MEKITEC · COMPLETE CCP

X-Ray CCP Readiness Guide

A 60-minute Evidence Drill and fifteen-point review for food manufacturers

ONE PRODUCT · ONE LINE · ONE RECENT HOUR

- Quality
- Production
- Maintenance
- Training

INSPECT | **REMOVE** | **PROVE** | **CHECK** | **RECORD**

Version 2.0 · August 2026

Practical team resource · Evidence Drill · Worksheets · Action log

Inside this guide

Use the Evidence Drill first, then route the findings through the fifteen-point review. The guide is a practical educational resource: it does not produce a score or determine compliance.

Scope every use to one product or product family, one package, one line and one defined operating range. The site's HACCP plan and applicable requirements remain the authority.

One X-ray inspection event can create a machine record. The evidence needed to review the complete Critical Control Point (CCP) may also involve quality, production, maintenance, change control, training and affected-product decisions.

This guide helps a cross-functional team retrieve that evidence for one defined production window, review the path without creating a compliance score, and then examine the complete X-ray CCP through five practical questions.

Use it for one product or product family, one package, one line and one defined operating range at a time. The site's HACCP plan and applicable legal, customer and certification requirements define what evidence is required. The lists in this guide are prompts to adapt, not a universal requirement list.

The method in one sentence: retrieve the site-defined evidence chain for one product, on one line, for one production window; record what the team can and cannot produce in sixty minutes; then give every finding an owner and a due date.

What this guide does — and what it does not do

The guide contains two connected exercises:

1. **The Evidence Drill** tests the existing retrieval path in sixty minutes. It produces an evidence-location map and a finding log.
2. **The fifteen-point readiness review** examines the control through INSPECT, REMOVE, PROVE, CHECK and RECORD. It helps the HACCP team decide what requires further assessment or action.

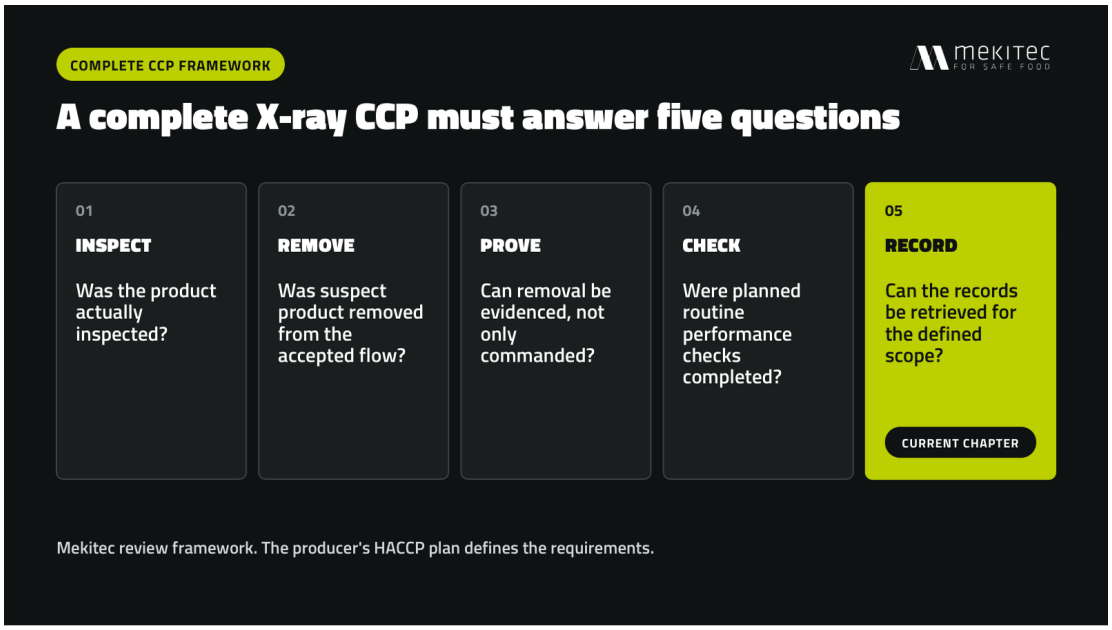
The exercises use records and procedures the site already has. They do not require new equipment or software.

This guide does **not**:

- create or replace a HACCP plan;
- determine whether a process step is a CCP;
- validate a control measure or an application;
- serve as an audit, certification-readiness assessment or compliance assessment;
- predict an audit or certification result;
- assign a score, percentage, grade, ranking, benchmark or pass mark; or
- confirm that a particular X-ray system, reject configuration or software option is suitable for a particular application.

Fast retrieval does not establish that the underlying hazard analysis, critical limit, validation, actions or decisions are adequate. Slow retrieval does not by itself establish non-compliance. Both conditions should be described accurately and assessed by the responsible team under the site's procedures.

The five questions a complete CCP has to answer



Mekitec's Complete CCP framework is a practical review framework. It is not a replacement for the seven Codex HACCP principles or for product- and process-specific hazard analysis.

