

CHAPTER NINE

Certification and Recognition of Your Manitoba HACCP Advantage System

1. INTRODUCTION

Before applying for certification you should understand the roles various parties play in certification and your responsibilities for maintaining certification. To help ensure certification of your GMP/HACCP system, there are a few important steps you can take.

A. A Short Lesson in Terminology

For many, one goal of HACCP implementation, beyond food safety, is acceptance of their HACCP system by customers, thereby improving marketability. Acceptance usually requires review by an independent external body. Such review can include terms such as “recognition” or “certification”; however, each of these words has a different meaning.¹

In general, governments provide HACCP recognition, while independent, external bodies provide certification. These certification bodies audit individual HACCP systems to verify that they meet standard requirements. Successful audits lead to certification. Certification leads to recognition.

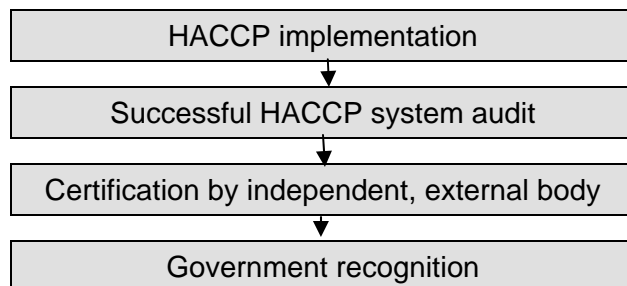


technical terms

Recognition is a formal government acknowledgment and approval of an implemented HACCP system.

Certification is the issuing of a written assurance (e.g., certificate) by an independent, external body that has audited a HACCP system and verified that it conforms to the requirements specified in the standard.

Figure 9.1: Flow diagram of auditing, certification and recognition



¹ International Organization for Standardization. “Certification registration and accreditation.” Retrieved June 2004 from www.iso.org.

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B. Why Apply for Certification, and Why Are Audits Necessary?

Certification is an important part of any HACCP program. Objective, independent certification provides regulators, stakeholders and most importantly, customers with evidence that food products are produced under an effective food safety (in this case, HACCP) system. Certification by a recognized body verifies that an implemented HACCP system conforms to a standard, is complete, and is effectively designed and maintained. The recognition that comes with certification can produce increased employee motivation and ownership of food safety, as well as improved consumer confidence.

Audits are necessary to determine if certification should be granted. During an audit your HACCP system is examined and assessed. Objective evidence is gathered to demonstrate that your HACCP system is properly implemented and working effectively. Audits also promote continual improvement in your food safety systems, thereby ensuring that you are supplying your customers with safe food.

C. Roles and Responsibilities

There are three main parties involved in HACCP recognition:

- the government
- the certification body
- you, the operator

i. Responsibilities of Government – Manitoba Agriculture, Food and Rural Initiatives(MAFRI)

In this regard, the key responsibilities are defining the standards and recognizing certified systems. MAFRI has defined the *Manitoba HACCP Advantage* standards in the *Manitoba HACCP Advantage Program Manual*; MAFRI has designated and recognized the Canadian General Standards Board (CGSB) as the certification body of the *Manitoba HACCP Advantage*; and MAFRI recognizes *Manitoba HACCP Advantage* systems certified by CGSB.

ii. Responsibilities of Certification Bodies

Certification bodies are responsible for auditing the HACCP system to ensure that it:

- meets the standards
- is implemented as written
- is effective in controlling food safety hazards

Certification bodies provide written assurances of successful certification (usually in the form of a certificate) to the operators. In the case of the *Manitoba HACCP Advantage*, CGSB will audit HACCP systems with respect to the standards

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defined in the *Manitoba HACCP Advantage Program Manual*. Certification bodies also conduct annual audits for ongoing certification.

iii. Responsibilities of Applicants/Operators

You, as the applicant and food processing operator, are responsible, for developing and implementing an effective HACCP system specific to your facility. You must then maintain your system by:

- monitoring each GMP program
- monitoring and verifying each CCP
- keeping accurate records
- taking appropriate corrective actions when deviations are identified
- updating your system as needed

Management is ultimately responsible for the effectiveness and accuracy of the HACCP system and its documentation.

Operators also have responsibilities during the certification process. If any non-conformances are found during auditing, it is your responsibility to effectively address these in a set time frame. You must also inform the certification body of any changes or updates to your HACCP system before the start of any subsequent audits.

2. PREPARING FOR A CERTIFICATION AUDIT

Preparation is key to an efficient and successful audit. Organization and thoroughness are reflections of professionalism and a HACCP system that is in control.

Before you apply for certification, you should ensure that your operations and personnel are ready for auditing. There are some key steps you can take, such as internal audit, to help ensure your success.

You are ready to apply for certification after your HACCP system has been fully implemented and you are certain that it is functioning effectively. It is advisable that you allow your HACCP system to function for three to four months after implementation before applying for certification.



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Why invest the time and effort in an internal audit?

- identification of deficiencies
- determination of root causes of deficiencies
- correction of deficiencies prior to external audits
- preparation for external audits
- possibly fewer external auditing hours
- probably improved external auditing results
- continual improvement opportunities
- reinforcement of food safety awareness

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A. Internal Audit

i. What, Who and When?

An internal audit is a self-evaluation of your HACCP system. Using a critical eye, your HACCP system is thoroughly examined. It is commonplace for the HACCP Coordinator to conduct the internal audit. The best time to conduct your first internal audit is a few months after your HACCP system is implemented and prior to certification application. This allows some time for your HACCP system to start functioning as it normally would. It would be prudent to develop a regular schedule of internal audits to ensure that your system continues to operate effectively.

ii. How to Conduct an Internal Audit

To conduct an internal audit you should develop a method for assessing your HACCP system. Useful aids include worksheets or checklists. Your checklist should be tailored to your specific facility and HACCP system. As you develop your internal audit, refer to the *Manitoba HACCP Advantage Program Manual* for the requirements; you may even want to make reference in your worksheets/check list to specific standards.

To assist you in developing and conducting your own internal audit, sample checklists have been provided at the end of this chapter. You should adapt these suggestions to work for your facility.

There are three general stages you should include in your internal audit:

1. Check that your documentation is complete and there are no missing components.
2. Check that your written programs meet the requirements and will produce the required outcomes.
3. Check that your written programs are actually being implemented as written and that personnel are sufficiently trained and competent.

For example:

- Are the GMP programs followed as written?
 - Are monitoring procedures followed?
 - Are corrective actions taken when required?
 - Are results recorded?



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Internal Audit Follow-Up

One of the most important parts of an internal audit is your follow-up; a common pitfall following an internal audit is inaction. Simply recording a deficiency is not enough; the root cause of a non-conformance must be determined. Non-conformances must also be corrected or addressed. You must then verify that the measures taken were completed and effective.

