Ministry for Primary Industries
Manatū Ahu Matua

Guidance Document

Operator Verification

A Guideline for Risk Management Programme (RMP) Operators

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Guidance Document: Operator Verification

A guideline for Risk Management Programme (RMP) operators.

Who should read this document?

This Guidance Document has been developed to provide guidance for risk management programme (RMP) operators to assist them to meet the requirements of the Animal Products Act 1999 (APA).

You (i.e. RMP operator) should read this guidance together with the Risk Management Programme (RMP) Manual and any other relevant operational code or guide (e.g. Guidance Document Further Processing, Processed Meat Code of Practice).

Related Documents

The requirements and guidance to which this document relates are:

- Animal Products Act 1999
- Animal Products Notice: Specifications for Products Intended for Human Consumption
- Animal Products (Risk Management Programmes Specifications) Notice
- Risk Management Programme (RMP) Manual

Document history

Version Date	Section Changed	Change(s) Description
June 2020	N/A	New document

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Contents

1 Purpose

This Guidance Document provides guidance for risk management programme (RMP) operators in the development and implementation of effective operator verification to meet the requirements of the Animal Products Act 1999 (APA).

It has been developed to cover all animal product activities under a registered RMP, however not all examples provided will be applicable to each sector.

The requirements that have a strong regulatory basis are indicated by the term **"must"** and the relevant law has been cited in [square brackets]. You are expected to comply with the "must" procedures that are applicable to your products and processes.

Guidance, indicated by "**should**", provides explanatory information and examples or options for achieving a particular requirement. You may use alternative methods or approaches to those set out in this guide, provided they do not compromise your good operating practices (GOPs) and the achievement of the requirements.

Note: There are additional requirements that are not covered in detail in this Guidance Document such as General requirements for export (GREX), Overseas Market Access Requirements (OMARs) and export certificates (Official Assurances). You should take necessary steps to ensure that you are complying with all relevant requirements under the APA in regards to your operation.

2 Definitions

The terms used in this Guidance Document are generic to avoid conflict and confusion with other MPI documents. Where the terms are different from those used by your sector, refer to the definition(s) of the term(s) below for interpretation.

In this Guidance Document:

animal product, or product means any animal material that has been processed (other than simply transported or stored in such a way as not to involve any alteration to its nature) for the purpose, or ultimate purpose, of consumption or other use by humans or animals [APA]

corrective action means action taken when the results of monitoring indicate a loss of control. A corrective action can be a step towards a preventive action

external verification means the process of verification of activities conducted under a risk management programme by a recognised person

good operating practice (GOP) (including pre-requisite programmes, supporting systems, good agricultural practice, good hygienic practice and good manufacturing practice), means documented procedures relating to practices that:

a) are required to ensure animal material and animal products are fit for their intended purpose; and
b) are appropriate to the operating circumstances

HACCP (Hazard Analysis and Critical Control Point) is a system adopted by the Codex Alimentarius Commission and is a systematic identification of hazards and the measures for their control to ensure the safety of food

non-complying (non-compliance) means any material or product or input or procedure that fails to comply with regulatory requirements

operator, in relation to an animal product business, means the owner or the other person in control of the business

personnel include owners, directors, staff, operators, cleaners, other workers (such as maintenance contractors) and visitors

preventive action means action taken to rectify, eliminate the causes of and prevent reoccurrence of any non-compliance identified in the RMP

recognised evaluator means a person recognised by the Director-General under section 103 of the Act to perform evaluation functions and activities in relation to RMP

recognised verifier means a person recognised by the Director-General under section 103 of the Act to perform verification functions and activities in relation to RMP

root-cause means a fundamental cause of any problem/condition/failure of a process or system resulting in non-compliance or non-complying product(s)

routine monitoring is the day–to-day checks to determine if the systems and processes are complying with the RMP and to identify any non-compliances or problems

suitably skilled person means a person who in the opinion of the RMP operator is skilled in a particular activity or task through training, experience or qualifications

Any term or expression that is defined in the APA, or regulations made under the APA and used, but not defined, in this Guidance Document has the same meaning as in the APA or regulations.

