequencies for cleaning and sanitizing; and
   - methods to prevent the contamination of food or packaging materials during, or subsequent to, cleaning and sanitizing.

3. The identification of acceptable cleaning and sanitizing equipment and its intended use.

4. The identification of acceptable cleaning chemicals and/or compounds, their intended use, and instructions for proper application.

APPENDIX C
GUIDELINES FOR THE DEVELOPMENT OF A PEST[1] CONTROL PROGRAM

Sanitizing cannot be effective without a good pest control program. Pest Control is the reduction or eradication of pests (macro organisms). These include flies, cockroaches, mice and rats, as well as weevils and other animals and insects that can target food products. Pest control cannot be effectively accomplished unless and until proper cleaning and establishment maintenance has occurred. If no pests are present, cleaning followed by sanitizing is sufficient. If, however, pests are present, they must be controlled before the sanitizing step. This is because the pests will re-contaminate any surface that may have been sanitized.

Establishment management is responsible for identifying a competent person to develop a pest prevention and control program and to give them the necessary support to carry out the program and ensure that pesticides are used in accordance with label instructions. Persons who apply pesticides in industrial and institutional settings have a responsibility to use the needed pesticide, to apply it correctly (according to label instructions), and to be certain there is no hazard to man or the environment.

An effective written pest control program includes the following:

1. Controls to prevent the entrance of pests to the facility, including:

   - measures to prevent the entry of pests and animals, through proper construction and layout of facilities
   - measures to control the opening and closure of doors and windows
   - measures to exclude animals such as dogs, cats and birds.

2. Controls to eliminate or prevent the harbourage of pests in and around the facility, including:

   - measures to maintain an outside establishment environment that does not provide a habitat for pests (i.e., establishment surroundings must be free of debris, stagnant water or improperly disposed of offal),

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[1] In Canada, "pest" refers to the following four major groupings: insects (e.g., flies, cockroaches, weevils); rodents (e.g., mice, rats); birds (e.g., gulls, crows, pigeons, small building-nesting birds); and other animals (e.g., cats, dogs, wild mammals).

- where applicable, a list of chemicals and devices used for pest control, the concentration applied, the locations where applied, and the method and frequency of application,
- where applicable, a plan of bait and trap locations,
- where applicable, a system to record the date of chemical or device applications, chemicals or devices used, results of the application, corrective actions taken, and
- the name of the responsible person.

3. Identification of properly maintained pest control equipment and its intended use.

4. The identification of acceptable chemicals and/or compounds, their intended use, and procedures for proper application.

5. Procedures to ensure that the pest control program is carried out in a manner that does not contaminate food or packaging materials during, or subsequent to, pest control applications.

6. The name or position of persons responsible for pest control, including, where applicable, the name of the pest control company or the name of the person contracted for the pest control program.

APPENDIX D
GUIDELINES FOR THE DEVELOPMENT OF A PERSONNEL HYGIENE PROGRAM

Anyone who works in a food handling area must maintain a high degree of personal cleanliness, and the way in which they work must also be clean and hygienic.

In developing the QMP Plan, management must:

- decide what training or supervision their food handlers need by identifying the areas of their work most likely to affect food hygiene. Food handlers must receive adequate supervision, instruction, and/or training in food hygiene.

- take care to ensure that no persons, while known or suspected to be suffering from, or to be a carrier of, a disease likely to be transmitted through food or while afflicted with infected wounds, skin infections, sores, or with diarrhoea, is permitted in any food handling areas in any capacity in which there is a likelihood of that person directly or indirectly contaminating the food with pathogenic micro-organisms.

The Codex Alimentarius General Principles of Food Hygiene lists the following illnesses and injuries which should be reported to management so that any need for medical examination and/or possible exclusion from food handling can be considered: jaundice; diarrhoea; vomiting; fever; sore throat with fever; visibly infected skin lesions (boils, cuts, etc.); and discharges from the ear, eye, or nose.

The Prerequisite Plan should contain an effective written personnel hygiene program, which addresses the following:

1. Communication of the company policy on personnel hygienic practices, including communicable diseases, to employees, visitors and guests.

2. Cleanliness and conduct of personnel, including hand washing, use of hand and/or foot dips, clothing or jewellery which could contaminate food, unsanitary behaviour or practices

3. The health of personnel, including prevention of personnel suffering from a communicable disease or with open cuts or wounds from being employed in a processing area of an

establishment.

4. Prevention of contamination and cross-contamination of the food product by control over the storage of employee personal belongings, and the control of personnel and visitor traffic.

APPENDIX E
CRITERIA FOR AN ACCEPTABLE SUPPLIER QUALITY ASSURANCE AGREEMENT

See "Criteria for an Acceptable Supplier Quality Assurance Agreement" at:
http://www.inspection.gc.ca/english/fssa/fispoi/qual/sqaaqfe.shtml

APPENDIX F
GUIDELINES FOR THE USE OF ELECTRONIC RECORDS AND SIGNATURES

Electronic Records

When QMP records are created and/or stored using microprocessor technology, these electronic systems can be classified as "open" or "closed" systems. A closed system is an environment where the system access is controlled by the persons who are responsible for the content of the electronic records on the system. An open system is an environment in which the system access is not controlled by the persons who are responsible for the content of the electronic record on the system. For example, a processor has purchased off-the-shelf HACCP software to record and store data, and generate reports of CCP monitoring. If the processor does not have access to the data storage files generated by the software, this system is considered closed. If the processor has access to the content of those data files generated by the software the system is considered open. The distinction between open and closed governs who is responsible for implementing controls to ensure the authenticity and integrity of electronic records. If the system is closed then the software manufacturer is responsible, otherwise the food processor is responsible.

When fish processors use electronic records in place of paper records required for QMP, they must develop and implement additional controls to demonstrate the reliability of the electronic records.

Processors should be able to demonstrate compliance with the following requirements:

1. Documentation of the computer system operation, maintenance, and modifications is part of the QMP Plan.

2. Computer systems are validated to ensure their accuracy, reliability, consistency and ability to discern invalid or altered records.

3. Computer systems are able to generate accurate and complete copies of records in a readable text format for inspection purposes.

4. Computer systems contain an adequate means to protect records for accurate and timely retrieval throughout the record retention period. This may include systems to maintain appropriate backup records.

5. Computer systems limit record access to authorised individuals.

6. Computer systems have a rigorous security protocol to ensure that only authorised individuals can use the system, electronically sign a record, access the operation or computer system, alter a record, or perform operations.

7. Management establishes and implements policy that holds individuals responsible and accountable for data recorded and/or actions taken under their electronic signatures.

Electronic Signatures

When a QMP record is made it should be signed or initialled by the responsible party. Similarly, when an electronic record is created, the computer systems will require identification of the person who created the record, this identification is called the "electronic signature".

When electronic signatures are used in association with QMP records, the following characteristics should be associated with the electronic signature:

1. The electronic signature contains a unique identifier for the signer, the date and time of signing.

2. The electronic signature is clearly linked with one (or more) electronic record(s).

3. Controls are in place to ensure that electronic signatures and their links to records cannot be removed, copied, or otherwise manipulated.

4. Each electronic signature is unique to only one individual and is not re-used or re-assigned at any time.

5. Identity of persons authorised to use electronic signatures are documented in the QMP Plan.

APPENDIX G
GUIDELINES FOR VERIFICATION AND MAINTENANCE OF THE QMP

Purpose

This document provides guidelines about the requirements set out by Element 6 of the QMP Reference Standard - Verification and Maintenance of the QMP Plan; and specific requirements set out by Element 5 of the QMP Reference Standard - the HACCP plan.

Key Criteria

The objective in developing a verification and maintenance program is to use all available information to confirm that the QMP meets the needs of the fish processor in producing a safe, wholesome and fairly traded product. The key criteria for such a program are:

1. *Written outline* - The plan must have enough detail to clearly outline the "what" and "how" actions that will be completed when assessing each Verification and Maintenance element component. The plan should also outline "who" is responsible for carrying out the plan.

2. *Appropriate timing* - Verification and Maintenance activities should be timed so that changes can be made and implemented to ensure the QMP functions correctly and remains effective during production. The frequency of each Verification and Maintenance activities should be linked to the amount of change occurring in the operation (i.e., more often for rapidly changing products vs more stable production).

3. *Records* - Records must be kept for all verification and maintenance activities to demonstrate what took place, the extent of these activities, and the results.

4. *Amendments* - the processor must keep a list of all amendments made to the QMP (i.e., amendment log).

Compliance Guidelines

There are 4 main requirements to be met:

1) Complete review of QMP prior to implementation
2) Validation - before starting a process and when changes are made to the process
3) HACCP Verification while operating (Codex HACCP Principle 6)
4) Verification/maintenance activities for the entire QMP plan with specific requirements for the HACCP plan.

1) Complete Review

When submitting a QMP Plan for System Verification, the processor must provide evidence that the QMP Plan has been reviewed to confirm that it is *complete* and all the necessary controls and documentation for all elements of the Reference Standard are in place. One way to ensure this is accomplished is by using a checklist completed in sufficient detail to demonstrate that an assessment was carried out and the plan met the criteria (an example is available in Chapter 2, Subject 1, Appendix C of this manual).

2) Validation

Before implementation of the QMP, validation of HACCP controls and CCP critical limits must be completed and submitted as part of the initial QMP submission for System Verification. There are two parts to this validation:

a) **scientific evidence** - must be collected to establish that the parameters for the critical limits for each CCP are sufficient to prevent, eliminate or reduce to an acceptable level, the food safety hazards in the final product (examples of scientific evidence include a process authority (NFPA), published research data, Health Canada regulatory standard).

b) **in-plant testing** - sufficient tests and measurements must be conducted during test trials of the process to *clearly demonstrate* that the process is able to consistently meet the chosen critical limits.

Once production has started**, revalidation of HACCP controls or CCP critical limits** is required where changes are made to raw materials, products, or processes, or in response to adverse audit findings, recurring deviations, new information on hazards or new distribution and consumer-handling practices where potential hazards may be encountered:

For each Critical Control Point on the production line, the critical limits are *based on stable conditions,* i.e., the raw materials, the equipment and all the process steps remain the same. If any of these change, control measures must be evaluated to confirm they are still effective, and critical limits must be re-validated to ensure safe food is still being produced.

Other events such as, but not limited to, the following may point to a need to re-validate QMP controls or CCP critical

limits:

- adverse findings from a CV or other external audit which found problems with the process or controls.
- deviations from critical limits which keep occurring and cannot be eliminated.
- a new hazard is identified or a new time/temperature process is published by a process authority.
- changes to distribution/marketing, e.g., extended shelf life or consumer packaging (oxygen permeable packaging).

3) Codex HACCP Principle 6 - verification during production (Reference Standard 5.1.6)

Once production is underway the processor is required to perform two ongoing verification procedures to confirm that the HACCP system is working effectively (Principle 6 - Codex HACCP model). These activities would normally be completed by someone not directly involved in the production process, such as a supervisor, manager or some other person (e.g., Quality Control) with the authority to review the production.

a) **Records Review** of the monitoring actions for CCP critical limits and corrective actions taken must be verified frequently to confirm they are occurring as described in the plan. This includes calibration records of instruments used in the measurement of Critical Control Point parameters (e.g., temperatures, pH, weight, flow rate).

The Records Review is intended to verify that:

- monitoring activities were performed at the frequency required by the HACCP plan and all results were within the Critical Limits;
- no monitoring activities were missed and all records were completed accurately and correctly;
- all deviations were followed up immediately with Corrective Actions.

HACCP plans rely on accurate measurements (e.g., temperatures, pH, weight, flow rate) to ensure the CCPs are operating within critical limits. The instruments or equipment that require calibration for accurate CCP monitoring should be described in the HACCP plan. The recommended frequency of calibration is dependant on the likelihood that the instrument will go out of calibration and, if it does, the likelihood that a Critical Limit will not be met.

b) **Independent checks** must be completed to verify that the

control measures implemented at each CCP are adequate and effective. This verification step must be done on a routine basis, at an appropriate frequency so that corrective action could be successfully initiated and final product controlled if a problem were to be discovered.

Independent Checks are observations, measurements, analytical tests, samples, etc. These are completed separately from the monitoring activities and are intended to be an additional level of control to demonstrate that the identified hazard is being controlled adequately. Observations might involve a second individual watching the monitoring activity being performed. Measurements might involve a second individual performing the monitoring activity separately from the production monitoring.

The verification plan must include a description of the independent checks, the timing of the activity, the individual performing the checks, and the corrective action to be taken if the results indicate a problem with the monitoring.

4) Specific requirements for the HACCP plan and verification/ maintenance activities for the rest of the QMP

a) Specific requirements for the HACCP plan

The purpose of a HACCP is to prevent food safety hazards from occurring and to accomplish this, the entire HACCP plan must be evaluated at least once each year to confirm that it:

- is complete;
- accurately reflects current products and processes;
- has effective controls over all significant hazards;
- has monitoring of the critical limits at frequencies sufficient to ensure that products remain in compliance; and
- has corrective action procedures that work efficiently and effectively.

For processes that do not currently have significant hazards, it is crucial that the Hazard Analysis is reviewed to confirm that there have been no changes in the product formulation or process steps that might require a re-evaluation of hazards for significance.

b) Verification/maintenance activities for the rest of the QMP

The processor must review **all** other elements of the QMP Plan, (i.e., Management Roles and Responsibilities, Product Descriptions, Process Flow Diagram, Prerequisite Programs, RAP Controls) at least once every year. This review must verify that the QMP Plan is *current*, *complete* and *accurate*, such that the written document matches what is actually occurring during production.

This review would confirm that all corrective actions and any problems or consumer complaints that occurred over the year have been analysed with written amendments or other appropriate changes made to the QMP Plan.
The processor should consider their yearly operating schedule in order to best schedule the annual review of the QMP Plan. Some review activities require the establishment to be in full production mode in order to assess (for example, swab samples for microbiological analysis), while other review activities, such as equipment or instrument calibrations may better be scheduled during shutdown periods. All elements must be reviewed in the course of each year, but they need not all be reviewed at the same time.

The types of Annual Review activities can be found in Table 1.

Table 1 - Types of Review Activities

Examples of verification and maintenance activities include, but are not limited to, the examples provided in the following table.

QMP Element	What	How (Activities)
1. Management Roles and Responsibil-ities	**Changes:** Organization New Staff	Review responsibility for QMP and decision-making process.
2. Background Product and Process Information	**Changes:** Existing products (suppliers, formula, etc.) New products. **Problems:** Corrective actions to resolve problems	- Compare and review product descriptions with processed products in plant. - Examine records

	and/or non-conformities. **Review** One or more products with attention to those with significant hazards.	- Compare diagram and/or floor plan with actual layout of the production floor.
3. Pre-Requisite Plan	**Changes:** New equipment New sanitation products New procedures New work shift New employees New requirements **Problems** Deficiencies Corrective actions Non-conformities **Review** Sub-elements such as construction, sanitation program, pest control, product accountability and notification.	- Examine records - Recall simulation - Inspect facilities and equipment - Observe procedures - Verify effectiveness of cleaning (e.g., swabs, ATP testing) - Check effectiveness of training - Check for updates (e.g., FIR, standards)
4. Regulatory Action Point (RAP) Plan	**Changes** New supplier New label Coding New standard/ requirement New employees New procedures Production volume **Problems** Deficiencies Corrective actions Non-conformities Complaints **Review** Sub-elements (e.g., minimum acceptable product quality, ingredients, packaging, labelling and coding)	- Examine records - Confirm training - Check for updates - Observe procedures - Inspect product and labels - Check calibration records for completeness

5. HACCP Plan	**Changes** New hazard New employee Critical limit change New procedure SQA changes Change in production volume **Problems** Deficiencies Corrective actions Non-conformities Complaints **Review** Hazard analysis and HACCP Plan for a selected product	- Examine records - Confirm training - Literature search, check for updates - Review data to validate critical limits - Sampling to test for specific hazards (biological, chemical and/or physical) - Observations (ensure all hazards have been considered)

CHAPTER 3, SUBJECT 5
FSEP/QMP AUDIT POLICY FOR MULTI-COMMODITY ESTABLISHMENTS

1. SCOPE

This policy outlines the procedures for integrating audits of the Food Safety Enhancement Program (FSEP) and the Quality Management Program (QMP). It is intended to be applied in establishments which are federally registered under the *Fish Inspection Regulations* and the authority of another Act or Regulation administered by the Canadian Food Inspection Agency (CFIA).

2. REFERENCES

Canada Agricultural Products Act
Dairy Products Regulations
Processed Products Regulations
Processed Egg Regulations
Fish Inspection Act
Fish Inspection Regulations
Meat Inspection Act
Meat Inspection Regulations
FSEP Verification Policy
FSEP reference manuals
Facilities Inspection Manual (Fish Inspection Program)
Manual of Procedures (Meat, Dairy, Processed Products, Processed Eggs)

3. DEFINITIONS

"HACCP": means Hazard Analysis Critical Control Point - a systematic approach to the identification and assessment of the hazards and risks associated with a food operation and to the identification of the means for their control.

"FSEP": means the Food Safety Enhancement Program - described as a CFIA approach to encourage the development, implementation and maintenance of HACCP systems in all federally registered establishments excluding federally registered fish establishments.

"QMP": means the Quality Management Program - a fish inspection and control system which includes procedures, inspections and records, for the purpose of verifying and documenting the processing of fish and the safety and

quality of fish processed in Canada for export.

"Minor non-conformity": An isolated non-conformity within the sub-element of the prerequisite program, Regulatory Action Point, a CCP of the HACCP plan or other regulatory requirements being audited.

"Major non-conformity": A non-conformity that compromises the integrity of the HACCP system or may result in a fraudulent product.

4. PREFACE

The intent of this policy is to provide the scope and procedures for conducting audits in multi-commodity establishments which are operating under the FSEP and the QMP. This policy seeks to be consistent with the existing audit criteria that are being applied to establishments operating with FSEP or QMP systems.

5. BACKGROUND

During the early 1990's, HACCP systems were developed by two federal departments: Agriculture and Agri-Food Canada developed the Food Safety Enhancement Program (FSEP) and the Department of Fisheries and Oceans developed the Quality Management Program (QMP)

The creation of the CFIA merged the departments; however the two HACCP systems remain. FSEP continues to be utilised in the recognition and auditing of HACCP systems for agricultural commodities, and the Fish Inspection Program continues to implement the QMP. This resulted in two separate system evaluations being conducted by CFIA staff in an establishment registered under the Fish Inspection Regulations with a QMP, that also had FSEP for other products such as meat, dairy or processed fruits and vegetables.

FSEP and QMP share similar requirements for prerequisite programs and HACCP plans. The requirements of the FSEP prerequisite program meet the requirements of the QMP prerequisite program. Both programs require the implementation of regulatory action points (RAP) (note that RAPs are dependent on program requirements as described in their respective manuals). Also, both programs use the 7 principles of HACCP.

The policy will serve to satisfy five purposes:

- eliminate duplication of audit activities;
- improve utilisation of CFIA resources;
- provide a uniform approach to auditing HACCP systems;
- complete recognition and the partial audit for FSEP; and
- complete the compliance verification for QMP.

6. POLICY

6.1 General

The goal of this policy is to provide procedures for auditing the FSEP and the QMP simultaneously, while maintaining the requirements for both programs. The audit policy will provide the establishment with a consistent and uniform approach toward auditing, reporting of results, and expectations of corrective actions.

This policy will be applied to the following scenarios:

a) An establishment that has been FSEP recognized and is operating under QMP.

b) An establishment that is undergoing FSEP recognition and systems verification of the QMP at the same time. *Note: the systems verification will be completed independently by the QMP Auditor if the recognition process is not progressing in a timely manner. The certificate of registration issued under the authority of the Fish Inspection Regulations will not be issued until the systems verification has been completed.*

c) An establishment which has been FSEP recognized and has now applied for registration under the Fish Inspection Regulations (QMP). In this case, the QMP Auditor will evaluate the RAPs and the fish HACCP plan(s).

d) An establishment that is registered under the Fish Inspection Regulations (QMP) and has now applied for FSEP recognition. *Note: the compliance verification will be completed independently by the QMP Auditor if the recognition process is not progressing in a timely manner.*

6.2 Record Keeping

Establishments must comply with the most stringent record-keeping requirements as outlined in FSEP and QMP (i.e., records must be kept for all monitoring activities in prerequisite programs as required by the FSEP). For RAPs within the QMP, records by exception are permitted (i.e., when a deficiency is identified, the establishment is required to record the deficiency and the corrective action taken).

7. PROCEDURES

The existing FSEP and QMP policies and procedures are to be applied during the audit. Audit criteria and documentation that are similar in nature have been combined. Requirements that are specific to each program have been added to the scope of the audit. Every effort should be made to share results between programs and to avoid duplication of tasks (i.e., plant profile completed by responsible inspector should be shared with QMP auditors).

7.1 Documentation

1. When an FSEP recognition is conducted in conjunction with a QMP Compliance Verification (CV), the following forms (see Appendices) are to be used:

   - FSEP/QMP Audit Scope Worksheet
   - Opening Meeting Checklist for FSEP/QMP Audits
   - FSEP/QMP Prerequisite Program and RAP Worksheet
   - FSEP/QMP HACCP Plan Worksheet
   - FSEP/QMP Corrective Action Request
   - FSEP/QMP Audit Exit Report
   - Exit Meeting Checklist for FSEP/QMP Audits

2. When an FSEP partial audit is conducted in conjunction with a QMP CV the following forms (see Appendices) are to be used:

   - FSEP/QMP Audit Scope Worksheet
   - Opening Meeting Checklist for FSEP/QMP Audits
   - FSEP/QMP Prerequisite Program and RAP Worksheet
   - FSEP/QMP HACCP Plan Worksheet
   - FSEP/QMP Corrective Action Request
   - FSEP/QMP Audit Exit Report
   - Exit Meeting Checklist for FSEP/QMP Audits

3. When an FSEP verification is conducted in conjunction with a QMP CV, the following forms (see Appendices) are to be used:

- FSEP/QMP Audit Scope Worksheet
- Opening Meeting Checklist for FSEP/QMP Audits
- FSEP/QMP Prerequisite Program and RAP Worksheet
- FSEP/QMP HACCP Plan Worksheet
- FSEP/QMP Corrective Action Request
- FSEP/QMP Audit Exit Report
- Exit Meeting Checklist for FSEP/QMP Audits
- RAP Worksheet of the FSEP Manual, (to be used by FSEP auditor)(not included in Appendices)

7.2 Audit Team

The auditor(s) must have the appropriate FSEP and/or QMP training and be designated under the relevant regulations. The audit team should hold a pre-audit meeting to plan the audit (e.g., scope of the audit, checklist, time frames etc.). This could be done in person, by telephone or through e-mail.

7.3 Audit Scope

The scope for each audit will be comprised of the following items to ensure that all required elements are covered as per QMP and FSEP requirements:

- Open Corrective Action Requests (CARs)
- Log book entries
- CCPs from selected HACCP plans
- Random selection of pre-requisite programs with a possibility of targeting

The audit scope will also include those FSEP and QMP tasks that are not audited on every visit but must be completed within a series of audits (i.e., Regulatory Action Points, HACCP plan review tasks, Background Product and Process information, Verification/Validation, and Record Keeping requirements).

Auditing techniques and methodology will be implemented using the existing FSEP and QMP requirements (based on ISO standards). The FSEP/QMP Audit Scope Worksheet will be utilized to record the scope of the audit as described in the policies and procedures of the *Facilities Inspection Manual* and *the FSEP Manual.*

7.4 Non conformities

For the purpose of this policy, non-conformities will be identified to the establishment as either minor or major as per the FSEP Manual. Generally, the critical non-conformity from the QMP will be equivalent to a major non-conformity, and a non-conformity from the QMP will be equivalent to a minor non-conformity from the FSEP.

To provide clarification on classifying non-conformities, fraud related non-conformities within the authority of the *Fish Inspection Regulations* will be rated as major but will not have an affect on the Partial Audit Flow Diagram outlined in the FSEP Manual. Repetitive non-conformities related to the *Fish Inspection Regulations* may result in enforcement action as described in Chapter 3, Subject 3 of the *Facilities Inspection Manual* and the FIP Compliance Management Process.

Deficiencies identified in an establishment's written program may result in a non-conformity (QMP) or an incomplete (FSEP). In either case, the establishment would be responsible for amending their written program.

Non-conformities identified in one program must be shared with the auditor from the other program due to possible implications they may have on the other program. This includes non-conformities identified during FSEP Verification when the QMP auditor may not be present.

Establishments may appeal audit results to the Regional Director within 30 days of the decision that is being appealed.

7.5 Data Entry

For the purposes of tracking in CFIA information systems (i.e., Multi-commodity Activity Program (MCAP)), FSEP/QMP joint audits will be considered as two separate and distinct audits that will be captured in MCAP Audit for both the FSEP and QMP, when available.

When a non-conformity is identified, the CAR will reference the affected program (QMP, FSEP or both programs). Those non conformities identified with QMP or both programs will be recorded in the MCAP - Fish Component as either a non-conformity or a critical non-conformity as defined by the *Facilities Inspection Manual*.

8. FREQUENCIES OF AUDITING

In multi-commodity establishments, FSEP audits will be conducted at a frequency outlined in the FSEP Manual and QMP audits will be conducted as outlined in the Facilities Inspection Manual. The FSEP/QMP Audit for Multi-Commodity Establishments Policy will be implemented when a compliance verification coincides with an FSEP partial audit.

The coordination of audits will be the responsibility of Area/Regional Operations and should consider the schedule of the plant, products being processed and the availability of CFIA personnel.

8.1 FSEP Verification

FSEP verification will be applied as per the FSEP Verification Policy. Based on trade requirements for meat, the responsible inspector is required to be present in the establishment for two to three days per week. The audit scope, as outlined in the FSEP Manual, will be delivered over the course of a month instead of a consecutive two to three day period as per the Regulatory System Partial Audit procedures.

FSEP Verification presents a new challenge for the scheduling process in that QMP Compliance Verifications have been traditionally conducted over a 2-3 day period. It will be the responsibility of the FSEP contact person to communicate to the QMP Auditor in each of the Areas as each multi-commodity registered establishment initiates FSEP Verification. Communication between the FSEP and QMP Auditors is essential.

The seven elements of the QMP must be evaluated during a two or three year planning cycle through a series of audits. The scope of these audits may vary from one task to many tasks. Due to this flexibility in delivery, CVs can easily be coordinated with FSEP Verification audits by conducting many CVs, focusing on specific sections or elements of the Reference Standard.

The QMP Auditor and the FSEP Auditor will determine the audit scope. This will allow the QMP Auditor to decide if they will participate in any of the visits that are planned for the month, based on scheduling, production of fish products, and audit tasks that need to be covered in the QMP CV.

9. FORMS/DOCUMENTS

Appendix A - FSEP/QMP Audit Scope Worksheet
Appendix B - Opening Meeting Checklist for FSEP/QMP Audits
Appendix C - FSEP/QMP HACCP Plan Worksheet
Appendix D - FSEP/QMP Prerequisite Program and RAP Worksheet
Appendix E - FSEP/QMP Corrective Action Request
Appendix F - FSEP/QMP Audit Exit Report
Appendix G - Exit Meeting Checklist for FSEP/QMP Audits

3	5	A-1
New		03/10/31

APPENDIX A

3	5	B-1
New		03/10/31

APPENDIX B

3	5	C-1
New		03/10/31

APPENDIX C

3	5	D-1
New		03/10/31

APPENDIX D

3	5	E-1
New		03/10/31

APPENDIX E

3	5	F-1
New		03/10/31

APPENDIX F

3	5	G-1
New		03/10/31

APPENDIX G

CHAPTER 3, SUBJECT 6
QMP MENTORING POLICY

1. INTRODUCTION

Mentoring was introduced to the Quality Management Program (QMP) to compliment traditional Inspector learning methods (e.g., classroom training or self-taught modules). The mentoring process establishes a supportive environment for Inspectors to attain the skills and knowledge that can only be learned through operational experience.

This document describes the policy and procedures for mentoring CFIA personnel to achieve the level of competency necessary to participate as a team member and team lead on a QMP compliance verification (CV) team. Policy and procedures for compliance verification of federally registered fish processing establishments are found in the CFIA's Facilities Inspection Manual published by the Fish, Seafood and Production Division.

2. SCOPE

This policy applies to all CFIA personnel who participate in compliance verification of federally registered fish processing establishments.[1]

3. GUIDING PRINCIPLES

3.1 In order to prepare for, and conduct compliance verifications, the CFIA trains and mentors a work force with specialised abilities. This work force includes mentors, team leads and team members who are skilled and consistent in the delivery of compliance verifications.

3.2 Operations Branch manages the mentoring process, including the identification of mentors, the delivery of mentoring according to this policy and the assessment of team members and team leads.

3.3 The role of the mentor and supervisor are distinct. The

[1] Inspectors that were mentored and assessed prior to the issuance of this policy are recognised for the status level (team member, team lead) they have achieved. Persons recognised as mentors prior to the issuance of this policy may continue to serve as mentors.

mentor coaches by sharing knowledge and experience and helping the mentee to develop their own expertise in the QMP. The mentor provides the mentee's supervisor with objective evidence for use in the supervisory assessment of the mentee's qualifications.

3.4 Programs Branch supports the mentoring process by providing mentors with coaching and training development, QMP program guidance and communication, and by assessing the consistency of mentoring and compliance verifications.

4. POLICY

4.1 For the QMP, mentoring refers to the mandatory process of coaching and assessing new inspectors prior to qualifying as a team member or team lead. The coaching is led by a mentor and the final assessment is conducted by a supervisor.

4.2 The process of mentoring pairs the mentor with an inspector who is new to compliance verifications. Mentoring is a planned, individualised approach, set out in a "mentoring plan" developed by the mentor in consultation with the supervisor and mentee. By following the mentoring plan, the mentee receives knowledge from the mentor, gains practical experience, and receives constructive feedback and support to develop the technical skills necessary to conduct a CV.

4.3 Mentors are operational personnel (i.e., inspectors, supervisors, coordinators, and others) who are selected for the role of mentor on the basis of their possession of the following attributes:

- they have achieved team member and team lead status, and demonstrate substantial knowledge and skill in conducting compliance verifications,
- they have, and demonstrate, the ability to share and communicate their expertise in a way that supports and challenges others,
- they have, and demonstrate, the ability to transfer information in a clear, non biassed and constructive manner,
- they have, and demonstrate, the ability to determine to a colleague's accomplishments and communicate with the colleague in a positive manner,
- they are recognised by their peers as possessing these qualities, and

- they are willing to mentor others.

4.4 Operations Branch has the lead role in the identification of mentors, the determination of training needs for mentees, the delivery of QMP mentoring, and the support for mentors. Individuals identified as mentors should be further developed with training on effective mentoring.

4.5 Programs Branch provides support via the Program Network and the Fish, Seafood and Production Division. The Program Network supports Area mentors and reviews the delivery of QMP including mentoring. The Fish, Seafood and Production Division provides national program support, training development and issues certificates to personnel qualified as team members, team leads, and mentors.

4.6 In relation to mentoring, it is the role of the supervisor to:

a) establish access to mentors and, when appropriate, nominate new mentors,

b) determine training requirements for new inspectors,

c) facilitate training for new inspectors, as needed, prior to mentoring,

d) initiating mentoring,

e) review individual mentoring plans,

f) facilitate the accomplishment of the mentoring plan,

g) make the final assessment of achievement for team member and team lead status,

h) hold and/or convey confidential records of mentoring,

i) communicate the names of mentors and personnel qualified as team member and team lead.

4.7 It is the role of the mentor to:

a) develop the mentoring plan, in consultation with the mentee and the supervisor

b) provide guidance to the mentee

c) make a record of the mentee's accomplishments

d) communicate the mentee's progress regularly with both the mentee and supervisor.

4.8 The mentee is responsible for active participation in the mentoring process. The mentee's primary goal is to acquire the skills and knowledge necessary to participate in and lead a CV, thereby achieving team member and then team lead status.

4.9 The mentor/mentee relationship is a partnership of peers. Both parties are responsible to conduct themselves in an open and transparent manner. The relationship should foster the transfer of knowledge and experiences by the mentor and the opportunity to exercise abilities and learn CV skills by the mentee.

4.10 The mentoring plan is a key document. Each mentee will have one or more mentoring plans. The mentoring plan clearly identifies training and/or activities to advance the mentee toward team member or team lead status. The mentoring plan activities usually begin with close interaction between the mentor and mentee and gradually move toward independent actions as the mentee acquires and develops the required skill sets and abilities.

4.11 The Area Training Officer is responsible for the maintenance of a record of mentors, team members and team leads.

5. PROCEDURES

5.1 Supervisors nominate individuals to become mentors and provide a QMP Mentor Recommendation Report (Appendix A) to the Inspection Manager. The report describes the individual's attributes which will serve him/her in the mentor role. The Inspection Manager has the responsibility for accepting or declining the mentor nomination and advising the supervisor accordingly. The names of mentors should be communicated to the Area Training Officer and Program Network Chief.

5.2 The supervisor identifies an inspector for mentoring and verifies the inspector is designated under the FIR and has the necessary prerequisite training and skills, as indicated below, prior to beginning the mentoring process.

Knowledge and Skills Requirements for the QMP Mentee

Prerequisite Knowledge and Skills

Required prior to the beginning of the mentoring process

1. The Fish Inspection Act and Regulations
2. The Quality Management Program
3. Auditing techniques and procedures
4. Compliance verification skills
5. HACCP theory and application

Required prior to the completion of the mentoring process

6. Sanitation practices and procedures
7. Pest control practices and procedures

5.3 The supervisor arranges for a mentor to be paired with a mentee and notifies both parties. A list of mentors should be available from the Area Training Officer.