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- Are the HACCP plan(s) followed as written?
 - Are CCPs monitored?
 - Are corrective actions taken when critical limits are not met?
 - Are verification procedures performed?
 - Are results recorded?

As you conduct your internal audit, if you find any items that are missing, incomplete or ineffective, note these non-conformances. Following your audit you will need to:

- develop CAPs to fix the non-conformances
- carry out these plans
- check that your corrective actions were effective

If, during your internal audit, you identify areas that need further work, now is the time to fully address these areas. *You should not proceed with application for certification until you are certain you have addressed all non-conformances identified in your internal audit.* Proceeding before you are ready may lead to significant corrective actions to address before you can be certified or worse, a failed audit. Not being prepared will likely cost you more time, effort and money.

After you have conducted a few internal audits take the opportunity to examine your checklists for repeated non-conformances and determine how you could change your HACCP system to prevent them in the future. Such preventative measures can improve your auditing results and may lead to efficiencies in your HACCP system.

B. Preparing for a Certification Audit

Here are six other helpful hints to aid you in your preparation for audits.

i. Personnel Preparation

As part of your HACCP system, all personnel with HACCP responsibilities should be trained and able to answer interview questions regarding:

- their roles and specific duties
- the importance of their roles
- where to find information (e.g. manuals, supporting materials) regarding their roles
- the records they are responsible for

Training should emphasize the consequences of personnel not completing their duties as required.



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It is important that the management review the results of your internal audit. It is management's responsibility to ensure that the HACCP system is operating sufficiently before proceeding with the application for certification.

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ii. Confirmation of Outsourcing Effectiveness

It is your responsibility to ensure that outsourced programs (e.g. pest control or sanitation) are effective, meet the standards and are properly documented.

iii. Organized Documentation

The better organized your documentation, the better your HACCP system will be and the smoother your audits will proceed. Have all documentation stored in designated areas and organized in a manner that is easy to follow. You should also make sure that there are no inconsistencies in your documentation (e.g. HACCP plan forms, records).

iv. Designated Area

It is recommended that you have a designated area for auditors to sit and examine your documents; for example, a boardroom, a meeting room, an office or a quiet corner with sufficient workspace.

v. Management Involvement

Management should demonstrate commitment to the HACCP system by taking the time to meet the auditors and join the opening and closing meetings. This is also important for better management understanding, especially if corrective actions require their decisions and financial support.

vi. Personnel Practices and Safety Adherence

You should treat the auditors like any other visitors; they must follow your policies and procedures for Personnel Practices and safety procedures. Be sure to explain these to the auditors at your opening meeting and be prepared to provide them with any necessary apparel (e.g. boots, hairnets, coats/smocks).

3. **STEPS FOR MANITOBA HACCP ADVANTAGE CERTIFICATION**

Once you have implemented your HACCP system, monitored it for a sufficient time period and successfully completed your internal audit, you are ready to apply to CGSB for certification.

Only *Manitoba HACCP Advantage* systems certified by CGSB will be recognized by MAFRI under FSI. CGSB will administer the delivery of certification services for the *Manitoba HACCP Advantage* and will use the services of qualified food safety auditors to perform the audits of individual *Manitoba HACCP Advantage* systems. CGSB will provide details of the costs for certification and ongoing auditing. The types of fees you may expect include an application fee, an annual

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listing fee and hourly auditor fees. The certification process documented below is accurate at the time of publication of this guidebook.

Upon your request for application, CGSB will send you an application package. Once you have completed and submitted the application package, CGSB will begin the certification process and schedule the on-site audits.

CGSB auditors will conduct audits in three general phases:

1. Documentation Review

The documentation review is conducted to ensure that no major components of your HACCP system are missing. You will need to provide enough of your written programs to demonstrate that you have fully implemented your HACCP system.

2. Systems Audit

The systems audit is essentially a “desk audit” conducted to confirm that you have effectively addressed all the GMP program standards and that your HACCP plan(s) are complete and effective (the auditor(s) check what you say you are going to do). This phase of the audit may occur on-site or off-site. The location will be mutually agreed upon by the applicant and CGSB.

