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cGMP - Food Packaging v2.1

Certification Program Requirements



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PART I: Program Requirements

Introduction

Summary

Kiwa ASI administers the cGMP - Food Packaging Audit Program, a HACCP-based certification program establishing food safety, food defense, operational, and quality management criteria for food packaging and food-contact material manufacturing and converting operations.

These Certification Program Requirements (CPR) govern the Audit Program. Part I establishes the program requirements for application, certification scope, audit planning and conduct, reporting, certification, and maintenance of certification. Part II establishes the Audit Criteria against which site conformity is evaluated.

The Audit Program applies to organizations that manufacture, convert, process, print, coat, laminate, form, assemble, or otherwise produce food packaging, food-contact materials, or other packaging products and materials that may affect food safety or integrity. The certification scope includes associated receiving, handling, packaging, labeling, storage, warehousing, shipping, and distribution activities conducted as part of the site's manufacturing or converting operations. The products, processes, activities, and locations included within certification shall be established during the application process and confirmed during the audit.

The Audit Program evaluates the site's food safety management system and controls used to manage food safety and food defense risks throughout packaging manufacturing and converting operations. The Audit Criteria are mandatory, and Auditees shall also comply with applicable regulatory requirements. The terms *Facility, Auditee,* and *Site* may be used throughout these CPR in accordance with the Glossary.

The Audit Program is intended for global application. The Audit Criteria are grounded in HACCP principles, 21 CFR Part 117 cGMP principles, and internationally recognized food safety and industry guidance, which collectively inform Kiwa ASI's third-party certification requirements. This common framework supports consistent assessment across jurisdictions while applicable legal and regulatory requirements remain specific to the site's location, products, activities, and intended markets

Regulatory Compliance and Program Conformity

Auditees shall meet applicable legal requirements and these Certification Program Requirements. Where applicable law establishes a lower, different, or less stringent requirement than these CPR, the Auditee shall meet the more stringent program requirement.

Regulatory Compliance: The site shall identify and comply with applicable local, regional, and national laws and regulations governing its operations and products in the country of manufacture and intended markets. The site shall monitor relevant regulatory changes and maintain objective evidence of compliance with both its regulatory obligations and the Audit Criteria.

Program Conformity: Regulatory compliance establishes a minimum baseline and does not, by itself, establish conformity with these CPR. Regulatory exemptions, exclusions, modified requirements, or lower compliance thresholds do not waive, reduce, or remove an Audit Criterion.

Where an Audit Criterion expressly establishes different compliance conditions based on regulatory status, the Auditee shall satisfy the condition supported by its documented regulatory framework, certification scope, and operations. The Audit Criterion remains mandatory, subject to evaluation and shall be rated Compliant or non-conforming based on the documented objective evidence.

Certification and regulatory oversight: Certification does not replace regulatory oversight, constitute regulatory approval, or relieve the site of its responsibility for ongoing legal compliance.

Liability

Kiwa ASI publishes these Certification Program Requirements and other normative documents based on recognized industry practices and regulatory requirements. Kiwa ASI accepts no liability for any error or omission of any such information or opinion, including any information or opinion contained in this publication. The Kiwa ASI cGMP Food Packaging Audit Program is not accredited. Where a site requires certification to an accredited standard, Kiwa ASI offers suitable alternatives.

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Audit Scope and Applicability

Audit Scope

The scope of any Kiwa ASI cGMP Audit is established during the application process and confirmed during the audit by the auditor. The scope of the audit outlines where the site's responsibilities for the process begins and ends, as well as what products are being produced. Any changes relating to the location premise, design, or the products being produced shall be communicated with Kiwa ASI prior to or when the change occurs. Some changes may require a scope extension audit to maintain the site's certificate. All products within the scope of certification must clearly be outlined with Kiwa ASI during the application process and must be limited to those products which the facility actively produces.

The scope of certification and all certification activities are “site” or “address” specific, meaning that the audit and any associated certification records are strictly tied to the physical address being audited. All certification audits shall be conducted in person at the site, including any satellite facilities within the audit scope. Remote assessments shall not replace any required on-site audit activities. Certification may never be transferred to alternative locations or addresses.

Kiwa ASI may incorporate any reasonably distanced satellite addresses into the scope of certification activities, only if the additional address is a direct extension of the processes at the main facility and share master management systems. Any Satellite facility must be approved by Kiwa ASI and incorporated into the scope of certification activities during the application process, or through an Kiwa ASI scope extension audit. Any additional satellite facilities/areas may increase the duration necessary to complete a comprehensive compliance audit.

Scope Exclusions

It is the responsibility of the Auditee to ensure that all relevant activities under the intended scope are accurately represented, and any proposed exclusions are transparently disclosed to Kiwa ASI.

Any exclusions from the scope of the cGMP Audit must be clearly identified in writing to Kiwa ASI for review and formal approval prior to the start of a certification audit (*during the application or planning process*). Exclusions may include specific processes, product lines, or operations and must not compromise the integrity or completeness of the audit relative to food safety risks and regulatory compliance. If an exclusion is approved, the auditor may still require limited access to specific areas to verify no contributing risks such as pest activity, or adulteration to the product and facility areas within the scope of the audit.

A scope exclusion removes an approved product, process, operation, or area from the certification scope; it does not remove or modify an Audit Criterion applicable to activities remaining within the certification scope.

Mandatory Requirements

The Audit Criteria established in Part II are mandatory and shall be evaluated for every Auditee. An Audit Criterion shall not be waived, removed from evaluation, or assigned a non-applicable status based on regulatory applicability, customer agreement, site preference, or site-specific justification.

Where the condition addressed by an Audit Criterion is not present within the certification scope, the criterion shall remain subject to evaluation. The auditor shall verify the condition using objective evidence and document the basis for a Compliant rating.

The absence of a required program, procedure, control, record, or other required element shall not be considered an absent condition and shall be evaluated as a non-conformity.

Where an Audit Criterion expressly establishes different compliance conditions based on regulatory status, product, process, or operation, the condition supported by the Auditee's documented information and observed operations shall be evaluated. The criterion shall remain mandatory and shall be rated Compliant or non-conforming.

Where the Auditee believes applicable law prohibits compliance with an Audit Criterion, the Auditee shall notify Kiwa ASI before the audit and provide documentation of the legal conflict. Such notification does not waive the Audit Criterion and remains subject to Kiwa ASI review.

Shared or Leased Spaces

The Audit Criteria remain mandatory for Auditees operating in shared or leased facilities. The use of a shared space or reliance on a property owner/manager does not exempt an auditee from demonstrating conformity with the Audit Criteria. While this arrangement may influence certain elements, (i.e. service providers, building repair, or utility management), the responsibility to ensure compliance ultimately rests with the auditee. No Audit Criterion shall be waived on the basis that the facility is shared or managed under a lease or alternative ownership structure.

Audit Preparation and Planning

Preparing for an Audit

Before a certification audit, the Auditee shall:

1. Review the Audit Criteria and incorporate the elements into the site's food safety management system.
2. Conduct an internal audit against the Audit Criteria. The site may also elect to obtain an optional Kiwa ASI Mock Audit.
3. Complete the Kiwa ASI certification application and establish the proposed certification scope.
4. Coordinate audit scheduling, operational availability, and logistical requirements with Kiwa ASI.
5. Ensure required production history, records, personnel, and in-scope operations are available for audit in accordance with *Applicable Records* and *Active Operations During Audits*.

Insufficient production history, records, operational availability, or representative scope coverage may prevent the audit from proceeding or being completed.

Mock Audits

A site may choose to order an optional mock audit before the certification audit to evaluate the site's level of conformity with the Audit Criteria. Mock Audits are unofficial assessments meant to provide the Auditee with valuable objective feedback that highlight any compliance concerns. Certificates are never distributed for Mock Audits despite any final result. The final report will be distributed following agreement terms, and may be utilized to implement corrective actions prior to a certification audit.

Application Process

The application process ensures certification services and the scope of audit are clearly defined before an audit begins. The application process includes the following steps:

	Process	Description
1	Evaluation of Certification Needs	Kiwa ASI and the facility review certification needs, proposed certification scope, and applicable program requirements.
2	Quote and Terms Acceptance	Kiwa ASI provides a quote with the terms and conditions. The applicant reviews, checks and signs the quote to accept.
3	Finalize Facility, Personnel, and Scope Details	The facility clarifies provides necessary information to allow proper audit planning.

Sites must establish only active products and areas within the scope of certification during the application process, or as soon as practicable as changes to the facility occur. These scope details must outline the products and areas either "in-scope" or those that should be listed as "Exclusions" prior to an auditor's arrival. Any changes not communicated prior to auditor arrival for scheduled services may delay certification or disrupt a site's certification status.

Planning Process

Once the application has been completed, Kiwa ASI will coordinate with the facility to plan the audit. The planning process ensures that the audit is scheduled in a timely manner, aligned with operational needs, and conducted by a qualified auditor. Key planning steps include:

	Process	Description
1	Coordination with Planning Team	The facility will work directly with Kiwa ASI's Planning team to establish audit dates, timelines, and logistical requirements.
2	Assignment of Qualified Auditor	Kiwa ASI will assign an Auditor with the appropriate qualifications, experience, and impartiality for the audit scope.

	Process	Description
3	Audit Confirmation	Audit scheduling will be finalized and communicated to the facility in writing, ensuring mutual agreement and preparedness.

Auditor Assignment

Kiwa ASI shall retain sole authority for auditor assignment, reassignment, and rotation, including the use of qualified contract auditors. Site requests for specific auditors may be considered but are not guaranteed. Kiwa ASI may assign or substitute auditors based on availability, qualifications, and impartiality.

Kiwa ASI may reassign or rotate auditors case by case to safeguard impartiality and objectivity, including where familiarity or personal relationships create an actual or reasonably perceived conflict of interest. More than three consecutive certification audits at the same site may warrant rotation; however, no fixed audit count or time interval shall require rotation.

Audit Duration

The minimum duration for a certification audit shall be one (1.0) audit day. The minimum duration for a scope extension audit shall be one-half (0.5) audit day.

Audits are coordinated in half-day increments (0.5 day = approximately 4 hours / 1.0 day = approximately 8 hours). These durations are planning measures and do not establish fixed working hours, arrival times, departure times, or maximum daily audit durations. Actual audit time may vary based on facility operations, audit progress, and conditions encountered during the audit.

The duration of a cGMP Audit shall be established during the application and planning process and communicated to the site. Kiwa ASI may adjust the assigned duration, including additional time or multiple audit days, when necessary to adequately evaluate the certification scope and Audit Criteria. Duration shall be reviewed for re-certification and adjusted as necessary based on changes to the site or experience from previous audits.

Factors that may affect audit duration include:

- Size and complexity of the facility and any satellite facilities.
- Number of employees and operational areas.
- Number and complexity of products, processes, and HACCP or food safety plans.
- Certification scope and scope changes.
- Production or operating schedules.
- Availability and complexity of records and supporting evidence.
- Audit trails, findings, or other conditions requiring additional evaluation.

Active Operations During Audits

The Auditee shall ensure that production or operations within the certification scope are active while the auditor is present. Facilities are not required to produce every in-scope product simultaneously or on the audit day. Large-scale facilities and sites with varied production schedules shall arrange for observation of a representative range of in-scope product types, processes, and associated controls, to the extent reasonably feasible.

During audit planning, the Auditee shall notify Kiwa ASI in writing of known production limitations, identifying the products and processes expected to operate and those that will not be available for direct observation. Changes after audit confirmation shall be communicated before the audit begins.