5.4 The supervisor provides the mentor with a completed QMP Mentoring Entry Form (Appendix B) which contains a summary of the mentee's training and experience to be considered in the development of the individual mentoring plan. The mentor collaborates with the supervisor and the mentee to identify the individual needs to be addressed in the mentoring plan.

5.5 The mentoring plan should be developed based on the experience and knowledge of the mentee. The individual mentoring plan is directed at developing the additional skills and experience necessary to conduct a CV in accordance with the QMP policies and procedures. The mentoring plan includes a schedule of mentoring sessions, specific CV participation activities, and training if applicable. The mentoring plan should be designed such that training needs are met before CV activities which require specialised technical knowledge (e.g., sanitation training precedes CV activities for the evaluation of a sanitation program). The mentoring plan sets out activities designed to give the mentee assignments with increasing levels of responsibility. For example, the mentee may begin by observing the CV of all elements of the QMP Plan, then progress to assessing basic areas of the QMP Plan elements (e.g., pest control), and later advance to increasingly more complex elements.

The mentoring plan is designed to ensure that the mentee experiences the complete CV process (i.e., preparation, planning, conducting, closure) and evaluates each of the

seven elements of the QMP Reference Standard. The activities in the mentoring plan provide opportunities for the mentee to work with team members, team leads, and the mentor.

A template for a mentoring plan is included as Appendix C.

The mentoring plan sets out the time period for completing the mentoring plan in its entirety as well as the progressive steps defined in the plan.

5.6 The mentor will contact the mentee to schedule an initial meeting with the objective to discuss the mentoring process and the mentoring plan. At the initial meeting, the mentor will explain the mentor-mentee-supervisor relationship, the mentoring process, the mentoring plan, and the final assessment by the supervisor.

5.7 The mentor oversees the completion of the mentoring plan but the mentor is not responsible to accompany the mentee at every exercise; in many cases, it is appropriate and even beneficial for the mentee to work alongside a fully qualified team member or team lead to view another individual's technique.

5.8 The mentor schedules meetings regularly or on an as-needed basis, with the mentee and supervisor. These meetings are an opportunity to discuss the progress of the mentee and to identify issues which may be hindering the mentoring process. The supervisor and/or the mentee may also request meetings as required.

5.9 The mentor uses the QMP Mentoring Achievement Report for Team Member or Team Lead (Appendices D and E) to record the mentee's progress. (The mentor provides objective evidence and constructive remarks only.) Upon completion of the mentoring plan, the mentor will present the report with accomplishments indicated to the supervisor.

5.10 The supervisor uses the completed Mentoring Plan and QMP Mentoring Achievement Report, communication with the mentee and mentor, and other activities as required (e.g., supervisor may chose to do a field review of the mentee) to assess if the mentee has achieved Team Member or Team Lead status. The supervisor may also determine that additional mentoring and/or training is required; this decision initiates another cycle of mentoring including a succeeding mentoring plan.

5.11 The supervisor uses the Mentee Assessment Report (Appendix F) to record and communicate the achievement of Team Member or Team Lead to the mentee and the mentor. Copies should also be provided to the Area Training Officer and the Fish Program Network Chief through regular communication channels.

5.12 All records of mentoring are confidential. When the mentoring plan is accomplished, the mentor transfers all reports of mentoring to the mentee's supervisor who takes responsibility for handling the file.

5.13 The Fish Program Network Chief communicates the names of individuals achieving the status of Team Member, Team Lead, or the role of Mentor to FSPD. The Director, FSPD, will support the issuance of Certificates of Achievement for inspectors who successfully attain Team Member and/or Team Lead status and a Certificate of Appreciation for staff who are recognised to mentor others.

6. FORMS/DOCUMENTS

Appendix A - QMP Mentor Recommendation Report

Appendix B - QMP Mentoring Entry Form

Appendix C - QMP Mentoring Plan Form

Appendix D - QMP Mentoring Achievement Report for Team Member

Appendix E - QMP Mentoring Achievement Report for Team Lead

Appendix F - QMP Mentee Assessment Report

New 03/10/31

APPENDIX A
QMP MENTOR RECOMMENDATION REPORT

(To be completed by the Supervisor for approval by the Inspection Manager)

_____ ***(Name of person nominated) is nominated for the role of QMP mentor by*** _____ ***(Name of Supervisor).***	
Required Attributes for a QMP Mentor	Demonstration
The nominee has: 1. Team member and team lead status. 2. Substantial knowledge and skill in conducting compliance verifications. 3. The ability to share and communicate their expertise in a way that supports and challenges others. 4. The ability to transfer information in a clear, non-biassed and constructive manner. 5. The ability to determine a colleague's accomplishments and communicate with the colleague in a positive manner. 6. Recognition by their peers for possessing the above-noted qualities. 7. The willingness to mentor others.	
Additional Information (Operational needs may be addressed here): Supervisor: _____ Date: _____	

Inspection Manager Decision (Approved/Declined) _____

Inspection Manager_____ Date: _____

APPENDIX B
QMP MENTORING ENTRY FORM
(To be completed by the Supervisor)

Mentee Name:

Work Location (including address and phone no.):

Relevant Experience:

Training

A. The following training must be completed prior to beginning the QMP mentoring process for Team Member:

1) Knowledge of the Fish Inspection Act and Regulations:
   - ☐ A-03/A-04 The Fish Inspection Act and Regulations
   - ☐ Or equivalent (please specify):_____
2) Knowledge of auditing techniques and procedures:
   - ☐ A-01 Introduction to Auditing
   - ☐ D-15 Compliance Verification Audit Skills
   - ☐ Or equivalent (please specify):_____
3) HACCP Theory and Procedures:
   - ☐ D-09 Introduction to HACCP
   - ☐ Or equivalent (please specify):_____
4) QMP Training:
   - ☐ D-23 Introduction to QMP Regulatory Verification
   - ☐ Or equivalent (please specify):_____

B. The following training must be completed before or during the mentoring process:

1) Knowledge of sanitation practices and procedures:
   - ☐ D-13 Sanitation
   - ☐ Or equivalent (please specify):_____
2) Knowledge of pest control practices and procedures:
   - ☐ D-14 Pest Control
   - ☐ Or equivalent (please specify): _____

The above-mentioned Inspector is designated under the Fish Inspection Regulations and is available to begin the QMP mentoring process.

_____ _____
Date Supervisor Signature

APPENDIX C
QMP MENTORING PLAN
(To be completed by the mentor in consultation with the supervisor)

This mentoring plan was created for _____ (mentee) on _____(date) with the objective of achieving team _____ (member or lead) status.

Mentor: _____ Supervisor: _____

Schedule of compliance verifications & activities (formal training, meetings, self-study)

Date	Activities	Learning objective

Signed and Dated:

_____ _____ (Mentor, originator)

_____ _____ (Supervisor, in agreement)

_____ _____ (Mentee, upon review)

APPENDIX D
QMP MENTORING ACHIEVEMENT REPORT FOR TEAM MEMBER
(To be completed by the mentor for assessment by the supervisor)

The mentee has participated in the following compliance verifications:

Date of CV	Establishment Name and Registration No.	Mentor/Team Lead	QMP Reference Standard Elements Verified

Requirements	Demonstrated
Audit Techniques 1. Gathers objective evidence and determines findings in an objective and impartial manner 2. Uses appropriate audit techniques - observation, inspection, interviewing, measurement and or review of records 3. Communicates findings, verbally and in writing, effectively to team members and auditee	
Compliance Verification 4. Understands and applies CV policy and procedures from the Facilities Inspection Manual 5. Understands differences between inspection and auditing techniques 6. Understands and applies CV scheduling and planning as per Bulletin 24 7. Ability to follow the audit process (audit preparation, review plan, develop checklist, gather evidence, determine findings and report) 8. Ability to work cooperatively with team members; ability to work on own to complete tasks; ability to participate in team discussions 9. Adequately prepared to go on-site for the CV 10. Works together with team members to complete assignments within established time frames	

11. Reviews QMP plan and previous audit results and recognises potential problems or areas to direct CV activities 12. Cross-references and links information across elements of the QMP when appropriate 13. Evaluates and verifies data when appropriate 14. Evaluates information to determine compliance to regulatory and QMP Reference Standard requirements 15. Develops and reports findings to the team 16. Understands and applies team approach, seeks out technical assistance as needed 17. Participates in the team discussion, understands what constitutes a non-conformity and shows ability to develop a non-conformity with the team under the direction of the team lead 18. Reviews and evaluates corrective action plans to determine acceptability in conjunction with the team 19. Participates in the CV closure process	
Reporting 20. Completes all compliance verification documentation	
Additional Information:	

cc: Mentee
Mentee's supervisor
Area Training Officer
Area Fish Program Network Chief

APPENDIX E
QMP MENTORING ACHIEVEMENT REPORT FOR TEAM LEAD
(To be completed by the mentor for assessment by the supervisor)

The mentee has participated in the following compliance verifications:

Date of CV	Establishment Name and Registration No.	Mentor/Team Lead	QMP Reference Standard Elements Verified

Requirements	Demonstrated
Compliance verification management 1. Effectively and efficiently manages the CV by - organising and scheduling within time criteria - leading entry and exit meetings - overseeing on-site CV - evaluating corrective action process - facilitating CV closure	
Team work 2. Facilitates effective team work by: - delegating CV tasks according to team members experience and expertise - distributing workload equitably - assisting and guiding team members to complete their assigned tasks	
Decision making 3. Makes decisions in accordance with relevant policy 4. Non-conformities identified are appropriate and consistent with program policy.	

Communication 5. Negotiates resolution to issues with the team and Industry, including corrective action plans 6. Provides feedback to team members on their delivery of CV process 7. Provides clear direction to the team and Industry in ambiguous or controversial areas.	
Additional Information	

cc: Mentee
Mentee's supervisor
Area Training Officer
Area Fish Program Network Chief

APPENDIX F
QMP MENTEE ASSESSMENT REPORT
(To be completed by the Supervisor)

_____ (Name of Mentee),

☐ is recommended to continue to be mentored to achieve the level of team member.

☐ has achieved the level of Compliance Verification Team Member.

☐ is recommended to continue to be mentored to achieve the level of team lead.

☐ has achieved the level of Compliance Verification Team Lead.

Supervisor Signature: _____ Date: _____

I acknowledge having read and discussed this report with my supervisor identified above.

Inspector Signature: _____ Date: _____

cc: Mentee
Mentee's supervisor
Area Training Officer
Area Fish Program Network Chief

Please note that a new version of this document has been posted on the website, at:

www.inspection.gc.ca/english/fssa/fispoi/man/fimmii/compasse.shtml

CHAPTER 5, SUBJECT 2

CONSTRUCTION AND EQUIPMENT - CANNERIES

LIST OF ITEMS

CANNING EQUIPMENT

1.1 APPLICATIONS GENERAL

FIR, SCHEDULE II, SECTION 27

Canneries and all equipment and utensils used in the operations of a cannery shall be kept in good repair and in a clean and sanitary condition.

Reason

The condition of the equipment used to prepare the product, and fill and seal the containers, is one of the most important factors in determining the success or failure of the sterilization process. If the equipment is not well maintained, cleaned and sanitized, it will contribute to the contamination of the product, or cause it to be non-sterile.

In order to be effectively sanitized, equipment must be simply designed, easily cleaned and made of non-corrosive material.

Compliance

Equipment must be designed and constructed so that it can be easily cleaned and sanitized. The functioning and contact parts must be easily dismantled or easily opened to facilitate cleaning and servicing.

All welded equipment, including tables, bins and support brackets must have continuous, smooth and uniformly welded joints. Wherever possible, junctions and corners must be coved with a minimum radius of 0.6 cm (1/4 inch) for ease of cleaning.

Drip pans must be properly designed and located to prevent contamination by drippings from bearings, gears, belt drives, overhead motors, etc. They must be accessible for inspection and easily removed for cleaning.

All equipment and services must be installed in order to provide sufficient access for inspection, maintenance, cleaning and sanitizing.

All utensils and equipment must be made of smooth, non-absorbent, non-corrosive material, kept in good repair, and maintained in a clean and sanitary condition.

CANNING EQUIPMENT

1.1 APPLICATIONS GENERAL (cont'd)

All fixed equipment must be installed either sufficiently high off the floor to facilitate cleaning and sanitizing underneath, or be otherwise installed so that water, dirt and other debris cannot get under the equipment.

Electrical connections, cabinets and control panels must be completely sealed, to allow cleaning of equipment with water or steam.

Where there is food contact or a contamination hazard exists, painted surfaces must not be used.

All equipment must be maintained in good repair and kept properly adjusted.

Verification

Inspect all of the equipment and utensils used in preparing the product, and ensure compliance requirements are met.

CANNING EQUIPMENT

1.2 BUTCHERING, GUTTING, CLEANING AND PACKING EQUIPMENT

Reason

All fish cleaning and packing must be done in an area and on surfaces easily cleaned and sanitized. If these conditions are not met the product may be contaminated.

The use of wood in processing equipment is not acceptable. Bacteria may become "seeded" in the pores of the wood, and once established, may contaminate food materials.

Compliance

Fish cleaning and packing must be done in a clean and sanitary area. All tables, pans, cleaning surfaces and equipment must be made of non-porous, non-corrodible materials (i.e. no wood or galvanized metals), which are easily cleaned and sanitized. All surface joints must be smooth and watertight.

Verification

Inspect all equipment used in butchering, gutting, cleaning and packing and determine if it meets the requirements for contact surfaces and is constructed for ease of cleaning and sanitizing.

CANNING EQUIPMENT

1.3 CONTAINER WASHERS

Reason

Extraneous material adhering to the surfaces of filled containers is a potential source of contamination to the contents should any leakage into the container occur in subsequent stages of processing, handling, storage or distribution.

Compliance

When required, sealed containers shall be washed prior to retorting to remove any organic material adhering to the containers. Sealed containers should be rinsed to remove the protein residues and any packing media prior to being washed with hot water and detergent. Washing containers with hot water without pre-rinsing may coagulate soluble proteins making them difficult to remove.

The detergents used must be approved for use in food-processing establishments. The chosen detergent and all brushes used must not react with or affect the container enamel or plate.

Verification

Examine containers to determine if surface is free from any product/oil or adhering protein.

Confirm that detergents approved for food contact are used for container washing.

Verify that neither the brushes nor the chosen detergent react with or affect the container enamel or plate.

CANNING EQUIPMENT

1.4 CODING

FIR, GENERAL, SECTION 32

1) Every can of fish that is packed in an establishment for which a registration certificate has been issued shall be embossed with code markings that:

   a) identify the establishment;
   b) indicate the day, month and year of processing; and
   c) identify the product contained therein in accordance with the table to this subsection (see TABLE in regulations).

2) A copy of the key to every code marking required by this section shall be sent to the Minister each year before the commencement of processing operations.

Reason

Products must be coded to identify the establishment and packing date to facilitate the segregation of lots because of potential problems with safety or quality and if necessary to initiate a complete and rapid recall of any lot. It is also common practice to code batch/retort load and/or shift period/sub-period.

Compliance

Appropriate equipment must be in place to legibly emboss or otherwise permanently mark all containers at the time of container closing, with a code indicating the establishment, the day, month and year of processing and, where required, the product code.

The equipment must be maintained in good condition and be clean and sanitary.

Verification

Determine that coding is clear and legible and is not affecting the hermeticity of the container.

Inspect coding equipment to verify that it is constructed and functioning properly.

CANNING EQUIPMENT

1.5 CONVEYORS

Reason

Conveyor systems used in handling containers must be designed, constructed and operated so as to preserve the container integrity.

Compliance

Conveyors should be constructed of smooth, non-porous, non-corrosive material and designed so as to minimize contact with the double seam, i.e. containers should not be rolled on the double seams. All worn and frayed belting, container retarders and cushions should be replaced with non-porous material.

Conveyor systems which handle containers must be smooth and free of abrasive sections. Staples must not be used to join belt ends together.

Belts and conveyor systems must not contribute to container integrity problems due to abrasion or impact at the transfer sections of the conveyor system.

All mechanical conveyance systems must be designed, constructed, and operated so as to ensure that retort pouches, containers and ends are not subjected to physical abuse. All such conveyances must be free from sharp corners or projections that may damage the containers or ends.

Verification

Determine that containers are not being damaged or abused by the conveyor systems. Check that staples are not used to join conveyor belts.

Confirm that conveyor systems are properly constructed.

Inspect all equipment used for handling empty containers, when it is not in operation.

Inspect for sharp bends and long drop sections where empty containers could be damaged due to the momentum of those coming down the conveyor or chute.

CANNING EQUIPMENT

1.5 CONVEYORS (cont'd)

Confirm that there are no sharp points on welds, at junction points of conveyors and guide rails. Check for obstacles to the smooth free flow of containers, such as nuts, bolts and rivets protruding into the path that the containers travel.

CANNING EQUIPMENT

1.6 DISPENSING MACHINES

Reason

The equipment which dispenses additional ingredients such as salt, oil or water into the container must be properly constructed, functioning correctly and maintained in a clean and sanitary condition; otherwise the amount dispensed will not be accurate or the product could be contaminated.

If the amount of ingredients dispensed is not as per specifications, it could have a detrimental effect on the integrity of the seal, the adequacy of the thermal process and/or the quality of the product. Improper filling (over or under fill) may result in an inadequate thermal process or may interfere with seal and vacuum formation.

Compliance

The dispensing machines must be constructed of acceptable material, kept in good repair, dispense accurately and be maintained in a clean and sanitary condition.

Verification

Inspect the dispenser for proper construction, cleanliness, sanitation, and signs of corrosion.

Review the company quality control program, the control procedures, the records and product specifications.

Check the frequency of verification of accuracy of the dispensing equipment and associated instrumentation.

CANNING EQUIPMENT

1.7 FILLING MACHINES

Reason

It is essential that container-filling operations, either mechanical or manual, function such that they meet the requirements specified in the scheduled process for the package being produced. Improper container filling (i.e. underfilling or overfilling) may adversely affect the safety and shelf life of a product. Improper filling or overfilling may result in product being deposited on the flanges where it interferes with the double-seam formation during the seaming operation. Overfilling may lead to a high proportion of containers being produced with seam defects or with inadequate vacuum due to insufficient head space.

Similarly, with retort pouches, product or moisture deposited on the sealing area could result in an inadequate seal.

Filling machines may be contaminated with spoilage bacteria when the filler is maintained for long periods at temperatures within the thermophilic growth range. This might occur during operation from contact with a heated product, or during shutdown periods from leakage of steam valves. To prevent the growth of thermophilic bacteria, fillers must be dismantled, cleaned and sanitized as frequently as practicable.

Compliance

The filling machine knives must be kept sharp and nick free.

The filling machines must be constructed so as to be easily dismantled for thorough cleaning and sanitizing.

The filling machines must function so as to fill to specifications without depositing product on container flanges.

CANNING EQUIPMENT

1.7 FILLING MACHINES (cont'd)

Verification

Check the container-filling operation to determine the adequacy of the following:

a) shielding is in place to prevent filled containers from being contaminated during transfer to the seamer;

b) the filling machines must be constructed so as to facilitate ease of dismantling for cleaning and sanitizing;

c) the filling machines are adequate to ensure filling is within specifications.

CANNING EQUIPMENT

1.8 PACKING AND PATCHING TABLES

Reason

Potentially defective containers must be detected and removed during inspection at the patching table to prevent serious problems later in the process.

Seam interference problems, such as bone, skin or product on the flange must be detected and removed to ensure that a properly formed double seam will be made when the container is closed.

Patching underweight containers can lead to excessively overweight containers unless all patched containers are re-weighed prior to being returned to the line.

The scale used for measuring container weights at the patching table must be routinely cleaned since any product adhering to the scale will affect its accuracy.

Compliance

This area on the production line must have adequate lighting and must be able to accommodate the number of people necessary to carefully check and correct or remove deficient containers.

The accuracy of the weigh scale used for measuring container weights at the patching table must be checked regularly.

Verification

Inspect patching/inspection tables to ensure that adequate lighting is available for inspection.

Determine that adequate table space is available to enable company personnel to inspect all containers.

Confirm that the weigh scales are constructed and functioning properly.

Check the weigh scales for accuracy.

CANNING EQUIPMENT

1.9 PRE-COOKERS

Reason

The pre-cooking units, cooking racks and pre-cookers must be of sanitary design that can be easily cleaned at all times. All pre-cooking surfaces and materials coming into contact with the fish must be easily cleaned and sanitized. Where tuna is processed, no copper alloys or brass can be used on any surface which comes into contact with the fish, as it will cause contamination.

It is necessary to ensure that equipment and utensils do not become a source of bacteriological or other contamination of the product, and to prevent the greening and other discoloration of the fish flesh caused by contact with copper alloys or brass.

Examples of acceptable construction materials for cooking racks, trays, or pans, are stainless steel, saltwater-resistant aluminum alloys, high-density plastics and fibreglass-reinforced plastics.

The pre-cookers should be constructed of durable, non-absorbent, sound materials which are capable of withstanding high temperatures and repeated cleaning and disinfecting. As an example, mild steel is acceptable.

Compliance

All equipment and utensils must be constructed of acceptable materials and designed so that all places requiring cleaning and sanitizing are easily accessible.

In the case of tuna processing, copper alloys or brass must not be used on any surface which comes into contact with the fish.

Verification

The conditions as stated under compliance are the minimum requirements to meet this regulation.

CANNING EQUIPMENT

1.10 SEALING EQUIPMENT

FIR, SCHEDULE I, PART II - SECTION 28

Every cannery shall be equipped with one or more:

a) sealing machines of a type approved by the Minister.

Reason - Sealing, Headspace and Vacuum

The sealing machine is one of the most important pieces of equipment in the canning process as this operation, when done correctly, closes the containers with an hermetic seal.

Removal of air prior to closing minimizes the strain on the container from the expansion of air during thermal processing, and removes oxygen which may cause product degradation or internal container corrosion.

Hermetically sealed containers protect the thermally processed contents from recontamination with microorganisms, thus container integrity is critical for the safety and shelf stability of canned foods.

Headspace is vital for vacuum control in some sealing machines, and may influence the adequacy of the thermal process. It is generally controlled at 8 mm (approx. 10/32") to 12 mm (approx. 15/32") in containers.

As the container vacuum absorbs trapped gases, initial vacuum is always higher than the finished vacuum.

In jars, it is usual to have a higher vacuum and more headspace than in metal containers. In most cases, headspace volume should be not less than 6% of the container volume at the sealing temperature.

For retort pouches, residual air in the container must be closely controlled to prevent excessive "ballooning" and possible damage to the seal. This is particularly true for pure steam processes, as the residual air content is a critical factor of the scheduled process.

CANNING EQUIPMENT

1.10 SEALING EQUIPMENT (cont'd)

Compliance - Headspace and Vacuum

The equipment must be adjusted for the removal of air from the containers. The usual procedures are:

a) preheat and/or thermal exhaust closures: This involves heating the container contents just prior to filling, after filling or a combination of both. The heat causes the product to expand, reduces entrapped, occluded and dissolved air (gases) and increases the vapour tension in the headspace, dispelling the air before closure. A vacuum forms as the contents of the container cool and contract after closure.

b) mechanical vacuum closures: The product when placed in the container is slightly warm. The container then passes into a clincher which attaches the lid loosely but not air tight. From there the container goes into a vacuum chamber which draws a vacuum and firmly seals the lid (air tight).

c) steam-vac closures (steam flow, vapour vac): At the time of closure, steam is projected into the headspace which dispels the air and after closure, the steam condenses and creates a vacuum.

d) for retort pouches, the container is placed in a vacuum chamber for a pre-set time before the seal is made. Sealers designed especially for retort pouches are used. This requires both bottom and top sealing elements, good adjustment mechanisms on the bars and adjustable pressure controls.

Once the relationship of headspace volume for a specific product is established for a given container, the headspace may be measured with a depth or headspace gauge.

Sealing machines of a proven design must be properly installed and maintained in good condition.

CANNING EQUIPMENT

1.10 SEALING EQUIPMENT (cont'd)

Compliance - Sealing

The container seam measurements and inspection procedures followed must meet, as a minimum, those recommended in the by the can manufacturer, or, where not available, from the Government of Canada Metal Can Defects Manual.

The retort pouch seal measurement and inspection procedures followed must meet, as a minimum, those recommended in the Canadian General Standards Board standard, "Use of Flexible Laminated Pouches for Thermally Processed Foods".

Verification - Sealing Machines

Examine the container closing operations and determine:

a) the manufacturer and model number of the seaming unit and the recommended maximum speed (i.e. cans per minute). Compare this speed with that used in actual operation, as speeds above the maximum recommended may cause sealing defects;

b) whether the manufacturer's instructions concerning the operation, maintenance and adjustment of the seamer are properly followed.

Verify that visual closure inspections are made after a jam in a capper, after adjustment, or after a prolonged shutdown.

Examine the maintenance log book and find the dates and details of the latest repairs and overhauls.

If there is any doubt about the adequate maintenance of the sealing machine or the suitability for the application, consult the qualified Canadian Food Inspection Agency (CFIA) technical personnel in the region.

CANNING EQUIPMENT

1.11 WEIGHING MACHINES

Reason

It is essential that container contents meet the product specifications and net weight requirements, so that the scheduled thermal process will be adequate.

If the amounts are not weighed accurately, it could have a detrimental effect on the container integrity and/or the scheduled process.

Compliance

Prior to production the establishment must provide the CFIA with the product specifications for each type of product and style of pack to be produced.

Verification

Inspect the weighing machine for cleanliness, sanitation and signs of corrosion.

Review the company quality control program. Check the control procedures, the records and the product specifications.

Check the frequency of verification of the accuracy of the weighing equipment and associated instrumentation.

Check the accuracy of the weighing equipment.

EMPTY CONTAINER-HANDLING EQUIPMENT

2.1 APPLICATIONS GENERAL

FIR, PART I - GENERAL SECTION 7

Unless otherwise permitted by the Minister, fish shall be placed in new, clean, sound containers.

FIR, SCHEDULE II, SECTION 27

Canneries and all equipment and utensils used in the operations of a cannery shall be kept in good repair and in a clean and sanitary condition.

Reason

The careful handling of empty containers and ends is very important as improper handling will damage them and certainly precipitate problems later in the canning process.

Product containers which are not sound, clean and sanitary are a source of contamination to the final product. Defective containers and/or ends frequently cause defective seals on the closed container, and thereby compromise the safety of the product.

Compliance

All mechanical conveyance systems must be designed, constructed, and operated so as to ensure that containers and ends are not subjected to physical abuse. All such conveyances must be free from sharp corners or projections that may damage the containers or ends. The equipment must be maintained in a clean and sanitary condition.

Container-cleaning equipment must perform the following operations for cleaning and handling empty containers:

a) where appropriate, invert the containers to dump out dust and foreign matter; and

b) blast the inside of the containers to loosen and remove dust and foreign matter, using air, vacuum or steam; and/or

c) mechanically or manually wash containers with approved water.

EMPTY CONTAINER-HANDLING EQUIPMENT

2.1 APPLICATIONS GENERAL (cont'd)

Verification

Observe the empty container handling in operation from beginning to end and assess the effectiveness of each and every section.

Verify that the water used in container washing actually comes from the approved water source and that container washing is done with non-recirculated running water.

Check the pressure used for air or steam cleaning, and ensure it is high enough to give adequate results.

RETORT CONTROLS AND INSTRUMENTATION

3.1 APPLICATIONS GENERAL

FIR, SCHEDULE I, PART II - Section 28

Every cannery shall be equipped with one or more:

a) sealing machines of a type approved by the Minister; and

b) retorts equipped with properly installed

i) mercury-in-glass thermometer,
ii) pressure gauge,
iii) steam spreader, and
iv) venting valves.

FIR, GENERAL, SECTION 34

Canned fish shall be sterilized by a method approved by the Minister.

RETORT CONTROLS AND INSTRUMENTATION

3.2 PRESSURE GAUGES

Reason

An accurate pressure gauge is required at the retort to determine if there is a correct temperature/pressure equilibrium in the steam in the retort. When this equilibrium exists, it indicates that venting of all air has been completed and it is a confirmation of the accuracy of the thermometer reading.

A pressure gauge is also required on the steam supply line to ensure that the minimum pressure specified by the scheduled process is achieved.

A compound vacuum and pressure gauge is often required to indicate when the retort is under pressure or vacuum. Under some conditions when cooling water is introduced, the steam is condensed quickly and a vacuum is created. It is necessary to know if a vacuum is being drawn as containers may expand and even explode if the vacuum becomes too high.

Compliance

Every retort must be equipped with an accurate pressure gauge which has a range of 0-30 psi (0-200 kPa) pressure or a compound gauge with a range of 0 to 15 in. Hg vacuum in addition to the pressure range of 0-30 psi. The dial must be 11 cm (4 1/2 inches) or more in diameter.

The retort pressure gauges must be graduated in divisions of 2 psi (0.1 kg/cm^2) or less.

The gauges must be installed with a gauge siphon or a loop (goose-neck) in a short connecting pipe, to protect the gauge. The gauges shall not be more than 4 inches (10 cm) higher than the top of the goose-neck.

A pressure gauge must be installed in the main steam-supply line to the retorts.

Pressure gauges must be tested for accuracy against a known accurate standard upon installation and at least once a year thereafter, or more frequently if necessary, to ensure their accuracy. Each pressure gauge must have a tag or other method of identification that indicates the date of the last accuracy check.

RETORT CONTROLS AND INSTRUMENTATION

3.2 PRESSURE GAUGES (cont'd)

Records must be maintained showing the dates of the pressure gauge accuracy checks, the standard used, the method used, the results of each check and any adjustments made, and the name of the person who performed the test.

Verification

Inspect all of the gauges to ensure that they are operational and meet the requirements of the Compliance section.

Determine that the gauge can be easily read by the operator and that no bleeder is installed in the pressure line from the retort to the gauge. Inspect the tag on the gauge and determine the most recent date of calibration. Ensure that the required time span, for frequency of calibration, has not been exceeded.

Review the maintenance and calibration records to determine that the gauges are in good repair and are accurate.

See Appendix A, Table A.1 for temperature/pressure table.

RETORT CONTROLS AND INSTRUMENTATION

3.3 TEMPERATURE MEASURING DEVICES

Reason

The devices used for measuring, controlling and recording the time, temperature and pressure during the scheduled process are of critical importance in ensuring that a product is rendered commercially sterile.

The thermal process must meet minimum limits for time and temperature in order to obtain commercial sterility of the product and uniformity of quality.

Mercury-in-glass thermometers and RTD's (resistance-temperature devices) are the best known types of temperature-measuring equipment (thermometer) for accuracy and dependability. It is the official instrument for indicating temperatures during retorting. An automatic temperature recording device provides charts whereby the process can be audited.

Bleeders provide a flow of steam past the thermometer bulb and the sensor for the temperature recording devices. Bleeders also remove air which enters the retort with the steam and enhances the circulation of steam in the retort.

The temperature recorder may be combined with the steam controller as a recording/controlling instrument.

Compliance

Every retort is equipped with at least one calibrated mercury-in-glass thermometer having a range of about 53 C degrees (100 F degrees), approximately 77°C to 130°C (170°F to 270°F) on a scale at least 18 cm (7 inches) in length, subdivided in 1 or 2 degree divisions. An alternative instrument having equal accuracy, precision and reliability may be used subject to approval by a thermal process specialist.

The official temperature-measuring device must be tested for accuracy and calibrated against an accurate standard when installed and at least once a year thereafter, or more frequently if necessary, to ensure the accuracy is maintained. Each thermometer must have a tag or other method of indicating the date on which it was last checked for accuracy. Records must be maintained showing the thermometer

RETORT CONTROLS AND INSTRUMENTATION

3.3 TEMPERATURE MEASURING DEVICES (cont'd)

accuracy checks, date, standard used, method used, the results of the test and any adjustments made, and the name of the person who performed the test. When a thermometer has a divided-mercury column, it is removed immediately upon discovery, repaired and standardized, or replaced.

The mercury-in-glass thermometer - not the recorder chart - is the official reference for the process temperature. Thermometers must be installed where they can be read easily and accurately by the operator.

Bulbs of all thermometers must be installed either within the retort shell or in external wells attached to the retort and not in the lid or door. External wells or pipes must be connected to the retort through at least a 19 mm (3/4 inch) diameter opening and equipped with a 1.6 mm (1/16 inch) or larger bleeder, so located as to provide a full flow of steam past the length of the thermometer bulb. The bleeders for external wells must be designed to emit steam continuously during the entire processing period.

All aspects of a retort process must utilize only one temperature scale (either Celsius or Fahrenheit). The process specifications must utilize Celsius or Fahrenheit, but not both.

Verification

Inspect the mercury-in-glass thermometer and the installation. Look for breaks in the column, improper installation, lack of a bleeder, the field of view to the operator and any other aspect which would require corrective action. Check the physical size of the thermometer as well as the range and divisions on the scale.

Verify that the thermometer has been checked against an accurate standard, calibrated, certified and tagged showing the date, standard used, and the person who performed the test.

RETORT CONTROLS AND INSTRUMENTATION

3.3 TEMPERATURE MEASURING DEVICES (cont'd)

If the mercury column is broken or the thermometer is inoperative or has not been certified, it must be removed and replaced with a certified and fully operative thermometer before any further processing occurs. Determine if the product safety has been jeopardized by the use of the faulty or uncertified thermometer.

Confirm from log books, temperature charts and operating or maintenance personnel, if the pressure gauges have been kept in good condition and that the pressures shown during the operating cycles equate to the temperatures.

See Appendix A for temperature/pressure tables.

Check the retort operator's log to ensure that entries of temperatures from the thermometer are being made and assess their reliability.

Confirm that all aspects of the processing system uses only one temperature scale (either Celsius or Fahrenheit).