Question	Operational question	Evidence direction
INSPECT	Was the product actually inspected?	Defined scope, supported critical limit, application validation, approved setup, product presentation and monitoring evidence
REMOVE	Was the suspect product actually removed from the flow?	Reject action, controlled isolation, affected-product handling and disposition
PROVE	Can removal be evidenced, not just commanded?	Evidence from the configured monitored point, fault response and connection to the reject sequence
CHECK	Were the routine CCP performance checks completed as planned?	Site-defined check, result, attribution, response, verification, training and change review
RECORD	Can the records be retrieved for a defined line, product and time window?	Record ownership, location, connection, review and retention across the complete evidence chain

The Evidence Drill starts with RECORD because retrieval is the practical problem being tested. The retrieved evidence then allows the team to review INSPECT, REMOVE, PROVE and CHECK.

Before the session

Choose the right participants

Include the people who own the records. Asking quality to retrieve everything alone tests one department rather than the site's evidence path.

[ ] HACCP or food-safety lead

[ ] Quality or line QA

[ ] Operator or supervisor responsible for the selected period

[ ] Production representative

[ ] Engineering or maintenance representative

[ ] Owner of training and competency records

[ ] One facilitator who asks, observes and records but does not retrieve

If another function owns a record required by the site's plan, include that owner as well.

Protect site information

Run the exercise within the site's normal access, confidentiality and record-control rules. The worksheet can record a document identifier, system name or controlled location rather than copying sensitive production or employee data. Do not send or upload site records to Mekitec as part of a self-directed drill. If the site later requests technical support, agree the scope and data-handling route before sharing records.

Decide the scope before the clock starts

Use a recent, representative production window. A period that includes a routine performance check, reject event, change, stop or deviation can be useful, but the site decides what is appropriate.

Site: _____

Line / inspection point: _____

Product or product family / code: _____

Package: _____

Production date and time window: _____

Relevant CCP: _____

HACCP plan and version in force during the window: _____

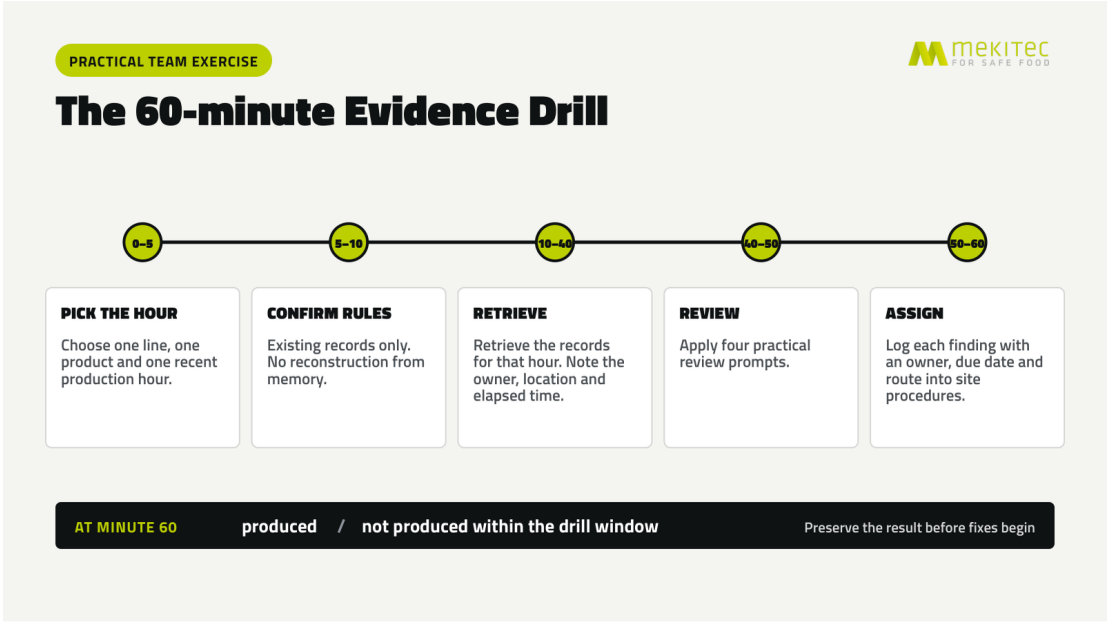
Facilitator: _____ **Drill date:** _____

Scope statement — write one sentence and do not change it after minute 5:

_____

_____

Part 1 — The 60-minute Evidence Drill



Define Time to Evidence

Time to Evidence is the elapsed time a site needs to assemble its site-defined CCP evidence chain for one product, on one line, for one defined production window, using only what already exists.

Time to Evidence is a Mekitec practical review term, not a regulatory metric or certification requirement.

Five rules keep it useful:

1. It measures **retrieval, not adequacy**.
2. The **site defines the evidence set** through its HACCP plan and applicable requirements.
3. There is **no score, pass mark, target, average or benchmark**.
4. The result is **not compared with another site**.
5. If the full site-defined set is not assembled in sixty minutes, each outstanding item is recorded as **not produced within the drill window**.