Where scheduling conflicts prevent full-scale production, the Auditee may demonstrate a small batch that adequately represents the relevant production steps and controls. For products or processes not directly observed, the auditor shall sample historical production records and supporting evidence in accordance with *Applicable Records*. This flexibility does not reduce the certification scope or waive any Audit Criterion.

Kiwa ASI reserves the right to abort the audit if no in-scope production or operations are active while the auditor is present. The auditor shall determine whether observed activities and available records are sufficient for representative evaluation of the certification scope.

For mock audits, the facility shall demonstrate, at minimum, a mock run or walkthrough of relevant production activities sufficient for the auditor to provide meaningful compliance feedback.

Documentation Reviewed During the Audit

Documented procedures and programs required by the Audit Criteria apply to every site. The following list identifies key required documents but is not exhaustive. Supporting forms, records, and other documented evidence related to these procedures and programs may also be reviewed by the auditor. Examples include:

- ✓ Corrective & Preventive Action (CAPA) Records
- ✓ Complaint Management Procedure
- ✓ Document Control & Record-Keeping Procedure
- ✓ Training Program
- ✓ Allergen Management Procedure
- ✓ Environmental Monitoring Program
- ✓ Hold & Release Procedures
- ✓ Rework Procedures
- ✓ Identification & Traceability Procedure
- ✓ Recall Program
- ✓ Supplier Approval Program
- ✓ Cleaning & Sanitation Program
- ✓ Pest Control Program
- ✓ Foreign Matter Detection & Control Procedures
- ✓ Shipping & Receiving Procedures
- ✓ Preventative Maintenance Program
- ✓ Calibration Procedures
- ✓ Good Hygiene Procedures
- ✓ Food Defense Plan
- ✓ HACCP Plan

Applicable Records

Record Availability

The site shall maintain and make available records from the applicable review period sufficient to demonstrate its production history and permit representative sampling of the products, processes, and associated controls within the certification scope. Records may be maintained in physical or electronic form.

Meeting the sixty (60)-day minimum production history does not, by itself, establish that sufficient records are available to conduct the audit. Available records shall also provide sufficient representation of the approved certification scope. The auditor may group products or processes for sampling where objective evidence demonstrates that their processes, hazards, and controls are sufficiently equivalent. The auditor shall document the basis for such grouping.

Applicable records include, but are not limited to, relevant production and batch records; receiving, storage, shipping, handling, and traceability records; required monitoring and verification records; annual or periodic program reviews; food safety and quality records; complaints, recalls, investigations, corrective actions; and other records required by the Audit Criteria.

Records shall be accurate, complete, legible, dated, attributable to responsible personnel, and readily retrievable during the audit. All applicable records within the review period shall be available for auditor-selected sampling. The site shall not limit the audit to site-selected records or samples. Verbal assurances shall not substitute for required documented evidence.

The availability of records does not obligate the auditor to review every record. Rather, the auditor shall determine the records and samples necessary to evaluate conformity with the Audit Criteria and ensure representative coverage of the certification scope.

Minimum Production History

The Food Packaging Audit Program requires an operating history based on actual manufacture or conversion of food packaging or food-contact materials within the proposed certification scope.

Before the audit start date, the site shall have completed and documented at least sixty (60) cumulative days of actual production within the applicable review period, except as provided under Seasonal and Intermittent Production.

A Production Day is a local calendar date on which actual manufacturing or converting activity within the certification scope occurred. Each calendar date counts as one Production Day regardless of the number of shifts, batches, production lines, products produced, or operating hours. Production Days do not need to be consecutive. Shutdowns, downtime, warehousing-only activities, and other dates on which no in-scope production occurred do not count toward the sixty-day minimum.

The site shall maintain records sufficient to verify the Production Days claimed toward the minimum. Production records and associated documentation shall collectively identify or corroborate the production date and the in-scope manufacturing or converting activity performed.

Procedures, blank forms, templates, schedules, or downtime records alone do not establish a qualifying Production Day.

The sixty-day minimum establishes the minimum production history required before a certification audit. It does not limit audit sampling to sixty days, replace annual, periodic, or event-driven record requirements, or establish sufficient representation of the entire certification scope.

Records generated from receiving, inventory control, cleaning and sanitation, maintenance, storage, warehousing, shipping, distribution, or other non-production activities may support evaluation against the Audit Criteria but do not independently count as Production Days. Records generated during the audit may support the evaluation but do not count toward the pre-audit production minimum.

Applicable Review Periods

The applicable review period establishes the period from which records shall be made available for audit sampling. It is separate from the sixty (60)-day minimum production-history requirement.

Initial Certification Audit: The applicable review period is the 365 calendar days immediately preceding the audit start date through completion of the audit. A site that has operated for less than 365 days shall make available all applicable records generated since operations commenced. The site must still satisfy the *Minimum Production History* requirements before the audit unless the *Seasonal and Intermittent Production* provisions apply.

Re-Certification Audit: The applicable review period begins upon completion of the previous certification audit and continues through completion of the current certification audit. The site shall make available applicable records generated throughout that audit cycle.

These review periods establish the normal period for certification-audit sampling. They do not reduce applicable record-retention requirements or prevent review of current procedures, validation studies, specifications, or other supporting documentation necessary to evaluate conformity with the Audit Criteria.

Seasonal and Intermittent Production

The site shall disclose seasonal production schedules, intermittent operating schedules, and known production-history limitations during audit planning. Audits of seasonal operations shall be scheduled during active operations in accordance with *Active Operations During Audits*. Applicable seasonal records within the review period shall be available, including relevant start-up, production, monitoring, verification, and shutdown records.

Sites that can accumulate sixty (60) qualifying production days within the applicable review period shall meet the standard sixty-day minimum.

Where the nature of a seasonal or intermittent operation does not allow the site to accumulate sixty (60) qualifying production days within the applicable review period, the site shall disclose this condition to Kiwa ASI before the certification audit is scheduled or confirmed. Kiwa ASI shall

determine whether the available production history, frequency of operation, records, risk, and anticipated scope coverage provide sufficient objective evidence for the certification audit to proceed.

Any authorization to proceed with fewer than sixty (60) qualifying production days shall be documented in writing by authorized Kiwa ASI technical personnel before the audit begins.

This provision modifies only the minimum number of qualifying production days required for eligible seasonal or intermittent operations. It does not modify any Audit Criterion, excuse missing records for activities that occurred, extend the applicable review period, or permit certification of activities for which sufficient objective evidence is unavailable. Seasonal or intermittent status alone does not establish record sufficiency.

Record Sufficiency

Record sufficiency and compliance are separate determinations.

> **Sufficiency:** The auditor shall determine whether available records provide sufficient quantity, time-period coverage, and representation of the certification scope to permit an adequate evaluation.
>
> **Compliance:** The auditor shall determine whether the records and activities selected for evaluation conform to the Audit Criteria.

A deficiency within an individual record does not automatically prevent that record from being used to verify that production occurred on a particular date where other objective evidence corroborates the production date and activity. Record deficiencies shall nevertheless be evaluated against the Audit Criteria. Deficiencies that collectively prevent verification of production history or representative scope coverage shall also be considered when determining sampling sufficiency.

During the audit, the auditor has authority to continue or abort the audit where available production history, records, or scope representation are insufficient to conduct a meaningful evaluation. The auditor shall document the identified limitation, its effect on the audit, and the basis for the decision.

Continuing an audit despite an identified record limitation does not establish compliance, approve a production-history allowance, modify an Audit Criterion, or guarantee certification.

Certification shall not be granted or renewed unless sufficient objective evidence supports the approved certification scope and all applicable production-history requirements have been satisfied. A passing audit score alone does not establish eligibility for certification when record sufficiency, production history, scope coverage, or another program requirement has not been satisfied.

Insufficient records identified during an audit shall not authorize removal of products, processes, or operations from the certification scope. Any proposed change to the certification scope shall be evaluated in accordance with *Scope Exclusions*.

An aborted audit is incomplete and does not provide a basis for granting or renewing certification.

Audit Process

Access and Confidentiality

Auditors reserve the right to implement a systematic approach to their compliance review which may require access to all areas of the facility (internal and external), management documentation, proprietary information, physical and electronic records, personnel/contractor/visitors and relevant information, etc. Denial of access is a Critical non-conformity (*see Non-Conformities*).

Mock Recall - As part of the certification audit, the Auditee shall complete an effective mock recall exercise within two (2) hours. The exercise completed during the audit does not count as the site's annual mock recall.

All information obtained during review will be held under strict confidentiality guidelines and shall not be distributed to any third party as outlined in the service agreement established between the Auditee and Kiwa ASI.

Audit Agenda

The audit agenda provides a general framework for conducting the audit and assisting the Auditee with preparation. The sequence and timing of activities are approximate and may be adjusted based on site operations, certification scope, risk, available objective evidence, findings, and audit trails. Activities may be combined, revisited, or continued across multiple audit days as necessary. Audit duration shall be established in accordance with *Audit Duration*.

The following illustrates a typical single audit day:

Approximately 8:00 a.m. – 8:30 a.m. | Opening Meeting

The opening meeting generally includes:

- Introductions and confirmation of site contacts.
- Confirmation of the certification scope, audit objectives, and operating conditions.
- Review of audit logistics, personnel availability, site access, and safety requirements.
- Review of previous findings or follow-up matters, where relevant.
- Overview of the audit and reporting process.

Audits are generally planned to begin between 8:00 and 8:30 a.m. local time. Alternative start times may be established during audit planning or based on operational or logistical considerations

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Morning | Facility Walkthrough / Site Evaluation

The auditor will evaluate site conditions, operations, and implementation of applicable controls. Areas of evaluation may include:

- Receiving and incoming materials.
- Processing, manufacturing, and packaging operations.
- Storage, warehousing, handling, and distribution.
- Personnel practices and hygiene.
- Equipment, utilities, and maintenance.

- Cleaning, sanitation, chemical, and allergen controls.
- Grounds, waste management, and pest control.
- Food defense and site security.
- Personnel interviews and observation of cGMP practices.

Throughout the Audit | Documentation, Records, Interviews, and Audit Trails

The auditor will evaluate documented programs, records, personnel practices, and other objective evidence necessary to determine conformity with the Audit Criteria. Records shall be made available in accordance with *Applicable Records*. Review may include:

- Management and food safety responsibilities.
- HACCP and food safety plans.
- Document and record controls.
- Training and competency.
- Complaints and incident management.
- Corrective and Preventive Action (CAPA).
- Supplier and incoming material controls.
- Traceability, recall/withdrawal, and product release.
- Sanitation, allergen, water, chemical, and pest management.
- Maintenance, calibration, verification, and validation.
- Food defense and site security.

The auditor may select samples, conduct interviews, request additional objective evidence, revisit previously evaluated areas, and follow audit trails as necessary. Significant food safety or certification concerns may be communicated when identified.

Meals and Break Periods

Break timing is flexible and may be adjusted based on audit progress and operational circumstances. Audit activities may continue through customary break periods by agreement between the auditor and Auditee as needed.

End of Audit | Closing Meeting

The closing meeting generally includes:

- Summary of the audit.
- Presentation and review of preliminary non-conformities.
- Clarification of supporting objective evidence, where necessary.
- Review of corrective action expectations.
- Explanation of Technical Review and the reporting process.
- Next steps and questions from site management.

Appropriate site management or designated representatives should remain available for the closing meeting. The anticipated closing time may be communicated during the audit but

The agenda does not establish a fixed sequence, allocation of time, or required completion time. The auditor may adjust the audit approach and areas of emphasis based on objective evidence, risk, observations, and audit trails, provided the certification scope and Audit Criteria are adequately evaluated

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Preliminary / Draft Findings

Findings communicated during the audit or closing meeting remain preliminary and in "Draft form" until completion of Kiwa ASI Technical Review. Technical Review may confirm or revise findings, grades, report content, or the audit score before issuance of the final audit report.