RETORT CONTROLS AND INSTRUMENTATION

3.4 TEMPERATURE RECORDERS AND CONTROLLERS

Reason

Accurate temperature recorders are necessary in order to provide an adequate record of the temperatures applied during the process.

Compliance

Each retort must have a temperature-recording device.

Temperature-recording devices must be installed where they can be read easily, are free from heat and vibration, with a minimum number of bends in the thermal tube (coils are not considered to be bends) and protected against damage. The manufacturer's instructions for operation and maintenance must be followed.

If a temperature-recording steam-controlling instrument is used and the temperature recorder bulb is mounted within an external well, the well should have a 1.6 mm (1/16 inch) or larger bleeder opening, emitting steam continuously during the processing period.

The temperature recorder is adjusted so it agrees with or reads lower than the mercury-in-glass thermometer in the range of 0.5°C (1°F). The temperature recorder must never read higher than the mercury-in-glass thermometer.

Temperature recording chart graduations do not exceed 1 C degree (2 F degrees) within a range of 10°C or 20°F of the processing temperature. The working scale is not more than 12 C degrees per cm or 55 F degrees per inch within a range of 10 C degrees or 20 F degrees of the processing temperature.

The time on the recorder chart must be adjusted to agree with the actual time of day on the official wall clock at the start of each shift.

The temperature recorder chart must identify retort number, date, product, batch, and other data as necessary so the chart can be correlated with the retort record of lots processed. The date and retort and chart number shall be recorded on the chart during placement in the recorder. The retort operator's signature or initials will mark each record and after the record has been reviewed the reviewer's signature or initials shall be added to the record.

RETORT CONTROLS AND INSTRUMENTATION

3.4 TEMPERATURE RECORDERS AND CONTROLLERS (cont'd)

The recorder charts used must be those specified by the instrument manufacturer. Recorder charts are also required to have ink available at all times.

A means of preventing unauthorized changes in adjustment must be provided. A notice from management is posted at or near the recording device as a warning that only authorized persons are permitted to make adjustments, or a lock is affixed to the instrument, to provide a satisfactory means for preventing unauthorized changes.

Air-operated temperature controllers require an adequate filtering system to ensure a supply of clean, dry, and oil-free air.

All aspects of a retort process must utilize only one temperature scale (either Celsius or Fahrenheit). The process specifications and temperature-measuring devices must utilize Celsius or Fahrenheit, but not both. Errors in conversion could result in improper processing.

Verification

Inspect the temperature recorder or recorder controller and confirm that it is properly installed and maintained. Check the retort operator's log book and ensure that the temperatures from the recorder charts are within .5 C degree or 1 F degree of the mercury-in-glass thermometer and also if these temperatures have ever been higher than the mercury-in-glass thermometer readings.

Determine if there is a means of preventing unauthorized changes in adjustment of the recorder and/or controller. Search for a lock, or a notice from management posted at or near the recording device warning against unauthorized adjustment. If there is no obvious lock or notice, discuss the importance of this factor with the processor and ensure that appropriate action is taken without delay.

Confirm that the temperature scale used, i.e. Celsius or Fahrenheit, is consistent with all other aspects of the processing system.

RETORT CONTROLS AND INSTRUMENTATION

3.5 TIMERS, CLOCKS

Reason

A reliable timing mechanism is a basic requirement and a critical factor in the scheduled process.

Compliance

Each retort area must be equipped with a large, readable, timing device. It must be installed where it can be easily read by the retort operator from the retort operating positions.

Each clock must have a backup, to ensure timing continuity in the event of a power interruption. Clocks must have sweep second hands or numbers on digital timers indicating both minutes and seconds in order to avoid a potential 2 minute timing error.

A wrist-watch, recorder or any other timing device, is not considered to be satisfactory for the timing process.

If more than one timer is required in the retort area due to the area's size or configuration, the timers must be checked for accuracy and synchronized at least once every 24 hours of operation.

Verification

Observe the timing device to ensure that it can be easily read by the retort operator from the operating position, and determine if it is this timing device that is used for timing the process.

Determine the accuracy of those timing devices that have hands, and ensure that the second and minute hands coincide accurately. Confirm that, if multiple timing devices are used, they are synchronized.

RETORT EQUIPMENT

4.1 APPLICATIONS GENERAL

FIR, SCHEDULE I, PART II - SECTION 28

Every cannery shall be equipped with one or more:

a) sealing machines of a type approved by the Minister; and

b) retorts equipped with properly installed

i) mercury-in-glass thermometer,
ii) pressure gauge,
iii) steam spreader, and
iv) venting valves.

FIR, GENERAL, SECTION 34

Canned fish shall be sterilized by a method approved by the Minister.

Reason

Proper thermal processing of canned food is the most important step in the canning procedure. This section covers the equipment commonly used in processing low-acid canned fish products and the proper installation of this equipment to assist canners to properly equip their plants and safely carry out thermal-processing operations.

A temperature distribution study is carried out to determine the distribution of temperatures throughout a loaded retort, under the most demanding normal operating conditions. The retort plumbing configuration and container loading arrangement will influence how the steam flow is delivered to the containers in the retort load. The most important information obtained from this study is the location in the retort of the lowest temperature. A temperature distribution study will determine the ability of a steam supply to completely purge all air from a retort, with a specific plumbing configuration and a particular loading arrangement, and the time required for this to be accomplished. This determines the venting schedule required.

Results of temperature distribution studies must be interpreted and evaluated by a thermal process specialist.

RETORT EQUIPMENT

4.1 APPLICATIONS GENERAL (cont'd)

Temperature distribution studies must be conducted when there are changes in retort plumbing or in the arrangement of the containers in the retort or when there is an introduction of dividers. As stated above, the distribution of temperatures and the lethality delivered may be affected as a result of these changes.

Compliance

Retorts must be installed to meet the minimum requirements. One set of specifications is set forth in the Recommended Canadian Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Foods in Hermetically Sealed Containers (Canned Foods).

A construction inspection of each retort installation is conducted annually to confirm that piping and retort layout has not been altered or has been done in accordance with the minimum requirements.

Temperature distribution tests or other documentation from the thermal process specialist is available for each retort installation, each container size and loading arrangement, to confirm that the venting schedules are adequate (see section 4.9).

The scheduled process to be followed for sterilizing canned fish must be submitted to the CFIA for filing prior to any commercial production.

For all applicable retorts in the facility, the company must have available temperature distribution data to support the adequacy of the vent schedule.

Verification

Inspect the records of temperature distribution tests for each retort and determine that the last study conducted refers to the current retort configuration.

Determine the frequency of temperature distribution studies (as specified by the thermal process specialist) carried out on each retort and the thermal process specialist who evaluated the results.

RETORT EQUIPMENT

4.1 APPLICATIONS GENERAL (cont'd)

In the case of "still" retorting, when using air pressure while processing in water, the adequacy of the water circulation to provide uniform heat distribution within the retort must be established in accordance with procedures recognized by a competent thermal process specialist.

In the case of "still" retorting, when using steam with air over-pressure for processing retort pouches or semi-rigid containers, the adequacy of the circulation system to provide uniform heat distribution in the retort must be established, by a thermal process specialist, using the racking system designed for these containers.

In the case of steam retorting using agitation and continuous container movement, temperature distribution data from the manufacturer or a thermal process specialist demonstrating that adequate venting is achieved must be obtained and kept on file by the processor for reference by the CFIA.

Confirm filing of the scheduled process with the CFIA.

RETORT EQUIPMENT

4.2 BLEEDERS

Reason

In retorts which use steam alone as the heating medium, bleeders must be used to continuously remove any air entering the retort with the steam and to provide circulation of steam in the retort, particularly around temperature-sensing elements.

Bleeders allow for a full flow of steam past the thermometer and the temperature recorder/controller sensing elements to ensure accurate readings of the temperature in the retort are obtained.

Compliance

Bleeders must be installed to meet specifications set forth in the Recommended Canadian Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Foods in Hermetically Sealed Containers.

Bleeders (except those in retorts that use air over-pressure during the processing) must be kept fully open and emit steam during the entire process, including venting. All bleeders must be located so that the operator can observe that steam and air are escaping during processing. A 1.6 mm (1/16 in.) or larger opening is used to bleed wells for mercury thermometers or temperature recorder bulbs. All other bleeders must be 3 mm (1/8 in.) or larger.

In horizontal retorts, bleeders must be located along the top of the retort within approximately 0.3 m (1 ft.) of the outermost locations of containers at each end. Additional bleeders are located not more than 2.4 m (8 ft.) apart along the top.

Vertical retorts must have at least one bleeder located in that portion of the retort opposite the steam inlet.

In retorts utilizing top steam inlet and bottom venting, an adequately sized condensate bleeder is installed in the bottom of the retort to indicate and assist in the complete and continuous removal of condensation. Its discharge is located so its operations can be observed.

RETORT EQUIPMENT

4.2 BLEEDERS (cont'd)

For crateless retorts with top steam entry, there is one or more 9.5 mm (3/8 in.) or larger condensation bleeder at the lowest point at the bottom. When a false bottom is employed in a crateless retort, it must have a 3 mm (1/8 in.) or larger condensate bleeder with its opening just below the false bottom, but at a point higher than the condensation bleeder.

When bleeders are equipped with mufflers or a noise suppressor to reduce their noise level, evidence that air removal is not significantly impeded by the mufflers is kept on file. This may be in the form of temperature distribution data, a letter from the manufacturer, the designer, or a thermal process specialist.

Bleeder mufflers must be periodically checked for proper operation. If clogged or in disrepair, they must be repaired or replaced.

Verification

Verify the location of all bleeders and determine if they would be easily seen to be emitting steam from the operator's position, are operative and kept in good repair.

RETORT EQUIPMENT

4.3 COMPRESSED AIR LINES

Reason

Compressed air is used on retorts for control systems, to provide air for pressure cooling, and in retorts used for flexible or semi-rigid containers to provide over-pressure during the cooking process. Proper design of equipment, piping and valves is essential to ensure the unrestricted operation of the control systems and to prevent any air leaking into the retort during the cooking cycle, which could result in inadequate processing.

Compliance

When air pressure is used during the cooking or cooling of containers in a retort, a globe valve, ball valve or equivalent must be used on the air-supply line to prevent any air from leaking into the retort when it is not required.

The air compressor used for pressure cooling on processing systems is separate from that used to supply air for controlling the instruments, and is suitably designed to provide oil-free air at sufficient pressure and capacity for the process being used, and has an adequate filter system. An alternative to a separate compressor would be an installation with an adequate air supply which could ensure no drop in pressure to the instruments, and could also provide clean air for pressure cooling.

When air is used for over-pressure during cooking, the proper pressure is controlled by an automatic pressure control unit and a pressure recorder is provided. A check valve is provided in the air-supply line to prevent water from entering the air system.

If air is used to promote circulation in retorts it must be introduced into the steam line at a point between the bottom of the retort and the steam-control valve.

Verification

Determine if there were any changes or modifications in the air lines to the retort since the last construction and equipment inspection.

RETORT EQUIPMENT

4.3 COMPRESSED AIR LINES (cont'd)

Check, with the compressed-air system pressurized, if there is any leakage of air from the closed shut-off valves which could result in inadequate venting or underprocessing due to air entering the processing steam.

Ensure that any air used in the retorts is from an oil-free, filtered supply and that a compressor, separate from that used for the control systems, is used for retort pressurizing or air circulation.

RETORT EQUIPMENT

4.4 CRATES, BASKETS, TRAYS AND STACKING RACKS

Reason

Insufficiently perforated bottoms and sides in crates, baskets and trays, may prevent adequate temperature distribution in the retort.

Rough projections or sharp corners may damage the containers.

Compliance

All crates, baskets, trays, stacking racks and false bottoms in crateless retorts must be made from approved material and adequately perforated.

All rough projections, weld beads, sharp corners or edges, and wire ends in baskets must be ground smooth to prevent any possible damage to the containers.

For water-cook systems, the crates, baskets, and trays are equipped with a cover to secure containers below the cook water level.

When perforated sheet metal is used for the bottoms and sides, perforations shall be approximately 2.5 cm (1 in.) holes on 5.0 cm (2 in.) centres or the equivalent in size and/or arrangement.

Verification

Inspect and verify that crates, baskets and trays, gondolas and other equipment used to hold containers in retorts are made of adequately perforated strap iron, sheet metal, or other suitable material, and that there are no rough or sharp projections that could damage containers.

Ensure that there are sufficient perforations for adequate distribution of the heating and cooling medium, as per temperature distribution tests (see section 4.9).

RETORT EQUIPMENT

4.5 DIVIDERS/SEPARATORS

Reason

Insufficiently perforated dividers prevent adequate distribution of the steam throughout the retort. The steam must be distributed uniformly throughout the retort to ensure that all containers receive the required exposure to heat.

Use of plastic spacers as dividers is preferred to metal as they cause less container abrasion.

Compliance

In still retorts, unless the scheduled thermal process is designed to take into account the effect of container nesting, containers that can nest must be placed in baskets with an adequate divider between each layer to prevent nesting.

Where dividers are used, they shall have 2.5 cm (1 in.) holes on 5.0 cm (2 in.) centres or the equivalent in size and/or arrangement, to allow the adequate circulation of steam during the process.

For retort pouches, special racks must be used to restrict the maximum thickness of the pouch and to allow the free flow of the heating medium (i.e., steam, hot water) on both sides of the containers. Racks incorporating false bottoms can be used for this purpose.

The use of baffles is not permitted as they restrict venting and steam distribution, except when used to prevent splashing-in-water cooling, below the steam spreader.

Use of burlap sacks, boards, sugar sacks, towels, or other similar materials for separators is not acceptable.

See Appendix A, Table A.2 for Divider Plate Perforation specifications.

Verification

Compare the design of dividers/separators against the specifications set forth in the Recommended Canadian Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Foods in Hermetically Sealed Containers.

RETORT EQUIPMENT

4.5 DIVIDERS/SEPARATORS (cont'd)

Verify that the dividers fit the baskets adequately in order to prevent can nesting at the outer edges of the dividers.

Check and record the size and arrangement of the holes in the dividers. Confirm that they meet minimum requirements.

Determine if the configuration of the containers allows nesting. If so, check the scheduled process to see if it specifies that nesting is allowed. If not, dividers must be used. If baffles are used, determine if they are located and used properly.

For retort-pouch processing, check that the racks being used restrict the thickness of the retort pouch to no more than the thickness specified in the scheduled process.

RETORT EQUIPMENT

4.6 DRAINS

Reason

Drains are required in retorts for rapid removal of water after cooling. They may also be used to ensure the removal of all condensate during the venting and cooking cycles. In vertical retorts, when steam is admitted at the top, the drain may also be used as a vent.

A large proportion of the air in a retort is absorbed into the condensate, which is continuously removed via the drain during venting.

Compliance

All retorts must ensure continuous removal of condensate throughout the venting process. A steam trap or "cracked drain" may be used for condensate removal from the retort during cooking.

In a vertical retort with top-steam entry, the drain must be open to the atmosphere when it is used as a vent.

Where there exists the potential for a can to enter or block the drain, screens or grates must be installed over the drain to prevent such an occurrence.

The drain should be large enough to permit rapid removal of water after cooling.

If drains are used to remove condensate, the drain opening must be visible to the retort operator.

Verification

Confirm that drains meet the specifications set forth in the company's retort drawings.

Confirm that the drain is able to remove all of the cooling water from the retort quickly. A drain at least as large as the inlet water pipe is the minimum size which will ensure this requirement.

RETORT EQUIPMENT

4.7 SAFETY AND PRESSURE-RELIEF VALVES (Retorts, Pre-Cookers and other pressure vessels)

Reason

A pressure-relief valve, approved by the agency having jurisdiction, of a capacity sufficient to prevent undesired increases in pressure, must be fitted to every pressure vessel, namely retorts and pre-cookers, for the safety of all personnel.

To avoid the danger of excessive pressure, retorts and pre-cookers must be equipped with safety valves with adequate capacity. These valves should be constructed, located and installed so that they cannot be rendered inoperative. Most pressure codes require that the relieving capacity of safety valves be such as to prevent a rise of pressure in the retort of more than 10% above the maximum allowable working pressure. Their discharge must face away from the operator's working area.

Pressure-relief valves protect against undesirable increases in pressure. Such valves automatically prevent the pressure from rising too high during the manual operation of the pressure cooling cycle. For retorts, they are typically set at 4-5 psi above the processing pressure.

Compliance

Any vessel which is used under pressure must meet certain safety standards. This may be a boiler code which is covered under ASME Code for boilers, or if it is unfired, it may be covered by the ASME Unified Pressure Vessel Code.

There are many special types of cookers, sterilizers, and pressure-treatment vessels used in the food industry, and even if the jacket alone is under pressure, it must meet certain specifications.

Verification

No inspector is to start or carry out the inspection of a pressure vessel which is not properly protected with a pressure-relief safety valve in good operating condition. If the inspector has any question as to the adequacy or reliability of the safety valves, the company is to supply information from the local boiler inspection service or other

RETORT EQUIPMENT

4.7 SAFETY AND PRESSURE-RELIEF VALVES (cont'd)

competent source, to prove that the safety valves have been tested recently and that they are in working order.

Inspect and ensure safety valves are installed on all retorts, are serviced annually (or when necessary) and checked during processing to ensure that they are not encumbered in any way such as being closed and secured with a wire to prevent blow off. The frequency of these safety-valve checks will depend on the retort usage. Usually the safety valves are checked once or twice per operating season if it is a short season.

RETORT EQUIPMENT

4.8 STEAM SPREADERS

Reason

Steam spreaders which are properly designed and installed ensure that the steam is distributed to all areas in the retort for effective and uniform venting and heating.

Compliance

Effective steam spreaders must be installed in horizontal retorts, running the full length of the retort.

The perforations are along the top 90 degrees of the pipe, within 45 degrees of either side of top dead centre.

In vertical retorts, bottom-steam spreaders, if present, are in the form of a cross or straight pipe with the perforations along the top or sides of the pipes.

In crateless retorts with top-steam entry, steam enters through a circular steam spreader.

The number and size of holes in the steam spreader is such that there is a minimum of back pressure and a uniform flow of steam.

See Appendix A, Table A.3, for minimum hole requirements in steam spreaders.

Verification

Confirm that steam spreaders are installed to meet specifications set forth in the Recommended Canadian Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Foods in Hermetically Sealed Containers.

Inspect the steam spreader's installation and verify that the piping is secure and the original integrity of the piping, as documented on the retort diagram, has been maintained. Check the location, size, spacing and number of holes in the spreader and determine if the total cross-sectional area of the perforations is equal to 1.5 to 2 times the cross-sectional area of the smallest restriction in the steam-inlet pipe. Hole sizes may be measured using drill bits of known size.

RETORT EQUIPMENT

4.8 STEAM SPREADERS (cont'd)

Confirm that bottom-steam spreaders, if present in vertical retorts, are in the shape of a cross or straight pipe with the perforations along the top or side of the pipes. In crateless retorts with top-steam entry, steam should enter through a circular steam spreader.

RETORT EQUIPMENT

4.9 TEMPERATURE DISTRIBUTION TESTS

Reason

A temperature distribution test shall be conducted to establish an adequate venting schedule for each retort process. Temperature distribution tests must be carried out on each container size and configuration of loading or the venting schedule for the most difficult container size and loading configuration to vent must be determined and used as the standard.

Thermocouples should be located throughout the retort so that the processor has identified the location where the air removal from the retort system is the most difficult. Each retort system has an established venting schedule which will depend on such factors as the type and size of the retort shell, the size and configuration of the steam and vent piping, the quantity of steam supply, size and configuration of the valves, type of loading system in the retort, and the size and style of container being processed.

Having completed sufficient temperature distribution tests to establish the venting schedule for the particular retort installation, the processor must specify in the venting schedule, both a time and a temperature which will ensure that a saturated-steam environment is provided throughout the entire retort. Other factors, where deemed critical as a result of information gained from the distribution tests, must be specified in the venting schedule. Critical factors for a vent schedule can include minimum steam-supply pressure, maximum number of retorts which could be vented at one time, vent valve and supply-steam valve operation during the venting procedure, retort basket loading or partial loading of retorts.

Compliance

Temperature distribution tests must be available for review by the CFIA.

Verification

Determine from documented temperature distribution tests, that the processor has information available to verify that the venting schedule is adequate.

RETORT EQUIPMENT

4.10 VENT PIPING

Reason

Vents are large outlets, controlled by valves. They are required to ensure that all air is removed from the retort before the process timing is started.

Compliance

Every retort must be equipped with sufficient vent openings, controlled by fully opening valves such as gate or plug-cock type valves, to permit rapid discharge of air from the retort during the venting period.

Good quality, fully operational valves are required to ensure the unrestricted flow of air and steam through the vent piping during this short period.

All manifolds in vent piping must be constructed such that there is a minimum of restriction to the steam/air flow during the venting process. The piping must be properly designed and sized to ensure minimum restrictions to flow and minimum friction loss.

The vent is located in the opposite portion of the retort from which the steam is admitted. The vents and all external lines and manifolds are short and as free from bends as possible. There are no additional valves or check valves installed in the vent piping or vent manifolds as these impede proper venting.

Vents must not be connected directly to any closed drain system. There must be an atmospheric break in all vent lines which are connected to a drain.

If a vent manifold connects several vent pipes from a single retort, the cross-sectional area of the manifold pipe must be greater than the total cross-sectioned areas of all the connecting vent pipes (use as a guide Appendix A, Table A.4). The temperature distribution test is used to verify the effectiveness of the vent schedule.

RETORT EQUIPMENT

4.10 VENT PIPING (cont'd)

Verification

If a manifold header connects vents or manifolds from several retorts it must lead to the atmosphere within as short a distance as practicable and with as few bends as possible. No valves may be present. The cross-sectional area of the manifold header is at least equal to the total of the cross-sectional areas of all connecting pipes from the retorts which vent simultaneously.

Confirm that vent piping is designed to meet specifications set forth in the Recommended Canadian Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Foods in Hermetically Sealed Containers.

Refer to vent-piping schematic drawings during the construction and equipment inspection to determine if changes were made to any component of the venting system.

Inspect the vent piping from each retort to ensure that there is only one valve in the vent line. Vent valves must be shut-off valves (gate valves) and not a throttling type valve.

Record the type of valves used on the vent pipe or manifold. Determine if they are suitable valves, such as a gate or ball, which open fully to permit the rapid discharge of air from the retort during venting. Globe or similar type valves are not recommended due to the high internal friction which produces a high pressure loss.

Record vent valve size and the sizes and lengths of the vent pipe and manifold. Determine if the quantity of fittings, bends, and headers has been kept to a minimum.

Where the retort vents to the drain, verify that there are no direct connections from the retort to the drain which could allow back-siphoning from the drain into the retort. Confirm that the vent is in the opposite side of the retort from the steam spreader.

Determine how many retorts are brought up to temperature at any one time and that the available steam is sufficient when the venting of all retorts occurs simultaneously. This is especially critical when a number of retorts are running at the same time, either cooking or venting, as steam availability must be ensured.

RETORT EQUIPMENT

4.11 WATER PIPING AND CONTROLS

Reason

Some water lines are used as vents, as well as for circulating water during water cooks and for cooling containers in the retort after cooking. They must be properly designed and equipped with appropriate valves to ensure adequate venting as well as good heat transfer during cooking and cooling cycles.

The installation of back-flow prevention devices or vacuum breakers on the water-supply piping to the retort prevents the plant water supply from becoming contaminated from retort cooling water due to back-siphoning.

Dripping from the water spreader could cause underprocessing of any containers that may be located directly under the drip. Therefore the valves on the water-supply line must be maintained in good operating condition.

Both top and bottom water inlets to the retort may be desirable to provide for the most efficient cooling procedure.

Compliance

Water valves for throttling should be globe or equivalent valves with replaceable seals, which are maintained in good condition. For fully open or fully closed operations, gate or ball valves or equivalent are recommended.

If containers are to be cooled by flooding in the retort, the pressure and size of the water-supply line and inlet must be adequate to ensure rapid filling of the retort.

For spray cooling in the horizontal retorts, water enters at the top, through a full length water spreader inside the shell. The distribution of the water by the spreader must be uniform to ensure effective cooling.

A sufficient quantity of holes are made in the water spreader to provide adequate water distribution for proper cooling of the containers. It is suggested that there be at least three rows of holes in the lower 90° quadrant of the water spreader, to ensure that water is distributed uniformly. Alternately,

RETORT EQUIPMENT

4.11 WATER PIPING AND CONTROLS (cont'd)

there are at least two rows of holes facing upward to provide water splashing off the top of the retort for uniform coverage of the containers.

If the retort is to be vented through the water spreader, the total cross-sectional area of the holes is equal to, or greater than the cross-sectional area of the vent pipe. See Appendix A, Table A.5 for number and size of holes to be used when venting from the water spreader.

In horizontal "still" retorts, the water spreaders may be designed so that the header pipe extends past the location of the last retort basket. As an example, a single 6 mm (1/4 in.) diameter hole is drilled in the bottom of the header pipe, so that water will empty out of the header away from any product in the retort baskets. If a water valve is leaking, this hole will provide visual indication of this condition and if the water valve leaks during retorting the header will not fill up and the leaking water will drip away from any product being processed.

The overflow line is located near the top of the retort above the top layers of containers. Gate, or other suitable valves are used to permit unrestricted flow.

In retorts using water as the heating medium through circulation systems, the systems are installed in such a manner that:

a) the water is drawn from the bottom of the retort through a suction manifold and discharged through a spreader that extends across the top length of the retort;

b) recirculating pumps are equipped with a bleed petcock in the pump casing that is used at daily start-up to assure that the pump is free of air; and

c) the pump must be equipped with a pilot light or other signalling device to warn the operator if it is not running.

RETORT EQUIPMENT

4.11 WATER PIPING AND CONTROLS (cont'd)

Verification

During the annual construction and equipment inspection of each retort installation, record any changes that have been made to the retort (piping, valves, pumps, etc.) and if a critical change has been made to the system, a temperature distribution test must have been carried out to revalidate the vent schedule.

In retorts which vent through the water spreaders, check that the number and size of the holes in the water spreader are as specified in the compliance table. The holes may be measured using drill bits of known size.

Inspect the water spreader installation and look for secure piping and clean holes in the pipes. For water spreaders with upward facing holes, confirm that the spreader pipe extends past the last retort basket and that a 6 mm (1/4 in.) is drilled in the bottom cap for drainage.

Confirm that there is no dripping from the water spreader when the valve on the water-supply line is closed.

Follow the routing of the water-supply lines to the retorts, to determine that there are no bypasses after the water-treatment system.

RETORT EQUIPMENT

4.12 WATER RETENTION TANK FOR COOLING WATER

TO BE ISSUED AT A LATER DATE

STEAM SUPPLY AND BOILERS

5.1 APPLICATIONS GENERAL

FIR, SCHEDULE I, PART II - Section 27

An adequate supply of steam shall be maintained at a sufficient pressure for the operations of the cannery.

Reason

Steam, which is vaporized water, is the most extensively used heat-transfer medium in food plants. Steam can be generated at a central point and piped to many locations. The pressure is related to temperature in approximately the same ratio inside and outside containers when it is used for sterilization in retorts.

Dry, saturated steam is an ideal vapour, free from suspended droplets of water.

Wet steam contains unvaporized water in suspension, which may result from condensation after the steam has left the boiler. The quality of wet steam is expressed in terms of the percentage of the total weight which is vaporized. For example, 90% quality steam has 10% of the water left in it.

The scheduled thermal process is based on very strict limits for both time and temperature, in order to obtain commercial sterility.

A sufficient supply of steam is necessary to ensure complete venting of the air from the retort during the venting cycle. Inadequate steam pressure or quantity could delay the completion of the venting of the air in the retort and subsequently cause a deviation from the scheduled process.

If the steam pressure in the supply line or the quantity of the steam flow is inadequate to hold the required temperature for the required time, the scheduled process will not be achieved.

Compliance

The capacity of the steam producing equipment and the capacity of the pipes and valves supplying steam to the retort are such that the steam pressure to the retort is maintained at 90 psi (6.3 kg/cm^2, 620 kPa) or greater with the majority of the vents fully open, and the retorts being vented according to the filed process. Or where the steam

5.1 APPLICATIONS GENERAL (cont'd)

pressure to the retort is less than 90 psi, the adequacy of the steam supply is validated by the temperature distribution data and the minimum steam pressure - under specified operating conditions - is listed as a critical factor of the filed process.

Each retort must be equipped with an automatic steam controller to maintain retort temperature accurately, activated by air or electricity, and responsive to either temperature or pressure. If the controller valve is smaller than the steam-inlet pipe, an optional steam-bypass valve can be installed for use during the venting period when the steam demand is higher than the capacity of the automatic temperature control valve.

Steam lines are used to deliver adequate volumes of steam, at adequate quality and pressure, to each point of application, throughout the processing plant. Long lines must be provided with adequate condensate traps, to ensure that condensate is removed promptly in order to maintain acceptable steam quality.

Steam used directly for food processing must be free from contaminants, such as suspended alkalis or acids, that may contaminate the product. Rust or scale may clog lines or interfere with the operation of valves or instruments. Any impurity which will adversely affect the food must be kept out of the steam.

The steam supply system should:

a) be insulated to minimize the formation of condensation; and

b) have sufficient quantity of efficient steam traps to remove all the condensate properly; and

c) have adequate strainers to ensure the removal of all scale rust or other foreign materials in the lines.

STEAM SUPPLY AND BOILERS

5.1 APPLICATIONS GENERAL (cont'd)

The bypass valve at the steam control valve allows delivery of steam in case of problems with the regulating valve. In some installations, the steam bypass may be used regularly during the venting or come-up, if the steam demand is greater than that of the capacity of the control valve. This is particularly true if a small control valve is used. Since uncontrolled excessive pressure in the retort might lead to equipment damage and personal injury, the operator must never leave the retort while the bypass valve is open.

Verification

Confirm that the steam supply meets those specifications set forth in the Recommended Canadian Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Foods in Hermetically Sealed Containers.

Refer to steam-supply schematic drawings or the schematic of the system, to verify that no changes were made to any component of the steam-supply system since the last annual construction and equipment inspection. The following information should be maintained on file:

a) number of boilers and capacity (as noted on the manufacturer's nameplate, in hp) which supply steam to the retort(s) ;

b) header pipe sizes for the main steam supply;

c) size and capacity of the steam-control valve and associated bypass valves on each retort;

d) pipe size, its length to the retort and the quantity and sizes of branch lines off the main header.

Determine the maximum number of retorts that are brought up to process temperature at one time and if the available steam is sufficient when the venting of this maximum quantity of retorts occurs simultaneously.

During retort operation, watch for the following which could indicate that the steam supply may be insufficient:

STEAM SUPPLY AND BOILERS

5.1 APPLICATIONS GENERAL (cont'd)

a) excessive pressure dropping when retorts are vented;
b) inability to meet venting requirements;
c) extended come up time; and
d) temperature fluctuations.

Check on the possibility of contamination from steam condensate which accumulates on the steam line during shutdown. Check also for carry-over of boiler additives in the steam used to exhaust air from the containers. Such carry-over will leave a powdery film on the containers. A water-bath cook heated with live steam will show detinning of the containers.

The quantity of steam which a pipe will carry without an excessive drop in pressure depends on the pipe diameter, the quantity of bends, valves and other flow restrictions which are involved in the system.

POST-PROCESS HANDLING EQUIPMENT

6.1 APPLICATIONS GENERAL

FIR, PART IV - SECTION 34

Canned fish shall be sterilized by a method approved by the Minister.

FIR, SCHEDULE II, SECTION 27

Canneries and all equipment and utensils used in the operations of a cannery shall be kept in good repair and in a clean and sanitary condition.

FIR, GENERAL, SECTION 24

No person shall export or import or attempt to export or import cans of fish

a) that have not been properly sealed;
b) the tops or bottoms of which have been distorted outwards; or
c) that are otherwise defective.

Reason

The safeguarding of our food products against bacterial spoilage is dependent upon three conditions:

a) the application of heat to the product for a time and at a temperature sufficient to produce commercial sterility;
b) the sealing of the container in such a manner that microorganisms cannot re-enter and contaminate the sterilized product;
c) the proper post-process handling procedures which protect the finished closures from damage, which can cause leakage or post-process contamination.

The microbial load on the container-handling lines and resultant contamination transferred to the containers are related to the amount of moisture present. Moisture facilitates the transfer of bacteria to the container closure and also increases the ability of bacteria to move through the closure into the container.

The drying belt can be a potent inoculator. The use of the drying belt should be discouraged.

POST-PROCESS HANDLING EQUIPMENT

6.1 APPLICATIONS GENERAL (cont'd)

Procedures such as running containers at high speed into dead ends, sharp turns in line direction, excessive bumping or jamming, may cause small deformations and strains on the seams. Even a momentary break in the seal may pull bacteria into the container.

Compliance

Handling of hot and wet containers after retorting must be prevented. Only containers that are cool (less than 110 °F, 43 °C), not distended and preferably dry may be handled by employees or equipment, since the handling of hot, wet containers will aid the transfer of bacteria into the container (i.e., unloaded from baskets).

The containers must be protected from contamination while cooling. Potential sources of contamination include dust, dirt, debris, condensation, and pooled water.

The containers must not be subjected to rough handling or to shocks which would cause the containers to leak.

The conveyors and equipment must be maintained in good repair and be kept in a clean and sanitary condition. Wherever possible, equipment must be kept dry.

The area where baskets are tipped to drain off excess water must have restricted access to prevent contact of personnel and clothing, aprons, gloves, and other foreign objects with the hot and wet containers.

There must be perimeter barriers around the cooling areas which prevent the entry of unauthorized personnel.

The equipment used for post-process handling must be kept clean and sanitary.