Read these rules aloud

- Use only records that existed before the session started.
- Do not reconstruct an activity from memory or create a missing record during the drill.
- Do not accept “it is in the system” until the scoped item is displayed or produced through the site's normal controlled route.
- The facilitator does not search, suggest a location or complete the chain for the record owner.
- Record the location, owner and connection key used to match the item to the selected line, product and time window.
- Do not debate the seriousness of a finding while the clock runs. Record it; the HACCP team assesses it afterwards.
- Stop retrieval at minute 60.

The sixty-minute agenda

Minutes	Step	Action	Output
0–5	Define scope	Record one line, one product or code, one production window and the relevant CCP	Fixed scope statement
5–10	Confirm rules	Read the rules aloud; confirm the site-defined evidence set and owners	Agreed prompt list
10–40	Retrieve	Request each item; record owner, location, connection key, status and elapsed time	Evidence-location map
40–50	Apply practical prompts	Review retrieved items for attribution, currency, completeness and required review or approval	Prompt notes, not a score
50–60	Log findings	Record every gap, assign an owner and due date, and identify the site's route for assessment	Action log

At minute 60, stop. Preserve the result before discussing fixes.

The after-minute-60 rule

If an item is first produced after the clock has stopped, keep its drill status as **not produced within the drill window**. You may add the later location and actual retrieval time in a separate note, but do not rewrite the original result.

If one or more required items remain outstanding, the overall drill result is:

> **Full site-defined evidence set not produced within the drill window.**

That statement is a retrieval result, not a compliance conclusion. Route the item to the site's HACCP team for assessment.

Eleven evidence prompts to adapt to the site's HACCP plan

Before the drill, remove prompts that do not apply and add any site-required evidence missing from the list. Keep the numbering of added prompts in the worksheet so the result can be repeated.

Use these status terms:

- **Produced** — the scoped item was produced within sixty minutes.
- **Partial** — part of the scoped item was produced, or the connection to the defined window was incomplete.
- **Not produced within the drill window** — the scoped item was not produced before minute 60.
- **N/A under the site-defined scope** — the HACCP team has confirmed and recorded why the item does not apply.

#	Evidence prompt	Complete CCP question	What to connect it to
1	Current approved HACCP plan covering the step	Foundation for all five	Approved version, scope and owner
2	Hazard analysis and CCP rationale	Foundation for all five	Product, process and significant hazard
3	Current critical limit and supporting validation	INSPECT	Product, package, line, operating range and approval date
4	Monitoring records for the selected period	INSPECT, RECORD	Line, product, time window, result and responsible person or system
5	Equipment performance and reject-sequence checks	REMOVE, PROVE, CHECK	Method, test piece where applicable, configured response, result and time

#	Evidence prompt	Complete CCP question	What to connect it to
6	Deviations and corrective actions, if any	REMOVE, CHECK	Deviation, immediate correction, affected period and cause investigation where required
7	Affected-product evaluation and disposition, if any	REMOVE	Hold, evaluation, decision, approver and release or disposal
8	Verification and record-review evidence	CHECK, RECORD	Activity, reviewer, date, conclusion and follow-up
9	Calibration or accuracy records where applicable	CHECK	Instrument or function, status, date and applicable period
10	Operator training and competency evidence	CHECK	Person, role, procedure version and demonstrated response
11	Relevant maintenance and change-control records	INSPECT, CHECK	Change, assessed impact, approval and review or revalidation decision

Evidence-retrieval worksheet

#	Status	Owner	Controlled location / reference	Connection key used	Elapsed minutes	Note
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
Added: ___						
Added: ___						

Elapsed time to the last item produced within the drill window: _ _ _ _ _ _ _ _ _ _ minutes

Was the full site-defined evidence set produced within sixty minutes? Yes / No

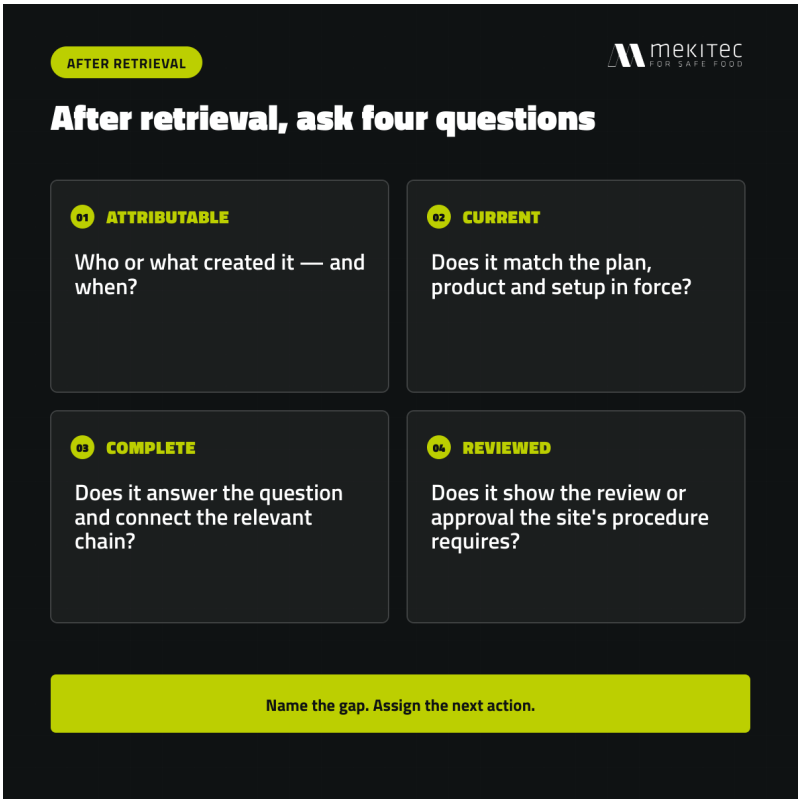
Items first produced after minute 60, if any:

Item	Original drill status	Later location	Actual elapsed time	Follow-up note
	Not produced within the drill window			

Item	Original drill status	Later location	Actual elapsed time
	Not produced within the drill window		
	Not produced within the drill window		

Do not total the number of produced items into a percentage or rating. An item can be retrieved quickly and still require assessment; another may be correctly controlled yet slow to retrieve.

Four practical retrieval prompts



Apply these four prompts to every item produced during the drill. They help the team describe a record. They are **not tests of legal sufficiency, record validity or HACCP adequacy**, and they must not be converted into a score.

1. Attributable

Can the team identify who performed the activity or made the entry, and when? For a system-generated item, can the site connect the record to the correct user, line or automated event as its procedure requires?

2. Current for the selected window

Does the item reflect the plan, critical limit, product, program, settings and configuration in force during the selected window? An easily retrieved file may still be a superseded version.

3. Complete for the question it is meant to answer

Does the item contain the information the site's procedure expects, and can the relevant links be followed? Examples may include reject command to configured confirmation evidence, product hold to disposition, or deviation to authorised restart where the site requires them.

“Complete” here describes the record against the site's defined purpose. It does not mean that the control measure or HACCP plan has been proven adequate.

4. Reviewed or approved where required

Does the item show the review or approval required by the site's procedure, including who completed it and when? Do not invent an approval requirement that the site's plan does not contain; confirm what applies to that activity.

Practical-prompt worksheet

Mark **Clear / Finding / N/A under site procedure** and add a note. Do not calculate a total.

Evidence item	Attributable	Current	Complete for its purpose	Reviewed or approved where required	Note / finding reference
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
Added: ___					

Close the drill without fixing during the clock

At minute 50, convert observations into findings. Keep each finding factual and scoped.

Useful wording:

- "The approved validation record for product A, package B and line 2 was not produced within the drill window."
- "The performance-check record was produced at minute 18; the worksheet did not identify the product program in force."
- "The reject event and product disposition records were produced, but the team did not identify a shared reference connecting them."
- "Retrieval depended on one record owner; no deputy or controlled retrieval instruction was identified."

Avoid wording that jumps to an unsupported conclusion, such as "the CCP failed," "the site is non-compliant" or "the audit will fail." The responsible HACCP team decides the significance and response under the site's procedures.

Initial finding log

ID	What was observed	Evidence prompt	Five-question route	Immediate escalation required under site procedure?	Owner	Due date
F-01						
F-02						
F-03						
F-04						
F-05						
F-06						

HACCP-team review date: _____

Person responsible for routing findings: _____

Part 2 — The fifteen-point X-ray CCP readiness review

The second part goes deeper than retrieval. Complete it after the Evidence Drill, or schedule it as a separate cross-functional session. Use the same defined product, package, line and operating range.

For each point, mark one of four descriptive statuses:

- **Yes** — the team identified the site's current evidence and no gap was recorded for this prompt.
- **Partly** — the team identified evidence, but also recorded a scope, connection, ownership or implementation gap for assessment.
- **No** — the team did not identify the required basis, procedure, implementation or evidence for this prompt.
- **N/A** — the HACCP team documented why the prompt does not apply to the defined scope.

These labels support discussion. They are not scores. Do not total them, weight them, turn them into colours that imply a grade, or compare them with another site.

INSPECT — Was the product actually inspected?

INSPECT begins before the machine. The team needs to establish why the control exists, what scope was validated and whether the selected production window remained within that scope.

1. Significant hazard is identified and supported

Review:

- the significant physical hazard for the defined product and process;
- evidence used to assess its significance;
- reasonably expected source, material, size, shape or other relevant characteristics; and
- the relationship between the hazard and the selected control measure.

The HACCP team owns this decision. An equipment specification does not replace hazard analysis.

2. The control measure, CCP decision and inspection point are documented

Confirm:

- why control is essential at this step;
- whether the verified process-flow diagram matches actual production;
- whether the hazard can be introduced after the inspection point;
- whether another step contributes to control of the same hazard; and
- who approved the CCP rationale and when it is reviewed.

A decision tree can support the assessment but does not replace product- and process-specific expertise.

3. The critical limit and technical acceptance criteria are defined and supported

Keep the HACCP critical limit separate from technical study criteria. Record:

- the parameter and critical limit that distinguish acceptable from unacceptable control;
- the basis supporting that limit;
- any technical detection, reject, false-reject or study acceptance criteria; and
- how a deviation is identified and handled.