3 Background

Operator verification is defined in the clause 4 of the Animal Products (Risk Management Programme Specifications) Notice [RMP Spec].

You must document an operator verification system that is carried out to check that your RMP has been implemented effectively, monitoring is occurring as scheduled, appropriate corrective actions and preventive actions are taken when limits are not met and all reporting requirements are met [RMP Spec 16].

An effective operator verification system will provide you and the external verifier with the confidence that your RMP is working as intended and the resulting animal products are fit for their intended purpose.

The Ministry for Primary Industries (MPI) performance based verification (PBV) system allows the frequency of external verification to be based on the RMP's performance. An effective operator verification system that ensures good performance will result in better outcomes during external verification and may sometimes have the added benefit of less frequent external verification or verification at intervals at the ceiling step.

4 What is Operator Verification?

Operator verification is the checks and activities performed by you as an operator that confirms your RMP is:

- in compliance with legislation;
- in compliance with your documented system; and
- effectively managing any food safety hazards, wholesomeness and false or misleading labelling.

Under the RMP Spec, you are required to have a documented operator verification system in your RMP. Refer to Part 5: What to include in your Operator Verification System? within this document for more detail.

Operator verification is not routine monitoring, validation or external verification. Routine monitoring includes all the day-to-day checks and activities to determine whether the systems and processes are implemented according to your RMP.

Note

Validation is the process of collecting evidence (e.g. scientific technical information or records) to show that your RMP is capable of consistently producing the desired outcome (i.e. to produce animal materials or animal products that are fit for their intended purpose).

The differences between operator verification and external verification are explained in Table 1: Difference between operator verification and external verification and Figure 1: How does external verification, operator verification and routine monitoring activities work within your RMP?

Table 1: Difference between operator verification and external verification

Operator verification	External verification
• Carried out by an RMP operator (e.g. day-to-day manager) or a contractor. • Periodic checks to confirm that the RMP is properly implemented, being followed, appropriate actions are taken when things go wrong and resulting products are fit for their intended purpose. • Gives confidence to the operator that the products are fit for their intended purpose. • Carried out through reviewing of monitoring records, internal audits, reality checks, etc. • Helps to identify the areas that need improvement. • Provide regular information about the compliance of the RMP.	• Carried out by an external verifier (i.e. recognised person). • Verification checks to determine whether the RMP operations are in compliance with the legislative requirements and the products are fit for their intended purpose. • Carried out through scheduled and unscheduled audits by the external verifier. • Audit report will identify any non-compliances that require immediate correction and the areas that need improvement if the RMP is in substantial compliance with requirements under the APA. • Provide a "snapshot" of the RMP at the time of the audit.