Audit Findings and Scoring

Finding Rules

Below is a general list of rules for Compliance teams to use when conducting review of activities associated with these Certification Program Requirements.

- ✓ **Corrections During the Audit -** Non-conformities shall be graded based on the condition identified by the auditor. Subsequent corrections made either during or post-audit shall not change the outcome, or the non-conforming rating.
- ✓ **Consolidation of Findings -** The same issue shall not be counted more than once. Issues affecting multiple Audit Criterion or involving multiple instances of the same root cause shall be consolidated into one finding at the highest applicable grade.
- ✓ **Reporting Basis -** Report statements and conclusions shall be supported by objective evidence from the records, processes, and conditions evaluated during the audit.
- ✓ **Site-Identified Issues -** Issues identified by the site shall not, by themselves, constitute audit findings. The site's response shall be evaluated under the Corrective Actions criteria.
- ✓ **Risk-Based Systems -** Auditors may use professional judgment to select and follow audit trails, first verifying minimum expectations, then assessing whether the site's risk analysis and resulting determinations, controls, and actions are adequately supported, appropriate to identified risks, and effectively implemented. Risk analysis alone shall not establish compliance or waive a mandatory requirement.
- ✓ **Technical Review -** All findings and ratings remain preliminary, and in "Draft" form, until Kiwa ASI Technical Review confirms or revises them for accuracy, consistency, and conformity with the Audit Program.

Compliant Ratings

A Compliant rating shall be assigned when the site fully satisfies the Audit Criterion and objective evidence demonstrates that the required policies, procedures, controls, practices, or conditions satisfy the applicable Audit Criterion.

A Compliant rating shall also be assigned where the site's technical processing or operational steps mean that the process, activity, material, or hazard addressed by the criterion is not present and no associated risk exists, as established under *Mandatory Requirements*. The criterion remains part of the audit and shall not be removed from evaluation. The auditor shall document the objective basis for the Compliant rating in the audit report.

Non-Conformities

Non-conformities shall be graded by the auditor as Minor, Major, or Critical. Each finding shall be recorded in the audit report with details of the expectations not met, the objective evidence, and the criterion that determines the grade. Only non-conformities supported by objective evidence obtained through the certification audit shall be reported.

Minor – A Minor non-conformity shall be issued when an Audit Criterion is not fully met, but the control remains in place and effective, no product intervention, hold, or regulatory action is needed, and no Major or Critical criterion applies.

Major – A Major non-conformity shall be issued when a failure affects the capability of a control to achieve its intended food safety result and no unsafe product is identified. This includes where:

a) a required control, procedure, program, or record system is absent or not implemented;
b) repeated or systemic failures show that a control cannot be relied upon, which may include two or more Minor non-conformities against the same program element, depending on risk and impact;
c) a condition gives a hazard a route to product, and product would be affected only if a further failure occurred;
d) a Minor non-conformity from a previous Kiwa ASI audit or visit is repeated and, based on severity, warrants an increase in grade;
e) a legal requirement is not met without product impact, including a lapsed license or registration where no product was produced or distributed during the lapse; or
f) the failure of a high-risk requirement, which may be graded Major at minimum.

NOTE: High-risk requirements are those whose failure removes or weakens control of a food safety hazard, such as allergen control, recall and traceability, critical or preventive control monitoring, and certification integrity.

Critical – A Critical non-conformity shall be issued when food safety, legality, or certification integrity is compromised. This includes where:

a) unsafe product is found, or evidence shows it was produced or shipped;
b) a critical limit or preventive control has failed without documented corrective action and control of affected product;
c) an active condition could contaminate exposed product without a further failure;
d) the condition requires regulatory notification, recall, or market withdrawal;
e) records are shown by objective evidence to be altered, backdated, or fabricated, or statements to the auditor are shown to be misrepresented;
f) access to any part of the site premises, or to records needed to evaluate risk, is denied;
g) the site operates without a legally required license or registration and product was produced or distributed under the lapse, or there is direct legal or consumer-safety exposure; or
h) a Major non-conformity from a previous Kiwa ASI audit or visit is repeated and, based on severity, warrants an increase in grade (*see Non-Conformities*).

A Critical non-conformity shall be communicated to site management when identified and to Kiwa ASI on the same day, and shall result in audit failure.

NOTE 1: Unsafe product is product that is adulterated or misbranded under applicable law, is contaminated, or does not meet a critical limit, specification, or labeling requirement.

NOTE 2: A late record entry or documented correction that is clearly identified as such is not falsification.

Some examples of Critical non-conformities are outlined below. The criteria above determine the grade.

- ⊗ Any active or likely contamination of raw materials, Work-In-Progress (WIP), or finished products.
- ⊗ Any instance that would result in the site initiating a recall or withdrawal.
- ⊗ Any live rodents found within the facility.
- ⊗ Any allergen mislabeling of finished products.
- ⊗ Any falsification of food safety records.
- ⊗ Any use of non-potable water as part of the production or cleaning of product contact surfaces.
- ⊗ Any cross-contamination of allergens.
- ⊗ Any equipment found out of calibration at a critical control point with no assessment of affected product.
- ⊗ Any failure to effectively take corrective action for a critical limit deviation.
- ⊗ Chemicals used improperly that could result in product or equipment contamination.
- ⊗ Any denial of access to site premises or to records needed to evaluate risk.

Repeat Nonconformities: A repeat non-conformity is a non-conformity against the same Audit Criterion, or arising from the same root cause, as a non-conformity identified in a previous Kiwa ASI audit or visit. At every subsequent audit or visit, regardless of its purpose, the auditor shall review the site's corrective and preventative action records for non-conformities from previous Kiwa ASI audits and visits and shall note any repeat non-conformity in the audit report.

A repeat non-conformity may indicate a systemic issue. Where a non-conformity is repeated, the auditor may increase its grade by one level (Minor to Major, or Major to Critical), depending on severity. In determining severity, the auditor shall consider hazard severity, proximity to exposed product, whether a critical or preventive control is involved, and the number of products, lines, or areas affected. Where a repeat does not warrant an increase, the original grade shall apply and the repeat shall be recorded.

Where a repeat non-conformity is increased in grade, the audit score deduction for the increased grade shall apply. A repeat non-conformity increased to Critical shall result in audit failure in accordance with the Critical non-conformity criteria.

Scoring Guidelines

The overall audit score is based on the total number and level of non-conformities. The overall audit is allocated 100%, and deductions based on auditor findings are made as follows:

MINOR	MAJOR	CRITICAL
-1 %	-5 %	-100 %

Audit Rating	Audit Score	Certificate Awarded
Excellent	90 – 100%	✓
Good	80 – 89%	✓
Complies	70 – 79%	✓
Fails	0 – 69%	X

Corrective Actions

Corrective action plans are not required to be submitted to Kiwa ASI as a condition of certification. The site shall, however, complete and document corrective and preventative action for each non-conformity identified in an Kiwa ASI audit or visit, including correction, root cause analysis, and action to prevent recurrence.

Corrective and preventative action records are expected to be available for review by the auditor at re-certification audits and at any other audit or visit. They are reviewed to confirm that the site's controls and policies are followed and to determine whether any non-conformity has been repeated (*see Non-Conformities*). Failure to complete, document, and implement effective corrective and preventative action may result in a repeat non-conformity and may indicate a systematic deficiency that carries a risk to product safety.

Reporting and Certification

Audit Report

At the conclusion of the audit, the Auditor will present the audit findings and leave either a hard or electronic copy of any non-conformities found during the audit. This list of non-conformities shall be considered a "draft" list of non-conformities and are subject to change during technical review.

After the audit is complete, Kiwa ASI's technical team will review the entire audit report for accuracy and completeness. There may be occasions when a non-conformity, initially compliant element, or audit score is revised based upon the results of the technical review process.

Technical Review

The Technical Review is the independent evaluation of the Auditor's report to ensure accuracy, completeness, and alignment with these audit program requirements prior to the issuance of a certificate.

Technical Review shall be conducted by qualified Kiwa ASI personnel who demonstrate the necessary technical competence and impartiality to assess the audit report and its findings. The Technical Reviewer has the authority to confirm, clarify, or request revisions to the Auditor's report where discrepancies, omissions, or errors are identified. Key steps include:

	Process	Description
1	Report Submission	Auditor submits completed audit report and supporting documentation to Kiwa ASI.
2	Review	A qualified Kiwa ASI Reviewer evaluates the audit report for accuracy, completeness, and compliance
3	Revisions (If required)	Reviewer issues requests for clarification, additional evidence or corrections to the auditor. Auditor addressed requests and re-submits report details.
4	Approval	Reviewer finalizes acceptance of the audit report once all issues are resolved and/or everything is approved.
5	Certification Granted	Upon successful review and a passing audit score, Kiwa ASI issues certificate and report.

Certification

Sites achieving a final audit score of 70% or higher may be certified only after successful Technical Review and satisfaction of all applicable program requirements established by these CPR and the applicable service agreement. A passing score alone does not establish eligibility for certification where another program requirement prevents certification. Release of Certification documentation is also dependent on full completion of these obligations.

Although certificates are issued to sites that receive 70% and above on an audit, external corporate or customer requirements may require a site to maintain a higher percentage audit score. This is to be agreed upon by the auditee and their customer(s), and shall not affect the progress or outcome of Kiwa ASI services.

The final audit report and certificate issued by Kiwa ASI are official documents and shall not be altered, edited, or otherwise modified by the auditee or any third party. All audit reports and certificates remain the sole property of Kiwa ASI. Certificates must be used only in their complete and original form; partial extracts, altered versions, or use in misleading marketing materials are strictly prohibited. Any misuse, unauthorized alteration, or misrepresentation of these documents may result in corrective action, suspension or withdrawal of certification, and or further legal action. Kiwa ASI reserves the right to publish, disclose, or otherwise verify the certification status of any auditee to ensure transparency and uphold the integrity of the Audit Program.

Maintaining Certification

Audit Frequency

cGMP Audits are conducted annually to maintain certification. A site's certificate expires thirty (30) days after the one (1) year anniversary of the last certification audit. Sites audited near the end of their current certificate's validity period should be aware that the review and approval process may extend beyond the certificate expiration date. In such cases, the certificate will lapse, and the site may temporarily be without a valid certificate until the review is completed, and the renewed certificate is issued. It is the responsibility of the certified site to schedule audits with sufficient lead time to minimize the risk of certificate lapse. If compliance is achieved, a new certificate, score, rating and expiration date will be issued as applicable.

Scope Extensions

Once a certificate has been granted, any significant changes to the site's scope of operations or certification, must be communicated to Kiwa ASI in writing. Examples of significant changes include, but are not limited to:

- The addition of a new structure or building
- The introduction of a new product type
- The introduction of new equipment
- The re-organization of processing/product management areas or equipment

Kiwa ASI shall review proposed changes to determine their effect on the certification scope and validity of the current certificate. Administrative changes may be approved through document review where no additional verification of operational compliance is required. Significant changes affecting products, processes, equipment, operations or facilities shall require an on-site scope extension audit before inclusion in the certified scope. Kiwa ASI shall retain sole authority to determine the assessment required

In situations where a scope extension audit is successful, but there are no changes to the certificate details (example: adding a new area or room to extend an in-scope process), the original certificate will remain in full force and effect. Kiwa ASI may issue a scope extension letter for compliance records at the request of the auditee. Records following successful scope extension audits shall preserve the original audit score, rating, certificate number, certification date and expiration of the existing certificate.

Changes in Ownership, Management, or Significant Personnel

Any major management, ownership, legal name, scope or operational changes shall be communicated to Kiwa ASI in writing as soon as possible.