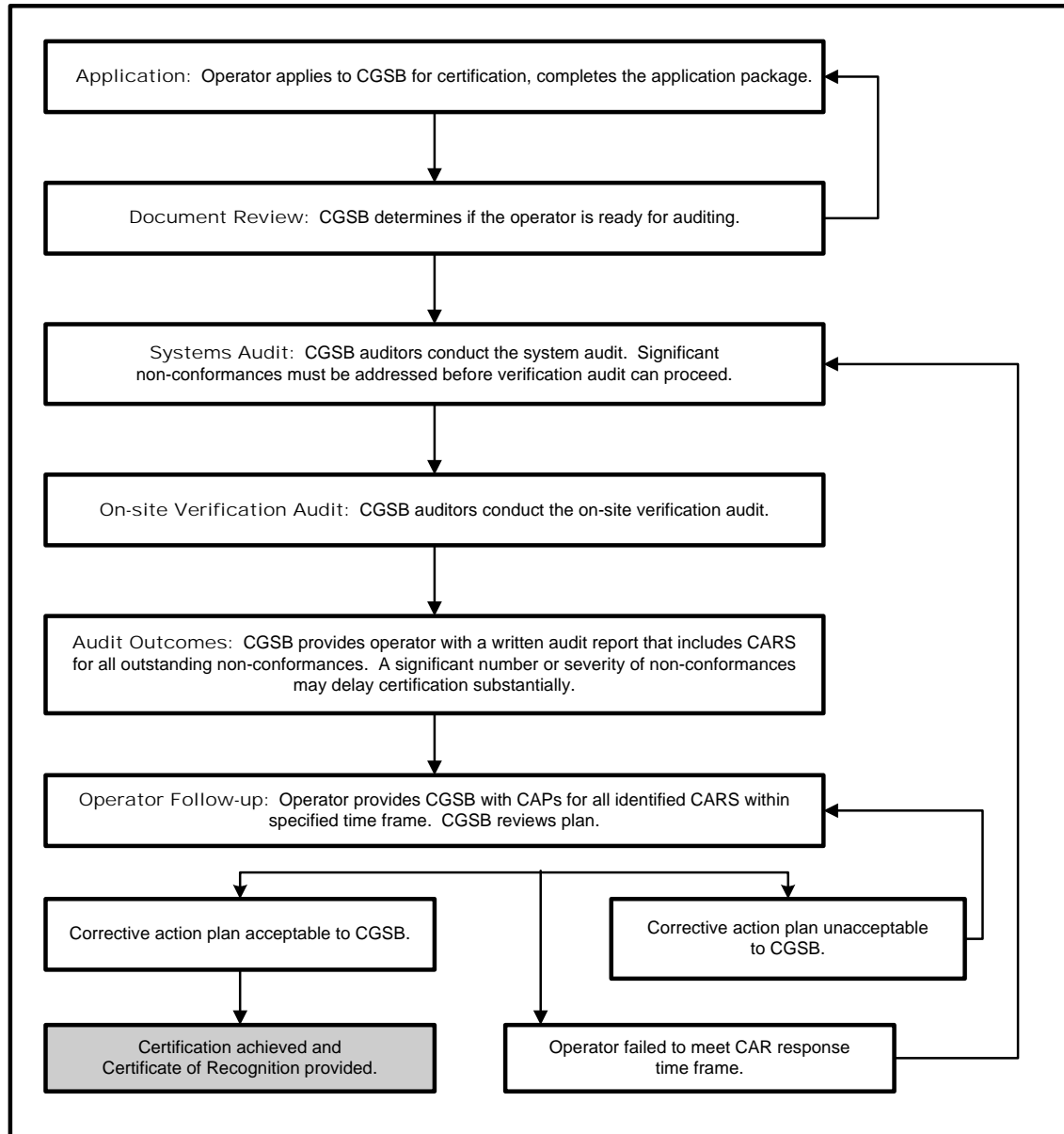
3. On-Site Verification Audit

The on-site verification ensures that your written GMP programs and HACCP plan(s) are performed as written (the auditor(s) check that you are doing what you said you would do).

CGSB auditor(s) will identify if any elements of your GMP/HACCP system are lacking. To obtain certification you are required to sufficiently address these Corrective Action Requests (CARs) in the set time frame.

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Figure 9.2: Flow Diagram of Steps to Achieve Manitoba HACCP Advantage Certification



A. How to Apply for Certification

The first step of applying for certification is to contact CGSB. For further information or to apply for *Manitoba HACCP Advantage* certification, contact *the Manitoba HACCP Advantage Certification Officer*:

By telephone: 1-819-956-3479
By fax: 1-819-956-5740
By email: roy.john@pwgsc.gc.ca

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By mail: *Manitoba HACCP Advantage Program*
Canadian General Standards Board
Place du Portage, Phase III, Floor 6B1
Gatineau, Quebec
K1A 1G6

Following this initial contact, CGSB will send you an application package with directions and forms to complete. You can expect to receive a manual and various application forms. You are obligated to read and understand the manual.

You may be asked to submit the following items in your application package:

- letter of Intent indicating management commitment
- FSMS policy
- identification of HACCP Coordinator/team
- checklist indicating all GMP program standards have been addressed
- list of products and HACCP plan groupings
- checklist of HACCP plan forms 1-8 for each HACCP plan
- blank copies of some sample records
- written procedures for program maintenance including logbook methodology
- internal audit results
- application forms provided by CGSB

From the materials you provide, CGSB will estimate the number of audit days, select the auditor(s) and develop their audit plan. CGSB will then schedule the audits and send you information pertaining to the audit plan, including identifying the auditor(s).

By submitting your application package, you are indicating that your Food Safety Management System, including the HACCP system, has been implemented and is ready for full review.

B. Document Review

CGSB auditors will review your documents to ensure that your facility is ready for auditing. During the document review, the auditors will identify any major components that are missing and need to be provided before the audit proceeds. For example, the auditors will verify that your FSMS includes a:

- policy statement that commits to observing all applicable legal requirements
- method for identifying all applicable laws
- method for keeping current with changes in legal requirements
- person designated by senior management as responsible for the FSMS

With regards to your legal requirements, the auditors will not undertake a legal compliance audit; compliance is a daily management responsibility.

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In their review, the auditors will verify that the HACCP documentation includes:

- the name of the HACCP Coordinator/team leader and team members, if applicable
- a list of the products produced and how the products are grouped into HACCP plans
- completed checklists indicating all GMP programs meeting the *Manitoba HACCP Advantage* standards
- completed checklists indicating the number of HACCP plan(s) with each including the eight *Manitoba HACCP Advantage* forms
- any scientific literature, research studies or background used to support decisions made regarding the HACCP system
- written procedures for maintenance and update of the HACCP system

The auditors will also verify that for each HACCP plan:

- products are identified as to their respective types and uses
- process(s) are adequately described

C. Audit Process: On-Site Systems and Verification Audits

Once you have submitted your application to CGSB and documentation has been assessed as complete, the certification process continues to the next phase, on-site audits. Prior to the on-site audits you will need to assign a contact person to participate with the auditor(s). The most appropriate person would be the HACCP Coordinator.

A general sequence of events will occur:

1. Orientation / Introductory Tour

Upon greeting the auditor(s) it would be helpful to give the auditor(s) a brief tour of your facility to help them become familiar with the facility layout and key personnel. The tour may take place before or after the opening meeting.

2. Opening Meeting

To officially begin the certification audit, the lead auditor will conduct an opening meeting. It is very important that the HACCP Coordinator, key personnel and management are present at this meeting. If you have engaged the services of a consultant to assist in your GMP/HACCP implementation, his or her presence is also helpful. The auditor(s) will explain the purpose and scope of the audit during this meeting as well as the proposed timing and schedule, and make any necessary arrangements (e.g. safety requirements, interview schedules, break times).



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If during the on-site audit(s), the auditor(s) identify a situation that constitutes an immediate threat to public health, the auditor(s) will notify you. You are then obligated to contact the applicable government authority immediately to discuss the nature of the threat and obtain further direction

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3. Systems Audit

The systems audit is essentially the desk audit of your written programs and procedures if on-site. The auditor(s) will need sufficient workspace in a quiet area of your facility to conduct this assessment. The HACCP Coordinator must be present to answer any questions from the auditor(s).

The auditor(s) will examine your written HACCP system documents. The purpose of this audit is to verify that each component of the *Manitoba HACCP Advantage* is sufficiently addressed.

The systems audit will be divided into a GMP program audit and HACCP plan audit.

For the GMP program audit the auditor(s) will verify that:

- all GMP program standards have been addressed
- control measures and monitoring procedures are adequate for each GMP standard
- appropriate documentation is in place
- appropriate recordkeeping forms have been generated

For the HACCP plan audit the auditor(s) will verify that:

- the written HACCP plan(s) contain all the necessary material as defined in the eight HACCP forms, as well as any supporting protocols and documents
- all products and processes are adequately described and grouped into appropriate HACCP plans
- all products that are produced fall under a documented HACCP plan
- recordkeeping forms for all monitoring, corrective action and verification procedures have been developed
- critical limits and control measures are validated
- where applicable, scientific literature or other background documentation is provided to support the decisions made in the HACCP plan(s)
- for each CCP, the following basic questions are answered:
 - What are the critical limits?
 - How is monitoring performed?
 - How frequently is it done?
 - Who is responsible?
 - What are the corrective actions?
 - What records will be kept to demonstrate adherence to the program?