With respect to all conveyors, container runs, junctions, diverters, turns and all micro switches, there are no sharp corners, sharp objects, abrupt reversals, collisions, very sudden stops or similar conditions that could cause damage to the containers.

The belts do not have any staples or broken sections which could cause damage to the containers.

POST-PROCESS HANDLING EQUIPMENT

6.1 APPLICATIONS GENERAL (cont'd)

Verification

Temperature abuse in storage areas must be prevented.

Determine what post-processing practices and procedures are followed to ensure that the heat-processed containers remain commercially sterile.

Inspect container-handling systems in the post-process area to ensure that systems meet requirements and prevent damage to containers.

Inspect the container cooling and drying procedure. If a drying belt is used, it must be properly maintained.

Observe the post-process handling procedures for rough or unsanitary practises. Determine the storage procedures and whether the containers are stored labelled or unlabelled (called "bright" when referring to metal containers).

Determine if there is any temperature abuse as well as the type of temperature control in the warehouse.

Check for the presence of rust on containers which could be an indication of improper temperatures and humidity levels in the warehouse.

POST-PROCESS HANDLING EQUIPMENT

6.2 COOLING AND INTERIM STORAGE

Reason

Hot and wet containers are very susceptible to contamination because the sealing compound has not yet hardened, and the container cooling will facilitate the movement of bacteria into the container, as a vacuum is drawn.

Since moisture on the double seam or container facilitates the transfer of bacteria and increases the ability of bacteria to pass through the closure into the container, the interim storage area is required to be constructed so that it can be maintained in a clean and sanitary condition free from sources of contamination. All workers in the cooling and interim storage area must be aware of the proper handling procedures for containers in this area.

Compliance

Entry to the post-process and container-cooling area must be restricted to authorized personnel only. Workers in the area must ensure that hot, wet containers are not touched by hand and that no impact damage occurs in the moving, or tipping for draining, of the crates, baskets or trays. Clean gloves, dipped in disinfecting solution, must be worn when handling the crates or baskets. Any sudden movements or sharp impacts must be avoided. The cooling area must be clean and sanitary and free from sources of contamination, such as dust, dirt, debris and condensed or pooled water which could contact the cooling containers.

The area where baskets are tipped, to remove excess water after exit from the retort, is designed for drainage of all water.

The interim storage area is a dry-working area and is constructed so that it can be maintained in a dry, clean and sanitary condition. Due to the nature of the operation, it is accepted that floors are level and drains are not considered mandatory providing their absence does not hinder sanitation.

Air for the forced-air cooling system is drawn from a source which is clean and free from dust and other contamination.

The use of foot baths is recommended for personnel entering the post-process area.

POST-PROCESS HANDLING EQUIPMENT

6.2 COOLING AND INTERIM STORAGE (cont'd)

The post-process and container-cooling area is separate and restricted to only those personnel authorized to be in the area. All people entering this area must be aware of the requirement that hot/wet containers are not to be handled.

Glove-dip facilities and rubber gloves must be available so that anyone handling baskets of containers which are cooling, must wear gloves which have been properly sanitized in a disinfectant solution.

Verification

Determine that any interim storage area used for post-process storage or handling of containers after retorting, meets the above compliance requirements.

POST-PROCESS HANDLING EQUIPMENT

6.3 HANDLING SYSTEMS

Reason

Proper hygienic design of container-handling equipment is a major factor in prevention of post-process contamination of canned foods. Poor hygienic design will create conditions which may encourage the growth of microorganisms on wet surfaces resulting in potential sources of contamination.

Protection of the canned food must extend to the post-cooling container-handling systems. Studies have indicated that excessive bacterial contamination may develop on wet and soiled post-cooling container-handling equipment, even though the cooling water is chlorinated and of good sanitary quality. Bacterial contamination may be transferred, in varying degrees, to the seam areas of the containers and may lead to contamination of the product.

Containers should be handled gently. If the containers are roughly handled after processing, the seams may be damaged and the container bodies dented. Dents may fracture the lacquer coating inside the container. Leaks caused by dents or by damaged seams can result in the contamination of the product. Containers are also very susceptible to loss of vacuum, due to rough handling. This loss of vacuum may also lead to contamination of the product.

Compliance

The palletizing machine, or bright stacker, must be designed so that it can be kept clean and sanitary at all times. Container runs are designed so that surfaces and runways are dry where they contact the seams of the containers.

The handling systems at all post-process stages must be designed, constructed and operated in such a manner that they can be easily cleaned. Rough handling, drops, collisions, and abrupt reversals must be prevented. All systems must be free of sharp projections, which may cause damage to containers. These systems must be inspected periodically and where rough handling is apparent, the operation or equipment must be adjusted to eliminate problems. Continuous belts are used in container-handling systems.

POST-PROCESS HANDLING EQUIPMENT

6.3 HANDLING SYSTEMS (cont'd)

Verification

Inspect all equipment used for handling filled containers to ensure that unnecessary contact between container double seams and conveying surfaces is avoided.

Inspect for sharp bends and long drop sections where containers could be damaged due to the momentum of those coming later and hitting them.

Determine that there are no sharp points on welds, at junction points on conveyors or guide rails. Check for obstacles such as nuts, bolts and rivets protruding into the path of the containers, which would prevent the smooth, free flow of containers.

APPENDIX A - TABLES

A.1 TEMPERATURE/PRESSURE TABLE

The following table shows the gauge pressure corresponding to a specified process temperature, at various altitudes:

Temp Deg. F	Sea Level	500	1000	2000	3000	4000	5000	6000	Temp Deg. C
				FEET ABOVE SEA LEVEL					
200	---	---	----	----	----	----	----	----	93.3
205	---	---	----	----	----	----	0.5	0.9	96.1
210	---	---	----	0.4	0.9	1.4	1.8	2.3	98.9
212	0.0	0.2	0.5	1.0	1.5	2.0	2.4	2.9	100.0
215	0.9	1.1	1.4	1.9	2.4	2.9	3.3	3.8	101.7
220	2.5	2.7	3.0	3.4	3.9	4.4	4.9	5.3	104.4
225	4.2	4.5	4.7	5.2	5.7	6.2	6.6	7.1	107.2
230	6.1	6.3	6.6	7.1	7.6	8.0	8.5	9.0	110.0
235	8.1	8.3	8.6	9.1	9.6	10.0	10.5	11.0	112.8
240	10.3	10.5	10.8	11.3	11.7	12.2	12.7	13.1	115.6
242	11.2	11.4	11.7	12.2	12.7	13.1	13.6	14.1	116.7
245	12.6	12.9	13.1	13.6	14.1	14.6	15.0	15.5	118.3
248	14.1	14.3	14.6	15.1	15.6	16.0	16.5	17.0	120.0
250	15.1	15.4	15.6	16.1	16.6	17.1	17.5	18.0	121.1
252	16.2	16.4	16.7	17.2	17.7	18.1	18.6	19.1	122.2
255	17.8	18.1	18.3	18.8	19.3	19.8	20.2	20.7	123.9
260	20.7	21.0	21.2	21.7	22.2	22.7	23.1	23.6	126.7
265	23.8	24.0	24.3	24.8	25.3	25.8	26.3	26.8	129.4
270	27.3	27.5	27.8	28.3	28.8	29.3	29.8	30.3	132.2
275	30.9	31.2	31.5	32.0	32.5	33.0	33.5	34.0	135.0

A.2 DIVIDER PERFORATIONS

SPECIFICATIONS FOR DIVIDER-PLATE PERFORATIONS		
Hole Size	**Distance Between Hole Centres**	**% Effective Open Area**
9mm (3/8")	20mm (3/4")	20%
13mm (1/2")	25mm (1")	20%
20mm (3/4")	38mm (1 1/2")	20%
25mm (1")	50mm (2")	20%
38mm (1 1/2")	76mm (3")	20%
45mm (1 3/4")	88mm (3 1/2")	20%
9mm (3/8")	14mm (9/16") staggered	40%
13mm (1/2")	25mm (1") staggered	23%
16mm (5/8")	21mm (13/16") staggered	54%
25mm (1")	44 mm (1 3/4") staggered	30%

A.3 HOLES IN STEAM SPREADERS

NUMBER OF HOLES FOR STEAM SPREADERS					
Size of Holes (inches)	**Number of Holes Steam Inlet Size - Standard Pipe (inches)**				
	1	**1 1/4**	**1 1/2**	**2**	**2 1/2**
3/16	47-63	82-109	111-148	183-244	261-347
7/32	35-46	60-80	82-109	134-179	192-255
1/4	27-36	46-61	63-83	103-137	147-196
5/16	17-23	30-40	40-54	66-88	94-125
3/8	12-16	21-28	28-37	46-61	66-87
7/16	-	-	21-28	33-45	48-64
1/2	-	12-16	16-21	26-35	37-49

A.4 GUIDELINE - PIPE SIZES FOR VENTING

MANIFOLD PIPE SIZE (inches)	CONNECTING PIPE SIZE (inches)										
	1/2	3/4	1	1 1/4	1 1/2	2	2 1/2	3	4	5	6
1	2										
1 1/4	[5]	[3]									
1 1/2		[4]	2								
2	6	4	2								
2 1/2	9	5	3	2							
3		8	5	3	2						
4			8	6	4	2					
5				10	6	4	2				
6					8	6	4	2			
8						10	6	4	2		
10							11	6	4	2	

Note: Numbers in [ ] exceed the area of manifold; all installations validated through a temperature distribution test.

A.5 HOLES IN WATER SPREADERS

VENTING THROUGH WATER SPREADERS

MINIMUM NUMBER OF HOLES IN WATER SPREADERS WHEN USED FOR VENTING						
Hole Size (inches)	SMALLEST RESTRICTION IN VENT OUTLET (inches)					
	1 1/4	1 1/2	2	2 1/2	3	3 1/2
3/16	55	74	122	174	268	359
7/32	40	55	90	128	197	264
1/4	31	42	69	98	151	202
5/16	20	27	44	63	97	129
3/8	14	19	31	44	67	90
1/2	--	11	18	25	38	51

CHAPTER 5, SUBJECT 3

COMPLIANCE GUIDELINES FOR MECHANICAL CAN SCREENING OPERATIONS USING DOUBLE-DUD DETECTOR AND CHECKWEIGHER

1. SCOPE

This document outlines the requirements an operator of a mechanical can screening facility must meet in order to qualify for a fish export licence (Fish Export Licence policy to be issued at a later date). These same requirements apply when a mechanical screening facility forms part of a registered establishment.

2. AUTHORITIES

Fish Inspection Act, R.S.C., 1985, c F-12; Part I
Fish Inspection Regulations (FIR), C.R.C., 1978, c. 802

3. DEFINITIONS

Biassed Sample - refers to a sample that has been selected by identifying a specific portion of the total population (see definition for Eject Cans). (*échantillon biaisé*)

Can Screening Report - means the report of the screening run containing the information found in Appendix B. (*rapport de tri*)

Checkweigher - the first machine in the screening line. The purpose of the checkweigher is to weigh all cans in a lot and to eject those cans above or below designated set-points. (*trieuse pondérale*)

Coincidental Ejects - cans that have been ejected from the double dud detector based on both top and bottom end deflections being outside the operating set-points.(*Boîtes éjectées pour double défaut*)

Commercially Sterile - the condition obtained in a food that has been processed by the application of heat, alone or in combination with other treatments, to render the food free from viable forms of microorganisms, including spores, capable of growing in the food at temperatures at which the food is designed normally to be held during distribution and storage. (*Food and Drug Regulations*) (*stérilité commerciale*)

Compliance Sampling - the compliance sampling plan for container integrity is based on a two-class attribute acceptance plan.

Inspection: sample size (n) is 200 cans and the acceptance number (c) is zero (0) serious defects.

Reinspection: sample size (n) is 1250 cans and the acceptance number (c) is zero (0) serious defects. (Reference: Government of Canada Visual Inspection Protocol) (*échantillonnage de conformité*)

Cull - means the removal of cans with serious defects from a lot of low-acid or acidified low-acid foods. (*Reference*: Government of Canada Visual Inspection Protocol) (*élimination sélective*)

Defective Cans - a unit which fails to meet one or more dimensional specifications or visual standards outlined in the Metal Can Defects Manual. (*boîte défectueuse*)

Defect Rate - means the frequency of serious defects per 100,000 cans screened. (*nombre de défauts*)

Double Dud Detector - the equipment designed to identify and eject low vacuum cans. (*détecteur bi-calibre*)

Eject Cans - means those cans with end deflections or gross weight outside of the operating set-points for either the dud detector or the checkweigher. These cans are more likely to contain defects than non-ejected cans and form a biassed sample of the total population. Eject cans are examined and may be returned to the lot if they are found after inspection to be good order cans. Any potentially defective cans must be held for confirmation and classification of the defect. (*boîtes éjectées*)

Ejection Rate - the percentage of ejected cans. (*taux d'éjection*)

End Deflection - the vertical distance from the top edges of the double seam to the lowest point on the can end. (*déformation des bouts*)

Good Order - meets the requirements of the regulations. (*bon état (en)*)

Hand Culling - means a combination of visual and tactile can-by-can examination, to identify and remove defective cans. (*tri manuel*)

Inspection - means the physical examination of a lot of low-acid or acidified low-acid foods to verify that it meets all the requirements of the *Fish Inspection Regulations* and *Food and Drug Regulations*. (*inspection*)

Inspection Lot - means a lot limited to one container type and size, one product type and style, originating from one processing establishment normally bearing one identical lot or production day code. (*Reference*: Government of Canada Visual Inspection Protocol) (*lot d'inspection*)

Laboratory - means a laboratory acceptable to the regulatory agency having jurisdiction. (*Reference*: Government of Canada Visual Inspection Protocol) (*laboratoire*)

Leakers - those cans which have lost hermetic seal (definition from Common Inspection Approach). (*fuyard*)

Mechanical Screening - means the use of a double dud detector and checkweigher or other automated equipment to draw a biassed sample in order to determine the safety of the lot. (*tri mécanique*)

Minor Defect - a minor condition is one which is clearly an abnormal container characteristic, but one which does not result in loss or potential loss of container integrity, and consequently does not represent a potential public health risk. (*Reference*: Metal Can Defects Manual) (*défaut mineur*)

Operating System - refers to documented procedures (e.g., standard operating procedures) that are developed, implemented and maintained by the operator of the mechanical screening facility to ensure that the facility is operating in compliance with the requirements of the FIR. (*système d'exploitation*)

Owner's Representative - the person duly authorised to act or speak on behalf of the owner of the lot of product. (*mandataire*)

Qualified Person - means a person competent to carry out the assigned task, normally gained through experience and/or training. (*personne qualifiée*)

Reconditioning - the removal of defective units from the suspect code. (*reconditionnement*)

Reinspection - for the purpose of this document, means the

inspection of a previously screened lot of low-acid or acidified low-acid foods for the presence of serious defects after the lot has been culled. (*réinspection*)

Screening Run - a screening run consists of one or more day codes from one production year from one establishment. Each screening run must have cans with uniform ends and bodies. (*lot soumis à l'examen*)

Serious Defect - means any container:

a) which is swollen;

b) which shows evidence that the hermetic seal is lost or seriously compromised; or

c) is unsuitable for distribution and sale as stipulated in the *Food and Drugs Act* section 4 and/or sections 27.003 and 27.005 of the *Food and Drug Regulations*.

These defects are described in the Metal Can Defects Manual. Some products may appear slightly swollen due to overfilling by design or due to gas packing. If this is verified by the inspector, these cans are not considered to be swollen. (*Reference*: Government of Canada Visual Inspection Protocol and Metal Can Defects Manual) (*défaut sérieux*)

Sort - means the segregation and control of product that has been damaged during storage or transportation. (*tri*)

Suspect Codes - means those codes that may contain unacceptable levels of defective cans. (*code suspect*)

4. ROLES AND RESPONSIBILITIES

4.1 The operator of the mechanical screening facility is responsible for the development, implementation and maintenance of a written operating system that provides a reasonable level of assurance that canned fish is assessed to verify compliance with standards for container integrity.

4.2 The operator of the mechanical screening facility is responsible for providing information to the owner or the owner's representative, for each screening run specific to the can code, the number of cans in the screening run and the number and classification of any defects identified.

4.3 The operator of the mechanical screening facility is responsible for ensuring that they contact the owner, or the owner's representative, to determine whether any swollen can suspected of not being commercially sterile should be sent to a laboratory for sterility analysis. The operator of the mechanical screening facility is responsible for informing the CFIA office of those lots containing swollen cans that are suspected of being non-sterile and holding the suspect code.

4.4 As part of a cannery's Quality Management Program (QMP) Plan, canneries may include can screening as a verification of a critical control point (CCP) in their HACCP plan, or as a CCP.

4.5 The cannery is responsible for providing the operator of the mechanical screening facility with information necessary for the operation of the checkweigher and double dud detector, such as the amount of allowable overfill (see point 7.1(5) below).

4.6 The cannery is responsible for providing product information to the buyer or the owner's representative to allow for compliance with the labelling requirements of the *Fish Inspection Regulations* and, if applicable, the *Consumer Packaging and Labelling Regulations*. This information includes, but is not limited to, the correct name of the fish species in the container, the container's net weight, and any special labelling information. The operator of the mechanical screening facility is responsible to ensure that they have this information prior to screening any products.

4.7 The cannery where the fish was processed is responsible for the identification of product distribution to its first shipping destination under its Lot Accountability and Notification Program.

4.8 The cannery where the fish was processed is responsible for the procedures to notify the CFIA of any valid health and safety complaints under its Lot Accountability and Notification Program.

5. MECHANICAL SCREENING FACILITY AND EQUIPMENT

5.1 Mechanical screening facilities must include in their operating system information on proper can handling procedures to prevent damage to the cans. Can-screening equipment must be constructed and operated so that can

damage is prevented (e.g., proper loading of the de-palletizer, automated boxing machines timing mechanisms, mechanical push bars, the absence of sharp edges on conveyors, design of eject collection boxes which will avoid abrasion and impact points).

5.2 The checkweigher and double dud detector must be installed and maintained according to the manufacturer's instructions, specifically:

- the checkweigher (CW) must be installed before the double dud detector (DDD) in order to remove excessively overweight cans and/or gross leakers before they reach the double dud detector;
- the DDD equipment must have separate can counters for each can end; and
- the DDD must ensure that coincidental ejects are accounted for during operation.

5.3 Suitable dry storage areas must be available for labelled and unlabelled product and a secure can storage area must be available to store defective cans.

5.4 All applicable inspection tools must be properly calibrated, i.e., weigh scales, deflection gauges, and micrometers. A description of the procedures for calibrating equipment must be included in the operating system plan.

6. EMPLOYEE QUALIFICATIONS

6.1 The operator of the mechanical screening facility will ensure that qualified persons are available to configure and operate the equipment on the screening line.

6.2 Only persons qualified to classify defective cans shall examine the ejected cans. Qualified persons shall classify the defects in accordance with the Metal Can Defects Manual.

6.3 The operator of the mechanical screening facility will ensure that qualified persons conduct an evaluation of each screening run, and complete and sign a Can Screening Report (see Appendix B).

6.4 Only qualified persons will perform the responsibilities associated with the reconditioning of any suspect codes.

7. CHECKWEIGHER (CW)

The primary purpose of the checkweigher is to weigh all of the cans in a lot and to eject those cans at or below an underweight set-point, and those cans at or above an overweight set-point. Ejected underweight cans may have leaked during the process but may still have maintained a vacuum (e.g., a pin hole that may be sealed by coagulated protein). Ejecting overweight cans will allow the DDD to sample cans with low end deflections due to low vacuum rather than excessive weight.

7.1 Checkweigher set-up

The operator of the mechanical screening facility must provide as part of their operating system a description of the set-up procedures they will follow in determining the checkweigher underweight and overweight settings, which includes the following steps:

1) *Define the screening run*
A screening run consists of one or more day codes from one production year from one establishment. Each screening run must have cans with uniform ends and bodies.

2) *Sampling to establish checkweigher settings*
The set-points are determined through the following sampling procedure.

   a) Sampling is carried out in order to establish checkweigher set-points if company weight data from in-season end-of-line monitoring is not available.

   b) Sample cans must be representative of the screening run. Therefore, they must be drawn from various locations throughout the pallets and from as many pallets in the screening run as possible.

   c) For a screening run containing five (5) day codes or less, the minimum sample size is 50 cans.

   d) For a screening run containing more than five (5) day codes, an additional 10 cans should be sampled for each additional day code, to a maximum of 100 cans.

3) *Calculation of average gross can weight*
The average gross can weight of each screening run is determined by:

a) calculating the average weight of the sampled cans; or

b) taking the average weight of the can codes as supplied from data gathered by the canner during in-season end-of-line monitoring.

4) *Determination of underweight set-points*
The underweight set-point can be determined by one of the following methods:

a) Determine the value for (t_1), which is a calculation that is equal to the declared weight minus the tolerance. The term (t_1) is used to describe a defective sample that exceeds the prescribed tolerance by one tolerance unit. The procedure for calculating (t_1) is outlined in the *Consumer Packaging and Labelling Regulations* (see Chapter 14 of the Fish Products Inspection Manual). These values are dependent on the can label weight. The set point is determined by subtracting the value for (t_1) from the average gross can weight of the sample.

OR

b) The set-point is determined by deducting 5 grams for each 100 grams of fill weight (calculated to the nearest whole gram).

OR

c) The set-point may be determined by using Quality Control data to determine the average gross weight of the can codes and subtracting three standard deviations to yield a set-point. (*Note*: The checkweigher calibration adjustment should be set at "0" and should not be changed.)

OR

d) Adjusting the set-point to obtain a minimum 0.25% ejection rate consistently throughout the screening run to ensure ejection of the "population outliers".

5) *Determination of overweight set-points*
The overweight set-point is determined by the canner as the amount of overfilling that will not result in bulging cans, when the product is heated to a temperature of 35 °C (*reference*: FIR Section 35). Examples of checkweigher overweight factors for canned salmon are included in Appendix A.

7.2 Overweight or underweight screening runs

Screening runs which had been identified as being overweight or underweight can be reconditioned using the screening line, providing the operating set-points of the checkweigher will not compromise the settings used to identify defective cans.

7.3 Checkweigher operating checks

a) Routine operating checks must be completed at least every four hours to: demonstrate that the checkweigher is operating within the specified limits; prevent a loss of control; and allow for adjustments of the checkweigher before a deviation occurs. The procedures must be described in the operating system. The operator must be able to demonstrate that their operating check achieves the desired results. An operating check requires that cans of known weight are run through the checkweigher at the normal operating line speed to verify the acceptance/rejection point of the checkweigher machine. As a minimum, a can that exceeds the checkweigher ejection set-point by 10 grams, and a can that is below the checkweigher set point must be ejected 100 % of the time. See Appendix A for an example of canned salmon operating checks.

b) If the line speed is changed more than ± 15 % of the normal operating speed, the checkweigher must be retested as in section a) above.

c) Each checkweigher must be challenge tested at least once every 40 hours of operation at normal operating line speeds. This activity provides a test of the checkweigher's calibration. For an example of the checkweigher 40-hour challenge testing see Appendix A.

8. DOUBLE DUD DETECTOR (DDD)

8.1 A properly operated double dud detector must:

- eject cans with zero vacuum, and
- select a biassed sample from the can population that is most likely to contain defects, i.e., lowest vacuum cans.

8.2 Double dud detector set-up procedures

The operator of the mechanical screening facility must provide, as part of their operating system, a description of the set-up procedures they will follow in determining the initial set-point, the minimum set-point and the upper set-point for the double dud detector.

8.3 Establishing manual dud detector setting

a) Sample cans must be representative of the screening run. Therefore, they must be drawn from various locations throughout the shipping pallets and from as many pallets in the screening run as possible.

b) Sample size should be 50 to 100 cans, depending on the number of codes in the lot. The recommended sample size is 50 cans for up to five (5) day codes, with an additional ten (10) cans for each day code above five codes.

c) Sample cans must be inspected prior to the DDD to ensure they are good order cans.

d) Initial set-point: For a 3 % ejection rate, select the second lowest end deflection reading for each end and adjust the DDD for 100 % ejection. For a 7 % ejection rate, select the third lowest end deflection reading.

e) Minimum set-point: Initial set-point minus 0.005 inches.

8.4 Establishing automatic double dud detector setting

a) Run the first 50 cans per screening run through the auto-DDD.

b) The operator is to check the cans and print out a histogram to ensure that the set-point is correctly established and all cans were good order. End deflection readings used to establish initial set-

point for the DDD should **not** be > 0.002 in. from the next value.

c) The DDD is automatically set to eject 100% of all cans with end deflections below the minimum set-point.

8.5 Double dud detector operating checks

a) Ensure that the target ejection rate is maintained at a 3% minimum total for each screening run. For example, either 1.5 % each end, or 2 % top (code) end and 1 % bottom (integral) end. Set-points may vary during the screening run to attain the target ejection rate (i.e., at 350 cans per minute, approximately five (5) cans per minute should be kicked-out for each end, i.e., 10 cans in total).

b) Equipment should not operate below the minimum set-points.

c) If the ejection rate becomes unmanageable and there is a requirement for the set-point to be lower than the established minimum, then the set-up procedure must be repeated to establish new set-points before continuing with the screening run.

d) The frequency of set-point adjustment should be kept to a minimum, i.e., once per pallet. The target ejection rate (for each end) should be evenly distributed throughout the screening run as described in point a) above.

e) Cans must all be oriented either all code-end up or all code-end down during the screening run.

f) For manual DDD only, the screening line operator shall:

1. calculate and record the ejection rate once per hour and at the end of the screening run; and
2. verify and record the operating set-point, at least once per hour, or more frequently as necessary to determine that the operating set-point does not fall below the minimum set-point. This is especially important when adjusting the setting downward.

   The following procedures should be used to verify the operating set-points.

- Measure the top and bottom end deflections of 6 good order cans.
- Measure the end deflections of 6 cans ejected for their bottom deflections and 6 cans ejected for their top deflections.
- Record, for each end, the highest end deflection of the ejects and the lowest end deflection of the corresponding good order ends as the operating range.

g) Each double dud detector must be audited (i.e., challenge tested) at least once every 40 hours of operation at normal operating line speeds following a procedure outlined in the operating system. The results of this test must show a unique distribution of the data for ejects as compared with the data for the good order cans. For an example of the DDD 40-hour audit see Appendix A.

9. HANDLING, CONTROL, AND DISPOSITION OF CANS

9.1 Handling ejected cans from the checkweigher

All cans ejected from the checkweigher (CW) must be manually weighed to identify gross underweight cans (potential leakers), as well as gross overweight cans. All cans ejected must be examined by a qualified person for any defects, with labels removed. Good order cans may be continuously returned to the line before the DDD (refer to Appendix A for information on canned salmon). All defective cans are marked for identification.

If no container defects are found, underweight cans are held for possible re-canning, or re-labelling. Gross overweight cans are destroyed.

9.2 Handling ejected cans from the double dud detector

All ejected cans shall be inspected for defects. All defective cans are marked for identification. Good order cans may be returned to the labelling line.

9.3 Defects properly classified

All ejected cans identified as being defective must be classified in accordance with the criteria identified in the Metal Can Defects Manual. Information on the screening run, (e.g., classification and number of all defective cans and the number of cans screened) shall be entered into the

Can Screening Report (see Appendix B). The deflections of defective cans must be determined and recorded for evaluation as described below in section 10.2.

9.4 Control and disposition of defects

All cans classified as containing a serious defect, minor droops, or as being overweight, must be kept in a designated, secure storage area within the establishment where the mechanical screening facilities are located.

All cans with serious defects must be destroyed. Cans with minor droops must either be re-canned or destroyed. Gross overweight cans must be destroyed.

An accurate system must be in place to control defective cans requiring destruction. The status of these defects must be recorded on the *Can Screening Report* and initialled by the appropriate personnel once the defective cans have been destroyed.

10. SCREENING RUN EVALUATION AND DECISION

To decide on the acceptability of the can screening run, the screening establishment must evaluate:

- can screening line performance;
- defects ejected by the checkweigher and double dud detector; and
- defect rate of the screening run.

10.1 Can screening line performance

The validity of the screening run results is dependent on both the checkweigher and double dud detector maintaining the target ejection rate throughout the entire screening run.

10.1.1 Provide selective sampling by ejecting a target 3 %.

Can screening operating records must demonstrate that a 3 % biassed sample of cans with low-end deflection and with low weight were ejected by the can screening line.

10.1.2 All cans in screening run passed through both machines

A review of the operating records for both the checkweigher and the double dud detector indicates that all the cans passed through both the checkweigher and double dud

detector before being labelled.

The evaluation must demonstrate that the can screening line was operating properly as described in this document. If this is not the case, the results of the can screening run are not valid and cannot be used.

10.2 Evaluation of the defective cans ejected by the can screening line

When an evaluation of the defective cans ejected by the can screening line shows that:

- a majority of the deflections of the defective cans are within the tolerance limit of the DDD 40-hour challenge test (Appendix A); or

- a considerable number of cans had the same type of defects,

there is a potential for an unacceptable number of serious defects still being present in the good order labelled production. In this case, the can screening warehouse must contact the owner or the owner's representative, who in consultation with the canner should take the appropriate actions to verify that there is no unacceptable number of serious defects present in the good order labelled production. An accurate record of the decision and any relevant information must be kept.

10.3 Evaluating the defect rate of the screening run

An evaluation of the defects by classification, canning line and by production code should be done, to determine if a particular code or type of defect was the major contribution to the defect rate.

When the serious defect rate is less than 25 per 100,000 cans, the can screening run results are acceptable and the product can be released for market.

When a screening run is found to have a serious defect rate of greater than 25 per 100,000 cans, the operator of the mechanical screening facility must contact the owner or the owner's representative, who in consultation with the canner should conduct an assessment to decide as the best way to:

a) cull the lot; or

b) conduct a compliance sample of the screening run,

using a sample size sufficient to be confident that the identified defect has been removed from the good order product.

A single serious defect identified in a small screening run (under 4,000 cans) would exceed the defect rate of 25 per 100,000. This screening run may be evaluated as acceptable if the canner has Quality Control data or data from other screening runs for the same code indicating that the code is acceptable.

11. CULLING OF SCREENING RUNS

When a decision has been made to cull the screening run, an evaluation of the screening run and the type of defects should be used for guidance as to whether the defects are linked to a specific code and the best method for culling. Based on this evaluation, the owner or the owner's representative, in consultation with the canner, may choose one of the following culling options.

11.1 Screening line

Results of the evaluation indicate that the suspect code or screening run will be successfully culled through the use of a screening line. Set-up and/or operating procedures should be followed that would ensure the particular defects are removed by the screening procedure. An evaluation of the culled lot should be performed to verify that the defective cans are removed.

11.2 Mechanical seam-scanning device

The results of the evaluation indicate that the suspect code will be successfully culled through the use of a mechanical seam-scanning device. The owner or the owner's representative may choose to utilize mechanical seam-scanning equipment to cull the suspect code, e.g., use of a Can Guard to remove cans with specific types of double seam defects.

11.3 Hand culling

The results of the evaluation indicate that hand culling will be successful in bringing a suspect code or entire screening run in compliance. Visual and tactile can-by-can examination (hand culling) must be carried out under the following conditions:

a) The hand culling crew must maintain concentration during the operation, otherwise the hand culling must be stopped.

b) Good lighting must be provided in the inspection areas to properly inspect cans and avoid eyestrain or fatigue. Section 1.7 of Chapter 5, Subject 1 of this manual sets out the light intensity levels that must be available.

c) The hand culling crew must not use gloves unless either the fingers are cut off or one glove is removed. This is to ensure that defective seams can be identified with bare fingers.

d) The evaluation indicates that either the suspect code will be successfully reconditioned without the removal of the labels, or the labels must be removed due to the location or type of defect.

Removing the label from the individual cans would not be necessary during a screening run where it can be demonstrated that the label would not interfere with the culling. However, the labels would have to be removed from each sample can during compliance sampling for can integrity assessment in accordance with the Government of Canada, *Visual Inspection Protocol*.

12. SHIPMENT MEETS REGULATORY REQUIREMENTS

12.1 Final shipment information

The operator of the mechanical screening facility must describe and implement a method to trace each shipment to the first shipping destination. The operator of the mechanical screening facility must maintain the following information for each shipment:

- the fish species;
- the quantity;
- the method of transportation including manifest, container numbers or other information sufficient to trace the location of each shipment;
- the date of shipment; and
- the date on which each shipment was mechanically screened.

12.2 Label and carton information

The operator of the mechanical screening facility must describe the procedures to be followed to ensure that label and carton information match the regulatory product information provided to them by the canner.

13. RECORDS

The following records are maintained by the operator of the mechanical screening facility. Examples of each record are included in the operating system.

a) The owner of each lot of canned product.

b) Each screening run of canned product shall have an operating log for the double dud detector detailing the operating information at that specific time (i.e., set-points, total cans screened, ejects). The printed auto DDD record will be considered a permanent operating record for the screening line.

c) Each screening run of canned product shall have an accurately completed *Can Screening Report*. This report must detail the quantities, disposition and classification of all defective cans, must be signed by the qualified person responsible for the operation of the screening line, and must be verified by a person responsible for the screening establishment operation.

d) The shipping records sufficient to identify or trace the canned product to the first destination.

e) Correct label information for each screening run.

f) The label being placed on each can matches the label information provided by the canner.

g) The outside carton information meets regulatory requirements,(i.e., proper can code shown on carton).

h) Notification to the owner or the owner's representative of any lot being screened, the can code, number of cans in the screening run and the number and classification of any defects identified.

i) Documentation of the results of routine operating checks and 40-hour challenge test completed on both the checkweigher and double dud detector.