If a certified site changes ownership (i.e. the business was sold), the new ownership is required to notify Kiwa ASI within thirty (30) calendar days of the ownership change. If the primary staff with responsibility for the management and oversight of the Food Safety System has been retained, Kiwa ASI may retain the same certification date, expiration date and certificate number.

If there are significant changes in site management, personnel, or operations, Kiwa ASI reserves the right to formally withdraw the certificate and notify the Auditee in writing. If a company is moving facilities while certified, Management must notify Kiwa ASI in advance of the known move date. The certificate will be considered null and void once the facility ceases operations in the certified facility and the certificate will be formally withdrawn on the agreed move date. The facility must then successfully pass a certification audit under the new ownership, management, or in the new facility to receive an updated certificate.

Recalls

In the event of a recall, in addition to the appropriate regulatory agency, Kiwa ASI shall be notified by the facility within 24 hours. Kiwa ASI shall work with the facility to determine if any follow up action is necessary to maintain certification. The site must comply with the expectations following recall investigation set forth by Kiwa ASI in order to maintain compliance. The site shall submit the following information to Kiwa ASI:

i. Summary of the event including date of notification and products involved.
ii. Ongoing communication regarding the activities conducted by the site to determine the scope of the food safety event.
iii. Follow up activities conducted by the site that addresses the reason behind the food safety event, implemented corrective action, and/or other follow up activities as appropriate.

Kiwa ASI shall be notified at us.recalls@kiwa-asi.com.

The site must comply with all criteria established by Kiwa ASI for recall notification, investigation, and corrective actions in order to maintain certification. Kiwa ASI reserves the right to withdraw certification if, after conducting a recall investigation, it is determined that the site failed to maintain conformity with Program Requirements including timely communication of the incident.

Use of Kiwa ASI Certification Marks and Logos

The Kiwa ASI Certification Mark and Kiwa ASI Logo (Collectively referred to as Kiwa ASI “Logos” or “Marks”) are owned by Kiwa ASI, LLC. All sites that achieve a certificate shall have the right to use the Kiwa ASI Certification Mark and/or Logo for the duration of the site's certification upon written approval from Kiwa ASI. The site may use the Kiwa ASI Certification Mark and/or Logo on marketing material, product displays, brochures, flyers, advertisements, press releases, company websites, internal documents, etc. The Kiwa ASI Certification Mark may not be used on finished product labeling or packaging.

Examples of the Kiwa ASI Certification Mark and Kiwa ASI Logo are shown below. Contact Kiwa ASI for approval and secure delivery of the current electronic file package.



Appeals & Complaints

Any site can initiate the formal appeal and/or complaint by submitting the appropriate Appeal and/or Complaint form to any Kiwa ASI staff member. Once the appeal or complaint is received, it will be investigated and resolved appropriately.

Auditees can email us.info@kiwa-asi.com or call 1-800-477-0778 to initiate appeals, complaints, and additional requests such as a logo use, certification verification, etc. These processes can also be initiated on our online form via the Kiwa ASI website (www.asifood.com).

PART II: Audit Criteria

Module 1: Food Safety Management System

1.1 Management Commitment to Food Safety

The Facility's Management team demonstrates effective commitment to the food safety system and actively supports the food safety team and the development of a positive food safety culture. The facility's Management Commitment Program shall be documented, current, and reviewed by management at least annually. The Management Commitment Program must include:

a) A Company "Commitment to Food Safety" statement or policy is documented, clearly posted, and made readily available for all staff and visitors.
b) An Organizational chart and Job descriptions that identify key Food Safety roles and clearly outline individuals' authority and responsibilities.
c) Ensure adequate systems and resources are provided to responsible employees to easily obtain customer, billing, receiving, manufacturing, and shipping records for traceability efforts.
d) Documented leadership and management involvement in the Food Safety Management System (FSMS), including attendance at management meetings and participation in food safety decisions.
e) Clear Evidence of management commitment to promoting a positive Food Safety Culture and ensuring personnel have adequate resources and support to fulfill their responsibilities.

1.2 Complaint Management

The site shall have documented procedures and practices in place for the management, investigation, and resolution of complaints. The established procedures and practices shall:

a) Identify and describe the personnel responsible for investigating, communicating, and resolving complaints, including those working at the facility as well as any external personnel involved in the process.
b) Ensure all product safety complaints are documented to assist in the identification of any trends.
c) Describe the process for documenting and conducting a root cause analysis and implementing corrective and preventative actions resulting from a complaint to ensure the issue does not reoccur.

1.3 Document Control and Record-Keeping

The site shall have documented procedures and practices to manage all documents and records as part of the food safety management system. The established procedures and practices shall:

a) Describe the method for the identification of the most current document version.
b) Include a detailed process, identifying individuals responsible, that describes how the site securely makes, revises, stores, and maintains legible documents and records for a specified period of time that meets regulatory requirements.

c) Ensure all electronic records clearly identify the individual responsible, include a system generated date and time stamp, maintain an audit trail of any modifications, and are subject to the equivalent control requirements as physical records.
d) Ensure all physical records are only written in permanent ink, not pencil, and white-out, or correction fluid, is not used on any record(s).

1.4 Training

The site shall have a documented training program and practices to ensure that all personnel, including temporary employees and contractors, are adequately trained upon initial hiring. The established training program and practices shall:

a) Ensure at a minimum all personnel and temporary employees receive appropriate training by a qualified individual covering current Good Manufacturing Practices (cGMPs), HACCP, Food Defense, Allergen Management, Reporting illness/injuries, local/state/federal regulations, and any role-specific responsibilities (e.g., CCP & PC Monitoring).
b) Include a training matrix indicating appropriate training topics assigned to which staff, which topics each employee has been trained on, and the most recent date of training.
c) Include a provision for refresher training at appropriate intervals (at a minimum annually).
d) Ensure trainers are qualified, through experience or certification, to provide training on the subject matter.
e) Ensure training is available in a language understood by all staff.
f) Require trainees to acknowledge understanding of the training material via signature or other verification method (i.e., quiz, exam, etc.).

1.5 Licensing

The site shall identify and maintain all licenses, permits, registrations, and regulatory authorizations required for its products and operations. Current documentation shall be readily available for audits.

1.6 Certification Integrity

The site shall maintain the integrity and credibility of its certification by ensuring the following:

a) Any certification marks, logos, and certificates are used in accordance with Kiwa ASI guidelines and that all records and audit-related information are accurate and free from falsification or misrepresentation.
b) All product, process, or area exclusions must be previously reported to Kiwa ASI, approved, and be accurate at the time of the audit.
c) The site shall provide auditors unrestricted access to all relevant areas, records, personnel, and processes without obstruction.

Module 2: Current Good Manufacturing Practices (cGMP)

2.1 Processing Controls

2.1.1 Process Flow, Segregation and Cross-Contamination Prevention

The site shall have established practices to ensure the process flow and employee practices promote required segregation and prevent cross-contamination appropriate to the scope of products and processing.

2.1.2 Personnel Processing Practices

The site shall have established practices to ensure that all personnel handle raw materials, Work-in-Progress (WIP), finished products, and packaging materials as to not pose risk to product safety.

2.1.3 Raw Materials

The site shall have established practices that ensure all raw materials, including packaging materials, comply with regulatory requirements for where the product is manufactured and/or sold.

2.1.4 Labeling

The site shall have established practices for finished product labeling that ensure products are labeled according to regulatory requirements for where the product is manufactured and/or sold. The established practices shall ensure labels are affixed to the correct product and finished products are not mislabeled.

2.2 Allergen Management

The site shall maintain documented procedures and practices to control legally defined allergens and prevent allergen cross-contact within the certification scope. The established procedures and practices shall:

a) identify and document allergens associated with materials, products, processes, or other potential sources within the operation;
b) establish controls to prevent unintended allergen introduction through personnel, visitors, materials, or manufacturing activities; and
c) establish appropriate segregation, handling, cleaning, or sanitation controls where allergen cross-contact could affect food-contact products.

2.3 Environmental Monitoring

The site shall maintain documented procedures and practices for a risk-based environmental monitoring program addressing microbiological hazards and environmental cross-contamination within the certification scope. The program shall:

a) Identify responsible personnel;
b) Include a documented risk assessment establishing monitoring areas, risk levels, sampling locations, target organisms or indicators, methods, frequencies, limits, and corrective actions;
c) Support risk-based determinations with relevant scientific, technical, regulatory, historical, testing, monitoring, or operational evidence;

d) Define corrective actions and verification activities for results exceeding established limits or action levels;
e) Include evaluation and trending of monitoring results; and
f) Be reviewed at least annually and whenever changes, findings, trends, incidents, or new information may affect the program.

Where the documented risk assessment establishes that environmental sampling is not required, the objective basis shall be documented. A verbal statement, unsupported conclusion, customary practice, or absence of known incidents shall not establish conformity.

2.4 Foreign Matter

2.4.1 Foreign Matter Detection

Where foreign matter detection or removal equipment is used, the site shall maintain documented procedures and practices demonstrating that the equipment is appropriate to its intended purpose and operates effectively. The established procedures and practices shall:

a) Describe how the site plans to detect foreign matter.
b) Describe the methods and frequency used to monitor and verify foreign matter detection.
c) Include provisions for the inspection and investigation of foreign matter that is detected by detection devices, including any corrective actions that arise from contamination instances.
d) Establish a process for routine verification checks of foreign material detection equipment, when present (e.g., sensitivity testing with certified test pieces), at a frequency sufficient to confirm ongoing effectiveness and proper equipment performance between calibrations.
e) Describe the methods and frequency used to calibrate foreign matter detecting equipment according to manufacturers' recommendation, national, and international standards.
f) Document equipment calibration activities at minimum annually.

2.4.2 Foreign Matter Controls

The site shall have documented procedures and practices for the control of foreign matter. The established procedures and practices shall:

a) Exclude all wood, glass, brittle plastic, ceramics, or other similar materials from areas where open products and product packaging are handled where possible. Where not possible,
b) Ensure there are no loose objects on equipment or overhead structures.
c) Ensure all surrounding equipment, building materials, and pallets are clean and in good repair.
d) Include an inspection process to ensure the facility, equipment and tools remain in good repair as to not cause potential foreign matter contamination.
e) Include provisions for the protection and/or management of the damage, breakage, or deterioration of wood, glass, brittle plastic, ceramic, or other similar objects that cannot be removed from the processing area and how the site monitors the objects to ensure no risk to product safety.
f) Describe the methods for how the site controls the use of metal cutting instruments used in processing and packaging operations.

2.5 Non-Conforming Goods

2.5.1 Hold and Release

The site shall have documented procedures and practices for holding and releasing non-conforming raw materials, Work-in-Progress (WIP), finished products (including returned products), and packaging materials. The established procedures and practices shall:

a) Ensure that non-conforming goods are clearly identifiable and not comingled with products not on hold.
b) Ensure that non-conforming goods are quarantined and stored to prevent accidental release or cross-contamination.
c) Include a process for the decision-making by qualified and authorized personnel on identifying the root cause and continued use or disposal of the non-conforming goods.

2.5.2 Rework, Recoup, and Repacking

Where the site performs rework, recoup, or repacking of raw materials, Work-in-Progress (WIP), and/or finished product, the site shall have documented procedures and practices. The established procedures and practices shall:

a) Ensure reworked, recouped, and repacked goods are clearly identifiable and dated for traceability.
b) Describe how each batch of reworked, recouped or repacked product is inspected and analyzed before its release for use.
c) Ensure reworked, recouped, and repacked products are processed so they do not expire prior to the expiration date of the finished product.
d) Ensure reworked, recouped, and repacked products are safe to use and processed "like-to-like."

