November 16, 2026

Kiwa ASI cGMP & cGDP CPR Change Summary

Version 2.0 to Version 2.1

Introduction

Version 2.1 represents the continued development of the Kiwa ASI cGMP and cGDP Audit Programs. Building on Version 2.0 and experience gained through program implementation and stakeholder feedback, the updates are intended to improve clarity, audit consistency, operational applicability, and efficiency while preserving the core requirements and objectives of the programs.

Change Summary

Version 2.1 includes substantive updates to the organization and application of the CPRs. Core cGMP and cGDP controls remain recognizable, while requirements have been reorganized and clarified to improve interpretation, objective evaluation, and consistency across the three Audit Programs.

Key changes common to the CPRs include:

- **Program structure:** The CPRs follow a clearer hierarchy of **Part I: Program Requirements → Part II: Audit Criteria → Appendix A: Glossary and References**.
  Part I governs administration and certification, Part II contains the auditable requirements, and the Glossary supports consistent interpretation.
- **Mandatory evaluation:** Every Audit Criterion remains subject to evaluation and receives a rating. Where the condition addressed by a criterion is genuinely absent, objective evidence may support a *Compliant* rating. Criteria are not removed, waived, or assigned N/A. There is no longer an option to rate a finding as "Exempt" or "Not Applicable."
- **Required controls:** Absence of a required procedure, program, control, record, qualification, or other mandatory element is evaluated as a non-conformity and cannot be treated as an absent condition.

Audit Criteria Updates

Module 2

- **Allergen Management and Environmental Monitoring** are separated from the former 2.1 section into distinct control areas, improving organization, audit flow, and evidence collection.
- **Allergen Management** is more specifically aligned to each Audit Program:
  - Food Processing addresses the full allergen-control lifecycle, including materials, processing, segregation, cleaning/changeover verification, and finished-product labeling.
  - Food Packaging focuses on allergen sources and cross-contact controls relevant to packaging manufacturing.

  - cGDP focuses on product identification, package integrity, receiving, storage, handling, damaged product, segregation, and distribution.
- **Environmental Monitoring** remains mandatory for evaluation but is explicitly risk-based. Monitoring decisions must be supported by a documented assessment addressing the site's products, processes, environment, and applicable microbiological hazards. Where routine sampling is not required, the objective basis for that determination must be documented.
- **Food Defense** is reorganized around three core requirements:
  I. a qualified **Food Defense Coordinator**,
  II. a documented and tested **Food Defense Plan**, and
  III. appropriate **training and access controls**. Coordinator qualification must be supported by documented training; job experience alone does not satisfy the training requirement.

Module 3

- Module 3 is reorganized into a clearer food safety and hazard-control lifecycle covering qualified personnel, documented plans, product and intended-use information, process flow, hazard analysis, controls, limits or parameters, monitoring, corrective action, validation, and verification/reanalysis.
- *HACCP qualifications* are separated from plan content and made more objectively auditable. Team Leader and backup requirements are retained without requiring continuous on-site or shift-specific certified coverage.
- *Hazard controls* are separated into individually auditable requirements, with risk-based determinations, limits, control parameters, and validation supported by documented scientific or technical evidence.
- *PCQI applicability* is clarified for Food Processing and cGDP through a documented regulatory-status pathway. Food Packaging remains HACCP-based and does not contain a standalone PCQI qualification criterion.

Findings and Grading

- Minor, Major, and Critical grading expectations are clarified to better address control effectiveness, product impact, regulatory exposure, record integrity, audit access, and repeat findings.
- Findings continue to be based on objective evidence, with clearer grading expectations intended to improve consistency between auditors and Technical Review.

Certification

- Audit scoring is retained, while certification eligibility is more clearly distinguished from the numeric score. Certification also depends on required operating history, sufficient records, representative scope coverage, required corrective actions, Technical Review, and other applicable program prerequisites.

- The Superior rating is discontinued. Removing the historical-audit component previously used in determining Superior status better aligns the rating structure with objectivity, impartiality, and performance demonstrated during the current certification cycle.