The auditors will note any non-conformances. If the non-conformances negatively impact the integrity of the overall GMP/HACCP system, corrective actions must be implemented and will be subjected to a second systems audit prior to proceeding with the verification audit. This means that you would need to fix the problems with the written program and the auditors will return at a later time to approve the corrective actions and conduct the audit. If deficiencies are minor and do not impact the integrity of the overall GMP/HACCP system, the on-site verification audit will proceed.

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4. Verification Audit

The verification audit allows the auditor(s) to confirm that your written GMP/HACCP system has been effectively implemented as written. During the verification audit, the auditor(s) will gather evidence needed to assess whether each component of your HACCP system is implemented as written, effective, current and reflects current operating conditions. The auditor(s) will gather evidence through physical observations of your facility and its operations, examination of records and monitoring results, and interviews with personnel responsible for each component. The auditor(s) will look for proof your system is working as written, all involved personnel understand their roles and are completing necessary tasks as required. The auditor(s) will also verify that records are accurately completed.

In addition, for the GMP program verification audit, the auditor(s) will verify that:

- the facility meets all design, construction and maintenance requirements described in the GMP program standards
- the personnel responsible for GMP program activities are adequately trained, knowledgeable about their duties and are following the written program

In addition, for the HACCP plan verification audit, the auditor(s) will verify that:

- the process flow diagram and plant schematic are accurate
- the personnel responsible for CCP monitoring activities are adequately trained, are knowledgeable about their duties and are following the written program

Throughout the verification audit the auditor(s) will make note of their findings, including documenting any non-conformances.

5. Closing Meeting

A closing meeting will be held after the auditor(s) have completed their assessment of your GMP/HACCP system. At the closing meeting the auditor(s) will inform you if a recommendation for certification will be made. You will be informed of the audit findings including all observations, minor non-conformances and major non-conformances. The closing meeting will also be an opportunity to correct any misunderstandings or misinformation. It would be beneficial for the HACCP Coordinator, key GMP/HACCP personnel and management to be present at the closing meeting. This will ensure that the appropriate decisions and corrective actions are made in your audit follow-up.

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D. Audit Outcomes and Follow-up

i. Audit Observations and Audit Report

During an audit the auditor(s) determine if each of their findings have an impact on food safety. The severity of the impact is considered when the auditor(s) categorize each of their findings as a major non-conformance, a minor non-conformance or an observation. A non-conformance indicates that an element does not meet the requirements of the *Manitoba HACCP Advantage*.

Major Non-Conformance

A major non-conformance is a non-conformance that requires an acceptable modification of procedures in your HACCP system before CGSB will deem it to be in conformance with the *Manitoba HACCP Advantage*. Generally, a major non-conformance puts the GMP/HACCP system at risk of failure.

Minor Non-Conformance

Minor non-conformances relate to non-conformances of less severity. Overall, the system is still effective in meeting the requirements. You must provide a response to each with the action taken or at least your intended action to correct the finding. Should a minor non-conformance not be corrected in sufficient time to determine its effectiveness before the next audit, it will automatically become a major non-conformance.

Observation

If the element being assessed is not a major or minor non-conformance, but the auditor(s) have a remark, it is considered an observation. An observation could be an interpretation of a *Manitoba HACCP Advantage* requirement or a statement of opportunity for improvement. You are not required to respond to an observation, but it is to your advantage to improve the program through these observations.

You will be officially notified of your audit results in a written audit report from CGSB. The report will detail the audit findings, identify non-conformances and indicate whether or not certification will be granted. The report will identify the CARs, formal requests for action to correct non-conformances identified during an audit.

ii. Responding to Audit Reports and CARs

You will be required to take action to correct, revise or amend the GMP/HACCP system to address the audit findings. Major and minor non-conformances will need a formal response to each CAR, usually within 30 days. The formal response may be written notification of correction of the non-conformance or a written corrective action plan (CAP) to address the non-conformance in a set period of time.

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CGSB must find all corrective actions plans acceptable and will verify their effectiveness and completion in the next audit. Implementation of corrective actions for major non-conformance may be verified in a follow-up audit prior to the next regularly scheduled audit. You are responsible for providing the auditor(s) with evidence that the required corrective actions have been completed. The auditor(s) may conduct a follow-up audit to confirm this. Follow-up visits for minor non-conformances may occur during the next scheduled surveillance audit. At this time the auditor(s) will confirm that these corrective actions are adhered to and effective.

1. Response Meeting

Key GMP/HACCP personnel, including management and the HACCP Coordinator/team, should meet to review each component of the audit report and decide upon appropriate and detailed CAPs for non-conformances. The CAPs should identify the actions that will be taken to correct or address the non-conformances.

2. Response to CARs

When non-conformances have been identified by auditors, you will be given a set time frame (typically 30 days) to address these. Within this time period you will need to develop a corrective action for each non-conformance. The corrective action should address or correct the occurrence. You should be able to defend the actions you have chosen. When the actions are complete, record them.

The response to a CAR should include:

- your identifying information
- date of audit
- reference to the GMP program standard or HACCP plan element that is not in conformance
- reference to the audit report details of the non-conformance finding;
- action to be taken
- who is responsible for corrective action
- timeline for completion



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Take the opportunity from all audit findings (internal and external audits) to focus more attention in the areas identified. Consider making changes and improvements to your GMP/HACCP system.

For example:

- further or more focused training (e.g., using a more appropriate training method)
- new equipment (e.g., thermometer or chill tank)
- procedure improvements (e.g., assigning a more appropriate person for a task)
- changes to GMP programs (e.g., frequency of preventive maintenance)
- changes to HACCP plan (e.g., adjusting CCPs or revised control measures)

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3. Appeals

You may appeal certification decisions to CGSB. CGSB has developed an appeals process as a fair and impartial method of resolving any audit disputes.

iii. *Manitoba HACCP Advantage Certificate*

In order for your facility to be HACCP certified, the following conditions must be met:

- CGSB auditor(s) recommend your facility for certification assuming all non-conformances are addressed.
- Corrective actions for all non-conformances are submitted to CGSB for review within required timeframe.
- CGSB auditor(s) find all corrective actions acceptable.

CGSB will notify MAFRI of certified (and decertified) facilities. Certification may be withdrawn if corrective actions are not completed as scheduled.