2.5.3 Identification and Traceability

The site shall have documented procedures and practices for the identification and traceability of all raw materials, Work-in-Progress (WIP), finished products, and packaging materials throughout the entire process. The established procedures and practices shall:

a) Ensure all raw materials, Work-in-Progress (WIP), finished products, and packaging materials are clearly identified throughout the entire process.
b) Ensure finished products are traceable to the customer (one forward) including packaging.
c) Ensure raw materials and packaging materials are traceable to the manufacturing supplier (one back).
d) Ensure when product is on hold, and where rework/recoup is performed, traceability is maintained.

2.5.4 Recall Program

The site shall have documented procedures and practices for the recall of products. The established procedures and practices shall:

a) Include a list of key personnel (i.e., Recall Team) responsible for initiating, handling, and investigating a product recall with specific responsibilities identified.

b) Include an up-to-date list of key contacts that includes the above key personnel involved in the product recall, emergency services, customers, suppliers, regulatory agencies, and certification body.
c) Include a plan for communicating key information to customers, suppliers, regulatory agencies, and consumers.
d) Describe how the site plans to recover or dispose of affected products.
e) Recall Records shall include at minimum regulatory classifications, summary of recall, Lot #(s), Quantity of Raw Materials Received, Quantity Produced, Quantity In-house, Quantity of Finished Product shipped, Verification of in-house count, duration of recall, corrective actions.
f) Include the testing of the recall procedure (one forward and one back) at least annually during a mock recall, or an actual recall event.
g) The site is also required to successfully complete a mock traceability/recall exercise in under 2 hours while the auditor is present during the audit.

The site must demonstrate ability to trace one back for raw materials (suppliers) and recall one forward for finished product (customers). The exercise completed during the audit does not count as the site's annual mock recall.

2.6 Food Defense

2.6.1 Food Defense Coordinator

The site shall designate a Food Defense Coordinator responsible for the Food Defense Program. The Food Defense Coordinator shall:

a) Be employed by the organization and assigned responsibility for the site;
b) Have authority to develop, implement, maintain, test, and review the Food Defense Program;
c) Oversee threat and vulnerability assessments as well as mitigation measures;
d) Oversee food defense awareness and role-specific personnel training; and
e) Maintain documented training from a recognized food defense training source sufficient to demonstrate qualification for the assigned responsibilities. Training records shall identify the individual, source, content, and completion date.

Personnel may be site-based or corporate. External consultants or contractors may provide technical support but shall not independently satisfy the Food Defense Coordinator requirement. Job experience alone shall not satisfy the training requirement.

2.6.2 Food Defense Plan

The site shall maintain and implement a documented Food Defense Plan covering the products, materials, processes, activities, and locations within the certification scope. The Food Defense Plan shall:

a) Identify and evaluate relevant threats, vulnerabilities, sensitive areas, and access points;
b) Establish mitigation measures and assigned responsibilities;
c) Establish monitoring, reporting, incident response, corrective action, and verification procedures;

d) Address continuity of assigned responsibilities during absence of the Food Defense Coordinator; and
e) Be tested and reviewed at least annually and following significant changes, incidents, or new threat information.

2.6.3 Food Defense Training and Controls

The Food Defense Coordinator shall oversee food defense training and awareness appropriate to personnel responsibilities and site access. The site shall:

a) Provide documented role-specific training to personnel assigned food defense responsibilities;
b) Provide documented food defense awareness training to employees and temporary personnel;
c) Provide visitors, contractors, drivers, and other persons granted site access with food defense instructions appropriate to their activities and access;
d) Establish authorization, identification, restricted-area access, and supervision or escort controls;
e) Establish procedures for reporting suspicious activity, unauthorized access, or food defense concerns; and
f) Maintain required training and access records.

Personnel shall receive required training before independently performing assigned food defense responsibilities.

2.7 Internal Audits and Inspections

2.7.1 Internal Audits

The site shall have documented procedures and practices for conducting internal audits to verify the effectiveness of the entire food safety management system. The established practices shall:

a) Ensure an internal audit of the entire food safety management system, including all documentation and the facility, is completed at a minimum annually.
b) Ensure internal audits are recorded and identify any non-conformities, root cause, and corrective actions taken.
c) Ensure internal audits are conducted by an individual(s) familiar with the site and with adequate training or experience to perform an effective internal audit.

2.7.2 Pre-Operational Inspections

The site shall have documented procedures and practices for conducting pre-operational inspections to verify that production is ready to begin. The established practices shall:

a) Ensure employees are following cGMP policies and facilities and equipment meet sanitary and operational needs before production begins.
b) Ensure inspections are recorded and identify any non-conformities and corrections or corrective actions taken.

2.8 Supplier Approval Program

The site shall have documented procedures and practices for approving suppliers of raw materials and packaging materials. The established procedures and practices shall:

a) Include a current list of all approved suppliers.
b) Identify who is responsible for the approval and monitoring of suppliers.
c) Describe the criteria for how the site selects, evaluates, approves, and monitors suppliers.
d) Include a provision for the use of non-approved temporary suppliers for emergencies and how the site verifies the safety of raw materials before use.
e) Include the review of all approved suppliers at minimum annually.
f) Describe the process and criteria for removal of an approved supplier.

2.9 Good Hygiene Practices

2.9.1 Illness and Injuries

The site shall have documented procedures and practices to ensure employees are not vectors for the transmission of diseases. The established procedures and practices shall:

a) Inform all employees of the signs and symptoms of infectious diseases which would prevent them from working with products.
b) Include a system for all employees to report symptoms to senior management.
c) Ensure employees with exposed cuts, sores or lesions do not handle products.
d) Ensure minor exposed cuts are covered with bandages and disposable gloves that are of material appropriate for the processing environment and monitoring procedures.
e) Ensure areas, where the spillage of bodily fluids (e.g., blood, vomit, etc.) occurs are adequately quarantined, cleaned, and sanitized using proper PPE before being released by authorized personnel.

2.9.2 Personal Hygiene

The site shall have documented procedures and practices to ensure that personnel hygiene practices do not pose a risk to product safety. The established procedures and practices shall:

a) Ensure smoking, vaping, chewing tobacco, eating, and drinking are only conducted in permitted areas away from product handling areas (drinking water is permitted in designated product handling areas as long as it does not pose a risk to product safety).
b) Ensure personnel do not wear false fingernails, fingernail polish, or false eyelashes and natural fingernails are kept clean and short as to not pose a potential source of contamination.
c) Ensure personnel have clean hands and are effectively washing their hands at appropriate frequencies.
d) Ensure personnel are trained on proper handwashing techniques, and signage instructing personnel to wash their hands is located in close proximity to handwashing stations.

2.9.3 Personal Clothing, Jewelry, and Personnel Belongings

The site shall have documented procedures and practices to ensure that personnel clothing, jewelry, and personnel belongings do not pose a risk to product safety. The established procedures and practices shall:

a) Ensure personal attire is clean to prevent contamination from entering the facility.
b) Ensure that there are a sufficient number of uniforms and/or protective clothing items for each employee.
c) Ensure uniforms and protective clothing is suitable to prevent contamination of the product and is changed at an appropriate frequency (i.e., when clothes are soiled).
d) Ensure racks (or equivalent method) are provided at appropriate entrances and exits to ensure there is no contamination of clothing.
e) Ensure hair and beard nets are worn where hair or facial hair could present a contamination risk to exposed product, product-contact surfaces, or product-contact packaging.
f) Ensure that all protective clothing (unless disposable) is effectively cleaned, either by an approved contractor or in-house, at a frequency that minimizes risk to product safety.
g) Ensure that dirty and clean protective clothing is adequately separated, and clean clothes are protected from contamination.
h) Ensure hands are washed before putting on gloves, and gloves are replaced as needed to prevent cross contamination at a frequency that minimizes risk to product safety.
i) Ensure no jewelry, except for a plain wedding band or medical alert bracelet, shall be worn.

2.10 Cleaning and Sanitation

2.10.1 Cleaning and Sanitation Program

The site shall have a documented cleaning and sanitation program outlining practices that ensure the environment is sanitary for food production. The established cleaning and sanitation program and practices shall:

a) Identify what is to be cleaned/sanitized on Master Cleaning and Sanitation logs, and assign individuals responsible for monitoring and maintaining cleanliness/sanitation as required.
b) Describe the methods and frequency for cleaning and sanitation based on risks. This includes cleaning and sanitation chemicals as well as materials to be used.
c) Define the process for mitigating spillage, including use of any dedicated spill-kits.
d) Identify who is responsible for verification and what methods are used to verify cleanliness/sanitation.

2.10.2 Cleanliness of the Facility

The site shall ensure all facilities and equipment are maintained in a clean and hygienic condition, as to not pose a risk to product safety. Cleaning operations should not interfere with manufacturing operations and should not pose a potential risk to product safety.

2.11 Chemical Controls

The site shall have documented procedures and practices for the secure procurement, storage, and use of all chemicals. The established procedures and practices shall:

a) Include a chemical approval process and a list of approved chemicals used onsite.
b) Ensure all chemicals are stored and used properly so that they are effective and do not pose a risk to product safety.
c) Ensure all food-grade chemicals are stored separately from non-food-grade chemicals.

d) Ensure all chemicals are stored in their original container or clearly labeled secondary containers (including spray bottles).
e) Ensure that Safety Data Sheets (SDS) are on file for each chemical used onsite.
f) Ensure that sanitizers are appropriate for their intended use and verified for effectiveness using the correct test kit corresponding to the sanitizer in use.

2.12 Pest Control

2.12.1 Pest Control Program

The site shall have documented procedures and practices for the control of pests (IPM Program). The established procedures and practices shall:

a) Clearly define the responsibilities of the site and/or contractors involved in the development, implementation, and maintenance of the pest control program (Including name of pest control operator, scope and frequency of service, service reports, appropriate logs, and methods of monitoring).
b) Include a bait station map that identifies the type, location, and number of the traps or bait stations used. The map must be verified and signed by the pest control operator at a minimum annually.
c) Ensure that traps, bait stations, insect light traps, and pheromone traps are properly stored and regularly maintained to prevent the attraction of pests from the exterior, and do not pose a risk to product safety.
d) Include a list of regulatory compliant pesticides used with their Safety Data Sheets (SDS).
e) Ensure that pesticides used and/or stored at the facility do not pose a risk to product safety.
f) Define the frequency of the monitoring of pest traps or bait stations.
g) Describe how the site records and trends the sighting of pests and how the site effectively handles recommendations from pest control personnel, including corrective actions and preventative measures.

2.12.2 Pest Control Personnel

The site shall ensure that all personnel, either staff or external contractors, involved with the application of pesticides do not pose a threat to product safety. Pest control personnel shall:

a) Be trained and qualified to conduct pest control activities and meet regulatory compliance.
b) Be licensed and approved by the relevant authorities, and provide documentation to auditee (Certificate of insurance, Business License, Pesticide Applicator's license/certificate).
c) Only use regulatory compliant pesticides and abide by usage directions and restrictions.
d) Provide a documented report of findings and pesticides used during the inspection. Pesticide usage log must include date, name of chemical/EPA number, Location, amount/concentration used, target pests, and applicator.

2.12.3 Pest Infestations

The site shall effectively prevent pest infestations inside the facility. The site shall not have any evidence of pests or pest excretion on or near raw materials (including packaging materials), Work-in-Progress (WIP), or finished goods.