Do not transfer a contaminant size, number of repetitions, probability-of-detection target or false-reject limit from another application without product- and process-specific justification.

4. Application validation covers the defined scope

Within the broader validation of the HACCP plan, X-ray application validation should establish whether the complete control measure is capable for the defined product, package, line and operating range. A routine test-piece challenge is a different activity and does not replace application validation.

The Codex Guidelines for the Validation of Food Safety Control Measures, CXG 69-2008 provide the primary international reference for validation concepts.

Validation-file prompts

[ ] Significant hazard and intended control outcome defined

[ ] Product or product family defined

[ ] Package materials and geometry defined

[ ] Production line and inspection point defined

[ ] Operating range, including relevant line speeds and presentation conditions, defined

[ ] Critical limit and separate technical acceptance criteria identified

[ ] Approved protocol, responsibilities and acceptance criteria set before the study

[ ] Relevant test samples and justified method documented

[ ] Test-sample material, dimensions and traceability recorded

[ ] Repetition or sampling approach appropriate to the study objective

[ ] Representative product and packaging conditions included

[ ] Representative credible adverse conditions included where justified

[ ] Relevant positions and orientations considered

[ ] Approved product program, system configuration and settings recorded

[ ] Detection, reject, isolation and configured-confirmation criteria defined

[ ] Missed detections, detected packs not removed and unintended rejects recorded as distinct outcomes

[ ] Variability, deviations, adjustments and limitations recorded

[ ] Results and conclusion approved by an authorised reviewer

[ ] Monitoring, corrective-action, verification and record procedures linked to the validated basis

[ ] Changes and unexplained failures that trigger documented review and possible revalidation defined

If a probability of detection or false reject rate is used, record the denominator, study design, calculation method, treatment of uncertainty and application-specific acceptance criteria. An observed perfect result in a finite challenge does not by itself establish a true detection probability of 100%.

5. Product presentation remains within the validated conditions

Compare the selected production window with the validated scope:

- product and package;
- product height, density, variation and orientation where relevant;
- conveyor speed;
- pack spacing and stability;
- inspection program and settings;
- upstream or downstream changes that affect presentation; and
- any bypass, recirculation or restart condition.

Record deviations and route them under the site's procedures. Do not assume that an approved program name alone proves that the complete application remained within its validated range.

REMOVE — Was the suspect product actually removed from the flow?

Detection and a reject command do not complete the product-control decision. Review the physical path and the site's handling of suspect product.

6. Reject action works under representative production conditions

Review the complete reject sequence with the actual product, package, speed, spacing and reject timing within the approved test method. Consider:

- whether the reject device acts at the intended point;
- whether the pack clears accepted-product flow;
- the response to closely spaced packs or unstable presentation where relevant;
- the response to loss of air, power, bin capacity or another monitored condition where configured;
- unintended rejection of unaffected product; and
- how a failed sequence is identified and handled.

The site defines the safe test method. Do not compromise food safety, machine guarding or personnel safety to perform a challenge.

7. Rejected product remains controlled until disposition

Confirm:

- the reject destination and physical containment;
- access control and authorised removal;
- identification of suspect product and affected lot or time window;
- handling when the reject container is full or unavailable;
- transfer to hold or evaluation where required;
- who evaluates the product;
- who authorises release, rework, disposal or another disposition; and
- the record connecting the reject event to the decision.

An integrated reject bin can support isolation. The producer still owns affected-product evaluation and final disposition.

8. Loss-of-control and affected-product actions are specific

Use this tabletop scenario:

> **A scheduled system challenge or function check shows that the configured reject sequence did not operate as specified. Product has been running since the last satisfactory check.**

Can the team answer each question from an approved procedure without improvising?

1. Who can stop the line and place product on hold?
2. How is the potentially affected production window determined?
3. How is affected product identified, segregated and controlled?
4. Who evaluates the product and decides disposition?
5. How is the immediate cause investigated and corrected where required?
6. What conditions and authorisation permit restart?

7 What review, maintenance, verification or revalidation decision does the event trigger?

8 Where are the event, decisions, actions and approvals recorded?

Deviation and affected-product worksheet

Field	Entry
Date, time and line	
Product, code and lot	
Relevant CCP and critical limit	
Deviation or failed function observed	
Last satisfactory check	
Defined potentially affected period	
Potentially affected quantity	
Immediate process correction	
Product hold identification and location	
Evaluation and disposition	
Cause assessment and action to reduce recurrence where required	
Restart conditions and authorisation	
Required review or revalidation decision	
Record reviewer and date	

PROVE — Can removal be evidenced, not just commanded?

9. The evidential scope of reject confirmation is understood

Map what the supplied sensors and logic can actually show. Distinguish among:

- detection or reject decision;
- reject command;
- actuation of the reject device;
- passage through a configured confirmation point;
- arrival in a controlled reject destination, if specifically monitored; and
- final product evaluation and disposition.

Do not infer one stage from evidence of another. A signal at a configured point does not automatically establish final disposition, and reject confirmation is not the same as HACCP verification.

