Best Practice in Operational and GMP Auditing

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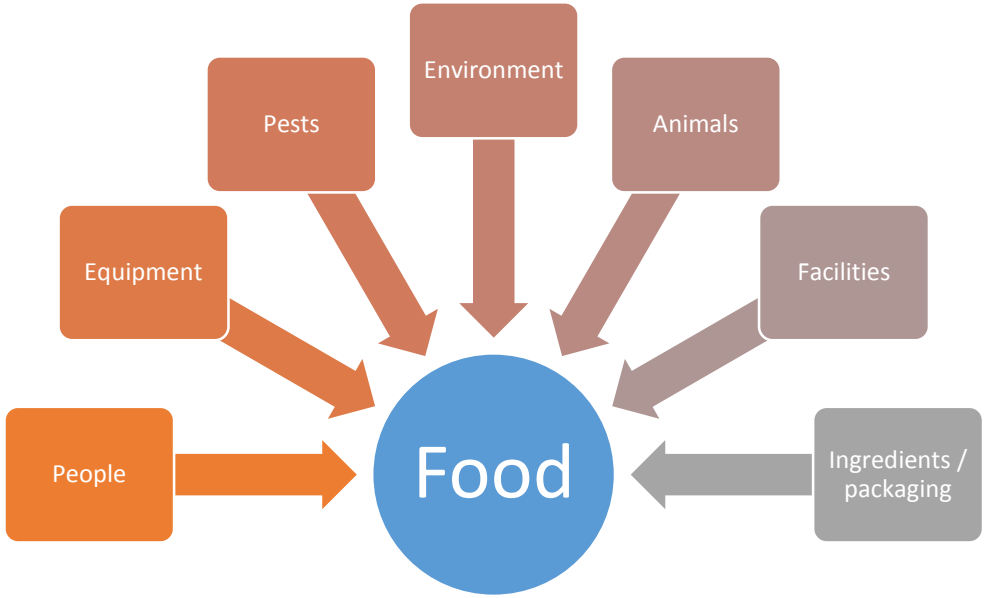
Background

- Hygienic operation is critical for safe food
- Required for regulatory and commercial compliance
- Provide a “Due Diligence” defense
- Meet the hygienic condition of the plant - prerequisite for HACCP
- Building and maintaining your customer’s confidence
- We have seen shift in how this is being achieved

Hazards & Contamination

- Sources of contamination in the food plant are varied
- People, facilities, equipment, animals, pests, the plant environment, ingredients, packaging
- Development and implementation of operation / GMP audits requires resources
- Source of stress and consumption of time

Sourced of Contamination



Evaluation & Monitoring Operational Standards

- Most accepted way is through a food plant hygiene audit
- Also called pre-operational or GMP audit
- This type of audit is a systematic and independent examination
- Determines whether cleaning, sanitation or operational activities are being carried out as planned
- “As planned” is the output of HACCP planning

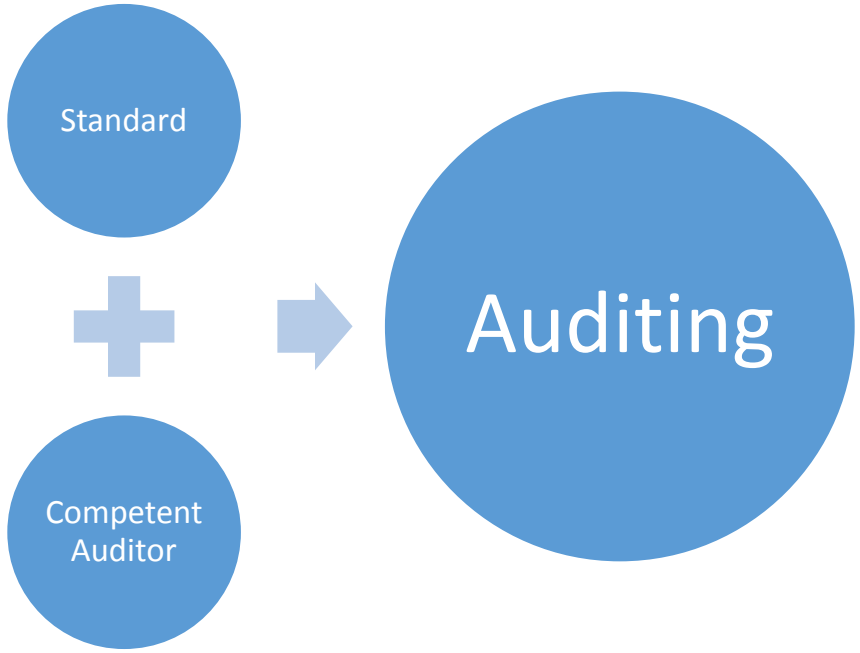
Evaluation & Monitoring Operational Standards