APPENDIX A

DOUBLE DUD DETECTOR AND CHECKWEIGHER OPERATING CHECKS FOR CANNED SALMON

This appendix describes the specific set-point determination procedures and operating checks for screening canned salmon, using double dud detector and checkweigher.

1. Determination of "Underweight" Checkweigher Set-points

a) Subtract specific weight factors (t_1) from the average can weight of the sample. These weight factors are dependent on the can label weight. The term "t_1" is used to describe a defective sample that exceeds the prescribed tolerance by one tolerance unit. The procedure for calculating "t_1" is outlined in the *Consumer Packaging and Labelling Regulations* (see Chapter 14 of the Fish Products Inspection Manual).

OR

b) The set-point is determined by **deducting** 5 grams for each 100 grams of fill weight (calculated to the nearest whole gram).

OR

c) The set-point may be determined by using quality control data to determine the mean gross weight of the screening run and subtracting three standard deviations to yield a set-point. (**Note**: The checkweigher calibration adjustment should be set at "0" and should not be changed.)

OR

d) Adjusting the set-point to obtain a minimum 0.25% ejection rate consistently throughout the screening run will provide for the ejection of the "population outliers".

2. Determination of "Overweight" Checkweigher Set-points

For canned salmon, the overweight checkweigher set-point is determined by adding the following weight factors to the label weight of the can:

CAN SIZE	LABEL WEIGHT	WEIGHT FACTOR
301 x 106	106 grams	15 grams
307 x 111 307 x 111.40	170 grams 180 grams	22 grams 22 grams
307 x 115 307 x 200.25	213 grams 213 grams	25 grams 25 grams
301 x 408	418 grams	30 grams

3. Checkweigher routine operating check

Routine operating checks will be completed at a frequency included in the operating system. Cans of known weight must be run through the checkweigher at the normal operating line speed to verify the acceptance/rejection point of the checkweigher machine. Cans that deviate from the checkweigher ejection set-point by 10 grams must be ejected 100 % of the time.

First test
The checkweigher passes if a can that is 10 grams below and 10 grams above the set point is ejected.

If the cans are not ejected, then conduct a second test by running the cans through the checkweigher 5 to 10 times.

Second test
If the test results are 100 % ejection, then the checkweigher passes.

If the can does not eject 100 % of the time, then re-calibrate the checkweigher and re-test.

4. Checkweigher 40-hour challenge test

Both the underweight and overweight set-points must be tested.

a) *Underweight Set-point*: Use a minimum of five (5) cans with exact weights in increments of 2 grams. For example, if the ½-lb. underweight eject set-point is 256 grams, then test the checkweigher with cans weighing 256, 254, 252, 250, and 248 grams respectively. Repeat this test 5 times. The results of the test should agree with the chart below. Use either the pass criteria for ejection rate, or ejections per

5 challenges, depending on the number of cans used during the test.

Test weight (grams)	256	254	252	250	248
Pass criteria ejection rate	50%	75%	90%	100%	100%
Pass criteria, ejections per 5 challenges	2/5	3/5	4/5	5/5	5/5

b) *Overweight Set-point*: Use a minimum of five (5) cans with exact weights in increments of 2 grams. For example, if the ½-lb. overweight eject set-point is 276 grams, then test the checkweigher using cans weighing 276, 278, 280, 282, and 284 grams, respectively. Repeat this test 5 times. The results of the test should follow the following chart. Use either the values pass criteria for ejection rate, or ejections per 5 challenges, depending on the number of cans used during the test.

Test weight (grams)	276	278	280	282	284
Pass criteria Ejection rate	50%	75%	90%	100%	100%
Pass criteria, ejections per 5 challenges	2/5	3/5	4/5	5/5	5/5

Results of Checkweigher 40-hour challenge

First test
If test results were as specified in above tables, then the checkweigher passes.

If test results are lower than the above ejection rates, then conduct a second test.

Second test
If test results were as specified in above tables, then the checkweigher passes.

If the test results are lower than the above ejection rates, then re-calibrate the checkweigher and re-test.

5. DDD Routine operating check

Check automatic double dud detector sensor calibration using the following procedures:

- measure the end deflection of a can,
- pass the can through the auto-DDD, and
- compare the digital readouts to the actual measurements.

First Test
If the DDD readout is within 0.005 inches of the end deflection of the test can, the set-point calibration is acceptable.

If the DDD readout is not within 0.005 inches of the end deflection of the test can, then retest.

Second Test
If the DDD readout is within 0.005 inches of the end deflection of the test can, the set-point calibration is acceptable.

If the DDD readout is not within 0.005 inches of the end deflection of the test can, then adjust the DDD and retest.

6. DDD 40-hour audit

Each double dud detector machine must be tested at least once every 40 hours of operation at normal operating line speeds using the following criteria:

a) At the time of drawing the 40-hour sample, the auto-double dud detector should be in automatic mode.

b) Sample 25 top ejected cans, 25 bottom ejected cans, and 25 good order cans.

c) Measure the end deflections of the sampled cans. Ejected cans only require measurements of top *or* bottom end deflections as appropriate, while good order cans require measurement of both top *and* bottom end deflections (i.e., total of 100 measurements).

d) Plot end deflections on a graph with the end deflection measurements along the horizontal axis and the number of measurements on the vertical axis.

First Test
The DDD operation is acceptable if the a graphical plot of

the end deflections of good order and ejected cans shows that:

- the mean of good order cans is greater than the mean of the ejected cans; and
- the maximum overlap is 0.010 inch between good order cans and low deflection eject cans.
- If the results exceed the above criteria, then retest.

Second Test

If the DDD meets the above criteria for an acceptable test, then the DDD operation is acceptable.

If the DDD does not meet the above criteria, then the equipment must be adjusted and retested.

APPENDIX B
CAN SCREENING REPORT

Date	**Lot #**	**Inspection #**
Packer	**Screening Co.**	
Ctn/can size	**Lot Size**	**Label Order #**
Label	**Quantity (ctn.)**	
Destination		**Marks**

CAN CODE	QUANTITY (ctn.)	CAN CODE	QUANTITY (ctn.)
1		6	
2		7	
3		8	
4		9	
5		10	

Manual Dud Detector Settings (0.001")* **Canner's End** _____ **Manufacturer's End** _____

*** attach automated Dud Detector computer printout**

Checkweigher Settings (grams): **Underweight Setting**_____ **Overweight Setting**_____

Serious Defects					
	Total		**Total**		**Total**
Abrasion, Severe		**False Seam**		**Knocked Down Flange**	
Cut-over		**Fractured Bottom Profile**		**Metal Plate Flaw**	
Cut Down Flange		**Fractured Seam**		**Pin Hole**	
Cut Seam		**Knocked Down Curl**		**Scrap-in-die Mark**	
Double End		**Knocked Down End**		**Vee**	
Droop					
Minor Defects					
Droop, Minor		**Flipper**		**Overweight**	

Total Serious Defects: _____ **Total Minor Defects:** _____

Total Cans Screened: _____ **Total Cans Labelled:** _____

DEFECT RATE_____**/100,000 cans** **SIGNATURE:** _____

Remarks:_____

_____

CHAPTER 6, SUBJECT 2

OPERATIONS - CANNERIES

LIST OF ITEMS

5. STERILIZATION PROCESSES AND PROCEDURES

5.1 Applications General
5.2 Filed Process Posted
5.3 Process Submitted and Filed
5.4 Process According to Filing Procedures
5.5 Process Deviations
5.6 Records Accurately Completed
5.7 Records Accurately Kept on File

6. WAREHOUSING / POST-PROCESS HANDLING

6.1 Applications General
6.2 Handling Hot Containers
6.3 Records Accurately Completed
6.4 Records Accurately Kept on File
6.5 Storage and Warehousing

CANNING OPERATIONS

1.1 APPLICATIONS GENERAL

FIR, PART I, GENERAL, SECTION 7

Unless otherwise permitted by the Minister, fish shall be packed in new, clean, sound containers.

FIR, SCHEDULE II, PART I, SECTION 12

Unnecessary material or equipment shall not be stored in a working area of an establishment.

FIR, PART I, GENERAL, SECTION 24

No person shall export or import or attempt to export or import cans of fish:

a) that have not been properly sealed;
b) the tops or bottoms of which have been distorted outwards; or
c) that are otherwise defective.

FIR, SCHEDULE II, SECTION 27, CANNERIES

Canneries and all equipment and utensils used in the operations of a cannery shall be kept in good repair and in a clean and sanitary condition.

FIR, PART III, CODE MARKINGS, SECTION 32(1)

Every can of fish that is packed in an establishment for which a registration certificate has been issued shall be embossed with code markings that:

a) identify the establishment;
b) indicate the day, month and year of processing; and
c) identify the product contained therein in accordance with the table to this subsection.

New 96/02/23

CANNING OPERATIONS

1.1 APPLICATIONS GENERAL (cont'd)

Table

Product	First letters of code marking
1. Salmon Blueback	B
Chum	K
Coho	C
Pink	P
Sockeye	S
Spring	T
Steelhead	H
Mixed species of minced salmon	M
2. Lobster	L
3. Tomalley or lobster paste	LT
4. Lobster cocktail	LC

(2) A copy of the key to every code marking required by this section shall be sent to the Minister each year before the commencement of processing operations.

FIR, PART III, CODE MARKINGS, SECTION 33

Notwithstanding subsection 32(1), any hermetically sealed glass container containing fish is exempt from the embossing requirement referred to in that subsection, if such container or the label affixed thereto is otherwise permanently marked with the code marking required by that subsection.

FIR, PART IV, CANNED FISH, SECTION 34

Canned fish shall be sterilized by a method approved by the Minister.

FIR, PART IV, CANNED FISH, SECTION 35

All canned fish, except canned fish packed in flat drawn cans, shall have sufficient vacuum to ensure that can ends do not bulge when the product is heated to a temperature of 35 degrees celsius.

CANNING OPERATIONS

1.2 AREA SANITATION

Reason

Unless there is a complete washdown and sanitizing of the processing surfaces, bacteria will grow on the working surfaces. Tables shall be washed and sanitized at the end of each work shift. The containers used to transport finished material to the filling machine should be washed after each use.

Unsanitary filling machines will result in contamination of the product. The filling area and the area around the canning line must be kept in a sanitary condition at all times as part of general housekeeping.

Compliance

The filling area and filling machines are kept clean and sanitary at all times.

All processing surfaces and equipment are cleaned, washed and sanitized at the end of each work shift.

The cleaning and sanitizing program is monitored by the plant. Appropriate records are maintained.

Verification

Inspect all aspects of the housekeeping as well as cleaning and sanitizing programs followed for the filling area and services to ensure they are adequate.

CANNING OPERATIONS

1.3 CONTAINERS PROPERLY HANDLED

Reason

Filled containers are susceptible to damage from impact or abrasion which could affect the integrity of the container.

When conveyors, chutes and systems for loading retorts or crateless retorts are poorly designed, maintained or operated, they may cause damage to the containers.

Impact abuse occurs when containers abruptly change speed or direction, resulting in dents to double seams and/or container bodies.

Sealed containers with adhering organic matter should be washed to remove extraneous material prior to retorting to remove organic matter from the containers. Extraneous material should not be allowed to remain on the container, as these residues will induce corrosion and rust formation. Even after thorough drying, such residues have a tendency to absorb moisture from the air and thereby promote rusting of the container.

All sealed containers should be rinsed in cold water to remove the majority of the residue and then washed with hot water and detergent before sterilization. Hot water must not be used prior to rinsing in cold water as it will coagulate soluble proteins making them difficult to remove. Detergents, approved for use in food-processing establishments, must be used for container washing because of the possibility of leakage into a container. The detergent and brushes used must not react with or affect the container enamel or plate.

Compliance

Where necessary to remove adhered organic matter, water and detergent in appropriate quantities and at an adequate temperature are used to clean the outside of the containers after closing but before retort processing.

Conveyors are designed, operated and maintained so as to minimize the damage at impact points. Attention is paid to conveyor speeds and transfer points to ensure that no damage occurs to containers from impact, and that containers do not fall off the conveying system.

CANNING OPERATIONS

1.3 CONTAINERS PROPERLY HANDLED (cont'd)

Verification

Check container-handling systems for situations which could result in container damage.

Inspect transfer points on filled container conveyor systems for evidence of rough container handling.

Determine if there is rough handling of the filled sealed containers en route to the retort. The dropping of filled sealed containers into baskets, without some cushioning, is not acceptable. Cushion water of acceptable quality must be used.

Observe that containers are not being abused through rough handling by personnel. Observe if the company practice in filling retort baskets ensures that subsequent abrasion damage will not occur.

Confirm that containers are adequately cleaned.

CANNING OPERATIONS

1.4 CONTAINERS PROPERLY SEALED

Reason

Proper sealing of a container depends on the precise formation of a double seam. A double seam is an hermetic seal formed by mechanically interlocking and ironing together the curl of the container end and the flange on the container body. It keeps bacteria from entering the container and it prevents the contents from seeping out of the container. To be mechanically sound a complete inter-locking of the end hook and the body hook must occur around the complete perimeter of the container. To be mechanically sound the seam must have adequate tightness and any voids that exist in the mechanical seal must be filled with some form of gasket material.

Damaged containers entering the sealing machine may result in improperly formed seals which compromise the safety of the final product. Likewise, a high proportion of defective containers will result from product being deposited on the flange such that it interferes with the double-seam formation.

For retort pouches, the hermetic seal is formed by applying heat and pressure to fuse the two sides of the pouch together. Inadequate seals will result from product or moisture on the sealing area or from the incorrect application of heat or pressure to the pouch sealing bar.

Compliance

Adjustments and maintenance of the seaming equipment are routinely performed to give correct seam contours and to prevent seam problems. Variations in container materials, plate thickness and temper are checked and taken into account when setting up the seamer.

All container body flanges are free from defects as described in the Government of Canada Metal Can Defects Manual.

Container ends have the proper type, amount and placement of sealing compound on the end curl. The end curl is free from defects as described in the Government of Canada Metal Can Defects Manual.

CANNING OPERATIONS

1.4 CONTAINERS PROPERLY SEALED (cont'd)

The solder placement on the side-seam of three-piece container bodies is not thick at the lap, so as to create problems at that point when the double seam is formed.

For retort pouches, adjustment and maintenance of the sealer equipment are routinely performed to ensure that an adequate seal is obtained. Variations in retort pouch materials are checked and taken into account when setting up the pouch sealing bar.

All bones/skin or product lying on or adhering to the flange must be removed. This involves continuous monitoring since debris left on the flange could cause formation of an improper double seam upon seaming the container.

To ensure a proper seal on the retort pouches, all product and moisture must be removed from the sealing area and continuous monitoring for clean sealing area is essential.

As each tube of ends is put into the clincher or seamer, the ends are inspected by rotating the tube and inspecting for evidence of damage. All ends showing evidence of damage are removed and discarded.

Visual can seam inspections are made during production runs at periods not to exceed 30 minutes. For retort pouches all containers are inspected after sealing. Results of inspections, including defects observed and corrective actions taken are recorded and kept on file.

Qualified personnel complete a top double-seam teardown inspection of one container from every container seaming head operating in the plant. This procedure is carried out at least once every 4 hours of seamer operation, after a jam-up, or after a lengthy shut down and the results are recorded in a logbook.

For retort pouches, qualified personnel complete a burst test of one pouch for each position on the sealing bar(s) at the beginning of production, approximately every hour of production, and after interruptions in production. The results of these tests are recorded.

CANNING OPERATIONS

1.4 CONTAINERS PROPERLY SEALED (cont'd)

Plant personnel inspect container integrity and container code legibility and accuracy by following an inspection schedule, which contains details on the type of test, frequency and sample sizes.

Verification

Examine the seaming operations. Observe that routine visual examinations are being performed at least once every 30 minutes and the results are recorded.

Determine the manufacturer and model number of the seaming unit and its recommended maximum speed in containers per minute. Compare this speed with that used in actual operation, as speeds above the maximum recommended may cause sealing defects.

Determine that the processor maintains manufacturer's instructions on the operation, maintenance, and adjustment of the seamer.

Observe if container seaming, or retort pouch sealing operations are stopped when container integrity defects are found, or if seam measurements deviate from the container manufacturer's guidelines.

Check for potential sources of seam interference such as:

a) the presence of product bones, skin or fins adhering to the container flange;
b) the presence of ingredients adhering to the container flange; and/or
c) the presence of product or moisture on the sealing area of retort pouches.

Determine that teardown examinations for container double seams are performed and records are maintained.

For closures other than double seams, determine that appropriate tests are being performed and records maintained. For glass containers, determine that the appropriate tests are being performed and records maintained.

CANNING OPERATIONS

1.5 CONTAINER VACUUM (for those containers requiring a vacuum)

Reason

When overfilled containers are sealed they may have low vacuum, which causes the ends to be distended if the temperature is increased or the altitude is increased above sea level. When there is not enough vacuum to hold the ends in place, a sharp blow may cause either or both ends to bulge. Overfilling may also result in the product being trapped on the flange and in the seam which causes serious seam defects and compromises the safety of the final product. In addition the excessive fill will create an increased internal pressure on the container during heat processing, thereby creating undue strain on the closure.

An adequate vacuum holds the ends of the container in an acceptable concave position. Any position other than concave is an indication of possible spoilage.

An excessive amount of vacuum may cause panelling. This is more pronounced with double cold-rolled (2CR) tinplate at the start of the sterilization cycle. Insufficient vacuum may cause bulging of the container if the outside pressure is low, as might happen if the container were stored at high elevation.

In large flat containers, the vacuum holds the sides of the container in direct contact with the product which improves the rate of heat transfer and stabilizes the product shape.

It is essential to control both the headspace and the filling temperature to ensure sufficient vacuum in the container.

An increase in gross headspace results in a decreased vacuum for a hot-filled product and an increased vacuum for containers closed using steam injection.

Also, as the filling temperature (closing temperature) is increased, the resultant container vacuum for either of the above methods is increased assuming that the headspace is held constant.

In retort pouches, a vacuum is drawn to minimize the residual air in the retort pouch which could cause "ballooning" during the heating process with possible resultant underprocessing or seal damage.

CANNING OPERATIONS

1.5 CONTAINER VACUUM (cont'd)(for those containers requiring a vacuum)

Compliance

Vacuum-closing machine operations and steam or heat-exhaust operations are monitored by plant personnel in order to ensure proper vacuum drawing procedures provide sufficient vacuum to maintain container ends concave at 35°C (95°F).

The usual procedures for the removal of air from the containers are as follows:

Preheat and/or Thermal Exhaust Closures:

The container contents are heated just prior to filling, after filling, or a combination of both. The heat causes the product to expand, reducing entrapped, occluded, and dissolved air and gases. It also increases the vapour pressure in the headspace dispelling the air before closure. As the contents of the container cool and contract after heat processing, a vacuum forms.

Mechanical Vacuum Closure:

Warm product is placed into the containers. The container passes into a clincher, which loosely attaches the end, but does not form the double seam or make the container air tight. From the clincher it goes into a vacuum chamber in the closing machine, which draws a vacuum and completes the formation of the double seam. The container is then air tight.

Steam-Vac Closures (Steam flow, Vapour Vac):

At the time of closure, steam is injected into the headspace, dispelling the air. After closure, the steam condenses and creates a vacuum.

Retort Pouch Sealing Machine:

Retort pouches are placed in a vacuum chamber with the neck of the pouches across the sealing bar. A vacuum is drawn on the chamber for a preset time in order to remove the air from the retort pouch; heat and pressure are then applied to complete the seal.

CANNING OPERATIONS

1.5 CONTAINER VACUUM (cont'd)(for those containers requiring a vacuum)

Verification

Determine that adequate vacuums are attained and observe if checks for proper container fills are performed.

Determine the headspace (gross or net) specification for each product. Headspace is vital for vacuum control and proper processing and generally should be controlled at 8 mm (approximately 10/32 inch) to 12 mm (15/32 inch). As container vacuum absorbs trapped gasses, the initial vacuum should be higher than the desired finished vacuum.

Determine how often vacuum is checked.

For retort pouches, residual air determinations must be made for each production run to ensure that the maximum value specified in the filed process (typically 10 cm^3) is not being exceeded.

It is usual to have a higher vacuum and more headspace in jars than in containers. In most cases, headspace volume should be not less than 6% of the container volume at the sealing temperature. Once the relationship of headspace volume for a specific product is established for a given container, the headspace may be measured with a depth or headspace gauge rather than by volume.

In steam-vac closures, check on the possibility of contamination from the steam condensate, which accumulates in the steam line during shutdown. Determine what boiler water additives are used by the company and if they are acceptable.

Check for carry-over of boiler additives in the steam used to exhaust air from the containers. Boiler additives carry-over will usually be noted after retort operations. A steam-pressure cook with boiler-water additives carry-over will leave a powdery film on the containers; a water-bath cook heated with live steam will show detinning of the containers.

CANNING OPERATIONS

1.6 CODING

Reason

The code which is embossed or marked on the container ends or on the retort pouch during closure is important as a means of keeping track of production and inventory, particularly in the event of a product recall. The code embossed on the container shall identify the establishment, year and date of pack as well as species, as required.

It is also common practice to code the batch and shift period or sub-period. Should problems arise with a product, codes will be essential for identifying the source and date of production. In addition, a written procedure to facilitate the complete and rapid recall from the market of any lot of finished food products should be established by and tested by the processor.

Codes which are embossed with too great an imprint force may result in enamel damage, rust or perforation. Irregularities in the embossing may also cause variations in end deflections and produce problems where can-screening operations are employed.

Compliance

Routine visual examinations are made to check the legibility of codes as well as the imprint.

Submissions of the explanations of codes are sent annually or more often as necessary, prior to the commencement of operations, to the Canadian Food Inspection Agency (CFIA) Regional Inspection designate of the region in which the cannery is located.

All containers are legibly embossed or otherwise permanently marked, at the time of container closing, with a code indicating the product (where specified in the FIR), the identity of the establishment, the day, month, year of processing and if possible, batch number and code, retort number, and code shift period and sub-shift period.

All hermetically sealed glass containers containing fish are exempt from the embossing requirements if such container or the label affixed thereto is otherwise permanently marked with the required code markings.

CANNING OPERATIONS

1.6 CODING (cont'd)

Verification

Confirm that containers are being coded in accordance with the submissions of explanations of codes, which were provided to the CFIA prior to the plant commencing production.

Determine that each container carries an identifying code, either permanently inked or embossed on the container. The code must identify the product (where specified in the FIR), the establishment, and the processing day, month and year.

Verify that the containers are coded at the time of sealing.

Check containers to see that the code is legible and accurate.

Check that all hermetically sealed glass containers containing fish have been permanently marked with the code on the container or the label affixed thereto.

CANNING OPERATIONS

1.7 EQUIPMENT CLEANING

Reason

Unless there is a complete washdown and sanitizing of all processing surfaces, tables and containers used during processing, there will be an accumulation of fish or other ingredient residues and an increase in bacterial growth, thereby contaminating any product coming into contact with these surfaces.

If containers are left on the packing tables or in conveyor systems during clean-up, they are likely to become splattered with dirty water or debris, particularly if high-pressure hoses are used in cleaning.

Compliance

All processing surfaces and equipment are washed at each break during production to remove all accumulated protein material.

By anticipating the shutdown of the canning line at breaks and end of shift, the flow of containers to the filling machine or packing table is controlled so that none are left in the conveyor lines or the packing racks when the operation stops. Those containers left are either removed or so shielded that they will not become contaminated or obstruct the cleaning.

All processing surfaces and equipment are washed, cleaned and sanitized at the end of each work shift.

The filling machines are dismantled, cleaned and sanitized at the end of each shift and when unsanitary conditions occur.

The cleaning and sanitizing program is monitored by the plant personnel, and accurate records of the activities performed are maintained.

Verification

Verify that the requirements of this sub-item are met.

Observe the cleaning and sanitizing program at start-up and shut-down of production.

CANNING OPERATIONS

1.8 EQUIPMENT OPERATION

Reason

The operational adequacy of the filling machine(s) must be checked before the canning operation begins.

Filling machines may be a source of spoilage bacteria because the temperature of the filling area may be within the thermophilic growth range. This might occur during operation from contact with a heated product, or during shutdown periods from leakage of steam-supply valves. Fillers should be dismantled and cleaned as frequently as practicable to prevent growth of spoilage bacteria.

The filling machine is susceptible to container jam-ups which damage containers and create hazardous conditions.

The containers and product can be contaminated from various sources during their travel through the filling line.

Underfilled containers may cause the product to receive an excessive heat process thus causing a loss of product quality. Such containers also normally present a violation of the weight declarations.

An increase in the amount of oxygen in the headspace accelerates the corrosion of the container. This is a chemical reaction in which the acidity of the product combining with the available oxygen in the headspace can cause detinning or even pinholing of the container itself. If the headspace is not completely evacuated, oxidation of the product at the headspace surface can cause the product to turn brown.

Compliance

The filling machines are checked for accuracy at the beginning of each work shift and after each dismantling.

All damaged containers or retort pouches are carefully controlled and periodically removed from the process area for disposal or returned to the manufacturer. Reconditioning of damaged containers or ends is not permitted.

CANNING OPERATIONS

1.8 EQUIPMENT OPERATION (cont'd)

Precautions are taken to prevent contamination of the containers and product during the filling and cleaning operations.

Filled containers going to the closing machine must be continually monitored for adequacy of fill which includes shortweights, with insufficient product and/or packing media, as well as overfills with excessive product and/or packing media.

Automatic check-weighing machines must be kept clean and adjusted, if necessary, for accuracy at the beginning of each shift. This procedure is also conducted after any extended break in production.

If manual check-weighing is utilized the scales should be kept clean and calibrated at the beginning of each shift and also after any extended break in production. In addition, continual visual monitoring is required to spot obvious excessively overfilled containers which would create seaming problems.

The air is evacuated from the headspace before the containers are sealed.

Verification

Observe the container-filling operation and determine that the following are done satisfactorily:

- controlling container fill and headspace within specifications by evacuating trapped air from filled containers;
- dismantling, cleaning and sanitizing the equipment on the filling line;
- taking corrective action after a container jam-up; this includes inspecting the cans involved for missing metal, checking the filler for metal fragments, determining the cause of the jam-up, taking steps to prevent a recurrence, and documentation;
- avoiding splashes from being reintroduced into the following containers;
- shielding filled containers from contamination during transfer to seamer; and
- culling out underfilled and overfilled containers

The conditions under the compliance are the minimum requirements to satisfy the Regulations.

CANNING OPERATIONS

1.9 PACKING WORKMANSHIP

Reason

Container filling is the last point where visual inspection can take place and where defective material can be removed from the product. At the packing table, the condition of the container flanges must be continually monitored. Containers with damaged flanges or product over the flange must be removed as they frequently cause improper seam formation. This inspection area must have sufficient lighting and enough space for people to adequately carry out this function.

It is essential that container-filling operations, mechanical or manual, ensure that the filling requirements specified in the scheduled process for the particular type of pack being produced are met. Improper container filling, overfilling or underfilling can adversely affect the safety and shelf life of a product.

Improper filling or overfilling can result in product being deposited on the flange where it interferes with the double-seam formation during the seaming operation and leads to containers being produced with seam defects or with inadequate vacuum due to insufficient head space.

All ingredients such as salt, oil, broth, and sauces being added to the container must not be contaminated with dust, dirt, insects, or other foreign material prior to or during their storage or during production. All ingredients must be food grade quality to ensure an acceptable quality finished product.

Improper filling may produce containers with low vacuum, which causes the ends to be distended if the temperature is increased above normal or if the pressure is reduced. When there is not enough vacuum to hold the ends in place, a sharp blow may cause either or both ends to bulge. Bulging ends may indicate a container which has low vacuum or is non-sterile.

For retort pouches the thickness of the filled container must not exceed the maximum thickness specified in the filed process, otherwise underprocessing could result.

Patching underweight containers can lead to excessively overweight containers unless all patched containers are re-weighed prior to being returned to the line.

CANNING OPERATIONS

1.9 PACKING WORKMANSHIP (cont'd)

The scale used in measuring container weights at the patching table must be routinely cleaned since any product or skin adhering to the scale will affect its accuracy. The "patching tableweight", the weight of a filled container without lid, must be routinely checked.

Compliance

Prior to container filling, employees visually inspect on a continual basis all cleaned material for the presence of offal, foreign matter and off-coloured flesh. All defective material found is removed from the processing line and re-worked or rejected as required.

For retort pouches, all product to be filled is examined to ensure that there are no projecting bones or other sharp objects that could pierce the pouch when the vacuum is drawn. All defective material is reworked or rejected as required.

Loins or steaks are cut neatly and uniformly to ensure proper piece size for the intended style of pack. The sharpness of filling-machine knives are checked at least every 2 hours, to ensure that loose product is not being deposited on the container flange. The filling-machine knives are checked at least once per hour for the presence of nicks.

Container flanges are inspected continuously to ensure that no product is adhering to the flange which could interfere with the proper formation of the double seam.

Retort-pouch sealing areas are inspected continuously to ensure that there is no adhering product or moisture which could cause an improper seal.

All ingredients are food grade, are clean and not contaminated with any foreign substance.

All containers with defective flanges are removed from the processing line.

Plant staff monitor the container-filling operations at the container-filling inspection station, on each line, by using suitable weighing devices, to ensure that fish fill and net content specifications are met.

CANNING OPERATIONS

1.9 PACKING WORKMANSHIP (cont'd)

Retort-pouch filling operations are monitored, using suitable gauges or measuring equipment to ensure that the maximum thickness requirement is not being exceeded.

Containers which do not meet weight specifications are removed from the processing line and are rejected or corrected as required.

Accurate records of weight (thickness measurements for retort pouches) and quality-control inspections are maintained for a period of not less than 36 months.

Verification

Observe if all defective material and containers are removed prior to the completion of filling.

Observe that all product to be packed in retort pouches is inspected for sharp projections that may pierce the pouch material, and that unacceptable material is reworked or removed.

Check that there is continuous monitoring for product over the flange and that all unacceptable containers are removed and the flange interference problem corrected before it is placed back on the production line.

Check that there is continuous monitoring of pouches for product or moisture on the sealing area and that all unacceptable pouches are corrected before further processing.

Determine that critical factors, as indicated in the scheduled process, are checked and recorded at an adequate frequency to demonstrate the safety of the thermal process. Examples of product critical factors include ratio of solids to liquid, percent solids, headspace, consistency, fill temperature or style of pack.

Check that the patching of underweight containers is done correctly and does not create problems such as overfills.

Observe that the retort pouch thickness is monitored to ensure that the maximum specified thickness is not exceeded.

CANNING OPERATIONS

1.9 PACKING WORKMANSHIP (cont'd)

Determine that the company procedures are followed, to ensure that underweight and overweight containers are patched to an acceptable weight.

Be on the alert for signs of overfill, such as excess spillage of product on or about the filler, or product streaked on the outer surface of the container.

For glass containers, determine the quality-control procedures established in the case of glass breakage and any records maintained. See if there is a gap detector in the closing machine which could indicate breakage on the line.

Measure the amount of light on the packing table using a standard light meter to confirm acceptable levels of illumination.

EMPTY CONTAINER HANDLING

2.1 APPLICATIONS GENERAL

FIR, PART I, GENERAL

Unless otherwise permitted by the Minister, fish shall be placed in new, clean, sound containers.

EMPTY CONTAINER HANDLING

2.2 CONTAINER INSPECTION, HANDLING AND CLEANING

Reason

As there is always a possibility that containers may be soiled or contain foreign matter, they must be satisfactorily cleaned.

Product containers which are not clean and sanitary are a source of contamination to the final product. Defective or damaged containers or ends will frequently result in defective seals on the final product and thereby compromise the safety of the product.

Compliance

Empty containers or retort pouches are inspected to ensure that no defective or soiled containers are being fed into the production line. All defective containers which are removed from the line are placed under the control of the plant quality-control section and destroyed or returned to the container manufacturer.

Containers and retort pouches are conveyed in such a manner as to prevent damage and maintain container integrity.

All manual handling of empty containers and ends is done with adequate care to ensure that they are not damaged.

All empty containers are inverted (where appropriate) and air or steam cleaned and/or washed with approved water prior to filling. Both air-pressure nozzles and vacuum systems are considered acceptable as a cleaning system for empty containers.

There are three steps in the inverted, hot-water rinse container cleaning operation:

1. The containers travel a short distance in an inverted position to allow dust particles and pieces of solder to fall out.
2. The containers are flushed and rinsed with hot water (about 82°C or 180°F).
3. They travel a short distance in an inverted position for the purpose of draining off excess water.

EMPTY CONTAINER HANDLING

2.2 CONTAINER INSPECTION, HANDLING AND CLEANING (cont'd)

A cold-water wash, steam or air blast may be used but these are considered less effective than the above method of cleaning.

By anticipating the shutdown of the canning line, at breaks and end of shift, the flow of containers to the filling machine or packing table is controlled so that none are left in the conveyor lines or the packing racks when the operation stops. Those containers left are either removed or so shielded that they will not become contaminated or obstruct the cleaning.

Verification

Determine whether containers are handled or conveyed so as to prevent any damage before use.

Determine that all empty containers are inverted (where appropriate) and air-, vacuum- or steam-cleaned and/or washed with approved water prior to filling to ensure that they are clean. Both air-pressure nozzles and vacuum systems are considered acceptable.

Check whether container conveyors are shielded to prevent contamination of the containers during cleaning, especially for glass containers, and whether, at the end of a day's operation, container conveyors are emptied of unused containers to avoid contaminating them during clean-up operations.

Determine that containers are not used for any purpose other than packing food, such as for ash trays, waste containers, or receptacles for small machine parts.