Reject-evidence map

Sequence stage	What the site needs to know	Available evidence	Sensor / logic / record source	What this evidence does not show	Failure response
Detection / decision					
Reject command					
Reject-device action					
Configured confirmation point					
Controlled destination					
Evaluation and disposition					

Confirm the actual supplied configuration for the application. Do not assume that complete reject confirmation is present on every system or that every configuration provides the same evidence.

CHECK — Were routine CCP performance checks completed as planned?

CHECK is broader than one button, screen or test card. Keep four activities distinct so that one record is not asked to prove something it was never designed to prove.

Activity	Primary question	Defined by	Typical evidence direction
Application validation	Is the complete control measure capable for the defined scope?	HACCP team and approved validation protocol	Study plan, conditions, results, limitations, conclusion and approval
Monitoring	Is the CCP under control according to the plan now?	HACCP plan	Defined observation or measurement, result, time and responsible person or system
Site-defined routine CCP performance check	Did the configured inspection and reject workflow respond as planned at the scheduled point?	Site procedure	Method, test piece where applicable, product/program, user, time, result and response
Verification	Is the validated plan followed and does it continue to work as intended?	HACCP plan	Record review, observations, challenge activities, calibration/accuracy checks where applicable, audits and follow-up

The activity represented by a routine performance-check record depends on the site's HACCP plan. Do not label every challenge “validation” or automatically classify every confirmation signal as “verification.”

10. Monitoring method, frequency, responsibility and records are defined

Confirm that the plan states:

- what is monitored;
- how it is monitored;
- when or how often;
- who or what system performs it;
- the acceptable condition or critical limit;
- where the result is recorded; and
- what constitutes a deviation and what happens next.

Frequency is application- and requirement-specific. Do not copy a frequency from another product, sector, customer or jurisdiction without justification.

11. The site-defined routine performance check is controlled and recorded

Review whether the procedure defines:

- purpose of the check;
- product, package, line and product program;
- approved test piece or other method where applicable;
- positions, sequence and repetitions where required;
- scheduled frequency and trigger events;
- person or system responsible;
- expected inspection, reject and configured-confirmation response;

- handling of the test piece and challenged product;
- response to failure, including affected-product scope;
- restart conditions; and
- record content, review and retention.

Routine performance-check record prompts

Field	Entry
Line / inspection point	
Product / package / program	
Date and time	
User or responsible person	
Check due / check completed	
Test piece or method identifier where applicable	
Defined sequence	
Inspection result	
Reject result	
Configured confirmation result	
Overall result under site procedure	
Failure response, if applicable	
Review or approval where required	

12. Verification is defined separately from monitoring

Verification may include, as defined by the site's plan:

- review of monitoring, deviation and corrective-action records;
- review of affected-product evaluation and disposition;
- direct observation of monitoring and reject handling;
- documented performance challenges;
- calibration or accuracy checks where applicable;
- confirmation that procedures and the verified flow are followed;
- internal audits; and
- review after changes, failures or new information.

The Codex General Principles of Food Hygiene, CXC 1-1969 and the FDA's HACCP Principles and Application Guidelines describe the relationship among monitoring, corrective action, verification and records. Apply the requirements that govern the site, product and market.

13. Relevant changes and unexplained failures trigger documented review

The change-control procedure should prompt assessment of changes that may affect the validated basis, including relevant changes to:

- product or product family;
- ingredients, density, dimensions or presentation;
- packaging material or geometry;
- process flow or inspection-point position;
- conveyor speed, spacing or upstream handling;
- inspection program, settings or software configuration;
- X-ray source, detector or other significant equipment component;
- reject device, timing, sensors or confirmation logic;
- utilities or environmental conditions where relevant; and
- applicable legal, customer or certification requirements.

An unexplained detection, reject or control failure should also trigger documented review. Where food-safety performance may be affected, the team decides and records whether revalidation is needed.

Change-review worksheet

Change or event	Date	Potential effect on validated scope	Immediate control	Review owner	Revalidation decision and rationale	Approval

14. Operators understand the procedure and demonstrate competency

Training attendance alone may not show that a person can execute the site's defined response. Review whether relevant people can:

- identify the correct product program and approved setup;
- perform the monitoring or routine performance check assigned to their role;
- control test pieces or test packs where applicable;
- respond to a reject, alarm, failed check or loss of control;
- identify and control potentially affected product;
- record the activity and escalate without reconstructing the event later; and
- work from the current approved procedure.

Record the person, role, procedure version, training date, competency method, reviewer and any required refresh or reassessment.

RECORD — Can the records be retrieved for the defined scope?

15. The required evidence chain is attributable, connected, reviewed and retrievable

Use the Evidence Drill result to examine the record architecture, not only individual documents.

Confirm:

- which records the site's plan requires;
- who creates, owns, reviews and retains each one;
- the controlled system or location for each record;
- the shared keys used to connect product, line, lot or code and time window;
- time synchronisation and time-zone handling across systems where relevant;
- attribution for manual and system-generated entries;
- version control for plans, limits, procedures, product programs and settings;
- correction or amendment controls;
- review and approval required by the site's procedure;
- access, backup and retrieval during expected retention periods; and
- the response when a record is missing, inaccessible or cannot be connected.