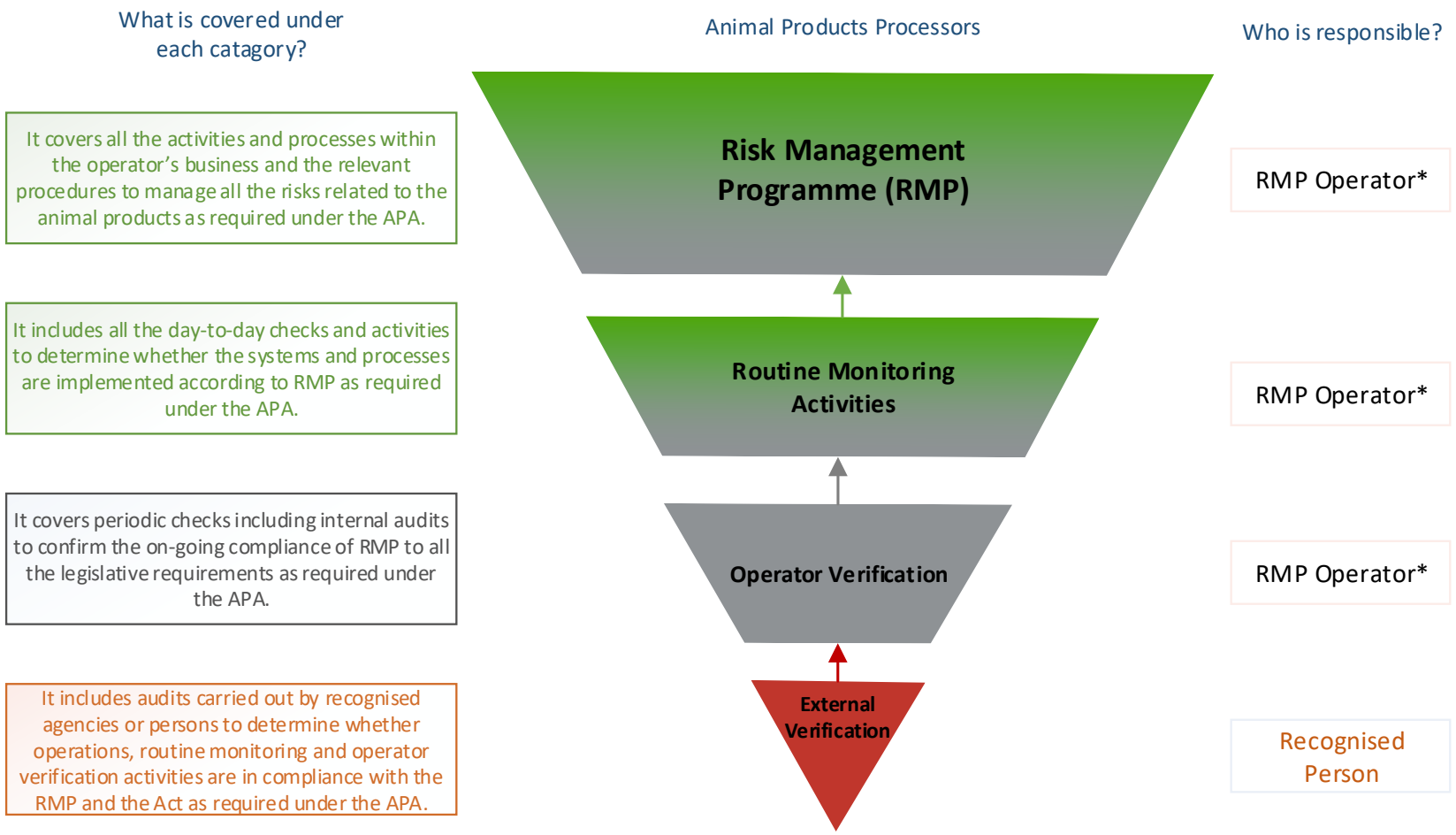
External verification is not part of operator verification but the outcome of external verification may provide you with an insight on what to focus on during operator verification. For example, if external verification finds a number of non-compliances that have not been identified by you, then this indicates that some part(s) of your operator verification system or the routine monitoring system may not be working properly. It is acknowledged however that external verification is a "snapshot" at a particular point in time and some differences in findings may be expected.

You must carry out operator verification to determine whether your operations and processes are complying with the RMP. Ideally the person carrying out operator verification should be independent of the process being verified, i.e. the personnel who verifies should not be checking their own work. It is noted that in small operations this may not always be possible [RMP Spec 16].

Operator verification can be viewed as a form of self-assessment. If you are not picking up your mistakes or deviations from documented procedures and rectifying them, it is both an indication of a lack of operator control(s) and that your current operator verification system is inadequate and should be reviewed.

Examples of activities under routine monitoring, operator verification and external verification are listed in Table 2: Examples of activities under routine monitoring, operator verification and external verification.

Figure 1: How does external verification, operator verification and routine monitoring activities work within your RMP?



*Note: Though the day-to-day Manager is responsible for managing all activities related to their RMP, routine monitoring and operator verification, it is acknowledged that these activities may be performed by several others (e.g. staff members, contractors) within the RMP and reported to the day-to-day Manager.