Glossary and Interpretation

- Appendix A is reorganized to distinguish Program and Audit Terminology from Food Safety and Technical Terminology.
- Key concepts including Audit Program, Audit Criteria, objective evidence, representative sampling, record sufficiency, Risk Assessment, and Scientific or Technical Evidence are clarified to support consistent interpretation and application.
- Glossary definitions support interpretation of the CPRs but do not replace applicable legal or regulatory definitions.

Food Processing: Notable Version 2.1 Changes

Version 2.1 retains the comprehensive food and feed manufacturing focus of the program while strengthening the integration of HACCP, preventive controls, PCQI oversight, and supporting food-safety programs.

- **Allergen Management:** Expanded to address the full allergen-control lifecycle, including applicable legal allergens, material handling, processing and rework, cross-contact prevention, cleaning/changeover verification, and finished-product labeling.
- **Environmental Monitoring:** Clarified as a documented, risk-based program. Monitoring and sampling decisions must be objectively supported, including the documented basis where routine sampling is not required.
- **Food Defense:** Reorganized around a qualified Food Defense Coordinator, documented and tested Food Defense Plan, and personnel training/access controls.
- **Module 3:** Reorganized into a complete HACCP and hazard-control lifecycle with separately auditable requirements for qualifications, plan development, hazard analysis, controls, monitoring, corrective action, validation, and verification/reanalysis.
- **PCQI:** Added as a distinct qualification criterion with a documented regulatory-applicability pathway. Sites must substantiate when PCQI oversight is not required rather than relying on an unsupported exemption claim.

Food Packaging: Notable Version 2.1 Changes

Version 2.1 maintains the HACCP-based manufacturing and converting focus of the program while more clearly tailoring requirements to food packaging and food-contact material operations.

- **Allergen Management:** Revised to focus on allergen sources and cross-contact pathways relevant to packaging materials and manufacturing activities without imposing unnecessary food-processing controls.
- **Environmental Monitoring:** Clarified as a documented, risk-based program that reflects the materials, processes, facility environment, and microbiological exposure of the packaging operation.
- **Food Defense:** Reorganized around the same *Food Defense Coordinator → Food Defense Plan → Training and Access Controls* structure used across the CPR family.
- **Module 3:** Reorganized into a clearer HACCP and hazard-control lifecycle using packaging-specific product/material descriptions, process flows, hazard analysis, controls, monitoring, validation, and verification.
- **PCQI:** No standalone PCQI qualification criterion is introduced. The program remains HACCP-based and tailored to packaging manufacturing and converting.

cGDP Storage & Distribution: Notable Version 2.1 Changes

Version 2.1 more clearly establishes cGDP as a dedicated storage, warehousing, logistics, transportation, and distribution program rather than applying manufacturing-oriented requirements to non-manufacturing operations.

- **Storage Conditions:** Dry and environmentally controlled storage requirements are consolidated into a broader requirement covering product protection, segregation, environmental conditions, monitoring, deviations, condensation/moisture, and affected-product disposition.
- **Allergen Management:** Revised for practical distribution operations, with emphasis on product identification, package integrity, receiving, storage, handling, damaged or exposed products, segregation, and cleaning/verification where a credible cross-contact pathway exists.
- **Environmental Monitoring:** Clarified as a mandatory risk-based evaluation. The required monitoring approach reflects product exposure, storage conditions, moisture, sanitation, repacking, damaged goods, and other operational conditions.
- **Food Defense:** Uses the common Food Defense framework with additional emphasis on receiving, storage, loading, shipment, transportation interfaces, returns, and custody/access vulnerabilities.
- **Module 3:** Reorganized around a storage/distribution-specific hazard-control lifecycle while maintaining a structure parallel to Food Processing.
- **HACCP and PCQI:** HACCP qualification is mandatory across the program. PCQI applicability follows a documented regulatory-status pathway, allowing a Compliant rating where the governing framework clearly establishes that PCQI oversight is not required.