Electronic and paper records can both support the evidence chain where applicable requirements and the site's procedures permit. Format does not remove the need for appropriate attribution, integrity, accessibility, retention and review.

There is no universal retention period in this guide. The site must determine and document the legal, customer, certification and internal requirements that apply to its products and markets.

Evidence-location map

Evidence set	Creator	Owner	Reviewer	Controlled location	Connection key	Retention basis	Deputy / retrieval instruction
HACCP plan and hazard analysis							
Critical limit and validation							
Monitoring							
Performance and reject-sequence checks							
Deviation and corrective action							
Product hold, evaluation and disposition							
Verification and record review							
Calibration / accuracy where applicable							
Training and competency							
Maintenance and change control							

Printable fifteen-point checklist

Site: _____ **Review date:** _____

Line / inspection point: _____

Product / package: _____

Operating range: _____

HACCP plan / version: _____

Reviewers and functions: _____

Mark **Yes / Partly / No / N/A**. Do not calculate a total, percentage, colour grade or pass/fail result. Record an owner and due date for every **Partly** or **No** finding, and for any **N/A** that requires HACCP-team confirmation.

#	Question	Readiness prompt	Yes	Partly	No	N/A	Evidence reference / finding ID
1	INSPECT	Significant physical hazard is identified and supported					
2	INSPECT	Control measure, CCP decision and inspection point are documented in the verified process flow					
3	INSPECT	Critical limit and separate technical acceptance criteria are defined and supported					
4	INSPECT	Application validation and the wider HACCP-plan validation cover the defined scope as applicable					
5	INSPECT	Product presentation and operating conditions remain within the validated scope					
6	REMOVE	Reject action works under representative production conditions within the approved test method					
7	REMOVE	Rejected product remains identified and controlled until authorised disposition					
8	REMOVE	Loss-of-control, affected-product and restart actions are specific and recorded					

#	Question	Readiness prompt	Yes	Partly	No	N/A	Evidence reference / finding ID
9	PROVE	The evidential scope of the supplied reject-confirmation configuration is understood and failures trigger the defined response					
10	CHECK	Monitoring method, frequency, responsibility, limit and record are defined					
11	CHECK	The site-defined routine CCP performance check has a controlled method, record and failure response					
12	CHECK	Verification activities and responsibilities are defined separately from monitoring					
13	CHECK	Relevant changes and unexplained failures trigger documented review and a recorded revalidation decision where needed					
14	CHECK	Relevant personnel are trained, understand escalation and demonstrate competency for their role					
15	RECORD	The site-defined evidence chain is attributable, current, connected, reviewed where required and retrievable for the defined scope					

Consolidated action log

Use one row per finding from the drill or fifteen-point review. The finding description records what was observed; the HACCP-team assessment records why it matters and what the site's procedures require.

ID	Source: Drill / Review	Five-question route	Factual finding	Product or period potentially affected	Immediate control or escalation	HACCP-team assessment / required action	Owner	Due	Closed / evidence
A-01									
A-02									
A-03									
A-04									
A-05									
A-06									
A-07									
A-08									

Review outcome — record a decision, not a score

[ ] Findings routed for assessment under the site's food-safety procedure

[ ] Immediate product or process action taken where the site's procedure required it

[ ] Follow-up technical, procedural, training or record-control work assigned

[ ] Relevant validation or revalidation decision recorded

[ ] Closed actions checked by the responsible reviewer

[ ] Repeat drill scheduled after actions close

HACCP-team decision and rationale:

_____

_____

_____

Decision owner: _____ **Date:** _____

Authorised reviewer: _____ **Date:** _____

Repeat drill date: _____ **New product / period:** _____

For a repeat drill, choose another appropriate product or period and apply the same site-defined method. Compare the retrieval path with the site's previous path. Do not compare the result with an invented industry benchmark, and do not treat a shorter time as proof that the underlying HACCP decisions are adequate.

Where Mekitec equipment and software can support the chain

The requirements and the site's method come first. Equipment and software support defined parts of the evidence chain; they do not own the producer's HACCP responsibilities.

Complete CCP questions	Product	Approved support boundary
INSPECT, REMOVE, PROVE	**MEKI ONE**	Supports the physical equipment layer: inspect, reject, isolate, confirm and report. Confirm the supplied configuration for the application.
CHECK	**MEKI AI Validation Mode**	Can schedule, enforce and record the site-defined routine CCP performance check. It does not replace complete application validation.
RECORD	**MEKI Analytics**	Helps QA review connected-system activity for the correct line, product and time window and prepare reporting from time-stamped evidence.

MEKI ONE: INSPECT, REMOVE and PROVE

MEKI ONE supports X-ray inspection, integrated rejection, controlled isolation in the supplied reject arrangement, configured reject confirmation and system reporting. The supplied reject device, bin, sensors, logic and reporting scope must be confirmed for the application.