Following successful auditing and corrective actions, you will receive a *Manitoba HACCP Advantage* certificate. The certificate indicates the legal name of your company, the scope of the certification and the location of the facility as indicated in your application package. The certificate is valid for three years, provided yearly surveillance audits are successful.

Once a certificate has been granted, MAFRI will provide recognition of *Manitoba HACCP Advantage* certification by adding your facility to the listing of certified facilities on the MAFRI *Manitoba HACCP Advantage* Web site.

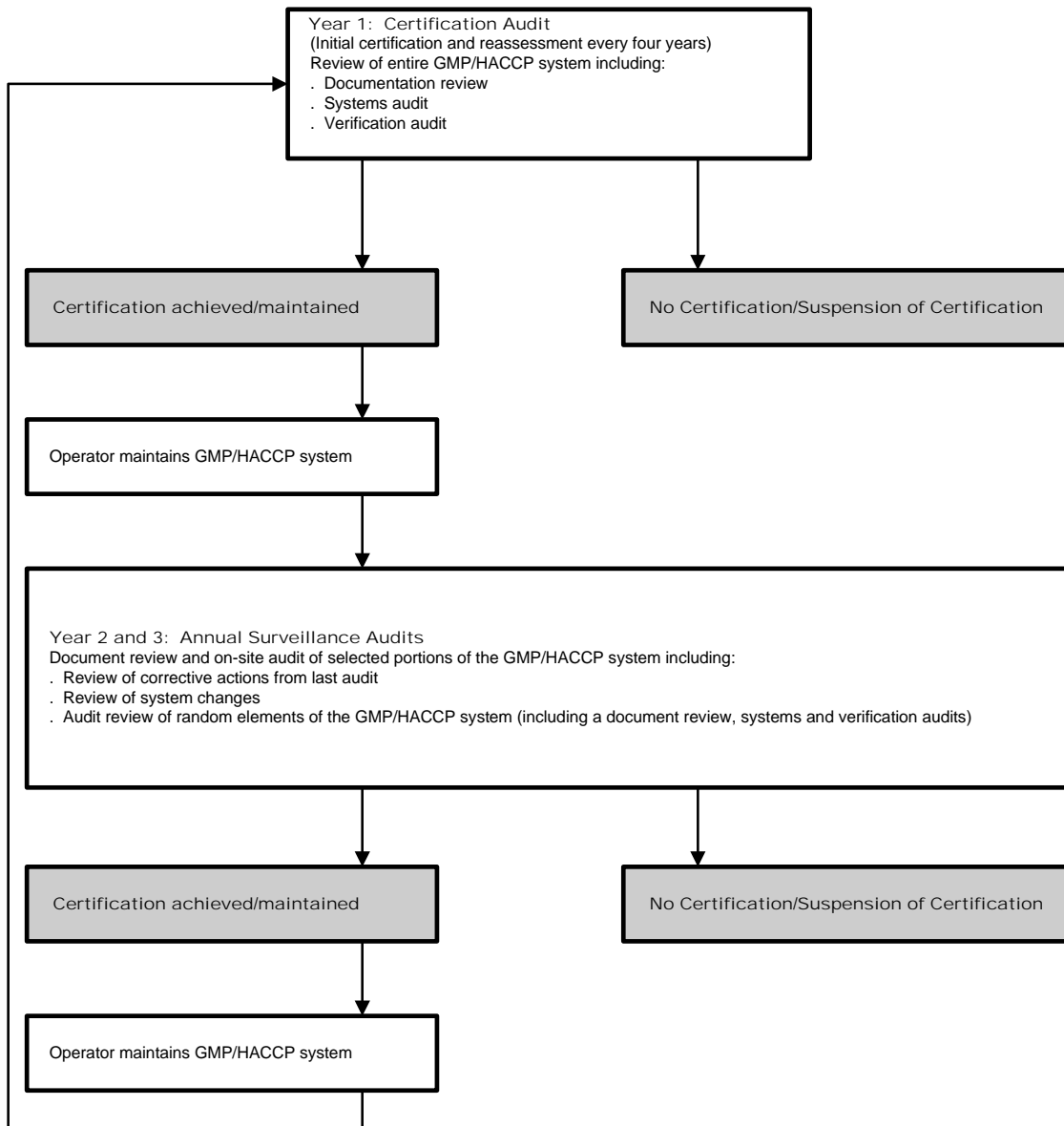
iv. Ongoing Certification

You should keep in mind that certification is not a one-time event. To maintain your status as a certified plant you must continually maintain your GMP/HACCP system and update written programs and activities as needed.

Ongoing certification involves maintenance and updating of your FSMS, corrective action follow-up, surveillance audits and reassessments. Once you have become certified, your facility will be audited on (at least) a yearly basis. Ongoing audits are necessary to ensure that your GMP/HACCP system continues to operate effectively and allows for any changes or updates to be incorporated into your certified system. Failure to pass any audit can lead to decertification. The following flow diagram illustrates the ongoing certification process.

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Figure 9.3: Flow Diagram of Ongoing Certification Process



v. Audit Cycle

Certification audits occur on a three-year cycle. To remain certified, your GMP/HACCP system must requalify by passing yearly audits. You will be contacted by CGSB to schedule your next audit. The audit cycle is described here.

Year 1: Full certification audit.

The full certification audit of your entire *Manitoba HACCP Advantage* system includes the documentation review, systems audit and on-site verification audit.

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Year 2: Surveillance audit.

A surveillance audit includes a review of a random sample of GMP programs and HACCP plan CCPs as well as a review of implemented corrective actions from the previous audit and any new additions or changes to the system to ensure effectiveness.

Year 3: Surveillance audit.

The same process used in year 2 is used in year 3. Random GMP/HACCP system elements audited in year 2 will likely not be audited again in year 3.

Year 4: Full certification reassessment audit, identical to year one.

The cycle begins again in the fourth year with a full audit of the entire GMP/HACCP system, including the documentation review, systems audit and on-site verification audit. These are conducted every three years or potentially when significant changes are made to your GMP/HACCP system. Reassessment audits are used to confirm your demonstrated commitment to maintaining your GMP/HACCP system.

vi. Your Responsibilities as an Operator for Ongoing Certification

For a facility to keep its certification, management must ensure maintenance of the FSMS as described in previous chapters. For example, you need to document compliance with changing food safety legislation and regulatory requirements, and update your GMP/HACCP system when changes are made (e.g. new HACCP plan/new CCP, new equipment or rooms, new technologies, altered product formulations).