EMPTY CONTAINER HANDLING

2.3 RECEIPT OF EMPTY CONTAINERS AND ENDS

Reason

All lots of containers and ends brought into the cannery shall be inspected according to predetermined standards and procedures. Containers shall be inspected for:

a) proper type of inside enamel and outside coating;
b) defects and integrity of the side seam, if present;
c) bottom double seams;
d) can body manufacturing defects;
e) shipping damage; and
f) general cleanliness.

Retort pouches shall be inspected for manufacturing defects, shipping damage, and general cleanliness when they are brought into the cannery.

Storage areas for empty containers and ends must be dry and protected from all hazards such as dust, debris, the weather and pests.

Compliance

For rigid containers:

- the container makers provide guidelines for double seams, enamel, and tin coating;
- handling practices which could result in damaged seams and flanges are to be avoided;
- the tin coating and enamel is appropriate for the product being canned.

Ends for containers which are to be opened with keys or by pull tabs, are examined carefully to ensure that the scoring is even and deep enough for the container to be opened easily, but not so deep that the end will tear during sealing, heat processing or under the mechanical strains the container would normally encounter during distribution.

Regular samples of incoming container bodies and container ends are inspected for compliance with the container manufacturer's guidelines, and for container manufacturing defects as described in the Government of Canada Metal Can Defects Manual.

Retort pouches are examined on receipt for defects such as:

EMPTY CONTAINER HANDLING

2.3 RECEIPT OF EMPTY CONTAINERS AND ENDS (cont'd)

a) general cleanliness;
b) outside dimensions as specified;
c) defects such as delamination, improper side or bottom seams or improper tear notches; and
d) solvent or other off-odours from the interior of the pouch.

Glass containers are examined on receipt for defects such as:

a) tramp glass (loose glass in the jars or carton); and
b) hairline fractures.

Caps for jars are examined on receipt for:

a) enamel faults, absence of enamel, scratches, weak adhesion of the enamel; and
b) complete absence or poor distribution of the gasket compound or the use of the wrong type of material.

All pallets and cartons of container bodies, ends, retort pouches or glass containers are handled in such a way that the likelihood of damaging them is avoided.

The company is to follow these procedures:

1. torn or damaged packing or obvious physical damage to retort pouches, container bodies or ends are identified when containers are received;
2. if the condition of retort pouches, empty containers or ends is not satisfactory, the problem lots are refused or are 100% culled;
3. pallets or cartons of retort pouches, container bodies or ends that have been dropped or damaged during handling or damaged during storage, are separated from the total inventory and held back from production until the pallets can be 100% visually inspected; and
4. all defective retort pouches, containers and ends are carefully controlled for either disposal or return to the manufacturer.

Verification

Determine that all lots of containers and ends arriving at the plant are inspected by qualified personnel who ensure that all pallets and cartons of container bodies, ends, retort pouches or glass containers are handled in such a way that the likelihood of damaging them is avoided.

EMPTY CONTAINER HANDLING

2.3 RECEIPT OF EMPTY CONTAINERS AND ENDS (cont'd)

Determine that the measurements and inspection procedures used are those recommended in the Recommended Canadian Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Foods in Hermetically Sealed Containers (Canned Foods).

Check container handling and storage practices for situations which could result in damage or contamination.

Ascertain if container integrity defects are identified and classified in accordance with the Government of Canada Metal Can Defects - Identification and Classification Manual, or the Flexible Package Integrity Bulletin (National Food Labs Inc. (formerly National Food Processors Association - NFPA) Bulletin 41-L).

EMPTY CONTAINER HANDLING

2.4 RECORDS ACCURATELY COMPLETED

Reason

Records must be kept on the container lots and compiled in such a manner that container lots may be related to finished product-container codes, in order to be able to back-track to the sources of problems.

Compliance

Qualified personnel complete an inspection of a representative sample of containers and ends before use in production and the results are recorded.

Plant personnel inspect container integrity by following an inspection schedule, which contains details on the type of test, frequency and sample sizes.

Each pallet or carton of container bodies and ends has a manufacturer's identification ticket attached. Each lot of container bodies and ends has an identifying code so that container manufacturing information may be obtained. These records relate the usage of the container ends and container bodies to the finished product-container codes. Pallet identification tags from the container supplier are used. The ticket is placed, or recorded, in a reference file.

Accurate records of empty container and end inspections are kept by plant quality control and maintained for a period not less than 36 months.

Dates of receipt and dates of use of every lot of containers and ends is recorded and kept on file for at least 36 months.

Verification

Obtain a list of all of the empty container-handling records being maintained by the production and quality-control personnel, and check them carefully to ensure that all required empty container-handling records exist and are accurate and are up-to-date.

Determine the amount of time that the company keeps the records on file.

RETORT OPERATIONS

3.1 APPLICATIONS GENERAL

FIR, PART IV, CANNED FISH, SECTION 34

Canned fish shall be sterilized by a method approved by the Minister.

FIR, SCHEDULE II, SECTION 15

A record of the sterilization treatment used for each batch of fish shall be kept on file at the cannery for a period of not less than twelve months.

FIR, SCHEDULE II, SECTION 16, CANNERIES

Water used for cooling canned fish shall be chlorinated to give a chlorine residual of at least two parts per million, except where canned fish is cooled in a retort using a water supply approved by the Minister.

FIR, SCHEDULE II, PART II, SECTION 26

Floors in wet-working areas shall be kept clean and shall be thoroughly washed and disinfected daily.

FIR, SCHEDULE II, PART II, SECTION 27

Canneries and all equipment and utensils used in the operations of a cannery shall be kept in good repair and in a clean and sanitary condition.

RETORT OPERATIONS

3.2 AREA SANITATION

Reason

The areas around all retorts must be kept clean and sanitary to prevent contamination of the product.

Compliance

All areas around the retorts, particularly those where carts or baskets of processed product are handled, transported through, or removed from the retort, are kept in a clean and sanitary condition.

Floors do not have areas of standing water which result in splashing of contaminated water from the wheels of the retort baskets or carts.

The handling of wet containers after retorting and prior to cooling is prevented. The retort baskets are handled only by plant personnel wearing clean gloves that have been sanitized.

Verification

Determine that the area is restricted to authorized personnel working therein and maintained in a clean and sanitary condition.

Examine the procedures for handling retort baskets when they are being moved from the retort to the post-process area.

Determine that containers are not being handled while hot and wet.

Note whether there is any standing water on the floor which would splash from the wheels of retort baskets or carts onto the underside of the processed containers.

RETORT OPERATIONS

3.3 CONTAINERS RETORTED WITHOUT DELAY

Reason

Time lapse is controlled to minimize microbial growth and prevent the formation of heat stable toxins (*S. aureus* enterotoxin). Prompt retorting may also be necessary to maintain the heat transfer characteristics of the food and the specified minimum initial temperature.

This is a complex issue and there are many factors that can impact on the safety of the product such as the initial microbial load, the ambient temperature, the product temperature, the type of product and product pretreatment.

Compliance

Conditions which may permit the production of heat-resistant toxins in fish and other ingredients are controlled.

Generally, elapsed time from sealing to retorting does not exceed one hour unless:

- the manufacturer can demonstrate that the product is commercially sterile and is free from toxins under the most extreme time, temperature and product conditions
- sealed product is held at temperatures that will not permit the growth of micro-organisms that could impact on the safety of the process (less than 4°C or greater than 65°C)
- the heat transfer characteristics of the product are not affected

The manufacturer has control over the time lapse between sealing and retorting, e.g., reporting of line breakdowns or interruptions that may result in excessive lapse times.

If the time lapse exceeds that demonstrated by the manufacturer to be safe, the product is treated as a process deviation and is held for safety evaluation.

If there are line breakdowns or interruptions, the manufacturer processes the product in partially filled retorts to ensure that the maximum lapse time is not exceeded.

RETORT OPERATIONS

3.3 CONTAINERS RETORTED WITHOUT DELAY (cont'd)

To measure the Initial Temperature (IT)

The thermometer is inserted so as to determine the product temperature of the coldest container to be processed at the time the sterilization cycle begins.

In determining the IT, it is standard procedure to establish the minimum IT which is present in the retort load. In a crateless retort use the last few containers entering the top of the retort, or the temperature of the cushion water, or the first container of the retort batch prior to retorting, whichever is coldest.

Product lots with an IT lower than that established in the scheduled process are segregated as a process deviation and reviewed by a thermal process specialist.

Verification

Verify that the requirements stated under Compliance are met.

RETORT OPERATIONS

3.4 COOLING WATER

Reason

The water used for cooling containers could be a source of contamination to the product or to the retort environment.

There is a correlation between the microbial population present in post-process cooling water and the rate of container spoilage. Increased contamination of cooling water causes a proportional increase in product spoilage in the containers.

The water used for cooling containers must be of good quality and must be chlorinated to minimize the chance of contamination. A measurable level of free chlorine residual is required in the cooling water at the discharge end of the retort. The presence of a chlorine residual at the discharge indicates there has been sufficient chlorine in the water during the cooling cycle.

The amount of chlorine needed and the contact time required to inactivate bacteria cells and spores depends on initial water quality, pH and water temperature.

The acidity of the cooling water is best in the 6 to 7 pH range, to minimize the detrimental effect of pH on the effectiveness of the chlorine.

When containers are cooled quickly to between 35 and 40 °C (95 and 104°F), the potential for thermophilic growth and the development of corrosion on the container exterior from insufficient drying is reduced.

Compliance

Free residual chlorine tests are made at the retort overflow, drain or tank discharge. Free residual chlorine is measured at least twice per packing shift. The results are recorded and maintained for a period not less than 36 months.

The cooling water receives sufficient chlorine and contact time to produce a measurable level of free chlorine in the cooling water after the cooling cycle.

The acidity of the cooling water is near the 6 to 7 pH range.

RETORT OPERATIONS

3.4 COOLING WATER (cont'd)

The cooling water is discharged after the completion of the container cooling cycle.

At all times throughout the cooling process, there is a measurable level of free chlorine at the discharge end of the retort.

Care is taken to ensure the levels of chlorine are not so high as to damage the exterior finish of the containers.

When the water used for cooling is used for more than one batch it is circulated in a closed system through filters, holding tanks and treated to ensure that its quality meets the same conditions as required for an original supply, as described above.

Where an alternative method of treatment is used, it must be equivalent to the use of chlorine.

Verification

Check the source and quality of the cooling water. Unless an alternate treatment method is used, all retort cooling water must be chlorinated or otherwise sanitized to a point where there is a measurable level of free chlorine, at the point of cooling water discharge.

If an alternate method of treatment is used, check its reliability and effectiveness as compared to the use of chlorine.

Check the contact time allowed after the introduction of the chlorine to verify it is sufficient.

Determine the frequency of chlorine tests that are made on the retort cooling water.

Check that any recirculated cooling water is properly filtered and treated in a closed system before it is used a second time.

RETORT OPERATIONS

3.5 DIVIDERS AND SEPARATORS

Reason

Dividers and separators must be of approved design and construction and maintained in good condition such that they do not contribute to container damage.

If any other means is used to separate layers of containers, other than using dividers made of acceptable materials, with the proper sized and spaced holes, there may be interference with the circulation of the heating medium which will cause underprocessing.

Stacking of more than one divider may result in the blockage of the holes and thereby impair steam/water circulation during the thermal process.

Compliance

The dividers used fit the retort baskets such that there are no gaps or spaces between the divider and the basket which would allow nesting of cans.

Metal dividers are not damaged and are maintained in good condition, such that they will not result in container damage.

When dividers are placed on the bottom of retort baskets to minimize container abrasion, temperature distribution tests are performed with the dividers in place.

Only single dividers are used between layers in retort baskets.

Burlap sacks, boards, sugar sacks, towels or other similar materials for separators within the basket or buggy are not used.

Verification

Observe the condition of the dividers and separators to determine that they are not damaged.

Determine that only single dividers are being used.

Determine the practice used to mark and separate code changes.

Determine that, where dividers are used, cans do not nest.

RETORT OPERATIONS

3.6 LOADING BASKETS

Reason

Seams may be damaged or the container bodies dented during the loading if they are not handled carefully. Metal containers are also susceptible to vacuum loss due to rough handling.

Jumble pack is not permitted for containers which nest unless the heat process was developed with containers nesting as a variable.

Retort pouches may be punctured or scratched due to rough handling.

Compliance

When loading containers into the retort basket, care is taken to ensure that retort pouches or containers and double-seams are not damaged. Dropping or banging containers during loading is avoided. In jumble packs, containers are cushioned by water or other means to slow the impact and minimize denting. All containers which are dented or damaged are removed.

When loading the retort basket, containers are arranged so that the flow of steam will not be impeded.

When loading retort pouches into the racks, the loose edges of the pouches may overlap but the product inside the pouch must not overlap. The flow of steam is maintained around the pouches by the false bottom of the racks.

Containers are loaded into baskets in such a manner so as to prevent damage to the containers.

Records of basket loading are made. Basket loading records indicate approximate number of containers, container size, code, and time on the clock when loading of the basket was started and completed.

RETORT OPERATIONS

3.6 LOADING BASKETS (cont'd)

Verification

Verify that there is no rough handling of the filled, sealed containers on route to the retort which may induce seam defects or other damage. The dropping of filled, sealed containers into baskets, without some kind of cushioning, is not acceptable.

Observe the arrangement of containers for loading to the retort. Verify that it is consistent with that specified in the scheduled process.

Verify that the required records are completed promptly, legibly, and accurately.

RETORT OPERATIONS

3.7 PROCESS INDICATORS & TRAFFIC CONTROL

Reason

It is vital that an effective means be used to prevent uncooked product from by-passing the retort. In batch operations the sterilization status of the containers must be clearly indicated.

All retort baskets, trucks, cars or crates containing unretorted food product or at least one of the containers on the top of each basket must be plainly and conspicuously marked with a heat-sensitive indicator, or by other effective means, which will visually indicate whether or not the unit has been retorted.

Heat-sensitive indicators such as paint, tape or tags are available for this purpose. After they are used they must be removed and stored, or recorded, to provide verifiable information that each retort basket in each retort load was subjected to heat such as in a retort. Colour change systems are only an indication that containers have been subjected to heat, and are not a verification that an adequate heat process was performed.

It is essential that a system for product traffic control in the retort room be established to prevent unretorted product bypassing the retort process and being mixed with retorted product.

All baskets and crates are clearly marked with heat-sensitive indicators that undergo changes in appearance after exposure to a high temperature. These are heat specific in that the process temperature has to have been attained to result in the colour change. This, however, does not ensure adequate processing time.

Compliance

A traffic-control system such as a double-ended retort, a barrier, gate or other suitable device is installed to ensure that no uncooked containers in any form of conveyance can by-pass the retorts.

Retorts are not closed temporarily during loading. They are closed only when the retort operator is ready to start the process.

RETORT OPERATIONS

3.7 PROCESS INDICATORS & TRAFFIC CONTROL (cont'd)

Heat-sensitive indicators are marked with the code or lot number and the clock time when the first container is placed into the basket.

Each retort basket, truck, car or crate used to hold containers in a retort, or one or more containers therein, are marked with a heat-sensitive indicator, or by other effective means, to indicate visually those units that have been retorted.

Information based on colour change only, on heat-sensitive indicators, must not be used to check that adequate heat processing has occurred.

Visual checks are made to determine whether or not, as a result of retorting, the appropriate change has occurred in the heat-sensitive indicator for all retort baskets, trucks, carts or crates.

If there is any uncertainty as to whether containers have been subjected to the heat process, they are immediately retorted, and segregated for further evaluation, or destroyed.

After containers have been processed, cooled and either boxed or bright stacked, each retort heat-sensitive indicator is removed and stored or recorded, for verifiable evidence that the retort baskets were subjected to a heat process.

Records of the visual checks of the heat-sensitive tags and resultant actions taken are made and kept for the minimum of 36 months.

Verification

Observe the procedures used in the post-process area to determine that all baskets are being retorted.

Observe whether all retort baskets containing unretorted containers, or as a minimum practice, some of the containers on the top of each basket, are plainly and conspicuously marked to indicate that the containers require processing.

RETORT OPERATIONS

3.7 PROCESS INDICATORS & TRAFFIC CONTROL (cont'd)

Determine the marking system used to identify unretorted and retorted containers, specifically determine which colour indicates processed and which colour indicates unprocessed product.

Observe the traffic pattern for baskets of uncooked containers and for the baskets of cooked containers for each retort installation.

Determine if baskets of uncooked containers could by-pass the retorts. If it is possible, discuss with the processor the need to have physical barriers to prevent this from ever happening.

Ensure that colour-changing tags or paint are not being used to check that adequate heat processing has occurred.

Check the company records maintained for this area.

Determine the procedures used by the company when dealing with containers of unknown status with respect to processing.

RETORT OPERATIONS

3.8 RECORDS ACCURATELY COMPLETED

FIR, SCHEDULE II, SECTION 15

A record of the sterilization treatment used for each batch of fish shall be kept on file at the cannery for a period of not less than twelve months.

Reason

Records of sterilization treatment show the results of verification and confirm the effectiveness of process controls.

Compliance

Permanent process records are prepared clearly and promptly as the various steps of the retorting process are completed.

The recorder chart identifies retort number, date, product, batch, retort operator's name and reviewer's name.

The initial temperature (IT) on every retort load for every container/product type is determined and recorded in the retort log.

Retort logs must include the following information:

a) company and plant name
b) address
c) registration number
d) date of processing
e) retort operator's name
f) retort operator's signature
g) product processed
h) style of pack
i) company code - numbers and/or letters for:
    product
    establishment
    day, month and year
j) approximate number of containers in the retort batch
k) container size
l) scheduled process time and temperature requirements
m) IT of product
n) retort number
o) chart number from the temperature recorder
p) "venting time" from start to closing of the vent valve

RETORT OPERATIONS

3.8 RECORDS ACCURATELY COMPLETED (cont'd)

q) time on the clock that the cook or scheduled process starts
r) temperature readings from the MIG thermometer
s) temperature readings from the temperature recorder/controller
t) readings from the pressure gauge
u) estimated time steam should be turned off
v) actual time steam is turned off, end of cook
w) actual processing/cooking time, in minutes
x) residual chlorine in cooling water is at least at a measurable level

Verification

Review the records being maintained by the production and quality-control personnel, and check them carefully to ensure that all required records exist and are accurate.

Observe whether the required retort records are prepared clearly, promptly and permanently, as the retorting procedures are being carried out.

RETORT OPERATIONS

3.9 RECORDS AND CHARTS KEPT ON FILE

Reason

In case problems develop in the finished product, a record of inspections by quality control must be available to evaluate whether all aspects of the scheduled process are under control and recorded.

Compliance

Records are retained for a minimum of 36 months, preferably for a period that exceeds the shelf life of the product.

Verification

Determine that accurate retort records are available for inspection by the CFIA and that they are maintained up-to-date at all times and determine the period of time that the records are retained.

RETORT OPERATIONS

3.10 RETORT OPERATOR QUALIFICATIONS

Reason

To ensure adequate commercial sterilization of canned fish, retort operators must be certified or under the continuous supervision of a certified retort operator.

Compliance

The designated person in control of the retort operations has successfully completed a recognized course in thermal processing and retort operation.

Verification

Identify the designated retort operators and determine that they are qualified.

This requirement is met by the operator having successfully completed a thermal-processing course offered by one of the following institutions:

British Columbia Institute of Technology - Burnaby, B.C.

Holland College - Summerside, P.E.I.

Institut de Technologie Alimentaire et Agricole - St. Hyacinthe, Que.

St. Clair College, Windsor, Ont.

Technical University of Nova Scotia, Halifax, N.S.

Newfoundland and Labrador Institute of Fisheries & Marine Technology, St. John's, Nfld.

University of Guelph, Guelph, Ont.

SEAM INSPECTION PROCEDURES

4.1 APPLICATIONS GENERAL

FIR, GENERAL, SECTION 24

No person shall export or import or attempt to export or import containers of fish

a) that have not been properly sealed
b) the tops or bottoms of which have been distorted outwards, or
c) that are otherwise defective.

Reason

Proper sealing of the container depends upon the precise formation of the double seams. In order to consistently produce high-quality double seams, constant attention must be given to the adjustment and the maintenance of the seaming equipment. Routine scheduling of seam inspections must be performed to give correct information on the adjustment of the seaming equipment.

For retort pouches, proper sealing depends on the precise application of heat and pressure to the sealing bars. In order to consistently produce proper seals, constant attention must be given to the adjustment of the alignment of the sealing bars, the temperature and pressure settings and the protective cover of the sealer bars must be regularly inspected for deterioration.

Compliance

Visual examinations of the containers coming from the seamer must be made at frequent intervals, not exceeding 30 minutes, in order to detect any abnormalities. External seam inspections should be completed by qualified staff, examining each container carefully under good lighting conditions.

Complete double-seam inspections, including tear-downs, must be done on a regular schedule, in order to ensure that the double seams conform with the container manufacturer's guidelines.

Plant personnel inspect for container integrity, container code legibility and accuracy and double-seam compliance in accordance with the Canadian Food Industry Code of Practice or those procedures specified by the can supplier, where equivalent.

SEAM INSPECTION PROCEDURES

4.1 APPLICATIONS GENERAL (cont'd)

Qualified personnel complete a top double-seam teardown inspection of one filled container from every container seaming head operating in the plant. Water-filled cans may be used at line start-up, otherwise production teardowns are performed on containers filled with product. This procedure is carried out at least once every 4 hours of seamer operation, after a jam-up, or after a lengthy shut down and the results are recorded.

Tear-down examinations are also done:

a) at start-up;
b) after work has been done on the seamer;
c) after a prolonged shutdown;
d) after a seamer jam-up; and
e) after changing container size or body and end material.

Whenever defective container seaming heads are adjusted or repaired, the double seams are re-tested and pass inspection before the seamer is put back into production.

Seaming operations are stopped when container integrity defects are found, or when the double seam dimensions are determined to deviate from the container maker's guidelines or specifications.

Accurate records are kept for a period of not less than 36 months and consist of:

a) container integrity inspections;
b) double-seam teardown examinations; and
c) seamer operating and maintenance records.

Qualified plant personnel conduct inspections and tests of retort pouch seals following appropriate methods and frequencies. Water-filled cans may be used at line start-up, otherwise production teardowns are performed on containers filled with product.

For retort pouches, burst tests are performed for each position of the sealer:

a) at start-up;
b) after work has been done on the sealer;
c) after a prolonged shutdown;
d) after a jam-up; and
e) at approximately every 1 hour of operation.

SEAM INSPECTION PROCEDURES

4.1 APPLICATIONS GENERAL (cont'd)

For retort pouches, qualified staff must examine 100% of the pouches coming from the sealer in order to detect abnormalities. Burst or pressurization-hold tests are performed on a regular schedule to ensure that the seals are adequate.

For retort pouches records are kept for a period of at least 36 months which consist of:

a) seal strength burst tests;
b) residual air tests;
c) container integrity inspections; and
d) sealing machine operating and maintenance records.

Verification

Ensure that measurements and inspection procedures used are equivalent to those recommended in the Recommended Canadian Code of Hygienic Practices for Low-Acid and Acidified Low-Acid Foods in Hermetically Sealed Containers (Canned Foods).

For retort pouches, ensure that measurements and inspection procedures used are equivalent to those recommended in the CGSB National Standard of Canada "Use of Flexible Pouches for Thermally Processed Food".

Determine that the qualifications of the individuals making the closure examinations and equipment adjustments are acceptable.

Determine who has the authority to stop the production line if the container seams fall outside the operational specification and record this information.

Determine what action is used to evaluate containers which may have been improperly sealed prior to the identification of a problem at the seamer.

SEAM INSPECTION PROCEDURES

4.2 RECORDS ACCURATELY COMPLETED

Reason

In case problems develop in the finished product, a record of inspections by quality control must be available to verify that all aspects of the seaming operation were under control, and recorded.

Hermetically sealed containers must protect the thermally processed contents from recontamination with microorganisms. Thus, container integrity is critical for the safety and shelf stability of canned foods.

Batch-coding and production records facilitate the isolation of lots which may be abnormal or pose a potential health hazard.

Compliance

Permanent records for container double seam, glass container closure, or retort pouch seals are prepared legibly, promptly and accurately.

Verification

Determine what container closure or retort pouch sealer records are maintained, and check them carefully to ensure that all required records exist and are accurate.

Observe whether the required container closure records are prepared clearly, promptly and permanently, as the container closure examinations are carried out.

SEAM INSPECTION PROCEDURES

4.3 RECORDS ACCURATELY KEPT ON FILE

Reason

Seam inspection records are essential to the plant management, as they provide a record of activities in case any abnormalities develop in the product. Review of production records is one method of monitoring the efficacy of the quality-control procedures in place.

Compliance

Records are retained for a minimum of 36 months and preferably for a period that exceeds the shelf life of the product.

Verification

Determine that accurate container-closure records are available for inspection by the CFIA and that they are maintained up-to-date at all times, and determine the period of time that the records are retained.

STERILIZATION PROCESSES AND PROCEDURES

5.1 APPLICATIONS GENERAL

FIR, PART IV, CANNED FISH, SECTION 34

Canned fish shall be sterilized by a method approved by the Minister.

Reason

In order to ensure adequate sterilization of canned fish it is important to have set procedures so that the instrumentation and the process controls are operated properly.

Compliance

The temperature standard is the mercury-in-glass (MIG) thermometer and the time standard is the wall clock.

The temperature recorder is used only as a record of the process time and temperature.

The time on the recorder chart is in agreement with the actual time of day as indicated by the wall clock. Temperature-recording charts are checked and adjusted by the retort operator or a qualified technician.

All times being recorded are taken from the wall clock which is positioned in a location that is clearly visible from the retort operator's station. Operators do not use wrist watches or pocket watches. Clocks with sweep second-hands are adjusted so that they agree with the minute hand.

During the processing, bleeders, particularly those in thermometer and temperature-sensing bulb wells, are examined by the retort operator to ensure that steam is continuously flowing from each bleeder location.

During the processing, condensate drain valves or traps are inspected by the retort operator to ensure that condensate is continuously removed from the retort.

After the retort procedure has been completed, the retort operator ensures that the valve on the water line to the retort has been securely closed and is not leaking.

STERILIZATION PROCESSES AND PROCEDURES

5.1 APPLICATIONS GENERAL (cont'd)

In the case of water cooks, after the come-up time has been completed, the retort operator ensures that the valve on the water line to the retort has been securely closed and is not leaking.

MIG thermometers and pressure gauges are located such that they are easily read by the operator.

Pressure gauges and thermometers are tested for accuracy, tagged and labelled. Each gauge has a tag or other method of identification that indicates the date on which it was last checked for accuracy, the standard or test method used and the person who performed the test.

Verification

Determine that the verification requirements as detailed in Chapter 5, Subject 2, Section 3, Retort Controls and Instrumentation and Section 4, Retort Equipment, are met.

Inspect every pressure gauge and MIG thermometer to determine that they have been checked against an accurate standard, certified and tagged (or provided with some other method of identification) showing the date and person who performed the test.

If the mercury column is broken or the thermometer is inoperative or has not been certified, it must be replaced with a certified and fully operative thermometer, before any further production. Determine if any product may have been processed while the thermometer was inoperative or uncertified.

If the original MIG had been giving false readings, then an investigation of all conditions must be carried out, on the assumption that there has been a deviation from the scheduled process. Determine if any product may have been processed while the thermometer was inoperative or uncertified.

Determine the procedure being followed by the retort operator in operating bleeders and condensate drain valves and the frequency of observing that steam traps are in operation. Ensure that visibility is not obscured in the retort area.

STERILIZATION PROCESSES AND PROCEDURES

5.2 FILED PROCESS POSTED

Reason

Schedules of filed processes for each container size, type and style of product must be posted near the retort operator's station or be readily available to the retort operator, so that there is no misunderstanding of the proper process to be followed.

Compliance

The scheduled process, including the vent, being followed at any particular time, is displayed at the retort operator's station.

The procedures posted, or made available to the retort operator, include specific instructions to follow in the event of a process deviation.

The time and temperature of the process are equal to or exceed those stipulated in the filed scheduled process.

Verification

Check the retort room or area to determine that the company has posted their filed scheduled processes, including venting schedules, for all types and sizes of containers and products being processed.

Determine what contingency plan is available to the retort operator in the event that a process deviation occurs and ensure that it is adequate.

STERILIZATION PROCESSES AND PROCEDURES

5.3 PROCESS SUBMITTED AND FILED

Reason

Scheduled processes are submitted to, and filed with, the CFIA Regional Inspection designate prior to their use in commercial production. Information must include all information contained in the CFIA "Submission for Filing of a Scheduled Process for Canned Fish and Fish Products".

Compliance

All retort processes including vent time and temperature, cooking time temperature and all critical factors of the process are submitted, on the CFIA form, and filed with the Regional Inspection designate prior to production.

Verification

Determine that processes being used in the cannery have been filed.

STERILIZATION PROCESSES AND PROCEDURES

5.4 PROCESSING ACCORDING TO FILING PROCEDURES

Reason

The actual procedure for processing in retorts is a predetermined sequence of setting of controls and the opening and closing of valves for specific lengths of time, which ensures that each of the three operations are performed correctly.

Commercial Sterility of Fish - Conditions obtained in a fish product which has been processed by the application of heat, alone or in combination with other treatments, to render the food free from viable forms of microorganisms, including spores, capable of growing in the foods at temperatures at which the food is likely to be held during storage and distribution.

Come-up Time - The come-up time is measured from the time the steam is turned on to the time the process temperature is reached in the retort. Within the come-up period, the retort operator must precisely follow a "venting schedule", which specifies a minimum time and a minimum temperature, to ensure that all air is removed from the retort before closing the vent valve.

Cook Time - After the retort has been thoroughly vented and the processing temperature has been reached, the timing of the process is started. During the cook process, it is very important that the retort temperature remains constant and that an accurate clock or timing device is available to time the process.

Throughout the cook process it is important that the retort operator maintains precise control on the temperature and the time. Any error in either time or temperature of the process will have an effect upon the total sterilizing value of the process.

Come-Down Time - After the processing period is completed, the pressure in the retort and in the canned products must be reduced to atmospheric (or zero-gauge) pressure.

Various cooling procedures may be used depending on the retort installation, the size of the container being processed and the type of product.

STERILIZATION PROCESSES AND PROCEDURES

5.4 PROCESSING ACCORDING TO FILING PROCEDURES (cont'd)

Water cooling should not reduce the temperature of the container below the point at which its surfaces will be dried by the residual heat in the container. Each container must retain sufficient heat to quickly evaporate any water droplets left on the container after retorting. Failure to do this may cause external corrosion of the container.

Compliance

The sequence of events and the times required are described in the detailed operating instructions and must be precisely followed.

Minor differences in valve adjustments, to account for unusual conditions in the retort, such as partial retort loads, are the only variations on the established procedure that are acceptable.

Verification

Observe and verify that all specifications of the scheduled processes are followed, including:

a) venting schedule;
b) bleeders operating;
c) the MIG thermometer, and not the recorder chart, used as the temperature reference;
d) the correct temperature/pressure correlation exists between the MIG thermometer and the pressure gauge;
e) the wall clock used as the time reference; and
f) condensate removal.

Verify, at the retort station, that the appropriate time and temperature are being adhered to on an on-going basis by ensuring that all systems, equipment, and operational aspects are functioning properly. Review, as applicable, plant quality-control records, process logs, cannery defects records, product analysis in pack, vacuum, indicator heat tags, chlorine residual recordings, and retort maintenance logs to ensure requirements are met. Also any other relevant information specific to the operation is to be reviewed.

STERILIZATION PROCESSES AND PROCEDURES

5.4 PROCESSING ACCORDING TO FILING PROCEDURES (cont'd)

Observe and confirm that the steam-line pressure does not fall below the required pressure at retort, when venting other retorts, or during any peak load period.

Observe whether required process records are prepared clearly, promptly and permanently as the various steps of the process are completed.

Verify that operators do not allow entry of unauthorized personnel into the retort area, and take necessary precautions against unauthorized changes in process operation.

STERILIZATION PROCESSES AND PROCEDURES

5.5 PROCESS DEVIATIONS

Reason

All deviations from the scheduled process, and the associated critical factors, must be thoroughly evaluated because of the potential for risk to health and/or safety.

Compliance

Deviations from the scheduled process are thoroughly documented and evaluated by the thermal process specialist. The company quality-control personnel ensure that the causes for deviations are corrected and properly documented. Problems causing deviations and their solutions are recorded in a completed deviation record.

Upon discovery of any deviations in retorting, the plant quality control is notified. All implicated product must be identified, segregated and controlled until corrective action is taken. Immediate action is taken to ensure that the deviation does not recur and increased monitoring of retort operation is initiated to verify that the problem has been corrected.

The retort records clearly indicate that a deviation has occurred.

The following information must be available along with a process deviation record:

a) date and time of deviation;
b) retort identification;
c) nature and scope of the deviation;
d) product description;
e) code and quantity;
f) corrective action taken (or under consideration), including product disposition; and
g) the name and signature of the thermal process specialist.

Verification

Review retort charts and log book to determine normal operating procedures. Determine who has responsibility for checking records and documentation.

STERILIZATION PROCESSES AND PROCEDURES

5.5 PROCESS DEVIATIONS (cont'd)

Determine that the company management has provided the retort operator with a contingency plan, in writing, which must be followed when a process deviation occurs.

The process deviation information may be initiated on the retort operator's records; however, a complete record of all required information on the process deviations will be the main reference. This record may be in the form of a permanent file or log book.

Review documented process deviations to determine that actions taken by the company after the identification of a deviation meet the requirements listed in the compliance section.

Records must include:

a) a written review of the deviation;
b) decision on product isolation and control;
c) product disposition; and
d) responsibility centre for these decisions.

STERILIZATION PROCESSES AND PROCEDURES

5.6 RECORDS ACCURATELY COMPLETED

Reason

Hermetically sealed containers must protect their thermally processed contents from recontamination with microorganisms. Thus, proper sterilization procedures are critical for the safety and shelf stability of canned foods.