Table 2: Examples of activities under routine monitoring, operator verification and external verification

Category	Examples of activities
Routine monitoring	Regular checks at CCPs, temperature checks, pre-operational checks, load-in and load-out checks, etc.
Operator verification	Reality checks, record reviews, internal audits, GOPs review, etc.
External verification	A selection of areas within the RMP may be checked during each verification. The scope of the external verification can vary for each visit. Some activities within your RMP may be included in the verification at higher frequency.

5 What to include in your Operator Verification System?

Operator verification system includes dedicated activities designed to gather evidence that answers the following questions:

a) does your RMP documentation include all of the aspects that the legislation requires, i.e. is it up to date/still current?
b) do you do what you say you are doing in practice, i.e. is your RMP being implemented as written?
c) is what you are doing in practice, effective, i.e. are products fit for their intended purpose?

Operator verification system may include activities such as:

a) reviewing of monitoring records (including CCP monitoring) to confirm that the required checks are carried out according to the procedures;
b) confirming test limits and/or parameters continue to be met;
c) reviewing the list of product tests and their results;
d) reviewing of corrective action records to ensure that defects, non-compliances or non-complying products are being identified;
e) reviewing if appropriate corrective actions were taken or a procedure is in place to rectify the non-compliances within specified timeframes (including review of the disposition of any non-complying products);
f) reviewing of non-complying product to ensure it is adequately controlled and the root-cause that resulted in the production of non-complying product is included in the appropriate internal audit;
g) confirming that procedures have been reassessed after an event (e.g. non-compliances) or changes in the RMP (e.g. changes in personnel) to ensure that corrective (and preventive) actions taken are effective;
h) reviewing non-compliances close outs to ensure they are addressed adequately within the agreed timeframes;
i) reviewing of the hazard analysis critical control point (HACCP) system and its records;
j) carrying out internal audits of all aspects of the RMP; and
k) conducting periodic review of the whole RMP.

Operator verification system should be documented and include:

a) the identity of the personnel or position(s) who will carry them out;
b) when, where and how they will be carried out;
c) the frequency of operator verification;
d) clear references to various in-house non-compliance management systems i.e. it should be clear on how findings are recorded for effective follow up
(Note: most RMPs will have one non-compliances management system and some of the bigger RMP premises may have more than one);
e) the actions to be taken if non-compliances are found (i.e. procedures are not being followed, etc.);

f) the records to be kept to show that operator verification has been done as planned;
g) procedures for how any subsequent change in the frequency or operator verification system is made as a result of findings;
h) identification of the person(s) or position(s) (preferably someone representing management) who should acknowledge or sign off on the operator verification reports.

Operator verification system should include follow-up checks or increased surveillance to ensure that once a non-compliance is fixed, it doesn't recur. Not following up on previously identified non-compliances is frequently the biggest cause of unacceptable audit outcomes during external verification.

Some examples of what you can include in operator verification system are provided in Table 3: Suggested content for an operator verification system. Your operator verification system should cover all the key areas of operation and be tailored to your RMP.

Table 3: Suggested content for an operator verification system

Section	Suggested headings	Examples of what to include
1	Scope and purpose	A scope and purpose statement (e.g. The scope of operator verification is to conduct periodic checks including reality checks and internal audits to confirm the on-going compliance of your RMP to the legislative requirements and the operations within your RMP).
2	Authorities and responsibilities	Name of the personnel or position(s) responsible for operator verification, the designated back-up personnel and the skills or training required by them (e.g. internal audit training).
3	Materials and equipment (where appropriate)	List of the equipment used to perform operator verification? (e.g. temperature probe) How often will you be using the equipment to check your RMP?
4	Procedures	Specific detail of how operator verification will be carried out for each operation/process and information about the personnel carrying it out. This should include how the operations/processes will be randomised to remove risk of over familiarity with areas/shifts.
5	Recording and reporting	Requirements and responsibilities for recording and report writing (including a clear instructions of what is required to be recorded as objective evidence). **Note:** the reports should include information such as which records or operations were sighted, who was interviewed and against what version of the procedures the verification activities was done etc. It should include positive observations as well.
6	References to other relevant documents	Reference to your registered RMP that includes e.g. GOPs, management of non-compliance programme.