A record or logbook of any GMP/HACCP system changes is essential for continued certification. All changes to your GMP/HACCP system must be documented in a HACCP logbook. To be considered part of the GMP/HACCP system, changes must undergo documentation review, systems audit and on-site verification audit. It is the operator's responsibility to notify CGSB of any changes to the GMP/HACCP system that:

- are a result of a significant process change
- are a result of a significant change in control measures
- may directly affect food safety

The CGSB will decide if the change warrants an immediate audit or simply an addition to the next annual surveillance audit. Failure to notify CGSB may result in the facility being decertified. Please refer to CGSB application package or contact CGSB directly for more information regarding this process.

Operators should conduct internal audits at least yearly to ensure that the GMP/HACCP system continues to effectively control food safety hazards. This internal check will help maintain the commitment and diligence of personnel to their GMP/HACCP activities. It may also highlight any gaps in a changing system as well as areas that are not being performed adequately.

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vii. Suspension of Certification

Your facility's *Manitoba HACCP Advantage* certification may be suspended if it fails to meet the requirements. Certification may be suspended until all non-conformances are resolved. CGSB will provide operators with written notification of suspension of certification. While certification is suspended, operators cannot claim certification in any way (for example, on signs, documents, literature or promotional materials).

Furthermore, if the non-conformances are not resolved within a time frame acceptable to CGSB, the facility will be decertified.

You can voluntarily withdraw from the certification program by requesting to be delisted if you do not wish to continue your GMP/HACCP certification and ongoing audits. Once decertified or delisted, re-certification will require starting the application process from the beginning. After decertification or delisting, operators cannot claim certification in any way (for example, on signs, documents, literature or promotional materials).

CGSB will notify MAFRI of all suspended, decertified and delisted facilities, and they will be removed from the web site listing.

4. INTERNAL AUDIT SAMPLE CHECKLISTS

The following are some sample forms you can use to complete various parts of an internal FSMS and *Manitoba HACCP Advantage* audit. You should modify these forms as needed to meet the unique needs of your facility.

A. Internal FSMS Review

i. Food Safety Management System Checklist (excluding HACCP)

Objective: to confirm that the necessary components of the FSMS (excluding HACCP) are written in the FSMS protocol and are effectively implemented.

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Table 9.1: FSMS Checklist Example

Check off when complete

Requirements
1. There is a written policy statement that commits the company to observing all applicable legal requirements. <input type="checkbox"/>
2. A method is written and followed for identifying all applicable laws. <input type="checkbox"/>
3. A method is written and followed for keeping current with changes in legal requirements. <input type="checkbox"/>
4. A person is designated by senior management as responsible for the FSMS; this person clearly understands his or her responsibilities and can demonstrate that he or she is completing his or her responsibilities. <input type="checkbox"/>
Notes (e.g. missing elements, corrective actions required):

B. Internal GMP Program Audit

i. GMP Program Systems Audit

Objectives:

- to confirm that all written GMP programs are complete and accurate for the facility
- to confirm that the written GMP program policies and procedures meet the requirements of the *Manitoba HACCP Advantage*
- to prepare for the certification systems audit of the GMP programs

ii GMP Program Verification Audit

Objectives:

- to confirm that the GMP program monitoring and corrective actions are conducted as written and appropriately recorded
- to prepare for the certification verification audit of the GMP programs

Table 9.2 provides a sample checklist you could use to confirm that you have completed internal GMP program systems and verification audits. This checklist includes columns for each standard that allows you to check off that both the systems and verification audits have been completed.

Systems Audit: A systems audit typically involves reviewing your written policies and procedures to ensure completeness and accuracy.

- For each of the 60 standards ensure the following monitoring procedure information is provided:

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- what is done
 - how it is done
 - who is responsible
 - the corrective actions
 - what records are kept
- Ensure the written programs and procedures are complete and effective in controlling food safety hazards (based on e.g. scientific evidence, regulatory requirements, internationally accepted standards or expert determination).
 - Ensure that the monitoring results and corrective actions are fully documented and are performed by the designated, trained person.
 - Ensure that all records are accessible for auditor review.

Verification Audit: Typical activities required to complete this assessment include interviews and observations.

Some examples of systems and verification audit activities are:

P7.1 Water Treatment Program

- Examine the Water Treatment Program documents to ensure that they have been reviewed at predetermined intervals.
- Ensure that the program is suitable for the facility's current operations.

T1.1 Personnel Practices Training

- Examine training materials to ensure that appropriate updates have been made.
- Examine training records to ensure that all employee training is completed as described in the training schedule.

O1.3 Clothing/Footwear/Headwear

- Observe personnel to verify proper apparel.
- Inspect hair and beard coverings to verify sufficient coverage.

O6.1 Product Code/Labelling Monitoring

- Inspect labels to verify ingredients are declared, instructions are listed for handling/preparing/storing, and products are coded according to established system.
- Examine labels in storage for clear identification.
- Examine records to verify system of dating and coding of packages is documented and included in the recall program.

E3.1 Internal Structures and Fittings

- Inspect internal structures (e.g. floors, walls, ceilings, overheads, doors, windows, stairs) checking for physical integrity and condition (e.g. no loose screws, flaking, chipping).
- Verify that floors, walls, ceilings, overheads, doors, windows, stairs and other structures are cleanable.
- Verify that maintenance schedules are followed.

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E4.1 Equipment Design, Construction and Installation

- Inspect equipment for signs of degradation (e.g. cracks).
- Verify that equipment is clean, sanitized and maintained.
- Inspect for chipping, metal flakes, vibration, abrasion or pitting that could cause contamination.

Table 9.2: General Checklist for Written GMP Program Policies and Procedures Example

