



# **SQF: Risk Assessment and Equipment Calibration**

**Presented by  
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# Risk Assessments

Hazard Analysis

CCPs vs. CPs

Pre-requisite Programs (Preventive Controls)

Effectiveness of Pre-requisite programs

Calibration of equipment

# Risk Assessments

## Hazard Analysis.

Performance of a thorough Hazard Analysis leads to the question and determination of how are the “known to occur” hazards going to be controlled.

Critical hazards are controlled by HACCP Plans at CCPs.

Other hazards are controlled by Pre-requisite programs which are designed to prevent or control these hazards and are hence CPs and thus are called Preventive Controls.

# Risk Assessments

## Preventive Controls.

The challenge companies now find themselves facing is how do they demonstrate to the SQF auditor and the FDA inspector, in the future if Section 103 of FSMA is invoked as currently proposed, the effectiveness of these Pre-requisite programs as Preventive Controls in controlling these hazards from causing consumer concerns in the finished product.

## Pre-requisite program effectiveness

Facilities have to document how they show these programs are effective.

- Preventive Maintenance program (11.2.9).
- Calibration program (11.2.10).
- Pest Control Program (11.2.11).
- Sanitation program (11.2.13).
- Personnel programs (11.3 and 11.4).
- Storage and Transport (11.6)
- Waste Program (11.9)

## Preventive Maintenance Programs Effectiveness (11.2.9)

- Self audit identifies all equipment needing PM is on a schedule (2.5.7).
- Self audits spot checking PM records to verify PM has been performed (2.5.7).
- Self audits identifying no equipment or building issues are related to lack of adequate PM (2.5.7).
- Equipment breakdowns are very infrequent (11.2.9.2.ii).

## **Pest Control Programs Effectiveness (11.2.11.2.x).**

- Self audits (2.5.7).
- No rodent evidence
  - No employee sightings.
  - PCO reports showing no repeat problems.
- Evaluating PCO's performance.
- No customer complaints traceable back to pest issues (2.1.5).
- No regulatory citations based on pest issues (2.1.5).

## Sanitation Programs Effectiveness (11.2.13).

- Self audits (2.5.7).
- Pre-Op inspections (11.2.13.4).
  - ATP swabbing.
  - Allergen swabbing.
  - Environmental swabbing.
- No customer complaints traceable back to cross-contamination or cross-contact (2.1.5).
- No regulatory citations based on poor sanitation (2.1.5).



## Personnel Programs Effectiveness (11.3+11.4).

- Self audits (2.5.7).
- Supervisors signing off that employees GMP training was effective (2.9.7.vi).
- No customer complaints related to poor employee health, hygiene or practices (2.1.5).
- No regulatory citations of employees (2.1.5).

## Transportation Programs Effectiveness (11.6).

- Self audits (2.5.7).
- Shipping and receiving records review (11.6.7).
- Transportation temperature recorders (11.6.8.2).
- No customer complaints related to transportation issues (2.1.5).
- No regulatory complaints related to transportation issues (2.1.5).
- Sealed trailers and tankers (Food Defense 2.7.1)

## **Waste Control Programs Effectiveness (11.9.1.6).**

- Self audits (2.5.7).
- Pre-op inspections – waste removed daily (11.9.1.6).
- Exterior inspections (11.10).
  - Compactors not leaking on ground.
  - Dumpsters not overflowing.
- No regulatory citations based on waste problems (2.1.5).
- No roach problems due to cardboard recycling.
- No odor or fly problems due to inedible waste.

## Calibration Programs Effectiveness (11.2.10).

- Self audits spot checking measuring equipment (2.5.7).
- No regulatory citations related to improperly calibrated equipment (2.1.5).
- No customer quality complaints based on out of calibration equipment allowing out of specification products to be sent out (2.1.5).
- No Recalls due to unsafe product being dispatched because of being measured with out of calibration equipment (2.6.3).

## Calibration of Equipment (SQF 11.2.10)

Accuracy of an instrument used to measure a CCP or CP is critical to ensuring that the parameter being measured is being adequately measured so as to ensure the food safety of the product.

Hence several criteria need to be met to ensure this is in compliance.

# Calibration of Equipment (SQF 11.2.10)

- Need to document how calibration is done and by whom (11.2.10.1) and to what standards (11.2.10.4)
- Need to show frequency and justification for frequency (11.2.10.5)
  - Instrument manufacturer's recommendation.
  - Regulations.
  - Personal experience.

# Calibration of Equipment (SQF 11.2.10)

- Need procedures developed for the following
  - What to do with product measured with an instrument that is later shown to be out of calibration. (11.2.10.2)
  - A process to prevent accidental or deliberate adjustment of the calibrated instrument. (11.2.10.3)



# Thank you

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