5.1 Responsibilities and capabilities

You should ensure that you have a designated position or personnel and a backup personnel, where possible, who are suitably skilled persons to carry out operator verification.

5.1.1 Duties and responsibilities

It is very important that the personnel undertaking operator verification:

a) have the appropriate knowledge and skills;
b) understand the responsibilities associated with the role; and
c) are independent from the procedures and processes being checked as much as possible.

5.1.2 Minimum expected capabilities

Personnel (e.g. suitably skilled person) undertaking operator verification should:

a) have knowledge of the operations, processes and systems which they are verifying;
b) understand the legislation associated with the operations and processes which they are verifying;
c) understand the responsibilities associated with operator verification;
d) ensure the scope of internal audits covers ALL elements within the RMP over a period of a year;

Note

If you are exporting, you will need to include any additional market access requirements such as General Requirements for Export (GREX), the Official Assurance Specifications and Overseas Market Access Requirements (OMARs) within your operator verification programme.

e) have good auditing skills (Note: these skills can be maintained by personnel completing appropriate and relevant trainings or courses);
f) have good communication and report writing skills and be able to effectively record internal audit activities;
g) know who to report to if non-compliances are identified (or be able to action themselves);
h) know where to register or log the non-compliances and 'trigger' timely follow up; and
i) know how to escalate the non-compliances if they are not resolved.

5.2 Scheduling of operator verification

The main objectives for a scheduled operator verification are:

a) to verify all the GOPs are working effectively; and
b) to identify changes to the processes, procedures and new hazards within the RMP and ensure that all changes have been effectively managed.

The frequency of operator verification should be set at a level that is appropriate to your RMP. When setting frequencies, it is better to start with a higher frequency and review this over time. Refer to Table 4: Things to consider when setting frequencies for operator verification.

In considering frequencies, the following should be taken into account:

a) risk profile of the products and processes;
b) size of the production quantities or volumes;
c) overall complexity of the operation; and
d) experience of personnel.

Table 4: Things to consider when setting frequencies for operator verification

Activity	Consider continuing or potentially decreasing the frequency	Consider increasing the frequency
Internal audit	Evidence indicates your RMP continues to remain effective.	Evidence indicates that some parts of your RMP don't comply.
Performance at external verification	Continuation of acceptable outcomes.	Receiving an unacceptable audit outcome.
Personnel and management	Experienced and relatively stable workforce.	Frequent changes in personnel, particularly those with RMP oversight responsibilities, should always be monitored to see what impact this has had on your RMP operation. **Note:** Loss of key personnel is recognised as a common precursor for dropping performance.
The operation itself	Remains relatively consistent with little variation or change.	Is variable or changes frequently.

Businesses carrying out processing of low-risk products, or with a relatively stable workforce, may need less frequent operator verification (refer to Table 5: An example of operator verification frequency for businesses producing low risk products).

Table 5: An example of operator verification frequency for businesses producing low risk products

Activity	Frequency
Record reviews for each GOP	Once every 3 to 6 months
Reality checks of each GOP	Once every 3 to 6 months
Full review of RMP	Annually[1]

Businesses carrying out processing of higher risk products, or with a less stable workforce or frequently changing operations or with range of complex processes, may need operator verification more frequently (refer to Table 6: An example of operator verification frequency for businesses producing high risk products).

Table 6: An example of operator verification frequency for businesses producing high risk products

Activity	Frequency
Record reviews for each GOP	Weekly or monthly
Record reviews for critical records	More frequently (i.e. daily checks)
Reality checks of each GOP	Once every 2 months[1]
Full review of their RMP	Annually[1]

[1]Note: You should have a schedule of operator verification including RMP scope, administration, GOPs review and full RMP review.

5.3 Examples of operator verification

Your operator verification may include the following:

(**Note**: this is not an exhaustive list.)

5.3.1 Internal audits

The main purpose of internal audits are to gather objective evidence. Evidence can be:

a) historic (i.e. found in records) or current (i.e. observed or found in real time); and
b) positive (i.e. identifies compliance) or negative (i.e. identifies non-compliances).