A record of the procedures followed during the sterilization process, and subsequent checks by quality control must be available to verify that all aspects of the sterilization process and procedures were under control, and recorded.

The retort log serves as the official record of the process. This record permits verification of the temperature-pressure agreement, and the delivery of the scheduled process.

Compliance

Permanent process records are prepared legibly, accurately and promptly as the various steps of the process are completed.

Verification

Determine what process records are being maintained by the production and quality-control personnel, and check them carefully to ensure that all required records exist and are accurate.

Observe whether the required process records are prepared clearly, promptly and permanently as the various steps of the process are completed.

STERILIZATION PROCESSES AND PROCEDURES

5.7 RECORDS ACCURATELY KEPT ON FILE

Reason

Process records are essential to the plant management, as they provide a record of activities in case any abnormalities develop in the product. The retort log and the retort recorder charts provide a record of the scheduled process delivery.

Compliance

Records are retained for a minimum of 36 months and preferably for a period that exceeds the shelf life of the product.

Verification

Determine that accurate sterilization records are available for inspection by the CFIA and that they are maintained up-to-date at all times and determine the period of time that the records are retained.

WAREHOUSING/POST-PROCESS HANDLING

6.1 APPLICATIONS GENERAL

FIR, GENERAL, SECTION 6 (1)(a)

6. No person shall import, export or process for export or attempt to import, export or process for export:

(a) any fish that is tainted, decomposed, or unwholesome or otherwise fails to meet the requirements of these regulations.

FIR, SCHEDULE II, SECTION 27, CANNERIES

Canneries and all equipment and utensils used in the operations of a cannery shall be kept in good repair and in a clean and sanitary condition.

FIR, PART III, SECTION 31 (1)

Every carton and case in which containers of fish are packed at an establishment shall be legibly marked on one end in such a manner that the name of the establishment and the day, month, and year of processing can be determined by an inspector.

FIR, PART IV, CANNED FISH, SECTION 34

Canned fish shall be sterilized by a method approved by the Minister.

WAREHOUSING/POST-PROCESS HANDLING

6.1 APPLICATIONS GENERAL (cont'd)

Reason

If canned fish is not cooled quickly after heat processing, it will continue to cook.

Entry to the post-process and container-cooling area must be restricted to authorized personnel only. The cooling area must be clean and free of sources of contamination which could come in contact with the cooling containers.

Compliance

After the containers have been removed from the retort, procedures are followed to allow the containers to cool.

Entry to the container-cooling area is restricted to persons working therein.

The areas where baskets are tipped and where containers are cooled are maintained in a clean and sanitary condition at all times.

The containers are dried in a clean and sanitary area of the plant which is free from sources which could contaminate the containers with dirt, dust, debris, pooled water or condensation.

Verification

Determine the procedure being followed in the post-process area to cool the containers.

Determine that the post-process area is restricted to personnel working therein and that it is maintained in a clean and sanitary condition.

Observe the normal handling practices and sanitation procedures in the post-process area.

Note whether containers are handled roughly during or after drying.

WAREHOUSING/POST-PROCESS HANDLING

6.2 HANDLING HOT CONTAINERS

Reason

Hot and wet containers are not handled since moisture will aid the transfer of bacteria to the closure area, possibly causing post-retort contamination of the product inside the container.

Protection of the containers must extend to the post-cooling container handling systems. Studies have indicated that high levels of bacterial contamination may develop on wet and soiled post-cooling container handling equipment, even though the cooling water is chlorinated or is of good sanitary quality. Bacterial contamination may be transferred to the seam areas of the containers and may lead to post-process contamination of the product.

When cans are hot and wet, the seam integrity and sealing compound are not secure against microbial entry and cans must not be handled.

Compliance

Workers in the post-process area must ensure that hot and wet containers are not touched by hand and that no impact damage occurs in the moving, or tipping for draining, of the baskets. Clean gloves dipped in disinfectant solution must be worn when handling the baskets and any sudden movement or sharp impacts must be avoided.

Hot containers must be handled carefully and must be protected from rough handling and possible sources of contamination while being cooled.

Post-retort washing of containers after sterilization is not permitted. If final product container cleaning after cooling is required, the company must submit a proposal to the CFIA.

Verification

Confirm that the containers are not washed post-retort.

Confirm that the containers are handled according to the compliance requirements.

WAREHOUSING/POST-PROCESS HANDLING

6.3 RECORDS ACCURATELY COMPLETED

Reason

A record of the container integrity inspection by qualified personnel must be available to verify that process controls are in place and recorded.

Records of shipping documents must be available in the event that any product recall is necessary.

Compliance

A final product inspection, compliance sampling, or cull reports completed for each lot to document the results of the final product inspection.

Records are available to relate the lot number, product code, production date, and the quantity shipped to the consignee.

Verification

Determine that all required records exist and are completed promptly, legibly and accurately.

WAREHOUSING/POST-PROCESS HANDLING

6.4 RECORDS ACCURATELY KEPT ON FILE

Reason

In the event problems develop in the finished product, a record is available which documents all pertinent lot information, including product code, additional identifying marks and the quantity shipped to each first destination.

This information will be essential should a product recall be required.

Compliance

Records are retained for a minimum of 36 months and preferably for a period that exceeds the shelf life of the product.

Verification

Determine that accurate shipping records are available for inspection by the CFIA and that they are maintained up-to-date at all times and determine the period of time that the records are retained.

WAREHOUSING/POST-PROCESS HANDLING

6.5 STORAGE/WAREHOUSING

Reason

As containers are cased or palletized, the results of rough handling will be apparent as dents and distorted double seams.

If retort pouches or containers are placed in cartons, staples must not be used as they may score or puncture the containers.

It is essential that cartons and cases of products be identified by establishment, day code, and other pertinent information, in order to facilitate a recall or the segregation of lots.

Where low-vacuum dud detectors are employed, it is practical to check the container integrity at the point where cooled containers emerge from the cooling process and/or after bright stacking in a warehouse.

The detection of containers with low vacuum (duds) at the earliest opportunity after cooling indicates the number of gross defects in the packaging line, but slow leakage conditions may be missed. Low-vacuum (dud) detection after warehousing for some days removes faulty containers from distribution.

Warehouses must be kept in good repair, clean, have adequate lighting, and walls and a roof which do not leak. All containers must be protected from environmental conditions which will have an adverse effect on the containers or product.

Compliance

Warehouse handling practices and controls maintain container integrity prior to shipping.

Warehouses are in good repair, clean, have adequate lighting, and walls and a roof which do not leak.

WAREHOUSING/POST-PROCESS HANDLING

6.5 STORAGE/WAREHOUSING (cont'd)

All finished product is stored in warehouses with good ventilation and sufficient humidity and temperature control to prevent overheating, freezing, corrosion or chemical reactions which may adversely affect the product. The warehouse is free from other factors which may affect the odour, flavour, colour, texture, nutritive value or shelf life of the product.

A sanitation program is in place in each warehouse or storage location so that all stored final product is protected from dust, dirt, and debris. A corridor is maintained between the product and wall for purposes of inspection, cleaning, and ventilation.

A rodent and insect control program is maintained in the establishment and, where pesticides are used, the application thereof is made under the supervision of a responsible operator using proper equipment, in a manner that prevents contamination of the product.

All cartons and cases in which containers of fish are packed are legibly marked on one end in such a manner that the name of the plant and the day, month and year of processing can be determined by an inspector.

Verification

Observe that the company's handling and storage procedures prevent rough handling practices.

Evaluate plant procedures for inspection of container integrity and labelling.

Evaluate plant procedures for segregation of those lots while stored in the warehouse.

Review records for the results of container integrity inspection and product disposition/distribution.

Note whether there is adequate temperature and ventilation control in the warehouse.

Observe that the codes on the packing cartons and cases are the same as those on the containers packed therein in accordance with section 1.6, Coding, of this subject.

WAREHOUSING/POST-PROCESS HANDLING

6.5 STORAGE/WAREHOUSING (cont'd)

Check that only clean, sound material is utilized for cases, cartons, boxes and shrink wrapping.

Verify that the plant programs for sanitation, insect and rodent control in the warehouse area are satisfactory.

CHAPTER 13, SUBJECT 1

THERMAL PROCESS CONTROL POLICY FOR FEDERALLY REGISTERED CANNERIES

1. SCOPE

This document outlines the regulations, policies and procedures governing the control of thermal processes for the commercial sterilization of low-acid and acidified low acid canned foods. It explains thermal processing controls that are to be followed by registered canneries which are in addition to the general requirements for registration of establishments covered in Chapter 2, Subject 1; Chapter 5, Subject 2 and Chapter 6, Subject 2 of this manual.

2. AUTHORITIES

Fish Inspection Act, R.S.C., 1985, c F-12; Part I, Fish Inspection Regulations (FIR), C.R.C., 1978, c. 802

Section 34 (FIR)

Canned fish shall be sterilized by a method approved by the President of the Agency.

3. DEFINITIONS

Acidified Low-Acid Food: a low-acid food that has been treated in a manner, acid(s) or acid food(s) are added, so that all components have attained an equilibrium pH of 4.6 or below by the time the thermal process is completed.

Come-up Time: the time, including vent time, which elapses between the introduction of the heating medium into the closed retort and the time when the temperature in the retort reaches the required processing temperature.

Commercial Sterility of Canned Fish: the condition obtained in a canned fish product which has been processed by the application of heat, alone or in combination with other treatments, to render the food free from viable forms of microorganisms, including spores, capable of growing in the foods at temperatures at which the food is normally designed to be held during storage and distribution.

Such a process is designed to result in the reduction of

the reference organism, *Clostridium botulinum*, by 12 log (12D concept). This value may not ensure the destruction of all spoilage organisms. It is the processor's responsibility to determine which critical factors will be used to ensure destruction of the pathogen *C. botulinum* as well as spoilage organisms.

Can: means any hermetically sealed container.

Canned Fish: means any fish that is sealed in a can and is sterilized.

Control Measure: an action performed to eliminate a hazard or reduce it to an acceptable level.

Corrective Action: the procedure that is to be followed whenever a deviation from a critical limit in a HACCP plan occurs or whenever the results of monitoring procedures in respect of a prerequisite program plan or regulatory action point plan show that there is non-compliance with the Fish Inspection Regulations.

Critical Control Point: a point in a process operation at which control is to be applied in order to prevent or eliminate a hazard or reduce it to an acceptable level.

Critical Factor: physical and chemical factors that can influence the thermal response of a product to a thermal process, the variation of which may influence the scheduled process, including container, product, retort and processing conditions

Critical Limit: the maximum or minimum value to which a hazard must be controlled at a critical control point.

Deviation: failure to deliver the scheduled thermal process, meet critical factors related to the delivery of the thermal process, or critical limits relating to the process.

Deviation Procedure: documented set of corrective actions that are implemented when a process deviation occurs.

Documentation: the physical or electronic record of the procedures or activities that are to be followed as they relate to the thermal process. Documentation explains what controls are in place and how these controls are delivered. They include but are not limited to written formulae, procedures or specifications used by the processor or required by a manufacturer.

Equilibrium pH: the condition attained in an acidified low-acid food product in which there is no further change in the pH of any of the components.

Heat-Penetration Tests: scientific experiments conducted to determine heating and cooling behavior of a product/package combination, processed in a specific retort system, in order to establish safe thermal processes that will result in commercially sterile product or to evaluate process deviations. Chapter 13, Subject 3 contains a protocol for carrying out heat-penetration studies.

Hermetically Sealed Container: a container designed and intended to be secure against the entry of microorganisms, including spores.

Incubation: tests in which the thermally processed product is kept at a specific temperature for a specific period of time in order to determine if outgrowth of micro-organisms or other problems occur under tested conditions.

Initial Temperature: the product temperature of the coldest container to be processed at the time the sterilization cycle begins.

Inoculated Pack: a test pack used in scientific experiments wherein microorganisms to be targeted by the thermal process are added to a substrate (product) to confirm the adequacy of a theoretical process.

Lethality: F represents the time intercept from a thermal-death time curve (log t_{gm} vs T) at T = Tx. The F value is often referred to as the process lethality and it is the equivalent time in minutes, at a specific temperature, required to reduce the bacterial load of a target organism whose *z* value is known. The sterilizing value of a process is generally expressed as an F_0 value which is equivalent to the number of minutes required to destroy a specific number of organisms with a *z* value of 10 °C (18 °F), at 121.1 °C (250 °F).

Low-Acid Food: a food where any component of the product has a pH greater than 4.6 and a water activity greater than 0.85.

Minimum Initial Temperature: the lowest temperature in a container for which the thermal process was established.

Objective Evidence: information which can be proven true, based on facts obtained through observation, measurement,

test or other means.

Process Authority: means any person or organization that has been recognized by the Agency as being competent in developing and evaluating thermal processes.

This would include competency in the following areas:

- considerable knowledge concerning product characteristics, critical factors relating to the thermal process and the effect the commercial equipment and procedures will have on the heating and cooling characteristics of the product and the delivery of the thermal process;

- experience in conducting studies relating to thermal processing of food, such as heat-penetration and temperature-distribution studies, and thermal-death time and validation studies and the application of other scientific methods relating to thermal processing;

- the ability to evaluate data generated by scientific studies and tests in order to document: the effectiveness of the thermal process relating to the production of safe and commercially sterile product; and, that testing has been carried out to identify all possible factors which could affect the heating characteristics of the product and the safety of the final product.

Process Verification: written confirmation from a thermal process specialist or process authority that the calculated lethality from the use of a non-standardized process achieved commercial sterility or that the use of a standardized process resulted in commercial sterility.

Records: observations, measurements and other data written by the processor, or recorded by means of monitoring equipment to document the adherence to critical limits, critical factors, or other process requirements.

Retort: a pressure vessel designed for thermally processing food, packed in hermetically sealed containers, by an appropriate heating medium and where necessary with super-imposed pressure.

Scheduled Process: the thermal process alone or in combination with critical factors, and verified by the thermal process specialist or process authority, for a given product formulation, container type and size and thermal processing system to achieve commercial sterility

of the product.

Standardized process: a thermal process, that has been published and subject to peer review, based on generally accepted scientific principles, and designed to produce a commercially sterile product.

Temperature-Distribution Study: test(s) performed to determine the time, temperature or other parameters that must be met to ensure uniform temperature is established in the retort system.

Thermal Process: the thermal treatment required to achieve commercial sterility and is quantified in terms of time and temperature.

Thermal-Process Specialist: person(s) or organization having expert knowledge of thermal-processing requirements for foods in hermetically sealed containers, having access to facilities for making such determinations, and designated by the cannery to determine the scheduled thermal process(es) and vent schedule(s). The thermal-process specialist is responsible for:

- establishing the thermal process and identifying all critical factors;

- establishing the vent schedule;

- assuring the retort system is capable of delivering the thermal process; and

- analyzing process deviations and providing the processor with appropriate corrective actions.

Time Lapse: the time between sealing containers filled with product and retorting.

Underprocessed Product: product that has been thermally processed but not all of the requirements specified of the scheduled process have been met.

Unprocessed Product: product that has been sealed in containers but has not yet been subjected to a thermal process.

Venting: means the complete removal of air from steam retorts through the vents by the introduction of steam, or other appropriate methods, prior to the attainment of the sterilization temperature.

Vent Schedule: a schedule indicating a specific period of time and a specific temperature that must be achieved in order to effectively remove air from the retort, so that a uniform sterilizing temperature can be obtained throughout the retort. The vent schedule is determined by analyzing data generated during a temperature distribution study.

Verification: confirmation by examination and provision of objective evidence that specified requirements (standard) have been fulfilled.

Water Activity: the ratio of the water vapor pressure of a food to the vapor pressure of pure water at the same temperature and pressure.

4. POLICY

4.1 No thermal process shall be used to process canned fish in a federally registered establishment until a Quality Management Plan (QMP) has been developed and documented and the processor's system verification has been accepted by the Fish, Seafood and Production Division of the Canadian Food Inspection Agency (CFIA) for the specific canned fish product.

4.2.1 The following information must be in the processor's QMP and available for review by the CFIA:

a) management roles and responsibilities (recommended information);

b) product and process information;

c) the product description, which must identify those product attributes and characteristics as described in Section 2 of the Fish Inspection Regulations that are important in ensuring a safe and acceptable canned fish product;

d) the process flow diagram, which must outline all of the production steps and assist in identifying those steps that are important in processing a safe canned fish product meeting all regulatory requirements;

e) a Prerequisite Plan;

f) a Regulatory Action Point Plan; and

g) a Hazard Analysis Critical Control Point (HACCP) Plan.

4.2.2 The following is a list of the type of information that must be maintained in the QMP file:

a) name and address of the thermal-process specialist, or the process authority;

b) product preparation and formulation;

c) container type and size;

d) vent schedule (time and temperature) for the cannery's specific retort system;

e) the process time, process temperature, and cooling procedure for the specific canned fish product being processed;

f) heat-penetration data relating to the canned fish product, or a letter from the cannery's thermal-process specialist or process authority;

g) temperature-distribution study(s) for the retort system and a retort survey (a Cannery Retort Survey is included in Appendix A);

h) method of container loading of the retort;

i) written verification of the thermal process to be used by the processor, provided by the thermal-process specialist or process authority for standardized and non-standardized thermal processes;

j) non-standardized thermal process: written documentation expressing the minimum lethality being delivered by the thermal process in order to achieve commercial;

k) standardized thermal process: written verification provided by the thermal process specialist or process authority that the process produces a commercial sterile product;

l) all critical factors related to achieving commercial sterility must be identified to ensure the adequacy of the thermal process;

m) test conditions used to design the thermal process.

This list is not all inclusive as there may be other information which is relevant to a particular process and that must be recorded in the file.

4.3 The vent schedule shall be based on temperature-distribution studies performed under the supervision of a thermal-process specialist or process authority. The vent schedule shall identify the minimum time and temperature required for a specific retort installation to reach uniform temperature. The vent schedule shall specify the testing conditions and all critical factors that will impact on the retort system reaching uniform temperature. Consideration should be given to steam-header pressure, divider hole size/spacing, valve settings, container loading, maximum number of retorts being vented at one time, and other steam operations that may impact on venting.

4.4.1 The Fish, Seafood and Production Division recognizes Bulletin 26L (Thermal Processes for Low-Acid Foods in Metal Containers) published by the Grocery Manufacturers Association (GMA) as containing standardized processes. When using a standardized process from Bulletin 26L, the processor will not have to report the lethality (F_o) being delivered by the process.

However, the processor must have a thermal-process specialist or process authority verify in writing that the standardized process being used commercially by the processor satisfies all of the process design parameters and critical factors that have been identified with the product being thermally processed, and renders it commercially sterile. Commercial sterility is not defined in the regulations in terms of a sterilizing value (F_o) but it is internationally accepted that a minimum sterilizing value (F_0) of 3 minutes is required to render a low-acid food microbiologically safe. It is the processor's responsibility to determine which critical factors will be used to ensure destruction of the pathogen *C.botulinum* as well as spoilage organisms and based on such information, a sterilizing value (F_0) above 3 may be necessary. Written verification provided by the thermal-process specialist or process authority is to be placed in the processor's QMP file.

4.4.2 If an unstandardized process is used, the processor must have on file documentation supporting the design and development of the thermal process. The thermal-process specialist or process authority must verify in writing that the process being used commercially by the processor delivers a commercially sterile product and report the minimum process lethality (F_o), delivered by the process. Commercial sterility is not defined in the regulations in terms of a sterilizing value (F_o) but it is internationally

accepted that a minimum sterilizing value (F_0) of 3 minutes is required to render a low-acid food microbiologically safe. It is the processor's responsibility to determine which critical factors will be used to ensure destruction of the pathogen *C. botulinum* as well as spoilage organisms and based on such information, a sterilizing value (F_0) above 3 may be necessary to achieve commercial sterility.

4.4.3 All critical factors related to the product, as specified by the thermal-process specialist, must be monitored and controlled as part of the cannery's QMP. The processor must maintain records to demonstrate that these critical factors are being controlled.

4.5 A temperature-distribution test must be conducted to verify the effectiveness of the vent schedule when changes are made to the retort, steam supply piping or to ancillary equipment that may affect temperature distribution. The equipment must also be inspected by the thermal-process specialist, in accordance with the requirements of Chapters 5.2 and 6.2 of this Manual, before production commences. All relevant documentation verifying the vent schedule must be available for review.

Replacement of a steam spreader with an identical spreader would not require additional testing, but replacement of a pipe with a different diameter or a change in hole size or spacing would require a temperature distribution test to validate the change(s). New valves would be accepted providing the processor could demonstrate that the valves had the same flow coefficients (C_v value).

4.6 The CFIA shall audit all retort installations and scheduled thermal processes. The Canadian Food Inspection Agency shall also review the names and qualifications of the thermal-process specialist or process authority used by the processor. The results of the retort audit shall be recorded on the Cannery Retort Survey form (Appendix A) and this form will become part of the cannery QMP audit.

4.7 In the event of a process deviation, the processor shall be responsible under the QMP to have a procedure in place to effectively control the product; evaluate the deviation to ensure that potential health and safety hazards have been addressed and commercial sterility has been achieved; and to take product action as necessary. Product shall be held for evaluation and disposition by the thermal-process specialist or process authority when the critical factors of a scheduled process are not being met by the processor.

4.8 Heat-penetration and temperature-distribution studies being carried out in registered establishments, to develop scheduled processes or vent schedules, must be performed under the direction of a thermal-process specialist or process authority. All relevant data associated with these tests is to be documented in the QMP file.

5. FORMS/DOCUMENTS

The following documents are provided for optional use:

Appendix A - Cannery Retort Survey Reports

APPENDIX A

Cannery Retort Survey Report

PLANT NAME: _____ **LOCATION**:_____

PLANT ADDRESS: _____ **DATE**:_____

1. EQUIPMENT

RETORT SHELL

Diameter_____ Length_____

Single door _____ Double door _____

STEAM SUPPLY

1. Steam header pipe size _____(in.)
2. Pipe size to retort _____(in.)
3. Number of branch lines off main header _____
4. Size of regulating valve _____(in.)
5. Steam line pressure _____(p.s.i.) (regulated Pressure)
6. Steam spreader size _____(in.)
   number of holes _____
   size of holes _____(in.)
7. Boiler type _____
8. Capacity of boiler _____

INSTRUMENTS AND CONTROLS

1. Type of controller unit- _____
2. Controller probe wells bled - Yes_____ No_____
3. Thermometer - range _____
   - degrees per scale division _____
   - easily read from operating station _____
4. Thermometer wells bled _____
5. Pressure gauges - range _____
   - pounds per scale division _____
   - easily read _____
6. Date of last servicing _____

RETORT LOADING EQUIPMENT

Bussy cart _____ baskets _____

Jumble pack _____ divider plates _____ metal _____ plastic _____

divider plate holes- size_____ spacing_____

chimneys used _____

Note: **Attach a drawing of the retort piping and valve configuration to complete this section.**

2. OPERATION

Written instructions provided to retort operator for:

Venting procedure _____

Process time _____

Process temperature _____

Venting Schedule used:

Time_____(min), and

Temperature_____^{0}F minimum

Temperature distribution test conducted by: _____

Date of test: _____

Cooking Processes Used:

Product	Can Size	Init. Temp.	Validated Scheduled Process		
			deg. F	Time(min.)	Temp.(deg.C)
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____

Thermal-process specialist: _____

Can Cooling:

In retort _____
Water spray _____
Water flood _____
Air overpressure _____

Out of retort _____
In air _____
Water channel _____

Cooling Time_____(min.)

Cannery Retort Survey Report - Detailed

Plant Name:_____

Reg.No.:_____

Plant Address: _____ Date: _____

A. RETORT SHELL

Retort Number : _____

Horizontal: Diameter/Width _____ Length _____ No. Of Doors _____

Vertical: Diameter /Width _____ Height _____ No. Of Doors _____

Manufacturer/Date of Manufacture/Model (where available)_____

_____

B. STEAM SUPPLY:

1. No. of Boilers _____
2. Manufacturer/Model No./Capacity_____

   _____
3. Steam header pipe size _____ (in.)
4. Pipe size to retort _____ (in.)
5. Number branch lines off main header _____
6. Size of regulating valve _____ (in.)
7. Steam line pressure _____ (p.s.i., regulated pressure)
8. Steam spreader
   a. Location of spreader _____
   b. Configuration of spreader _____
   c. Pipe diameter _____ (in.)
   d. No. Of Holes _____
   e. Diameter of Holes _____ (in.)
   f. Location of holes on spreader pipe (sketch):
   Show placement of holes on spreader cross-section, indicate retort wall and direction to vent

C. VENT PIPING

1. Water-spreader used for venting? Yes _____ No _____
2. Location of vent (reference steam inlet) _____
3. Smallest restriction in vent outlet _____ (in.)
4. Valve type (if other than gate, describe in full) _____

   _____
5. Valve size _____ (in.)

D. WATER & AIR PIPING, BLEEDERS

1. Water Spreader
   a. Location of spreader _____
   b. Configuration of spreader _____
   c. Pipe diameter _____ (in.)
   d. No. Of Holes _____
   e. Diameter of Holes _____ (in.)
   f. Location of holes on spreader pipe (sketch):

Show placement of holes on spreader cross-section, indicate retort wall

2. Water/Air valves are positive-closing? Yes _____ No (describe) _____
3. Evidence of leaking water/air valves? No _____ Yes (describe)_____
4. Retort Bleeders
   i. Number _____
   ii. Bleeder opening diameter _____ (in)
   iii.Locations (on horizontal retorts reference distance from the retort ends, on all retorts reference steam inlet)_____

   _____
5. Condensate drain visible by operator? Yes _____ No (describe) _____

E. INSTRUMENTS AND CONTROLS

1. Controller Manufacturer & Model No. - _____
2. Controller probe wells bled? Yes____ No____
   a. Bleeder diameter _____ (in.) b. Smallest restriction to bleeder well _____ (in.)

3. Manufacturer's required/equivalent chart type(s):_____
4. Continous Time/Temperature Recorder
   a. Temperature range - _____
   b. No. of degrees per division - _____
   c. Time range - _____
   d. No. of minutes per division- _____
5. Temperature Measuring Device
   a. MIG thermometer ? Yes ____ Other (describe) _____
   b. Length of thermometer scale _____
   c. Temperature range - _____ No. of degrees per division - _____
   d. Easily readable by operator? Yes _____ No (describe) _____
   e. Last calibration date: _____
   f. Calibration records checked: Yes _____ No (describe) _____
   g. Evidence of break in mercury column No ___Yes Describe)_____
   h. MIG thermometer wells bled? Yes____ No____
      1) Bleeder diameter _____ (in.) 2) Smallest restriction to bleeder well _____ (in.)
6. Pressure gauges
   a. Locations: Retort: _____ Main steam supply to retort: _____
   b. Compound -type pressure gauge (on retort) Yes _____ No _____
   c. Gooseneck/Gauge siphon present (on retort) Yes _____ No _____
   d. Range of pressure gauges -_____
   e. Pounds per scale divsion - _____
   f. Easily readable by operator? Yes _____ No (describe) _____
   g. Last calibration dates: _____
   h. Calibration records checked: Yes _____ No (describe) _____
7. Wall clock
   a. No. of clocks: _____ b. Location _____
   c. Clock description (type/size/hh.mm.ss indicated) _____
   d. Easily readable by operator? Yes _____ No (explain) _____

F. RETORT LOADING EQUIPMENT

1. Container Loading Equipment

a. Retort baskets (4-walls & base) _____

i. Bottoms perforated Yes _____ No (describe) _____

ii. Hole diameter & spacing _____ (in.) on _____ (in.) centre, or describe,

_____

_____

b. Retort buggies (base, no walls) _____

i.Bottoms perforated Yes _____ No (describe) _____

ii. Hole diameter & spacing _____ (in.) on _____ (in.) centre, or describe,

_____

_____

c. Flexible container racking used _____

i. Maximum allowable pouch thickness(es) _____

ii. Racking design: Describe, _____

_____

_____

d. Container contact surfaces in good repair, no sharp edges ? Yes _____ No _____

e. Dividers used? Yes _____

i. Divider construction material _____

ii. Hole diameter & spacing _____ (in.) on _____ (in.) centre, or describe,

_____

_____

f. Are chimnies used? No _____ Yes _____

Comments:

**** Attach a drawing of the retort installation to complete this section.**

CANNERY RETORT OPERATION

A. RETORT OPERATION

1. Retort operation is

   a. Fully automated _____ , Describe _____

   b. Partially automated _____ , Describe _____

   _____

   c. Fully manual _____

2. Written instructions are provided to retort operator for:

   Venting procedure? _____

   Cooking time - temperature? _____

   Cooling procedure? _____

   Process Deviation? _____

3. Vent and Thermal Processes are Posted ? Yes _____ No (explain) _____

4. Can Cooling:

In retort?_____ Out of retort?_____

Water spray?_____ In air?_____

Water flood?_____ Water channel?_____

Air overpressure?_____

Where drains are large enough to allow passage of containers drains are screened?

Yes _____ No (describe) _____

Retort cooling water - _____ppm free residual chlorine at discharge from cooling cycle

Retort cooling water protected from contamination after treatment? _____

Cooling water temperature _____ (where critical)

Comments:

B. THERMAL PROCESSES IN USE (*Attach additional pages where required*):

Product Description	Vent	Thermal Process	Critical Factors

CHAPTER 13, SUBJECT 2

GUIDELINES FOR TEMPERATURE DISTRIBUTION STUDIES WHEN PROCESSING IN STEAM-STILL RETORTS EXCLUDING CRATELESS RETORTS

1. INTRODUCTION

These guidelines have been formulated jointly by Agriculture Canada, Fisheries and Oceans Canada and Health Canada. They represent important elements to be considered when carrying out a temperature distribution study[1] for any product to be thermally processed in steam-still retorts excluding crateless retorts.

When appropriate, temperature distribution studies will be evaluated by these departments using the elements given in these guidelines. Only persons experienced and knowledgeable on thermal processing in steam-still retorts should carry out and evaluate the results of such studies.

2. APPLICATION

Temperature distribution studies should be done to: develop or validate a venting schedule; to locate cold or slow heating zones in preparation for heat-penetration studies; in the case of new installations; and for any changes to an installation which may influence the temperature distribution in the product zone. Examples are: changes to steam spreaders, decreased steam pressure in lines, changes to the product loading patterns, changes to the basket and/or dividers, etc.

3. INVENTORY OF THE THERMAL PROCESSING SYSTEM

Prior to the selection of the test retort(s) a survey should be made of the following:

3.1 Lay-out Diagram

A detailed diagram identifying all equipment for which the use of steam is required (including the numbering system used to identify each retort) and the steam supply line

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[1]Adapted from Temperature Distribution Protocol for Processing in Steam-Still Retorts, from the Institute for Thermal Processing Specialists, P.O. Box 2764, Fairfax, Virginia, U.S.A. 22301-0764, (703) 591-1108.

arrangement should be made as prescribed in this section. (Note that it is recommended that all steam lines from the main line to the retort(s) be clearly identified in the diagram from those steam lines feeding other equipment).

3.2 Steam Supply to the Retorts

3.2.1 Boiler(s) Capacity (psi or kPa)

Record potential and actual settings, amount of steam developed and available, i.e., pounds or kilograms of steam produced per unit time.

3.2.2 Retort Header Pressure

It is important to insure that adequate steam pressure and volume is being delivered to the retort(s). This measurement should be taken when maximum operational demand is made on the steam supply.

3.2.3 Headers, Manifolds, Lines and Valves

Record pipe size and length, valve size and types, of the main steam line from the boiler(s) immediately before the pressure/steam regulator to the retort(s).

3.2.4 All Connecting Steam Lines Other than to the Retort

Record size of all connecting steam lines to the main steam line noting other equipment using steam (e.g., blanchers, exhaust boxes, etc.).

3.3 Retort(s)

A detailed diagram of each retort, including associated operational equipment as identified below, should be made. Where identical retort configurations exist, one diagram is sufficient. The designated retort number(s) must be shown on the diagram. The system should include the full manifold system.

3.3.1 Retort shell

Record retort type and internal dimensions. For vertical retorts, note the presence of centring guides and/or baffle plates.

GUIDELINES FOR TEMPERATURE DISTRIBUTION STUDIES

3.3.2 Retort Crates

Record maximum number of crates used in each run as well as their design and dimensions.

3.3.3 Steam Supply from Pressure/Steam Regulator to Retort

Record pipe sizes, valve type and sizes, pressure/steam regulators or reducers and all pipe fittings including steam by-pass lines and steam spreaders (shape, pipe size, length, location; number, size and location of holes in pipe).

3.3.4 Steam Control

Record type of controller (i.e., pressure to air, temperature to air) and location of sensor.

3.3.5 Air System for Controls (if applicable)

Record size of air compressors, air dryer capacity, filter type and location(s). Include the line pressure that must be maintained for operation of the controls and how this pressure is controlled.

3.3.6 Other Piping and Required Equipment

Record the following information:

1. Vents: location, length and size of pipes, also type and size of valves
2. Vent manifold or manifold headers: location, length and size of all pipes, connecting pipes, and valve(s) type(s) and size, where applicable.
3. Bleeders, mufflers: location, number, size and construction
4. Drains: location and size. In addition, note where they drain and whether they are open to the atmosphere.
5. Water supply (if applicable): location and size of pipes, valve type and size.
6. Air supply (if applicable): location and size of pipes, valve type and size, and the available air pressure.
7. Temperature-indicating device (Mercury-in-glass (MIG) thermometer or equivalent): location of the sensing point in the retort and date/year when it was last calibrated.
8. Temperature controller: sensing point location in the

retort.
9. Pressure gauge: location of the sensing point in the retort and date/year it was last calibrated.
10. Additional piping or equipment such as condensate removal systems, etc.