2.13 Water and Air Quality

2.13.1 Water, Steam, and Ice Management

The site shall have established practices to ensure all water, and any steam or ice, used onsite is potable and in compliance with regulatory requirements. The established practices shall:

a) Ensure the volume, temperature, and pressure of water are adequate to meet operational and sanitation needs.
b) Include an, at minimum, an annual microbiological and chemical analysis of the water supply within the facility (at all relevant points of use).
c) Ensure all water analyses are conducted by an accredited third-party laboratory.
d) Include the use of backflow prevention devices installed on main water lines, hoses, taps, and/or other similar water dispensing devices to prevent water contamination. A documented test of backflow devices must be performed at minimum annually.
e) Ensure all water, steam, and ice storage and dispensing devices are supplied with potable water, maintained, sanitized, and filtered as appropriate to prevent risk to product safety.
f) Ensure handwashing stations are appropriately placed in proximity to processing areas, have appropriate signage, are of adequate quantity for operational and sanitation needs, have a potable water supply, and are at an appropriate temperature.

2.13.2 Air Quality and Ventilation

The site shall have established practices to ensure all air or other gases that come in contact with the product or product contact surfaces do not pose a risk to product safety. The established practices shall:

a) Ensure air and other gases that come in contact with product or product contact surfaces are adequately filtered to an acceptable level based on risk, effectively monitored, and changed at an appropriate frequency determined by the preventative maintenance schedule.
b) If compressed air or other gases come into contact with product, or product contact surfaces, the air and/or other gas must be tested by an accredited laboratory at minimum annually.
c) Ensure ventilation is appropriately installed and maintained to effectively mitigate fumes, dust, particles, steam, vapors, and odors from processing. Ventilation shall be appropriately designed as to not pose a risk to product safety.

2.14 Waste Management

The site shall have established practices to ensure all waste is stored appropriately and removed regularly to prevent accumulation, contamination, and the attraction of pests. The established practices shall:

a) Ensure waste containers are clearly identified.
b) Ensure waste containers are clean and maintained regularly.
c) Ensure waste is stored appropriately and removed or emptied regularly.
d) Ensure external waste containers are kept closed.

2.15 Storage and Distribution

2.15.1 Storage Conditions

The site shall maintain documented practices to ensure products and materials are safely stored and protected from contamination, damage, and conditions that could affect product safety or integrity. Storage practices shall:

a) Ensure storage areas are suitable for their intended purpose and maintained to prevent contamination, pooling water, and moisture accumulation;
b) Ensure products and materials are stored off the floor on racks, pallets, or other suitable storage systems;
c) Ensure products and materials are identified, organized, and segregated as necessary to prevent contamination, cross-contact, mix-ups, damage, or unintended use;
d) Establish and document required storage conditions based on product specifications, hazard analysis, and applicable regulatory requirements. Temperature, humidity, atmosphere, or other environmental conditions requiring control shall be monitored and recorded;
e) Establish corrective actions for deviations from required storage conditions, including evaluation and disposition of affected products or materials; and
f) Ensure condensation, drainage, and other sources of moisture are controlled to prevent contact with products, materials, or packaging.

2.15.2 Receiving

The site shall have documented procedures and practices to ensure raw materials are received in an acceptable condition. The established procedures and practices shall:

a) Include inspection criteria and process for all incoming trailers and raw materials before unloading that includes the documentation of any findings and the resolution.
b) Describe the methods used for unloading to ensure minimal exposure of the product to detrimental conditions.
c) Describe the methods used to ensure the prevention of cross-contamination and that the raw material maintains its integrity throughout the unloading process.
d) Describe the methods used to ensure the load was secured from tampering or external elements.

2.15.3 Shipping

The site shall have documented procedures and practices to ensure finished products are shipped safely and prevent cross-contamination. The established procedures and practices shall:

a) Include inspection criteria and process for all trailers and product before loading that includes the documentation of any findings and the resolution.
b) Describe the methods used for loading to ensure minimal exposure of the product to detrimental conditions.
c) Describe the methods used to ensure the prevention of cross-contamination and that the product maintains its integrity throughout the loading process.
d) Describe the methods used to ensure the load is secure from tampering or external elements.

2.16 Facility and Equipment Design

2.16.1 Location Design and Layout

The site shall be in a location suitable for the intended purpose and mitigate opportunities for cross-contamination between and during operations. The site shall ensure:

a) The site's construction is maintained and in good repair.
b) The site's grounds and surrounding area are maintained and free from debris, standing water, and excessive dust.
c) The site shall have an 18” perimeter of maintained or no vegetation growth around the exterior of the facility to ensure there is no harborage of pests.
d) Roadways, loading, and unloading areas under the site's control are maintained and free from debris.
e) Clear segregation of processing, shipping, receiving, storage, employee facilities, restrooms, and exterior areas.

2.16.2 Internal Structures and Fittings

The site shall be suitable for the intended purpose and mitigate opportunities for cross-contamination between and during operations. The site shall ensure:

a) There is adequate space for the placement of equipment and storage of materials as necessary for access to maintenance and sanitary operations, and the production of safe products.
b) All floors, walls, doors, windows, ceilings, drains, and other building fixtures are constructed to not pose a risk to product safety, are designed to be easily cleanable, appropriately sealed, are maintained, and in good repair.
c) Light fixtures and skylights are constructed and placed to not pose a risk to product safety, are of appropriate intensity, are maintained, monitored, and in good repair.
d) Windows, light fixtures, and skylights that could pose a risk to product safety are shatterproof or protected against breakage.
e) There is no evidence of condensation, leaks, or buildup that poses a hazard to exposed materials or finished product. There is adequate ventilation and extraction to prevent condensation or excessive dust.
f) All external openings are effectively sealed when closed and prevent dust and pests from entering the building.
g) Hand washing stations are located upon entering processing areas and in easily accessible locations throughout product handling areas.
h) Plumbing is designed to ensure adequate water supply throughout the site and ensure liquid waste is removed in a way that does not pose a risk to product safety. Sewer drainage pipes shall not be located over exposed materials or processing areas.
i) Restrooms are easily accessible to all personnel and do not pose a risk to product safety. Restrooms must: have self-closing doors; not open directly into any production, packaging, or storage areas; have adequate quantity of hand-washing stations and toilets for employees; hand-washing signs, appropriate sanitary receptacles, adequate sanitary supplies for employees.

j) Employee facilities (i.e., breakrooms, locker rooms, etc.) are kept clean and maintained in good repair.

2.16.3 Equipment

The site's equipment shall be suitable for its intended purpose and designed as to not pose a risk to product safety. The site shall ensure:

a) All equipment and food/product contact surfaces are easily cleanable, maintained, and in good repair.
b) Any motors, fans, utilities or other equipment placed overhead or leading to the exterior are controlled and maintained as to not pose a risk to raw materials, packaging materials, Work in Progress (WIP), or finished goods.
c) Equipment is stored in a sanitary manner that does not pose a risk to product safety.
d) All hoses and cleaning equipment are stored on racks and/or off the floor.

2.17 Maintenance and Calibration

2.17.1 Preventative Maintenance Program

The site shall have documented procedures and practices to ensure the building structure, grounds, and equipment are maintained as to not pose a risk to product safety. The established procedures and practices shall:

a) Include a master preventative maintenance schedule to ensure all structures, areas, equipment and parts are clean and in working order.
b) Describe how the site documents unplanned maintenance.
c) Ensure that product safety is not jeopardized during maintenance and only designated tools are used to protect sanitary environments.
d) Include a process for maintenance staff to alert the appropriate supervisor when repairs pose a threat to product safety.
e) Verify that any product contamination hazards (tools, lubricants, debris, etc.) are completely removed from the area undergoing maintenance before the commencement of operations, including any appropriate cleaning and sanitation.
f) Include a provision for how the site controls and monitors temporary repairs so as not to pose a risk to product safety and ensures that temporary repairs do not become permanent. If a site does not allow temporary repair solutions, at minimum, the provision must account for emergency approval of temporary repair solutions (who, how, and when), and how the site monitors product safety until a permanent repair is verified.

2.17.2 Calibration

The site shall have documented procedures and practices to ensure all equipment used to measure factors that affect product safety are calibrated appropriately. The established procedures and practices shall:

a) Identify all equipment being calibrated with the valid calibration due date or frequency.
b) Calibrate equipment against national or international standards and according to manufacturer's recommendations.
c) Implement corrective actions if any critical equipment is found out of calibration.

Module 3: Food Safety and Hazard Control Plan

3.1 Food Safety / HACCP Team

The site shall maintain a documented, multidisciplinary team responsible for development, implementation, maintenance, and verification of the food safety and hazard control system. The site may identify this group as its Food Safety Team, HACCP Team, or equivalent terminology. The Team shall:

a) Include a designated “Food Safety” or “HACCP” Team Leader and backup;
b) Include personnel with appropriate technical, production, and management knowledge of the site's materials, products, processes, hazards, and controls;
c) Maintain documented membership, roles, responsibilities, and training records; and
d) Consist of qualified personnel employed by the certified organization and assigned responsibility for the site. Personnel may be site-based or corporate. External consultants or contractors may provide technical support but shall not independently satisfy required HACCP qualification roles.

3.2 HACCP Qualifications

HACCP qualification is mandatory under this Audit Program regardless of regulatory status. The designated Food Safety or HACCP Team Leader and backup shall:

a) Maintain current HACCP certification from an industry-recognized HACCP training course;
b) Be formally assigned responsibility for the site's HACCP system; and
c) Maintain documented qualifications readily available for audit.

The backup shall be qualified to assume assigned HACCP responsibilities when the Team Leader is unavailable (Continuous on-site or shift-specific coverage is not required).

3.3 Documented Food Safety / HACCP Plan

The site shall maintain a documented food safety and hazard control system covering all products and processes within the certification scope. The site may identify the system as a Food Safety Plan, HACCP Plan, or equivalent terminology. The documented system shall:

a) Address all requirements of this Module;
b) Include or clearly link required plans, procedures, records, and supporting evidence;
c) Be current, implemented, and maintained; and
d) Be readily available at all times, including during audits.

3.4 Product and Material Descriptions

The site shall maintain documented descriptions or specifications for each product or defined product group within the certification scope. Product descriptions shall include:

a) Product name or identification;
b) Composition and materials of construction;
c) Relevant biological, chemical, and physical characteristics affecting food safety or suitability;

d) Manufacturing, converting, or treatment relevant to product safety;
e) Packaging application, food-contact status, and applicable labeling or identification requirements;
f) Intended use and intended consumer or next user;
g) Intended market;
h) Shelf life or durability;
i) Storage and distribution conditions; and
j) Other characteristics necessary to support the hazard analysis.

Products may be grouped where their materials, processes, hazards, intended uses, and controls are sufficiently equivalent.

3.5 Intended Use

The site shall document the intended and reasonably foreseeable use of each product or product group, including the intended food-contact application, next user in the supply chain, and intended markets.

Intended use shall be considered when evaluating hazards and determining required controls

3.6 Process Flow Diagram

The site shall maintain documented process flow diagrams covering all products and processes within the certification scope. Flow diagrams shall:

a) Identify the sequence of all process steps from receipt of raw materials through finished product storage and distribution;
b) Identify relevant inputs and outputs, including raw materials, inks, coatings, adhesives, processing aids, rework, utilities, returned product, and waste streams; and
c) Identify designated Critical Control Points (CCPs) which are appropriately measured and managed for all products within the certification scope.

3.7 Flow Diagram Confirmation

The Food Safety / HACCP Team shall confirm process flow diagrams against actual site operations:

a) Before initial implementation;
b) Whenever significant process changes occur; and
c) At least annually.

Confirmation shall include representative operating conditions and be documented. Identified differences shall be corrected before the flow diagram is used as the basis for the hazard analysis.