The scope of the internal audits should vary each time and targeted specific parts of the RMP or the whole RMP. The main reason to vary the scope of internal audits is to avoid any inadvertent oversights by personnel carrying out audit(s) due to their familiarity with the processes. Internal audits can be scheduled or unscheduled, carried out in response to non-compliance, unacceptable external verification or if there is a change to the RMP operations.

You should ensure internal audits are carried out by a suitably skilled person at a frequency sufficient to:

a) ensure ongoing compliance with the RMP procedures; and
b) enable prompt identification of any problem.

The following examples (Sections 5.3.2 to 5.3.6) can be separate operator verification activities or form part of your internal audits.

5.3.2 Review the records

The purpose of reviewing the records is to confirm that the records have been completed as required by the procedures, accurate in terms of the information provided and signed off by the appropriate person.

The recorded information should provide confidence that the RMP is operating as intended and producing compliant products. Any non-compliances that occurred should have a record that appropriate corrective and/or preventive actions were taken.

The record should identify the investigation undertaken, the root-cause(s) identified, when the corrective actions were taken and if any procedures were updated. The record review should include a review of external verification findings, any customer audits and if there are any trends or recurring problems that indicate the RMP is not working.

5.3.3 Reality checks

The purpose of a reality check is:

a) to confirm that what happens in reality matches what is documented in the RMP; and
b) to observe daily practices of personnel and the many monitoring activities that are carried out.

It requires observations of tasks as they are performed. Reality checks include confirmation that:

a) what has been documented in the RMP has been implemented;
b) personnel are aware of and are following all of the required procedures;
c) appropriate training is provided to relevant personnel (i.e. observing the training being done);
d) the premises, internal and external environment, facilities and equipment are compliant; and
e) the records match what happened in reality.

5.3.4 Interviewing personnel

Talking with personnel can be used to confirm that they have the appropriate knowledge of procedures and awareness of the requirements. The discussion should confirm that they understand their role and

responsibilities, including the management of non-compliances. Open ended questions such as "what would you do?" can assist your understanding if the personnel are adequately trained.

5.3.5 Review of corrective action system

You should register all non-compliances (including findings from internal audits, external verification and customer audits) in a corrective action register to simplify tracking of corrective and preventive actions. Reviewing your corrective action system will help you to ensure that the identified non-compliances are followed up within their allocated timeframes.

Identifying the 'root-cause' of non-compliances will ensure that the corrective actions are effective. Refer to Appendix A: Analysis of Operator Verification Information for examples of root-cause analysis.

5.3.6 Review of ingredient, raw material and product testing programme

You should review your ingredient, raw material and product testing programme as a part of your operator verification. The scope of this review should include:

a) samples to be tested;
b) frequency of testing;
c) number of samples tested;
d) criteria to be met;
e) the capability of the suitably skilled person or recognised laboratory that will perform the approved tests;
f) test results; and
g) any corrective or preventive actions taken, when criteria were not met.

As a part of your review, you should ensure that the samples taken for ingredient, raw material or product testing are:

a) representative of the particular batch or lot of product or ingredient being tested; and
b) collected, packed and tested or dispatched by a suitably skilled person.

5.4 Recording and reporting

Operator verification system must include documented procedures for any recording and reporting requirements. All results and any action taken during operator verification must be recorded [RMP Spec 16 (1)].

Operator verification system should also allow for any internal reporting requirements (e.g. reporting to senior management) as appropriate. The reporting requirements may be more important in larger companies where there are multiple personnel involved in operator verification than in small companies (refer to Table 8: Differences in operator verification between small vs large animal products operations).