Program Meets the Standard (60 standards)					Notes (e.g. missing elements, corrective actions required)
GMP Program	Control Program	Training	Operational Control		
	Systems Audit	Systems Audit	Systems Audit	Verification Audit	
Personnel Practices	P1.1 <input type="checkbox"/>	T1.1 <input type="checkbox"/>	O1.1 <input type="checkbox"/> O1.2 <input type="checkbox"/> O1.3 <input type="checkbox"/> O1.4 <input type="checkbox"/> O1.5 <input type="checkbox"/> O1.6 <input type="checkbox"/> O1.7 <input type="checkbox"/> O1.8 <input type="checkbox"/> O1.9 <input type="checkbox"/>	O1.1 <input type="checkbox"/> O1.2 <input type="checkbox"/> O1.3 <input type="checkbox"/> O1.4 <input type="checkbox"/> O1.5 <input type="checkbox"/> O1.6 <input type="checkbox"/> O1.7 <input type="checkbox"/> O1.8 <input type="checkbox"/> O1.9 <input type="checkbox"/>	
Shipping, Receiving, Handling and Storage	P2.1 <input type="checkbox"/>	T2.1 <input type="checkbox"/>	O2.1 <input type="checkbox"/> O2.2 <input type="checkbox"/> O2.3 <input type="checkbox"/> O2.4 <input type="checkbox"/> O2.5 <input type="checkbox"/> O2.6 <input type="checkbox"/> O2.7 <input type="checkbox"/> O2.8 <input type="checkbox"/> O2.9 <input type="checkbox"/>	O2.1 <input type="checkbox"/> O2.2 <input type="checkbox"/> O2.3 <input type="checkbox"/> O2.4 <input type="checkbox"/> O2.5 <input type="checkbox"/> O2.6 <input type="checkbox"/> O2.7 <input type="checkbox"/> O2.8 <input type="checkbox"/> O2.9 <input type="checkbox"/>	
Sanitation	P3.1 <input type="checkbox"/>	T3.1 <input type="checkbox"/>	O3.1 <input type="checkbox"/> O3.2 <input type="checkbox"/>	O3.1 <input type="checkbox"/> O3.2 <input type="checkbox"/>	
Equipment Maintenance	P4.1 <input type="checkbox"/>	T4.1 <input type="checkbox"/>	O4.1 <input type="checkbox"/>	O4.1 <input type="checkbox"/>	
Pest Control	P5.1 <input type="checkbox"/>	T5.1 <input type="checkbox"/>	O5.1 <input type="checkbox"/>	O5.1 <input type="checkbox"/>	
Recall	P6.1 <input type="checkbox"/>	T6.1 <input type="checkbox"/>	O6.1 <input type="checkbox"/> O6.2 <input type="checkbox"/> O6.3 <input type="checkbox"/> O6.4 <input type="checkbox"/>	O6.1 <input type="checkbox"/> O6.2 <input type="checkbox"/> O6.3 <input type="checkbox"/> O6.4 <input type="checkbox"/>	
Water Safety	P7.1 <input type="checkbox"/> P7.2 <input type="checkbox"/>	T7.1 <input type="checkbox"/> T7.2 <input type="checkbox"/>	O7.1 <input type="checkbox"/> O7.2 <input type="checkbox"/>	O7.1 <input type="checkbox"/> O7.2 <input type="checkbox"/>	
Critical Control Point		T8.1 <input type="checkbox"/>			
Process Technology		T9.1 <input type="checkbox"/>			

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Environmental Controls			
	Systems Audit	Verification Audit	Notes
Facility Location & Construction	E1.1 <input type="checkbox"/> E1.2 <input type="checkbox"/>	E1.1 <input type="checkbox"/> E1.2 <input type="checkbox"/>	
Facility Design	E2.1 <input type="checkbox"/> E2.2 <input type="checkbox"/>	E2.1 <input type="checkbox"/> E2.2 <input type="checkbox"/>	
Facility Interior	E3.1 <input type="checkbox"/> E3.2 <input type="checkbox"/> E3.3 <input type="checkbox"/> E3.4 <input type="checkbox"/> E3.5 <input type="checkbox"/>	E3.1 <input type="checkbox"/> E3.2 <input type="checkbox"/> E3.3 <input type="checkbox"/> E3.4 <input type="checkbox"/> E3.5 <input type="checkbox"/>	
Equipment	E4.1 <input type="checkbox"/> E4.2 <input type="checkbox"/> E4.3 <input type="checkbox"/>	E4.1 <input type="checkbox"/> E4.2 <input type="checkbox"/> E4.3 <input type="checkbox"/>	
Water Supply	E5.1 <input type="checkbox"/>	E5.1 <input type="checkbox"/>	

C. Internal HACCP Plan Audit

i. HACCP Plan Systems Audit Checklist

Objectives are:

- to confirm that the written HACCP plan(s) are complete and accurate for the facility
- to confirm that the HACCP plan(s) meet the requirements of the *Manitoba HACCP Advantage*
- to prepare for the certification systems audit of the HACCP plan(s)

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Table 9.3: HACCP Plan Review Checklist Example

Complete for each HACCP plan; check off when complete.

Name of HACCP Plan: _____

Form 1: Product Description		Notes (e.g. missing elements, corrective actions required)
<input type="checkbox"/>	All individual products are identified by name in the HACCP plan. Like products are grouped in an acceptable manner.	
<input type="checkbox"/>	Product type is identified (e.g. cooked, raw, fermented, processed).	
<input type="checkbox"/>	Product characteristics important to ensure food safety are listed (e.g. pH, Aw). Characteristics listed are similar for all products covered by the HACCP plan.	
<input type="checkbox"/>	Recipe meets the requirements of the <i>Food and Drugs Act</i> .	
<input type="checkbox"/>	Label meets the requirements of the <i>Consumer Packaging and Labelling Act</i> and Regulations. Label for each product is available upon request and a sample of labels is found to be consistent with: "Product Name", "Intended Use", "Storage Instructions", and "Allergen Declaration" on the HACCP plan.	
<input type="checkbox"/>	Products that contain restricted ingredients as per the <i>Food and Drugs Act</i> are declared and do not exceed acceptable levels.	
<input type="checkbox"/>	Allergens as per Health Canada Guidelines are declared.	
<input type="checkbox"/>	Anticipated shelf life of the product(s) under intended storage conditions is stated. ("Shelf Life" must be consistent with "Important Product Characteristics", "Safe Labelling Instructions" and "Special Distribution Controls.")	
<input type="checkbox"/>	Storage instructions for the product are indicated. ("Storage Instructions" must be consistent with "Shelf Life", "Intended Use" and "Important Product Characteristics.")	
<input type="checkbox"/>	HACCP plan indicates the intended use of the product. This includes a description of any special delivery instructions (e.g. temperature and humidity requirements). HACCP plan indicates where the product(s) is to be sold, e.g. restaurant, retail, institution, further processing. Any sensitive populations or target groups, e.g. senior citizen homes, hospitals, baby food, are identified on the HACCP plan. ("Intended use" must be consistent with "Important Product Characteristics," "Shelf Life" and Storage Instructions." Special Delivery Instructions must be consistent with "Safe Labelling Instructions.")	