- Objective is to check system is working and capable of delivering safe and wholesome products
- The efficiency of operational standards is generally determined through “audits.”
- Expressed in operating procedures (SSOPs), other prerequisite programs and the HACCP system
- Generally determined through “audits.”
- We will look at the considerations of the operational audits from the auditor’s perspective

What is an Audit?

The systematic, independent and documented process for obtaining audit evidence, and evaluating it objectively to determine the extent to which the audit criteria are fulfilled.

Essential Elements of an Audit

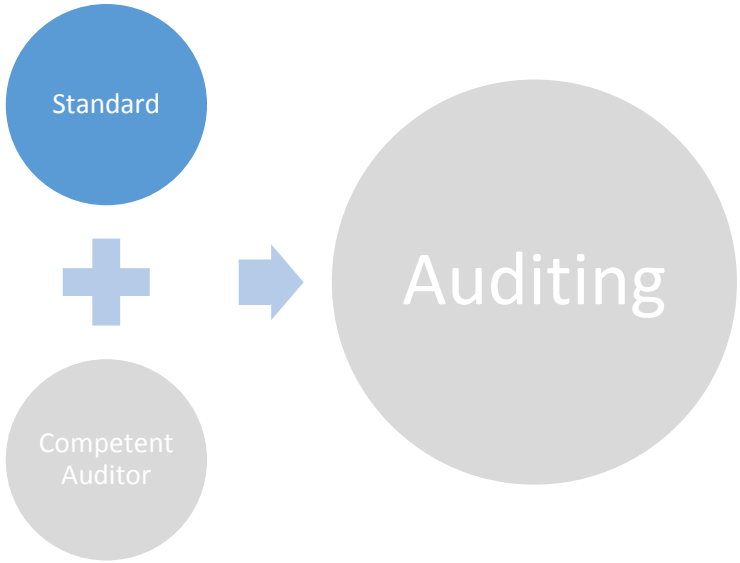


Primary Aim of Auditing

- To be an effective and reliable tool in support of food safety management policies and controls
- Providing objective ***evidence*** that ***requirements*** are being met

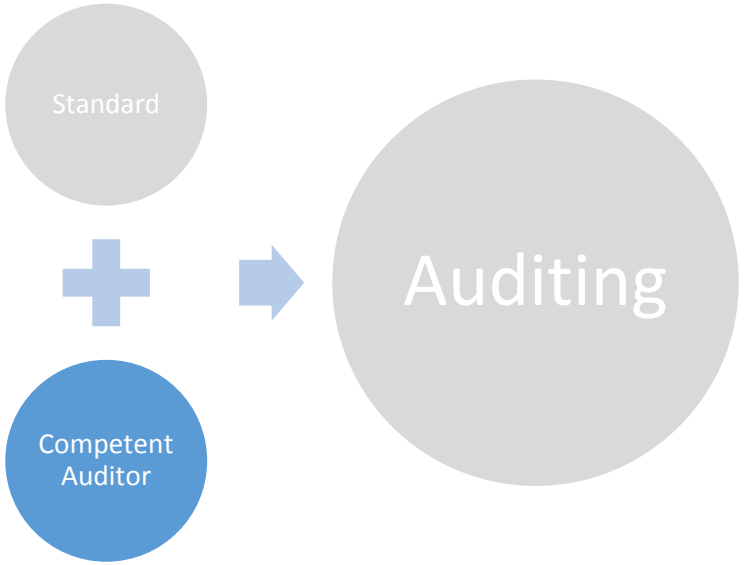
What Are Requirements?