Table 8: Differences in operator verification between small vs large animal products operations

Small animal products operations	Large animal products operations
• Operator verification manageable by 1 or 2 people • May have problems maintaining independence from routine monitoring activities • Annual review of documentation is realistic • Easier to see the "big picture"	• Operator verification should be spread across many people • Clarification of responsibilities and matching competencies are important • Review of procedures are on-going across the RMP throughout the year and annual review of the whole RMP

You must have documented procedures for notifying the recognised agency responsible for external verification of your RMP in writing, without unnecessary delay, of the following issues:

a) any significant concern about product's fitness for intended purpose;
b) where the cumulative effect of minor amendments means a significant amendment to the RMP that should be registered;
c) where the RMP is considered to be no longer effective;
d) where the premises are not or are no longer suitable for their use; and
e) where anything within the physical boundaries of the RMP is used for additional purposes or by other operators and the RMP has not adequately considered relevant hazards or other risk factors [RMP Spec 13 (3)].

Justification for all the decisions made should be clear and accurately recorded. All the recorded information must be stored on file for four years as evidence of due diligence and so they can be referred to at a later date, as required [RMP Spec 20 (1)].

5.5 Demonstrating the evidence of operator verification during external verification

Preparation for external verification should be part of operator verification. You should always be prepared for an external verification. If you are well prepared then you are more likely to have an acceptable outcome at external verification. Failure to identify, manage and resolve with non-compliances is one of the leading causes of unacceptable audit outcomes at external verification.

As part of preparation, you should confirm that all non-compliances identified at the previous external verification have been resolved or have a target date for resolution within an appropriate timeframe.

At the entry meeting with your external verifier, you should provide a record of or be able to explain:

a) what action was taken to resolve any identified non-compliances from the previous external verification;
b) any significant changes that have occurred to the RMP (including GOP), personnel or processes since the last external verification;
c) any planned changes to key RMP personnel;
d) any process failures, non-complying product, or any other failures;
e) any significant operator verification findings that are being managed;
f) any maintenance or other structural work that is planned or in progress; and
g) any planned minor or significant amendments to the RMP and the relevant documentation.

Appendix A: Analysis of Operator Verification Information

Once you have gathered the evidence from operator verification, analysing it will help you to determine whether or not the RMP is appropriate and effective.

To analyse the results from operator verification, you should consider whether the results indicate that:

a) the RMP continues to deliver the required outcomes;
b) there were any non-compliances that affect the ability of the RMP to deliver the required outcomes;
c) the RMP identifies non-compliances and allows for appropriate corrective and/or preventive actions to be taken; and
d) non-compliances that have been identified by the external verifier been appropriately addressed.

Indications that the RMP or parts of it are not working effectively may include:

a) a series or trend of non-compliance found during routine monitoring or operator verification;
b) out of specification product test results;
c) similar customer complaints;
d) multiple non-compliances identified by external verification;
e) non-compliances raised during the external verification that are not detected during the routine monitoring or operator verification;
f) failed external verification; or
g) market rejections.

Based on the evidence gathered and consideration of the above, you should determine if improvements to your RMP are needed.

Dealing with non-compliances, resolution and follow-up

When non-compliances are identified during operator verification, appropriate corrective action needs to be taken. Often there is an underlying root-cause and if this is not identified, the non-compliances may reoccur. Identifying the root-cause and taking appropriate preventive action reduces the likelihood of a recurring non-compliance.

When ongoing or recurring non-compliances do occur, the following should happen:

a) take appropriate corrective actions to regain control;
b) investigate to determine root-causes of non-compliances;
c) take appropriate preventive actions (i.e. make changes to operator verification system or the relevant GOP, if necessary);
d) increase surveillance of the operations and processes;
e) increase the frequency of internal audits on the operations and processes; and
f) seek further advice and assistance from relevant technical experts, if necessary.

Determining the root-cause

Determining the root-cause of the non-compliance is necessary to be able to effectively prevent reoccurrence. Preventive action is one element of corrective action.

Note that not all non-compliances will be as a result of a systemic problem or have an underlying root-cause. On many occasions, something simply goes wrong or breaks, corrective action is taken, the issue is rectified and it never occurs again.

However, other non-compliances may be associated with a root-cause or alternatively a number of smaller things going wrong at the same time that all contributes to a non-compliance. Corrective action can be taken

to fix the initial non-compliances, but unless the root-cause is identified and preventive action taken, it is likely that the non-compliances will reoccur.