3.3.7 Recording Device

Note type of recording device (recorder or recorder/controller). For more information consult section 7.6.2.2 of the **Recommended Canadian Code of Hygienic Practice for Low-acid and Acidified Low-Acid Foods in Hermetically Sealed Containers (Canned Foods)**.

3.4 Loading Equipment

Record the following information:
1. Container size, loading configuration and maximum number of containers per layer or per basket (scramble pack).
2. Maximum number of baskets in each retort.
3. Hole size and spacing of the basket base plate.
4. Determine the percent open area of the base plate and separator sheets if used in the crates or baskets. Where separator sheets are located over a base plate, they should be positioned to reflect the worst case scenario.

Note: It is important to document the survey findings correctly in order to enable a proper evaluation before selecting the test retort(s). The documented survey should be maintained on company's file and updated when necessary.

3.5 Selection of Test Retort(s)

All information required in section 3 above must be taken into consideration when selecting the test retort(s). The retort(s) selected should represent the worst possible condition that could influence the delivery of the venting procedure. Note that under certain conditions (i.e., when the plumbing and equipment configuration is not identical for all retorts), it may be necessary to carry out a temperature-distribution study of a number of retorts in a system in order to determine which one represents the worst case.

Where all plumbing and equipment configurations are identical, it is generally advisable to select as the worst

possible case the retort which is located at the end of the steam line. However, this is not always the case. This is an area where the knowledge and experience of the specialist supervising the study are of upmost importance.

4. TEST EQUIPMENT

4.1 Data Logger

Note if data logger has a sufficient number of channels to monitor adequately and record temperatures during the temperature-distribution study.

4.2 Thermocouples

Note if thermocouples and lead wires, or other temperature-measuring devices used are of an appropriate type, size, length and number to adequately monitor the temperatures within the retort.

4.3 Temperature-Indicating Device(s)

Note which type used (Mercury-in-glass thermometer or other) see 3.3.6 item 8.

4.4 Pressure-Indicating Device(s)

Note which type used (if required) see 3.3.6 item 9.

4.5 Stuffing Box (packing gland)

Note if diameter is sufficient to accommodate number of lead wires (if thermocouples are used as the temperature measuring device) and specify its location on the retort.

5. STANDARDIZATION OF TEST EQUIPMENT

5.1 **Retort Mercury-in-glass (MIG) Thermometer** (or equivalent temperature-indicating device)

The MIG shall conform with section 7.6.2.1 of the **Recommended Canadian Code of Hygienic Practice for Low-acid and Acidified Low-Acid Foods in Hermetically Sealed Containers (Canned Foods)**. Prior to performing a temperature-distribution test, the MIG thermometer (or equivalent) shall be certified by a recognized authority as

meeting the stated accuracy according to specifications, such as set out by the National Research Council of Canada (NRC), and calibrated. If it has been calibrated and certified in the past 12 months, then it should not have to be done again unless there is doubt as to its accuracy.

5.2 Temperature-Measurement System (e.g., data logger, thermocouples, extension wires or other temperature-measuring devices (TMD), etc.)

1. Prior to conducting a temperature-distribution test, standardization of test equipment (see Section 4) must be performed using the test retort selected. All leads, extensions and connections should be assembled as they will be used under actual operational conditions.
2. Place one or more TMDs in close proximity of the known accurate retort MIG thermometer probe (or equivalent). Care should be taken not to inhibit steam flow past the thermometer probe (or equivalent).
3. The retort is brought up to the temperature to be used during the temperature-distribution tests and the entire system is allowed to run for 10 minutes after equilibrium is reached.
4. All TMDs should be standardized at the intended retort operational temperature. Thus a variance amongst the TMDs to be used can be identified and those which vary by more than 0.3C° (0.5F°) from the standard thermometer should be discarded. The range of all thermometers should be no more than 0.6C° (1F°). After correction factors have been incorporated, all TMDs should give the same reading.
5. In order to meet the above calibration criteria, consideration must be given to minimizing errors due to variables inherent in any component of the temperature-measuring system. For example, the use of thermocouple wire from the same spool is recommended to make all thermocouple leads and extensions[2].

[2]For more information consult the "Standard Guide for Use in the Establishment of Thermal Processes for Foods Packaged in Flexible Containers" ASTM F 1168-88, 1988.

GUIDELINES FOR TEMPERATURE DISTRIBUTION STUDIES

6. PLACEMENT OF THE TEMPERATURE MEASURING DEVICES IN THE RETORT

A minimum of 12 TMDs (or equivalent) should be used. However, the number of TMDs depends upon many factors, for example, size of the retort chamber zone, container size, number and configuration in the baskets, etc.

TMDs shall be placed in the following locations in the retort vessel:

1. In close proximity to the MIG thermometer probe (or equivalent).
2. In close proximity to the temperature controller probe. If this probe is in close proximity to the thermometer probe, this location is not necessary.
3. Guidance as to the placement of TMDs in the product zone can be obtained from the design of the retort and the steam supply and distribution system as well as the loading pattern in the baskets or crates. However, location of cold zones does not always follow logic, specially when determining a venting schedule which requires freedom from steam/air pockets. This is an area where the knowledge and experience of the specialist supervising the study are of upmost importance.

As a general guidance it is recommended to place TMDs in the following manner:

3a. For **Vertical**[3] Retorts:
Temperatures should be measured in the middle of each basket at the top, centre and bottom. If more thermocouples are available, points along the edge at the top and bottom of each basket may be measured. If still more thermocouples are available, other points around the periphery of the basket may be measured.

3b. For **Horizontal**[3] Retorts:
In this type of retort the product is usually in cars. In a horizontal retort thermocouples should be located in the middle of the basket at

[3]Procedures for carrying out a heat penetration test and analysis of the resulting data. Prepared by Irving Pflug, University of Minnesota, 1975. Published by Department of Food Science and Nutrition, University of Minnesota, 100 Union Street, Minneapolis, MN 55455.

the top, centre and bottom of each car. If more thermocouples are available, they should be located at the centre of the outside of the four sides of the car.

Note: A schematic diagram of the placement of all TMDs within the retort and covering all three dimensions should become part of information recorded for the temperature-distribution tests.

4. For determining the initial temperature (IT), TMDs should be placed in a sufficient number of medium-filled testing containers. Generally two containers have been found to be acceptable. Alternatively, a hand-held thermometer may also be used to make that determination. Ideally all containers in the retort should be equilibrated to a previously identified IT.

7. PREPARING THE TEST CRATES OR BASKETS WITH CONTAINERS

a. Select the container size processed in the retorts, usually the smallest, that will yield the worst-case situation for the operation.
b. The product that has the highest heat absorption rate (convection heating) processed in the retorts should be used. Water may be used in the cans in place of product.
c. Containers are placed in the crates or baskets in a manner that is equivalent to the worst-case situation under the commercial operation. If separator or divider sheets are used between the layers of containers, the sheets having the smallest percent total open area shall be used for testing.

8. TEMPERATURE-DISTRIBUTION TEST

8.1 Set-up

1. Review the retort survey
2. Initial Temperature (IT):

The initial temperature is usually determined from the container having the lowest temperature. When determining the test IT, the range of initial temperatures to be encountered during normal commercial operation should be taken into account and the coldest IT be selected.

GUIDELINES FOR TEMPERATURE DISTRIBUTION STUDIES

8.2 Critical Items

The following are critical and should be monitored and recorded during the test.

1. Controller temperature set point.
2. Initial temperature (IT).
3. Retort steam header pressure.
4. Time steam on or "0" time.
5. Time when the drain is closed, if it is open during a portion of the vent.
6. Time that vent is closed, retort temperature at the time the vent is closed as determined by the reference temperature-measuring device (TMD).
7. Time when the reference temperature-measuring device reaches the processing temperature.
8. Time when the controller (if applicable) advances to the "cook" cycle in the program or when the cook begins.
9. Reference temperature-measuring device readings at sufficient intervals, including the time it reaches the processing temperature.

8.3 Important Items

In addition, the following points are important and are highly recommended to be monitored and recorded during the test.

1. Time when the temperature-recording device reaches the processing temperature set point.
2. Retort pressure gauge (optional) readings, at sufficient intervals.

8.4 Conducting the Test

1. The data logger should record the temperature of each TMD just prior to "steam on" and at sufficient intervals - not to exceed one minute - throughout the test. The data logger record shall become part of the test records.
2. Critical items (see 8.2) should be recorded, as required, at intervals of sufficient frequency to describe and verify retort operating parameters during the test. These records shall become part of the test records and shall include the temperature-recording chart(s).
3. The test should extend for at least ten minutes after the retort control systems have stabilized and a definite temperature profile has been established for

all TMDs.

4. In the absence of a maintenance system, each retort should be tested every two years under the worst-case scenario.

8.5 Required Parameters for the Determination of a Vent Schedule

1. On the basis of the data accumulated during the performance of temperature-distribution testing on steam-still retorts, excluding crateless retorts, a vent schedule should specify as a minimum the following critical parameters:
   a. Vent time ("steam on" to vent closed).
   b. Vent temperature (when the vent valve is closed).
   c. Where appropriate, minimum initial temperature (IT).
   d. Use of any opening in the retort (other than the vent valve) during the vent period to increase vent capacity.
   e. Time and temperature when the drain is closed if it is opened during a portion of the vent.
2. For a vent schedule to be determined successfully, it should be based on a minimum of three (3) repeatable runs, and conducted under "worst-case" conditions. "Repeatable" means that all three (3) runs, conducted under the same test conditions, must show that adequate temperature distribution is achieved.

For more information on vents and venting system refer to sections 7.6.3.1.7. and 7.6.3.1.8 of the **Recommended Canadian Code of Hygienic Practice for Low-acid and Acidified Low-acid Foods in Hermetically Sealed Containers (Canned Foods)**.

CHAPTER 13, SUBJECT 3

PROTOCOL FOR CARRYING OUT HEAT-PENETRATION STUDIES

Various methods and equipment may be employed in order to collect accurate heat-penetration data. The overall objective of these guidelines is to recommend procedures for carrying out heat penetration studies for establishing thermal processes necessary to produce commercially sterile foods packaged in hermetically sealed containers. **The following recommendations are to be considered voluntary guidelines.** While this does not preclude the application of other methods and equipment for collecting heat-penetration data, these guidelines have been developed by consensus of the Institute for Thermal Processing Specialists and should be given serious consideration for adoption as methodology by individuals performing heat-penetration studies.

1. NOMENCLATURE

t	Time
t_c	Retort come-up time is the time between the start of heating and the time when the retort reaches processing temperature (at times referred to as CUT)
t_p	Process time is the time from the end of the come-up period to the end of heating (at times referred to as the operator's process time)
T	Temperature
T_c	Container center or coldspot temperature (at times referred to as CT)
T_r	Retort temperature (at times referred to as RT)
T_w	Cooling water temperature (at times referred to as CW)

2. TERMINOLOGY

2.1 *Ballast Containers:* Containers may be required to fill the retort during heat-penetration studies to simulate production retort conditions. Type, shape and size of containers should be the same as used for the intended process. Material used for filling containers could be the test product, or any suitable material having heating characteristics similar to that of the test product, or in some circumstances, water.

2.2 *Cooling Time:* Time required following the introduction of the cooling medium to decrease the internal temperature of the product to a specified value, commonly 35 to 45+ °C (95 to 110+ °F).

PROTOCOL FOR CARRYING OUT HEAT-PENETRATION STUDIES

2.3 *Critical Factors:* Physical and chemical factors that can influence the thermal response of a product to a thermal process, the variation of which may influence the scheduled process, including: container, product, retort and processing conditions.

2.4 *Fill, Drain and Net Weights:* Fill weight is the weight of solids prior to processing; drain weight, the weight of solids after processing; and net weight, the weight of all product in a container.

2.5 *Heat-Penetration Curve:* Plot of the logarithmic difference between either retort temperature and product temperature (heating curve) or product temperature and cooling medium temperature (cooling curve) versus time.

2.6 *Mercury-in-Glass Thermometer (MIG):* Generally used as the retort reference temperature device and regulated for that application by government agencies in some countries. Other temperature-measuring devices may be calibrated against a MIG retort thermometer which has been calibrated against a traceable temperature standard.

2.7 *Resistance-Temperature Detector (RTD):* Thermometry system based on the positive change in resistance of a metal-sensing element (commonly platinum) with increasing temperature.

2.8 *Temperature-Measuring Device (TMD):* Device used for measuring temperature, including: thermometers, thermocouples, RTDs and thermistors.

2.9 *Thermistor:* TMD manufactured from semiconductor materials which exhibits large changes in resistance proportional to small changes in temperature. Thermistors are more sensitive to temperature changes than thermocouples or RTDs and are capable of detecting relatively small changes in temperature.

2.10 *Thermocouple:* TMD composed of two dissimilar metals which are joined together to form two junctions. When one junction is kept at an elevated temperature as compared to the other, a small thermoelectric voltage or electromotive force (emf) is generated which is proportional to the difference in temperature between the two junctions.

PROTOCOL FOR CARRYING OUT HEAT-PENETRATION STUDIES

3. DESIGN OF A HEAT-PENETRATION STUDY

The purpose of a heat-penetration study is to determine the heating and cooling behaviour of a product/package combination in a specific retort system for the establishment of safe thermal processes and evaluating process deviations. The study must be designed to adequately and accurately examine all critical factors associated with the product, package and process which affect heating rates. Numbers of containers per test run, and number of test runs to account for statistical variability are important and discussed in sections 5.11 and 5.12. Before commencing a heat-penetration study, an evaluation of retort temperature and heat transfer uniformity, at times referred to as a heat or temperature distribution study (IFTPS, 1992), should have been completed. A goal in conducting these studies is to identify the worst-case temperature response expected to occur in commercial production as influenced by the product, package and process.

4. FACTORS AFFECTING HEATING BEHAVIOUR

Several product, process, package and measurement-related factors can contribute to variations in the time-temperature data gathered during a heat-penetration test. Establishment of a process requires expert judgement and sound experimental data for determining which factors are critical and the effect of changing those factors both within and beyond established critical limits. The list of items addressed in this section is extensive, but should not be assumed to cover all possible factors. Quantitative data on variability should be recorded where appropriate and all pertinent data should be documented to better understand and account for possible variations in heat-penetration behaviour.

4.1 *Product:*

4.1.1 Product formulation and weight variation of ingredients should be consistent with worst-case production values. Changes in formulation may necessitate a new heat-penetration study.

4.1.2 Fill weight used for heat-penetration studies should not be less than the maximum declared on the process

schedule. Excess product may be expressed as percent overfill.

4.1.3 Solids content should be measured for nonhomogeneous products both before and after processing. Solids content deposited in a sieve should be weighed and expressed as a percentage of total weight. Note: Addition of compressed or dehydrated ingredients may result in increased drained weight.

4.1.4 Consistency or viscosity of semi-liquid or liquid components should be measured before and after processing. Flow behaviour will change with type and concentration of thickening agent (starch, gums, etc.), temperature and shear rate. Changes may be reversible or irreversible which may be important when reprocessing product.

4.1.5 Size, shape and weight of solid components should be measured before and after processing.

4.1.6 Integrity and size of solid component clusters may change during processing and affect temperature sensor placement in the product and coldspot location.

4.1.7 Methods of product preparation prior to filling should simulate commercial practice. For example, blanching may cause swelling, matting or shrinkage which could influence heat-penetration characteristics.

4.1.8 Product matting or clumping may change heat-penetration characteristics and influence coldspot location. Also, caution should be exercised with sliced products which may stack together during processing.

4.1.9 Rehydration of dried components, either before or during processing, is a critical factor which may influence heat-penetration behaviour, as well as process efficacy with respect to spore inactivation. Details of rehydration procedures should be recorded during the heat-penetration study.

4.1.10 Product may heat by convection, conduction or mixed convection/conduction depending on its physical properties. Some foods exhibit complex (broken) heating behaviour. Product may initially heat by convection, then due to a physical change in the product, change to

conduction-heating behaviour. For example, for products such as soups which contain starch, the change in heating behaviour may be due to starch gelatinization at a particular temperature. Small variations in product formulation or ingredients may cause the transition from convection to conduction heating to occur at a different temperature and related time. Special care should be taken to identify and control specific product and process variables related to the heating rates of these products.

4.1.11 Additional product characteristics such as salt content, water activity, pH, specific gravity, concentration of preservatives, and methods of acidification may influence heat transfer or microbiological resistance and should be recorded.

4.2 *Container:*

4.2.1 Manufacturer and brand name information should be recorded in case information related to filling, sealing or processing is required.

4.2.2 Container type (metal cans, glass jars, retort pouches, semi-rigid containers), size and dimensions should be recorded.

4.2.3 Nesting of low profile containers can influence heating behaviour. Heat-penetration studies on jumble-loaded retorts (no racks or dividers) should include tests conducted on stacks of nested cans as well as single cans.

4.2.4 Container vacuum and headspace should be recorded for rigid containers. For flexible and semi-rigid containers the volume of residual gases in the container should be determined. Entrapped gases may create an insulating layer in the container causing a shift in the coldspot location and a decrease in the heating rate. Controlled overpressures during processing have been found to reduce these effects.

4.2.5 Maximum thickness of flexible packages (pouches) has a direct relationship to the coldspot temperature history with thicker packages heating more slowly. Heat-penetration studies should be carried out at the maximum specified package thickness.

PROTOCOL FOR CARRYING OUT HEAT-PENETRATION STUDIES

4.2.6 Container orientation (vertical or horizontal) within the retort may be a critical factor for some product/package combinations and should be studied where appropriate. Changes in container orientation may also influence vent schedules and come-up time.

4.2.7 Postprocessing examination of test containers for abnormalities should be conducted with special emphasis on the slowest and fastest heating containers. It is strongly recommended that flexible packages be carefully examined following processing to identify the thermocouple junction location. If the intended sensing location has shifted, it is likely that heat-penetration data collected are not reliable.

4.3 Method of Fill:

4.3.1 Fill temperature of the product should be controlled. It will affect the initial temperature which may influence some heat-penetration parameters (lag factor, retort come-up period). This may constitute a critical control point for a process, particularly for products which exhibit broken heating behaviour.

4.3.2 Fill and net weights may influence heating rates both in still and rotary cooks. Information on variability may be found in statistical process control and product quality control records.

4.3.3 In most cases, controlling headspace by determining net weight is not sufficient due to possible variations in the specific gravity of the food product. Care should be taken to avoid incorporation of air which would affect the headspace vacuum. In rotary processes, container headspace is a critical control point since the headspace bubble helps mix the product during agitation.

4.4 *Closing or Sealing:* Closing or sealing equipment should provide a strong, hermetic seal which is maintained during the thermal process. Vacuum in cans and jars for most canned foods is recommended to be between 35-70 kPa (10-20 in-Hg) measured at room temperature. Vacuum is affected by variables such as: headspace, product temperature, entrapped air, and vacuum efficiency of the closing equipment. Some products such as vegetables vacuum-packed in cans may have a minimum vacuum as a critical control point. For others packed in flexible or

semi-rigid containers, vacuum setting will influence the residual air content in the package, also constituting a critical control point.

4.5 *Retort System:* The type of retort system used may have a significant influence on the heating rates of products processed in the retort. Results from a heat-penetration test should be reported with reference to the retort type and conditions existing at the time of testing.

4.5.1 Retort come-up time should be as short as possible, consistent with obtaining satisfactory temperature distribution. Laboratory size retorts may be used for development work on heat-penetration behaviour. Results will be conservative when the smaller retorts have shorter come-up times and cool more quickly than production retorts. After development, the thermal process should, if physically possible, be verified in an appropriate production retort.

4.5.2 Racking systems may be used to separate layers of cans or jars, constrain the expansion of semi-rigid and flexible containers, provide support and circulation channels for thin profile containers, and ensure maximum pouch thickness is not exceeded. Care should be taken to understand the influence of a specific rack design on retort performance and heat transfer to containers.

4.5.3 Still batch-retort systems vary in operation based on: type of heating medium (steam, steam/air, water immersion, water spray); orientation of the retort (vertical, horizontal); method of heating medium agitation (fans, pumps, air injection); and other factors which may influence the heating behaviour.

4.5.4 Rotational batch retort systems (axial, end-over-end) are designed to rotate (or oscillate) entire baskets of product during processing. Container agitation may provide faster rates of heat penetration to the container coldspot as compared to still cooks. However, while this is true for some containers, it may not be so for all containers within a load and caution must be exercised to identify the slowest heating containers. This may entail a detailed can position study. It is recommended that during initial testing, data be collected at small time increments (15 s) particularly for viscous fluids where the coldspot may move in relationship to a fixed

thermocouple during rotation, producing erroneous results. Slip-ring connectors should be cleaned and thermocouple calibration verified at regular intervals. Critical factors in these retorts include: headspace, product consistency, solids to liquid ratio, initial temperature, container size, rotational speed and radius of rotation.

4.5.5 Continuous retort systems may move containers through the processing vessel along a spiral track located at the outside circumference of a horizontal retort shell or be carried through a hydrostatic retort in chain driven flights. Regardless of the configuration, it becomes difficult or impossible to use thermocouples to collect heat-penetration data in these systems. Data may be obtained using self-contained temperature measurement and data storage modules in the commercial vessel or by using process simulators.

5. TEMPERATURE MEASUREMENT AND DATA ACQUISITION

5.1 *Data Acquisition System*: Accuracy and precision of the data acquisition system (datalogger) used for heat-penetration studies will affect temperature readings. Dataloggers are typically comprised of a multi-channel temperature-measuring and digital-data-output system. Calibration of a data-acquisition system should include verification of the data-acquisition rate, since errors in the time base would result in erroneous data.

5.2 *Type of Thermocouple:* The most common TMDs used in thermal processing are duplex Type T (copper/constantan) thermocouples with Teflon insulation. Common configurations are flexible wires (20-, 22- or 24-gauge) and rigid needle types. Details on thermocouples and connecting units are available in Bee and Park (1978) and Pflug (1975).

5.3 *Type of Connectors and Associated Errors:* Connectors used in a thermocouple circuit are fittings attached to a thermocouple within which electrical connections are made. Several types of connectors are available for specific applications and thermocouple type. Caution must be exercised to avoid certain sources of error which may be associated with the use of connectors and extension wires. These include: disparity in thermal emf between

thermocouples, connectors and extension wires; temperature differences between two wire junctions; and reversed polarity at the thermocouple-extension wire junction. Thermocouple connectors should be cleaned frequently with metal cleaner to assure good electrical contact and prevent errors in thermocouple readings. Similar concerns should be addressed when using RTDs and thermistors.

5.4 *Thermocouple Calibration:* Thermocouples should be calibrated against a traceable calibration standard (thermometer, RTD, thermistor). Inaccuracies in temperature measurements may result in errors in process evaluation; hence, frequent calibration is essential to provide reliable data. Factors affecting calibration include: worn or dirty slip-rings; improper junctions; metal oxidation; multiple connectors on one lead, and inadequate datalogger cold junction compensation. As a consequence, thermocouples should be calibrated in place as part of the complete data-acquisition system. Some precautions when using thermocouple-based data-acquisition systems include: minimizing multiple connections on the same wire; cleaning all connections; grounding the thermocouples and recording device; slitting thermocouple outer insulation outside the retort to prevent flooding of datalogger or data recording device (see NFPA, 1985, or ASTM, 1988 for illustrations); and using properly insulated thermocouple wires.

5.5 *Positioning of Thermocouple in the Container:* The method of inserting a thermocouple into a container should result in an airtight, watertight seal which should be verified after testing. Thermocouple sensing junctions should be positioned in the slowest heating component of the food product and situated in the slowest heating zone within the container. During insertion of the thermocouple, caution must be taken to avoid physical changes to the product. Also, the method employed for mounting the thermocouple into the container should not affect the container geometry which could influence heat-penetration characteristics. Flexible or rigid thermocouples may be inserted into rigid, flexible and semi-rigid containers using compression fittings or packing glands. For flexible containers, NFPA (1985) provides illustrations of thermocouple positioning into a solid particulate and several thermocouple positioning devices to ensure the thermocouple remains in a fixed

position within the container. The most appropriate device for a particular application will depend upon the product, racking system, container type and sealing equipment. Leakage may be detected by weighing the container before and after processing to determine changes in gross weight. If there is leakage caused by improperly mounted thermocouples, data collected for that container should be discarded. Note: Ecklund (1956) reported correction factors for heat-penetration data to compensate for errors associated with the use of non-projecting, stainless steel receptacles. While not reported in the literature, this may also be a concern with other fittings.

5.6 *Type and Placement of Containers:* The type and size of container used in the heat-penetration study should be the same as that used for the commercial product. The racking and loading of rigid (cans), semi-rigid (trays and cups) and flexible (pouches) containers should simulate commercial practice. Test containers should be placed at the slowest heating location in the retort, as determined by temperature and heat transfer distribution studies.

5.7 *Temperature of the Heating Medium:* TMDs should be positioned so as to prevent direct contact with racks or containers and identified according to their specific location in the retort. A minimum of two thermocouples is recommended for retort temperature measurement: one situated close to the sensing bulb of the retort MIG thermometer, the other located near the test containers. In addition, at least one thermocouple should be placed near the sensor for the temperature controller when that location is remote from the location of the MIG thermometer bulb.

5.8 *Retort Pressure:* Overpressure conditions during processing will influence package expansion by constraining the expansion of headspace gases. This may be beneficial by improving heat transfer to food in flexible and semi-rigid containers or detrimental by restricting the size of the headspace bubble in rotary processes. For steam/air retorts, overpressure conditions are also related to the steam content of the heating medium at a particular processing temperature which may influence heat transfer conditions within the retort. In addition, cooling without overpressure may result in

depressurization within a container upon collapse of steam at the end of a process, leading to accelerated decreases in temperature for fluid foods.

5.9 *Coldspot Determination:* The location of the slowest heating or coldspot in a container is critical to establishing a process. For a conduction heating product in a cylindrical can with minimal headspace, the geometric center of the can is considered to be the slowest heating spot. Generally, if a larger headspace is included, the coldspot may shift closer to the top of the can due to the insulating effect of the headspace which may be significant if the height-to-diameter ratio of the can is small. The coldspot location in vertically oriented cylindrical cans containing products which heat by natural convection may be near the bottom of the container. Products which exhibit broken heating behaviour may have a coldspot which migrates during heat processing as the physical properties of the product change. The use of containers with different geometries or constructed from different materials may have differing effects on coldspot locations. A coldspot-location study should be completed to determine the slowest heating location for a specific product/package/process combination. Usually, the coldspot location will be determined from a series of heat-penetration tests employing several containers with thermocouples inserted at different locations. Alternatively, more than one thermocouple per container may be used; however, multiple thermocouples may influence heating behaviour, especially for products in smaller containers. In all cases, care should be taken to determine the "worst case" anticipated during production. Careful judgement, based on a number of preliminary experiments, must be exercised to ensure the coldspot location has been identified.

5.10 *Initial Product Temperature:* Measurement of initial product temperature should be taken immediately prior to testing.

5.11 *Number of Containers per Test Run:* A heat-penetration test should evaluate at least 10 working thermocouples from each test run (NFPA, 1985). If the retort cannot accommodate this quantity, the number of replicate test runs should be increased.

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5.12 *Number of Test Runs:* Replication of heat-penetration test runs is important in order to obtain results which account for run-to-run, product, container and process variability. After initial coldspot-determination tests are completed and all critical factors have been determined, at least two full replications of each test are recommended. Should results from these tests show variation, a minimum of a third test is recommended. Variation in the results is expected and quite common, especially for products which are non-homogeneous or exhibit complex heating behaviour. Variability is generally evaluated based on plots of the heating and cooling curves and/or lethality calculations and should be considered when identifying or predicting the slowest heat behaviour of a process

6.0 SUMMARY OF DOCUMENTATION

The following provides a summary of details which may be incorporated in a checklist and documented in their entirety or partially as deemed appropriate for a specific study. Other factors not listed in this section may also be relevant.

6.1 *Pre-test Documentation:*

6.1.1 Product Characteristics
6.1.1.1 Product name, form or style, and packing medium
6.1.1.2 Product formulation and weight distribution of components
6.1.1.3 Net weight and volume
6.1.1.4 Consistency or viscosity of the liquid component
6.1.1.5 Size, shape and weight of solid components
6.1.1.6 Size of solid component clusters
6.1.1.7 pH of solid and liquid components
6.1.1.8 Methods of preparation prior to filling (ingredient mixing methods, special equipment)
6.1.1.9 Matting tendency
6.1.1.10 Rehydration of components
6.1.1.11 Acidification procedures
6.1.1.12 Other characteristics (% solids, density, etc.)
6.1.2 Container Description
6.1.2.1 Container material (brand name and manufacturer)
6.1.2.2 Type, size and inside dimensions
6.1.2.3 Container test-identification code
6.1.2.4 Maximum thickness (flexible container)
6.1.2.5 Gross weight of container

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6.1.2.6 Container nesting characteristics
6.1.2.7 Slowest heating or coldspot location in container
6.1.3 Data-Acquisition Equipment and Methodology
6.1.3.1 Identification of datalogging system
6.1.3.2 Thermocouple and connector plugs maintenance
6.1.3.3 Thermocouples and connectors numbered
6.1.3.4 Electrical ground checked
6.1.3.5 Thermocouples placed in heating medium and readings compared with a reference TMD
6.1.3.6 Type, length, manufacturer and identification code of thermocouples and connectors
6.1.3.7 Thermocouple location in container
6.1.3.8 Positioning technique for thermocouple
6.1.3.9 Calibration data for each thermocouple
6.1.4 Fill Method
6.1.4.1 Fill temperature of product
6.1.4.2 Fill weight of product
6.1.4.3 Headspace
6.1.4.4 Filling method (comparison to commercial process)
6.1.5 Sealing Operations
6.1.5.1 Type of sealing equipment
6.1.5.2 Time, temperature, pressure and vacuum settings (if applicable)
6.1.5.3 Gas evacuation method
6.1.5.4 Can vacuum
6.1.5.5 Volume of residual gases in flexible containers
6.1.6 Retort System
6.1.6.1 Retort system: still or rotary (end-over-end, axial, oscillatory)
6.1.6.2 Reel diameter (number of container positions) and rotational speed
6.1.6.3 Can-position study data for batch rotary retorts
6.1.6.4 Heating medium (steam, steam/air, water immersion, water spray) and flow rate
6.1.6.5 Circulation method for water or overpressure media
6.1.6.6 Temperature distribution records
6.1.6.7 Retort venting schedule
6.1.6.8 Retort identification number
6.1.7 Loading of Retort
6.1.7.1 Loading or racking system details
6.1.7.2 Location of test containers in retort (slowest heating zone)
6.1.7.3 Container orientation
6.1.7.4 Location of thermocouples for retort temperature measurement
6.1.7.5 Use of ballast containers to ensure fully loaded retort (some retort systems)

6.1.7.6 Selected time interval for data-logging system
6.1.8 Additional Information
6.1.8.1 Date
6.1.8.2 Test identification
6.1.8.3 Processor and location
6.1.8.4 Individual(s) performing heat-penetration test

6.2 *Test-Phase Documentation:*

6.2.1 Test run identification
6.2.2 Initial temperature of product at the start of heating
6.2.3 Time heating starts
6.2.4 Time vent closed and temperature, if applicable
6.2.5 Temperature indicated on MTG thermometer
6.2.6 Time retort reaches set point temperature (tc)
6.2.7 Pressure from a calibrated pressure gauge or transducer
6.2.8 Time process begins
6.2.9 Time cooling begins (pressure cooling, if applicable)
6.2.10 Time cooling ends
6.2.11 Rotation speed (if applicable)
6.2.12 Cooling water temperature
6.2.13 Any process irregularities or inconsistencies

6.3 *Post-Test documentation:*

6.3.1 Container net and gross weight check for leakage
6.3.2 Thickness of container
6.3.3 Location of the thermocouple and whether or not it is impaled in a food particle
6.3.4 Measurement of container vacuum (rigid metal and glass) or residual air content (flexible and semi-rigid containers)
6.3.5 Post-processing product characteristics: syrup strength, appearance, viscosity, headspace, drained weight, pH, consistency, shrinkage, matting, clumping
6.3.6 Container location and orientation (jumble pack)

7. LITERATURE CITED

ASTM. 1988. Standard Guide for Use in the Establishment of Thermal Processes for Foods Packaged in Flexible Containers. F 1168-88. American Society for Testing and Materials, Philadelphia, PA.

PROTOCOL FOR CARRYING OUT HEAT-PENETRATION STUDIES

Bee, G.R. and Park, D.K. 1978. Heat-penetration measurement for thermal-process design. *Food Technol.* 32(6): 56-58.

CFPRA. 1977. Guidelines for the Establishment of Scheduled Heat Processes for Low-Acid Foods. Technical Manual No. 3. Campden Food Preservation Research Association, Chipping Campden, Gloucestershire, UK.

Ecklund, O.F. 1956. Correction factors for heat penetration thermocouples. *Food Technol.* 10(1): 43-44.

IFTPS. 1992. Temperature Distribution Protocol for Processing in Steam-Still Retorts, Excluding Crateless Retorts. Institute for Thermal Processing Specialists, Fairfax, VA.

NFPA. 1985. Guidelines for Thermal Process Development for Foods Packaged in Flexible Containers. National Food Processors Association, Washington, DC.

Pflug, I.J. 1975. Procedures for Carrying Out a Heat-Penetration Test and Analysis of the Resulting Data. University of Minnesota, Minneapolis, MN.

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Institute For Thermal Processing Specialists
P.O. Box 2764 · Fairfax, VA 22031-0764
Telephone: (703) 591-1108 · Fax (703) 591-5903