3.8 Hazard Analysis

The site shall maintain a documented hazard analysis based on the confirmed process flow and covering products, raw materials and ingredients, processing aids, packaging, process steps, and other relevant conditions. The hazard analysis shall:

a) Identify biological, chemical, physical, allergen, and other reasonably foreseeable food safety hazards associated with the products and operations;

b) Evaluate the significance of identified hazards;
c) Determine which hazards require control; and
d) Identify controls necessary to prevent, eliminate, or reduce significant hazards to an acceptable level.

Risk-based determinations shall be supported by documented objective evidence in accordance with the Risk Assessment and Scientific or Technical Evidence definitions established by these CPR.

3.9 Food Safety Controls

The site shall identify and document the food safety controls required by the hazard analysis. Controls shall:

a) Identify the designated control measure;
b) Identify the hazard controlled by each control measure; and
c) Prevent, eliminate, or reduce the identified hazard to an acceptable level.

Designated controls may include Critical Control Points (CCPs) or other food safety controls required to manage identified hazards.

3.10 Critical Limits and Control Parameters

The site shall establish documented and measurable criteria for designated food safety controls.

a) CCPs shall have defined Critical Limits that distinguish acceptable from unacceptable conditions.
b) Other food safety controls shall have measurable parameters, values, frequencies, conditions, or other criteria sufficient to demonstrate control.
c) Critical Limits and control parameters shall be supported by applicable scientific or technical evidence.

3.11 Monitoring

The site shall maintain documented monitoring procedures for designated food safety controls. Monitoring procedures shall identify:

a) What is monitored;
b) The method and frequency;
c) Responsible personnel;
d) Required records; and
e) Actions required when established limits or control parameters are not met.

Monitoring records shall demonstrate implementation of the established controls.

3.12 Corrective Actions

The site shall maintain documented corrective-action procedures for deviations or failures involving designated food safety controls. Corrective actions shall:

a) Correct the identified condition and restore control;

b) Identify and control affected product or material;
c) Determine appropriate disposition;
d) Evaluate the cause of the deviation;
e) Implement action to prevent recurrence; and
f) Be documented including product or material disposition.

3.13 Validation

The site shall maintain documented validation demonstrating that food safety controls, Critical Limits, and control parameters are capable of achieving their intended food safety outcomes. Validation shall:

a) Identify the control, limit, or parameter being validated;
b) Be supported by applicable scientific or technical evidence; and
c) Be reviewed at minimum annually or following significant changes or other information that may affect the validity of the control.

3.14 Verification and Reanalysis

The site shall maintain documented verification activities confirming that the food safety and hazard control system is implemented as designed and remains effective. Verification shall include:

a) Review of monitoring records;
b) Review of deviations, corrective actions, and product or material disposition;
c) Verification of monitoring activities and calibration of monitoring equipment;
d) Review of validation and supporting evidence; and
e) Confirmation that required procedures and records are implemented and maintained.

The complete food safety and hazard control system shall be reviewed and reanalyzed at least annually and whenever significant changes, new hazards, recurring deviations, ineffective controls, or other relevant information may affect the hazard analysis or established controls.

Resulting changes shall be documented and incorporated into applicable plans, procedures, controls, records, and training.

Appendix A

Glossary

The following definitions establish the meaning of terms used throughout these Certification Program Requirements and support consistent interpretation and application of the Audit Program and Audit Criteria.

Terms specific to the structure, administration, and conduct of the Audit Program are presented first, followed by food safety and technical terminology used throughout the Audit Criteria. Where a term is not specifically defined in these CPR, its generally accepted regulatory, food safety, auditing, or industry meaning shall apply according to the context in which it is used.

Program and Audit Terminology

The following definitions establish terminology specific to these CPR and the administration and conduct of the Audit Program, including document structure, certification scope, audit activities, evidence, findings, and certification status.

Certification Program Requirements (CPR): This document in its entirety, including the program requirements established in Part I and the Audit Criteria established in Part II.

Audit Program: The Kiwa ASI cGMP Food Packaging certification framework governed by these Certification Program Requirements.

Program Requirements: The requirements established in Part I governing the administration, application, planning, conduct, reporting, certification, and maintenance of the Audit Program.

Audit Criteria: The auditable requirements established in Part II against which site conformity is evaluated.

Audit Criterion: An individual requirement within the Audit Criteria.

Audit: A systematic assessment conducted by Kiwa ASI under the Audit Program to evaluate conformity with the Audit Criteria.

Aborted Audit: An audit that is terminated before completion because conditions prevent sufficient evaluation of the certification scope or completion of required audit activities. An aborted audit is incomplete and does not provide a basis for granting or renewing certification.

Applicable Review Period: The period from which records shall be made available for audit sampling, as established under *Applicable Records* for the applicable certification audit.

Auditee: The organization subject to assessment under the Audit Program. Depending on context, Auditee may also refer to the personnel representing the organization during the audit.

Audit Day: A unit used to establish assigned audit duration. Audit days are coordinated in accordance with the *Audit Duration* provisions of Part I and represent planning measures rather than fixed working hours, arrival times, departure times, or maximum daily durations.

Audit Evidence: Objective Evidence obtained or evaluated during an audit and used to support audit findings and conclusions.

Audit Scope: The extent and boundaries of an individual audit, including the certification scope and locations, activities, processes, and period subject to evaluation.

Audit Trail: A line of inquiry followed by the auditor from an observation, record, process, interview, finding, or other objective evidence to related activities or evidence necessary to evaluate conformity with the Audit Criteria.

Certificate: The official certification document issued by Kiwa ASI identifying the certified site, certification scope, and certification status established under the Audit Program.

Certification: Formal recognition by Kiwa ASI that the Auditee has satisfied the applicable requirements for certification under the Audit Program.

Certification Audit: An audit conducted by Kiwa ASI against the Audit Criteria for the purpose of initially granting or renewing certification under the Audit Program.

Certification Scope: The approved products, processes, operations, activities, and locations covered by certification under the Audit Program.

Compliant: A rating assigned when objective evidence demonstrates that an Audit Criterion has been satisfied, including where the condition addressed by an Audit Criterion is not present and no associated risk exists in accordance with *Mandatory Requirements*.

Facility / Site: The physical location subject to assessment or certification under the Audit Program. Certification remains specific to the approved location and certification scope.

Finding: A conclusion resulting from evaluation of objective evidence against an Audit Criterion. Findings remain subject to Kiwa ASI Technical Review before finalization of the audit report.

Initial Certification Audit: The certification audit conducted for a site seeking initial certification under the Audit Program.

Mock Audit: An optional, non-certification assessment conducted against the Audit Criteria to provide the Auditee with objective feedback before a certification audit. A Mock Audit does not result in certification.

Objective Evidence: Verifiable information demonstrating whether a specified requirement or condition has been satisfied or exists.

Preliminary Finding (Draft Finding): A finding communicated before completion of Kiwa ASI Technical Review. A Preliminary Finding is subject to confirmation or revision before issuance of the final audit report.

Production Day: A local calendar date on which actual manufacturing or converting activity within the certification scope occurs. Each calendar date counts as one Production Day regardless of the number of shifts, batches, production lines, products produced, or operating hours.

Production History: Documented evidence of actual production conducted within the certification scope during the applicable review period, including evidence used to establish qualifying production days and support representative audit sampling.

Re-Certification Audit: A certification audit conducted to evaluate continued conformity and support renewal of an existing certification under the Audit Program.

Record Sufficiency: The availability of records in sufficient quantity, time-period coverage, and representation of the certification scope to permit an adequate audit evaluation.

Repeat Non-Conformity: A non-conformity against the same Audit Criterion, or arising from the same root cause, as a non-conformity identified during a previous Kiwa ASI audit or visit.

Representative Sampling: Selection of records, products, processes, operations, locations, or other objective evidence intended to provide appropriate representation of the certification scope and support evaluation against the Audit Criteria.

Sampling Sufficiency: The determination that available objective evidence provides adequate quantity, time-period coverage, and representation of the certification scope to permit an adequate audit evaluation.

Satellite Facility: An additional physical location approved by Kiwa ASI as part of the certification scope that operates as a direct extension of processes conducted at the primary certified site and shares applicable management systems with that site.

Scope Exclusion: A product, process, operation, activity, or area formally excluded from the certification scope with Kiwa ASI approval. A Scope Exclusion does not remove or modify an Audit Criterion applicable to activities remaining within the certification scope.

Scope Extension Audit: An audit conducted to evaluate a proposed change or addition to an existing certification scope where Kiwa ASI determines that on-site assessment is necessary before the change may be included in the certified scope.

Technical Review: The independent evaluation of the auditor's report by qualified Kiwa ASI personnel to confirm the accuracy, completeness, and consistency of audit findings, ratings, and supporting evidence before finalization of the audit report and certification.

Food Safety and Technical Terminology

The following definitions establish technical, regulatory, food safety, HACCP, and management-system terminology used in the Audit Criteria. These definitions support consistent interpretation of requirements and do not replace applicable legal or regulatory definitions where such definitions govern.

Acceptable Level: A level of hazard in a food at or below which the food is considered to be safe according to its intended use.

Adulteration: A condition in which a product has been contaminated, substituted, altered, or otherwise rendered unsafe, unsuitable, or nonconforming with applicable legal requirements.

Allergen: Substances that cause an exaggerated immune response in some people and that may result in a runny nose, watery and/or itchy eyes, a rash, wheezing, serious illness, or (occasionally) death.

Annual / Annually: For the purposes of these Certification Program Requirements, "annual" or “annually” refers to the last 12 month period of operation for initial auditees, or the interval between two consecutive audits conducted approximately one year apart. This does not necessarily align with the calendar year but is based on the scheduled frequency of the audits.

Brittle Plastic: Plastics made from acrylic resins that are brittle or break into pieces when subjected to forces beyond their impact resistance.

Batch: A specific quantity of product processed or produced under essentially the same conditions.

Bin/Container Management: Practices for proper storage, labeling, segregation, and handling of raw materials, intermediates, or finished products to prevent contamination or mix-ups.

Calibration: The adjustment of an instrument for accuracy relative to an established standard.

CAPA (Corrective Preventive Action): A systematic approach that combines corrective and preventive actions to address nonconformities and prevent their recurrence.

Cleaning: The removal of soil, food residues, dirt, grease, or other objectionable matter.

Cleaning Verification: The process of confirming that cleaning activities have been effective in removing soil, residues, or contaminants.

Conformance / Conformity: Fulfillment of a specified requirement. Within the Audit Program, conformity describes fulfillment of an Audit Criterion or applicable program requirement.

Contaminant: Any biological, chemical, or physical agent, foreign matter or other substances not intentionally added to food that may compromise food safety or suitability.

Contamination: The introduction or occurrence of a contaminant in the food or food environment.

Control:

- *Noun*: The state wherein correct procedures are being followed and any established criteria are being met.
- *Verb*: To take all necessary actions to ensure and maintain compliance with established criteria and procedures.

Control Measure: Any action or activity that can be used to prevent or eliminate a hazard or reduce it to an acceptable level.

Corrective Action: Action taken in response to a detected non-conformity, deviation, or loss of control to correct the condition, address affected product where necessary, identify the cause, and prevent recurrence.

Critical Control Point (CCP): A step at which a control measure or control measures, essential to control a significant hazard, is/are applied in a HACCP system.

Critical Limit: A criterion, observable or measurable, relating to a control measure at a CCP that separates acceptability from unacceptability of the food.

Cross-Contact: The unintended transfer of allergens or other hazardous substances from one product or surface to another.

Cross-Contamination: A situation that occurs when micro-organisms, allergens, chemicals, or other hazards that are carried by utensils, hands, towels, or other items are transferred from one product, raw material, or surface to another.

Current Good Distribution Practices (cGDP): Practices and controls used to maintain product safety, suitability, identity, and integrity during handling, transportation, and distribution.