The main focus of root-cause analysis is that you should be asking questions until the reason for the non-compliance becomes apparent or until every other cause for the non-compliance has been considered.

The following examples outlines a scenario illustrating how to identify the root-cause of a particular recurring non-compliance.

Example scenario 1:

A weekly routine monitoring identified that the chiller drain wasn't cleaned to an acceptable standard. An appropriate corrective action was taken (i.e. cleaning the area again) and the non-compliance was fixed. However, on further review of the cleaning records, it was identified that this non-compliance has been found on a semi-regular basis over a period of months and that there could be an underlying root-cause.

Further action was needed to identify the underlying root-cause and to implement a preventive action.

In order to determine the root-cause, a simple and powerful technique of asking '5 whys' can be followed (i.e. you have to ask a minimum of five 'why questions'). When following this method, you are expected to ask questions as below.

Question 1: why was the drain not cleaned to the appropriate standard?
Possible response: the person who cleaned the drain each time didn't meet the acceptable standard.

Question 2: why has this person's cleaning not met the acceptable standard?
Possible response: they have been cleaning only with water and not using the appropriate chemicals.

Question 3: why were chemicals not used?
Possible response: looking at the training records, the person wasn't fully trained and not signed off to do this job.

Question 4: why were they doing this job when they weren't fully trained and signed off?
Possible response: the person started their work at a busy time and the Supervisor thought that the cleaning procedure training wasn't important to be signed off.

Question 5: why did the Supervisor think that the cleaning didn't need to be signed off?
Possible response: the training sign off process was tedious and the cleaning of the drain didn't seem important enough to bother with all that effort.

The responses from the above root-cause analysis resulted in a number of corrective actions including:

a) full training of the cleaning personnel;
b) reviewing and simplifying the training and sign off process;
c) communicating the importance of overall cleaning process to all personnel;
d) providing suitable training to the Supervisor; and
e) allocating more resources to assist the Supervisor in their job, especially at busy times.

By asking 5 whys, you don't stop at the obvious answer (i.e. person needed to be retrained) but carry on and find out why the initial training wasn't effective.

There are also some occasions where the root-cause is not so obvious or alternatively a number of smaller things go wrong at the same time that contribute to the root-cause, further investigation is required.

The scenario given below is an example of how to approach a non-compliance where the root-cause is not immediately obvious.

Example scenario 2:

a) In this scenario, the product being processed is required to be heated until it reaches a core temperature of 72°C (CCP critical limit);
b) it has been identified that product tested, as part of operator verification, hasn't met the required microbiological criteria; and
c) to identify the root-cause in this scenario, the following possibilities could be considered:
    i) the critical limits were not met;
    ii) there was post-heat processing contamination issue(s); or
    iii) the cleaning and sanitation process was not effective.

The root-cause analysis for this scenario was carried out as below:

a) The below steps were considered:
    i) the processing records were checked to determine if there has been a loss of control;
    ii) subsequent review of the processing records confirmed that the time/temperature checks have been completed correctly, the critical limits have been met and there has been no recorded loss of control;
    iii) further observation of the process did not identify any obvious sources of post-heat processing contamination;
    iv) a full review of the cleaning and sanitation procedures were completed and all evidence indicated that the procedure is implemented as documented and is effective; and
    v) the records matched what actually happens in reality, the personnel had a good understanding of the procedures and the standard required. The Supervisor understood their role and the associated responsibility.
b) At this point it was necessary to consider the below:
    i) water supply (e.g. was that a source of contamination? review the reticulation system and the results of testing?);
    ii) calibration of temperature probes (e.g. was the temperature probe used for reading the critical limits accurate?); and
    iii) other activities that may have had an impact, such as has there been any maintenance recently, new personnel, changes in the microbiological load of raw material, etc.

As a result of further investigation, it was identified that the temperature probe was not functioning properly. When it was subsequently checked and calibrated, it was found to be out by over 5°C. Therefore while it was reading 72°C, the product was only achieving 67°C. Hence, the root-cause was identified.

Often several factors which individually are minor may culminate in a major lapse of process control. It is therefore important that operator verification is an in-depth review of the RMP.