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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



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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.



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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



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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



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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.



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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.



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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



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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 than 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



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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



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- 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



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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.



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- 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



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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.



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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.



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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



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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 and 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:



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- ◆ 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.



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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



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- 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



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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



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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



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- 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.



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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.



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**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	



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**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	
<p>Comments/Notes:</p> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>			
<p>Signature of CV team leader:</p>			



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**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				



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**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:



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**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)	



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**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



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**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: _____



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**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:



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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.



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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



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**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 Verification 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



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**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: <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	
Signature of team leader: _____	



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**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 - breeding - 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



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**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	<p style="text-align: center;">→ →</p> <p>The Task List is linked to the Objective Evidence column</p> <p style="text-align: center;">→ →</p>	<p style="text-align: center;">→ →</p> <p>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.</p>	The finding is a conclusion drawn about whether or not the QMP requirement is being met based on the objective evidence



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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?	<p>Examples</p> <p><u>Interview</u> 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?</p> <p><u>Observe</u> If a plan has 16 SOPs, look at the 5 most critical to compliance.</p> <p><u>Inspect</u> If there are 6 packaging materials, pick 2 that are in direct contact with fish being processed.</p> <p>If there are 8 ingredients used in the plant, look at the 2 being used in the process.</p>		



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<p>EXAMPLE</p> <p>Plant Sanitation, Employee Hygiene and Pest Control</p> <p>Control measures</p> <ul style="list-style-type: none"> - do they match those described in the QMP plan? - are they effective in achieving compliance? <p>Monitoring procedures</p> <ul style="list-style-type: none"> - do they match those described in the QMP plan? - are they effective in checking adherence to control measure? <p>Corrective actions</p> <ul style="list-style-type: none"> - are they effective and appropriate to correct the non-conformity and to prevent recurrence? - do records document non-conformities? 	<p><u>Observe</u></p> <ul style="list-style-type: none"> - 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? <ul style="list-style-type: none"> - Does the cleanup crew have adequate equipment? <p><u>Inspect</u></p> <ul style="list-style-type: none"> - 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? <p><u>Interview (suggested questions)</u></p> <ul style="list-style-type: none"> - 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? <p><u>Record Review</u></p> <ul style="list-style-type: none"> - 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? 		
---	--	--	--