Current Good Manufacturing Practices (cGMP): Practices and controls used to manufacture or process products under sanitary and controlled conditions appropriate to their intended use and applicable food safety requirements.

Current Good Storage Practices (cGSP): Practices and controls used to maintain product safety, suitability, identity, and integrity during storage and warehousing.

Deviation: A failure to meet specified requirements, criteria, or limits during operations or audits.

Documented Procedures and Policies: Written instructions and rules that define responsibilities, processes, and controls for maintaining food safety. They must be current, approved, and consistently applied.

Environmental Monitoring Program (EMP): A program for the evaluation of the effectiveness of controls on preventing contamination from the manufacturing, processing and distribution environment.

Flow Diagram: A systematic representation of the sequence of steps used in the production or manufacture of food.

Food Defense: Measures to protect food products from intentional contamination or adulteration intended to cause harm to consumers or the food business.

Food Fraud: The intentional substitution, mislabeling, dilution, addition or misrepresentation of materials, or adulteration of a food product for economic gain.

Food Grade: The specification for a food, ingredient, or food packaging that meets accepted definitions of purity for use in or in contact with food.

Food Safety: Assurance that food will not cause adverse health effects to the consumer when it is prepared and/or eaten according to its intended use.

Food Safety Culture: The collective values, attitudes, and behaviors within an organization that support the consistent prioritization and implementation of food safety practices.

Food Safety Management System: A set of interrelated or interacting elements to establish policy and objectives and to achieve those objectives used to direct and control an organization with regard to food safety. This system provides assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.

Food Safety Plan: A plan which identifies, evaluates, and proactively controls hazards that are significant for food safety

Foreign Matter: Any substance or object that does not naturally or normally belong in a product.

Hazard: A biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of a control.

HACCP Plan: Documentation or set of documents prepared in accordance with the principles of HACCP to ensure control of significant hazards in the food business.

HACCP System: The development of a HACCP plan and the implementation of the procedures in accordance with that plan.

Hazard Analysis Critical Control Point (HACCP): A systematic approach that identifies, evaluates, and controls hazards significant to product safety.

Hazard Analysis: The process of collecting and evaluating the information on hazards identified in raw materials and other ingredients, the environment, in the process or in the food, and conditions leading to their presence to decide whether or not these are significant hazards.

Incident Management: A documented process for detecting, investigating, resolving, and recording food safety or security events that may affect product integrity.

Internal Audit: An audit activity that is carried out by the organization as a form of self-assessment.

Like-to-Like (Rework): The practice of reprocessing or reusing product or materials in a manner that ensures the reworked item is identical or equivalent in composition, formulation, and safety characteristics to the original product.

Management Review: A formal assessment by facility leadership to evaluate the effectiveness of the food safety management system and determine necessary improvements.

Measurable Parameters: Specific minimum or maximum thresholds for a control to be effective at preventing a hazard; often applied in reference to Preventative Controls when a "Critical" limit may not be referenced.

Mitigation Strategies: Controls to remove or reduce to an acceptable level an identified risk, vulnerability, or threat.

Monitor: The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a control measure is under control.

Non-Conformity (Non-Conformance): A finding supported by objective evidence demonstrating that an Audit Criterion has not been satisfied. Non-conformities are graded as Minor, Major, or Critical in accordance with *Audit Findings and Scoring*.

Observation: A factual statement made by an auditor based on what is seen, heard, or verified during an audit. Observations may identify areas for improvement or potential nonconformities, but do not constitute a formal nonconformity unless a requirement is violated.

One-Forward (*Recall*): The ability to trace a product's movement from a specific point in the supply chain to the next immediate recipient or customer. One Forward traceability ensures that any affected product can be quickly identified and removed from distribution.

One-Back (*Traceability*): The ability to trace a product back to its immediate source, such as the supplier of a raw material or ingredient. One Back traceability allows identification of the origins of a product in the event of a safety or quality issue.

Pests: Any animal or insect of public health importance, including, but not limited to birds, rodents, roaches, flies, and larvae that may carry pathogens that can contaminate products.

Pest Harborage: Any condition or structural defect that provides a place for pests to live and reproduce.

Potable Water: Water suitable for drinking, free from pollutants and harmful organisms, and conforms to local legal requirements.

Personal Protective Equipment (PPE): Specialized clothing or equipment worn by employees to protect themselves from exposure to food safety hazards and to prevent contamination of food products. PPE includes items such as gloves, hairnets, beard nets, face masks, aprons, and protective footwear, and must be used in accordance with food safety and hygiene standards to ensure both personnel safety and product integrity.

Preventative Action: A proactive measure taken to eliminate the cause of a potential nonconformity or other undesirable situation before it occurs, thereby reducing the risk of food safety issues.

Preventive Control: Risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packaging, or holding of a product would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe manufacturing, processing, packaging, or holding at the time of analysis.

Preventive Controls Qualified Individual (PCQI): A qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by the FDA or is otherwise qualified through job experience to develop and apply a food safety system.

Quarantine: The holding of any raw material or product while awaiting confirmation of its suitability for intended use or sale.

Raw Material: Commodities, parts, or substances that are assembled or processed to form a final product

Recall: The process by which a food product that may pose a risk to health, safety, or regulatory compliance is removed from commerce and returned to the manufacturer, distributor, or regulator.

Record: Documented information retained as objective evidence of activities performed, results achieved, or requirements fulfilled. Records may be physical or electronic and shall meet applicable accuracy, completeness, legibility, attribution, retention, and accessibility requirements.

Regulatory Authority: The governmental agency responsible for oversight and enforcement of food safety laws and regulations.

Rework: The controlled reuse or reintroduction of non-conforming food, ingredients, or semi-finished product back into production, ensuring safety, traceability, and compliance with specifications.

Recoup: The recovery or salvage of acceptable product units from damaged, mislabeled, or otherwise unsuitable lots, with proper segregation and verification before release.

Repacking: The transfer of finished products into new packaging under sanitary conditions, maintaining traceability, labeling accuracy, and food safety compliance.

Risk: The likelihood of an occurrence and the size of the consequences of an adverse event.

Risk Analysis: The broader documented process used to identify and evaluate risk and determine appropriate controls or actions. Risk analysis incorporates risk assessment and

the resulting risk-management decisions, including implementation, communication, monitoring, and review of controls

Risk Assessment: A documented evaluation used to identify and characterize a hazard, threat, vulnerability, or condition and determine the significance of the associated risk.

A risk assessment shall include:

a) the subject, scope, and the hazard, threat, vulnerability, or condition being evaluated;
b) the likelihood and potential consequences;
c) the existing controls and evidence of their effectiveness;
d) the objective evidence supporting the determination, such as scientific, regulatory, technical, historical, testing, monitoring, or operational data;
e) the conclusion and rationale, with the resulting controls, limits, frequencies, monitoring, or verification activities; and
f) the qualified person or function who completed or approved it, and its review frequency or the conditions requiring reassessment.

The level of detail shall be proportionate to the nature and complexity of the subject. Numerical or quantitative scoring is not required unless an Audit Criterion specifies it.

A verbal statement, unsupported conclusion, customary practice, absence of known incidents, or assertion that a condition or activity is “low risk” is not a risk assessment and does not, by itself, establish conformity with an Audit Criterion.

Risk Management: The documented process of evaluating available control options and selecting, implementing, monitoring, and reviewing measures appropriate to the results of a risk assessment and the requirements of these CPR.

Root Cause: The underlying cause(s) of a problem.

Sample: A record, product, process, operation, observation, or other item selected for audit evaluation as part of representative sampling.

Sanitation Standard Operating Procedure (SSOP): Written procedures that detail cleaning and sanitizing practices necessary to maintain sanitary conditions in food facilities.

Scientific or Technical Evidence: Verifiable information relevant to the hazard, threat, vulnerability, process, product, equipment, or condition being evaluated and suitable to support a risk-based determination. Evidence may include applicable laws or regulatory guidance; recognized scientific, technical, or industry publications; validated studies or methods; manufacturer specifications; qualified expert or technical information; historical site data; testing or monitoring results; trend analyses; and other documented information relevant to the assessment.

Evidence shall be sufficiently relevant and representative of the condition being evaluated to support the conclusion reached.

Segregation: The physical or procedural separation of materials, products, or processes to prevent contamination, cross-contact, or mix-ups. Segregation ensures that raw materials, in-process items, finished products, or allergens are isolated according to food safety requirements.

Shelf Life: The length of time a food product is expected to remain safe and suitable for consumption under recommended storage conditions.

Ship-From: The originating facility, warehouse, or location from which goods are dispatched. The “ship-from” address establishes the traceability starting point for shipments and is critical for recall and supply chain accountability.

Ship-To: The designated customer, facility, or location to which finished products, ingredients, or materials are delivered. The “ship-to” address ensures traceability of where goods are sent in distribution or recall events.

Significant Hazard: A hazard identified by a hazard analysis, as reasonably likely to occur at an unacceptable level in the absence of control, and for which control is essential given the intended use of the food.

Specification: A detailed, exact statement of prescribed requirements for incoming materials or finished products.

Standard Operating Procedure (SOP): A set of step-by-step instructions compiled by a site to help employees carry out operations.

Supplier: A person or organization that provides a product or service.

Threat Assessment: A risk assessment designed to examine a location's processes for potential product security.

Traceability: The ability to identify and follow the movement of materials and products through relevant stages of receipt, processing, storage, and distribution using documented information.

Validation: Obtaining and evaluating objective scientific or technical evidence to demonstrate that a control measure, process, or system is capable of achieving its intended outcome when properly implemented.

Validation Study: A documented scientific assessment conducted to demonstrate that a control measure, process, or system consistently achieves the intended food safety outcome.

Vendor: A supplier or external entity that provides raw materials, ingredients, packaging, or services to the facility. Vendors are subject to approval and monitoring to ensure compliance with food safety and regulatory

Verification: Activities used to confirm through objective evidence that specified requirements, controls, procedures, or systems have been implemented and are operating as intended

Withdrawal (*products*): The removal of a food product from distribution or sale that is not necessarily linked to a food safety risk, often due to quality, labeling, or commercial reasons.

Work-in-Progress (WIP): Partially manufactured products.

References

The following regulatory, scientific, technical, and industry references were used in developing these CPR. Inclusion does not make a reference or all of its requirements part of the Audit Program. Sites remain responsible for identifying and meeting applicable regulatory requirements.

Primary Regulatory and Technical References

- 21 CFR Part 117 – *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food*
- 21 CFR Part 507 – *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals*
- 21 CFR Part 1, Subpart O – Sanitary Transportation of Human and Animal Food
- 21 CFR Part 121 – *Mitigation Strategies to Protect Food Against Intentional Adulteration*
- Food Safety Modernization Act (FSMA), Public Law 111-353
- Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), Public Law 108-282
- Food Allergy Safety, Treatment, Education, and Research Act of 2021 (FASTER Act), Public Law 117-11
- Codex Alimentarius CXC 1-1969 – *General Principles of Food Hygiene*, including the HACCP System and Guidelines for its Application
- Codex Alimentarius CXC 80-2020 – *Code of Practice on Food Allergen Management for Food Business Operators*

Supporting Industry and Guidance References

- FDA – *Guidance for Industry: Questions and Answers Regarding Food Allergens, Including Food Allergen Labeling Requirements, Edition 5*
- FDA – *Guidance for Industry: Mitigation Strategies to Protect Food Against Intentional Adulteration*
- FDA – *Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry*
- Food Safety Preventive Controls Alliance (FSPCA) – *Preventive Controls for Human Food Curriculum*
- International HACCP Alliance – HACCP training resources and guidance
- ISO 22000:2018 – *Food Safety Management Systems*
- ISO 19011:2018 – *Guidelines for Auditing Management Systems*