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Form 2: Ingredients and Incoming Materials		Notes (e.g. missing elements, corrective actions required)
<input type="checkbox"/>	All incoming raw materials and ingredients coming in contact with the product(s) or used in the preparation of the product(s) are listed.	
<input type="checkbox"/>	All processing aids coming in contact with the product(s) or used in the preparation of the product(s) are listed.	
<input type="checkbox"/>	All packaging materials coming in contact with the product(s) or used in the preparation of the product(s) are listed.	
<input type="checkbox"/>	All hazards associated with each incoming raw material/ingredient, processing aid and packaging material are identified, including indication as B (Biological), C (Chemical), P (Physical) in the HACCP plan.	
Form 3: Flow Diagram		
<input type="checkbox"/>	HACCP plan includes a complete step-by-step flow diagram of the process.	
<input type="checkbox"/>	All hazards associated with processing steps are identified as B (Biological), C (Chemical) or P (Physical) on the HACCP plan.	
<input type="checkbox"/>	On-site verification is performed to confirm that the flow diagram is accurate and complete in relation to hazard identification.	
Form 4: Plant Schematic		
<input type="checkbox"/>	HACCP plan includes a plant schematic of the facility and equipment used in the process. The plant schematic outlines product flow (e.g. raw versus finished) and people flow within the facility.	
<input type="checkbox"/>	Plant schematic indicates points of possible cross-contamination. All hazards associated with cross-contamination are identified as B (Biological), C (Chemical) or P (Physical) in the HACCP plan.	
<input type="checkbox"/>	On-site verification is performed to confirm that the plant schematic is accurate and complete in relation to hazards associated with cross-contamination from product and people flow.	
Form 5: Hazard Description and Critical Control Point Determination		
<input type="checkbox"/>	All incoming materials, all processing aids, all process steps, and all potential points of cross-contamination are identified. All items identified on Form #2, Form #3 and Form #4 are listed here.	
<input type="checkbox"/>	Hazards identified for each incoming material, processing aid, processing steps and all potential points of cross-contamination are specified (e.g. salmonella, antibiotic, metal) and a description of each provided (e.g. microbial growth versus microbial contamination).	
<input type="checkbox"/>	CCPs are determined by answering Form #5 questions 1-4 for each identified hazard.	
Form 6: Flow Diagram with Critical Control Points		
<input type="checkbox"/>	All CCPs are identified beside the appropriate step on the flow diagram.	
Form 7: Uncontrolled Hazards		
<input type="checkbox"/>	Hazards that cannot be controlled by the operator are indicated.	
<input type="checkbox"/>	Methods to address each uncontrolled hazard outside the establishment are indicated.	

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Form 8: HACCP Matrix		Notes (e.g. missing elements, corrective actions required)
The following checks must be done for each CCP.		
Critical Limits		
<input type="checkbox"/>	Critical limits are defined to maintain the CCP under control. When applicable, the critical limits meet regulatory/program requirements.	
<input type="checkbox"/>	Validate that the critical limits are appropriate (e.g. sampling plan, laboratory procedures).	
Monitoring Procedures		
<input type="checkbox"/>	Monitoring procedures exist for each critical limit.	
<input type="checkbox"/>	Monitoring procedures are complete (who, what, when and how).	
<input type="checkbox"/>	Monitoring procedures ensure that adequate control is maintained for this CCP and give information on a timely basis allowing a decision to be made on the acceptability of product.	
<input type="checkbox"/>	Results of monitoring procedures are readily available for auditors to review.	
Corrective Actions		
<input type="checkbox"/>	Corrective actions exist for this CCP.	
<input type="checkbox"/>	Corrective actions are complete (who, what, when and how).	
<input type="checkbox"/>	Corrective actions include methods to regain control of the hazard at the CCP, prevent reoccurrence and determine the disposition of affected product (i.e. product produced since the last satisfactory monitoring action).	
Verification Procedures		
<input type="checkbox"/>	Verification procedures exist for this CCP.	
<input type="checkbox"/>	Verification procedures are complete (who, what, when and how). Critical limits, monitoring procedures and corrective actions are appropriate to ensure food safety.	
Record Keeping		
<input type="checkbox"/>	The name and location of the records to be kept for monitoring, corrective action and verification procedures are identified.	

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ii. HACCP Plan Verification Checklist

Objectives:

- To confirm that for each CCP procedures are completed as described in the written HACCP plan(s).
- To prepare for the certification verification audit of the HACCP plan(s).

Figure 9.4: HACCP Plan Verification Checklist Example

Complete for each CCP. CCP # _____

Verification Audit		Notes (e.g. missing elements, corrective actions required)
Monitoring		
Interview the individual responsible for monitoring procedures of this CCP to confirm:		
<input type="checkbox"/>	Understanding of critical limits and the reason and importance of monitoring this CCP.	
<input type="checkbox"/>	How to perform the related monitoring procedures, including record keeping.	
Examine the following to confirm:		
<input type="checkbox"/>	Monitoring activities of those individuals responsible for this CCP are conducted in accordance/consistently with the written HACCP plan.	
<input type="checkbox"/>	Monitoring results are being recorded.	
Corrective Actions		
Interview the individuals responsible for monitoring procedures of this CCP to confirm:		
<input type="checkbox"/>	Ability to identify deviations from, reason for, and importance of corrective actions.	
<input type="checkbox"/>	How to perform the required corrective actions, including record keeping.	
Examine the following to confirm:		
<input type="checkbox"/>	Corrective action activities of those individuals responsible for this CCP are conducted in accordance/consistently with the written HACCP plan.	
<input type="checkbox"/>	Corrective actions are being taken, as needed, and recorded for this CCP.	
Verification		
Interview those individuals responsible for verification procedures of this CCP to confirm:		
<input type="checkbox"/>	Understanding of the monitoring procedures and corrective actions being verified, reason and importance of verification activities.	
<input type="checkbox"/>	How to perform the verification procedures, including record keeping.	
Examine the following to confirm:		
<input type="checkbox"/>	Verification activities of those individuals responsible for this CCP are conducted in accordance with the written HACCP.	
<input type="checkbox"/>	Verification results are being recorded.	

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IN SUMMARY

After reading this chapter, you should be able to provide answers to the following questions:

1. Why are audits necessary?
2. What are your roles and responsibilities for GMP/HACCP certification of your facility?
3. What is an internal audit, and why should you conduct at least one yearly?
4. How do you apply for certification, and what preparation is necessary for application?

Once you can thoroughly answer these questions and act upon them you will be well prepared to apply for certification of your GMP/HACCP system.

Points to remember

- Successful auditing and certification requires sufficient preparation. Good organization and thorough, accurate documentation can make the auditing process quicker and easier, and improve your chances for success.
- A self-assessment in the form of an internal audit is vital on at least a yearly basis to ensure that your GMP/HACCP system is effective and implemented as written, and continues to be so. When internal audits are thorough and any deficiencies rectified, your ongoing certification audit results will improve.
- GMP/HACCP certification is an ongoing process that requires maintenance and updating of your GMP/HACCP system, corrective action follow-up and successful completion of yearly audits. Surveillance and reassessment audits are conducted to ensure your GMP/HACCP system continues to meet the requirements of the *Manitoba HACCP Advantage*.