Count the seams while you run the drill. An X-ray CCP is often assembled from parts — the detector, the reject device, the reject destination, the confirmation sensing and the reporting — each specified, interfaced, commissioned, validated and maintained separately, and often bought from more than one supplier. Every seam is a place where the evidence chain can break without anyone noticing: the reject is commanded in one system, confirmed by another, and tied to a product code in a third. MEKI ONE supplies those five parts as one system, which means one configuration to validate rather than five to specify and commission, one set of operator instructions for the reject sequence, and one supplier to call when the confirmation stops matching the reject. It does not make the evidence chain complete; it reduces how much of it has to be built and connected before it can be shown.

Reject confirmation is supplied at more than one level, and the level decides what the record can show. Current public product information lists **standard reject confirmation** with the integrated rejector, and **complete reject confirmation as an option rather than a standard feature**. In broad terms, the standard arrangement evidences that a rejected pack reached the monitored point at the reject container and raises a fault when it did not; the fuller arrangement adds controlled access to the container itself. Do not assume that every system on site has the same level.

MEKI ONE does not determine whether a process step is a CCP. Product and package suitability, inspection performance, reject operation and the evidential scope of reject confirmation must be established for the actual line and operating conditions.

MEKI AI Validation Mode: CHECK

The food producer defines the purpose, method and frequency of its routine CCP performance check. MEKI AI Validation Mode can schedule, enforce and record that site-defined workflow within a compatible configured inspection system, including supported information such as the user, time, test card and result. Where enforcement is enabled, a failed check stops inspection until a user with Quality, Admin or Service credentials clears the condition; the site's own procedure still governs affected product and release decisions.

Scheduling and enforcement are configuration- and licence-dependent. Reminders at production start and end, reminders by elapsed time or product count, audible and visual alarms, and the setting that prevents a due check from being skipped are not all present in every setup, and Validation Mode is enabled per product rather than by default. During the drill, record what is actually enabled on the specific system rather than what the software can do in principle.

Two naming points recur in the field. Mekitec's product page describes this capability under the broader label Digital Validation; **Validation Mode** is the name of the guided workflow inside MEKI AI. The system's own screens call a routine check a validation session — that is the scheduled operational check, not application validation.

Validation Mode does not replace application validation. Availability, licensing and compatibility must be confirmed for the specific system before an external commercial commitment is made.

MEKI Analytics: RECORD

MEKI Analytics helps QA review activity from connected systems for the correct line, product and time window and prepare reporting from time-stamped inspection evidence. It can support the machine-generated part of the chain.

It does not establish that activities outside connected systems were completed, and it is not the producer's complete HACCP record system. The producer defines the required record set, attribution, review, connection and retention. Public availability, naming, compatibility and destination require product-owner confirmation before publication.

The responsibility boundary: Mekitec equipment and software support defined parts of the evidence chain. The food producer remains responsible for hazard analysis, CCP designation, critical limits, application validation, procedures, monitoring and verification decisions, corrective actions, affected-product disposition, training, record review and retention.

Facilitation handoff

Before ending the session, the facilitator should confirm that the team has:

- a fixed scope statement;
- the original sixty-minute result, preserved even if records were found later;
- a location and owner for every item produced;
- a factual finding for each item that was partial, not produced or could not be connected;
- notes from the four practical retrieval prompts, without a calculated result;
- completed or scheduled the fifteen-point review;
- assigned owners and due dates;
- routed urgent items through the site's procedures; and
- scheduled a repeat drill after actions close.

If a finding concerns product presentation, inspection settings, detection performance, reject configuration, confirmation logic or the data produced by the supplied system, the site can request a product- and line-specific application/evidence review: approved contact route to be inserted before publication.

Primary sources and companion references

1 FAO and WHO. General Principles of Food Hygiene, CXC 1-1969. Revised 2022.

2 FAO and WHO. Guidelines for the Validation of Food Safety Control Measures, CXG 69-2008.

3 U.S. Food and Drug Administration. HACCP Principles and Application Guidelines.

4 European Parliament and Council. Regulation (EC) No 852/2004, Article 5.

5 Mekitec. What Makes a Critical Control Point Complete?.

6 Mekitec. What Records Should You Be Able to Retrieve for an X-Ray CCP? — companion article URL to be inserted after publication.

7 Mekitec. MEKI ONE X-ray inspection system.

Use and limitations

This guide is a general educational and review resource. It is not a HACCP plan, validation protocol, compliance certificate, certification decision, legal opinion or confirmation that a particular control measure is suitable. It does not assess compliance or predict an audit result. Food businesses must apply competent, product- and process-specific hazard analysis and comply with applicable legal, customer and certification requirements. Product suitability, inspection performance, reject configuration and evidence scope must be established for the actual product, package, line and operating conditions.

Reuse, translation or adaptation by trainers, consultants, educators and partners requires the permission terms approved by Mekitec for the final published version. Until those terms are approved, request permission before reproducing substantial parts of this guide.

About Mekitec

Mekitec develops and manufactures X-ray inspection systems and software for food producers worldwide. Since the first MEKI installation in 2011, our systems have been used across four continents and in more than 40 countries, and our AI-based X-ray image analysis is covered by a granted US patent.

Version: 2.0 draft

Content review: Pending

Technical reviewer: Pending named Mekitec food-safety/application specialist

Last technically reviewed: Pending approval