- Standards
- Specifications
- Critical limits
- SOP's
- Procedure
- Policies
- Customer requirements
- Legal requirements

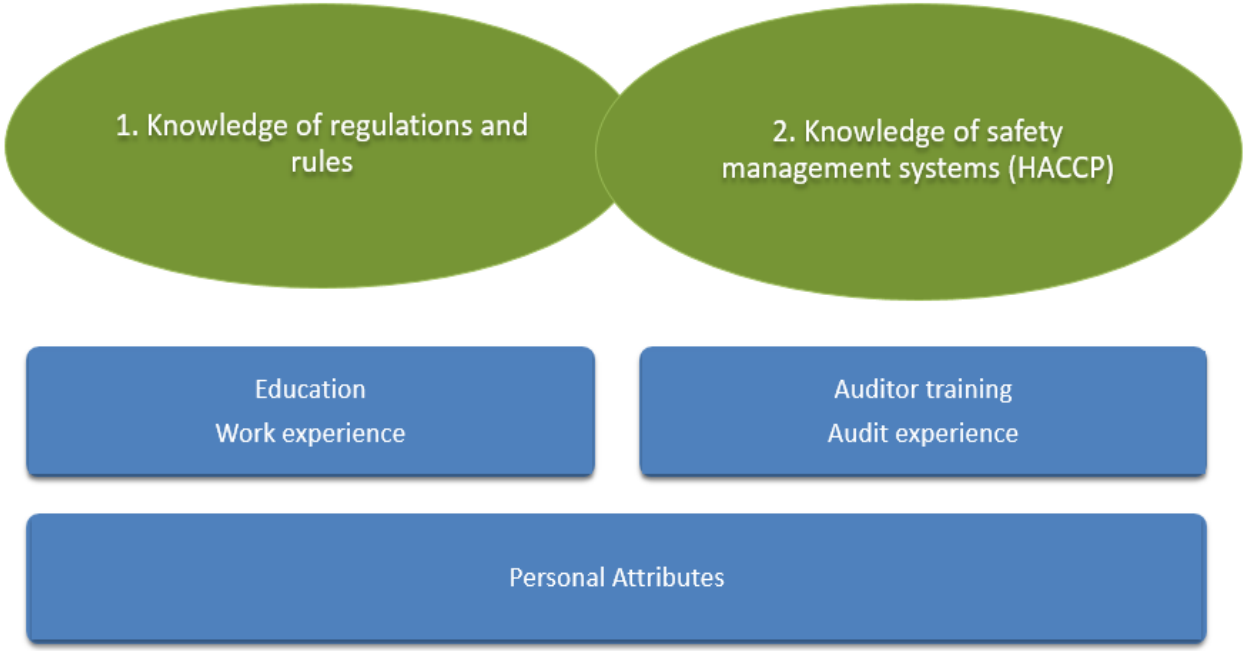


What is Objective Evidence?

- Records
- Statements of fact
- Other Information (Visual inspection)
- They are relevant to the audit criteria and verifiable
- They can be qualitative or quantitative.



What is a Competent Auditor



Who can be a Competent Auditor?

- Depends on the purpose of the audit.
- Food operational / GMP / Hygiene audits
- Company technical, supervisors or management personnel can opt to audit
- Standards compliance and verification of its own facility
- Verification of SSOPs and HACCP systems
- Contract with a third-party auditor is an option
- What level of training is required?

Fundamental Attributes of an Auditor

- Wear suitable clothing
- Use a flashlight
- Have a notepad and open mind
- Determine the area to be inspected
- Observe employee/in-plant practices
- Record defects notes

Fundamental Attributes of an Auditor

- Look at obscure places
- Be constructive, watch details
- Be complete, specific and brief
- Distribute, so immediate action can be taken
- Compliment/recognize good work
- Utilize outside inspection services

Types of Audits

- Various types of audits
- There is hierarchy depending on the objectives
- Scope, intent, frequency usually based on risk assessment

Hierarchy of Audits in Food Safety

The Emergence of the Pre-Operational Audit

- Recent shift in audit focus
- Retailers and GFSI driving the shift
- From the formal hygiene and systems audit to “CHECKING”
- Traditional auditing – more general and formal
- Extended frequencies
- Lack of confidence in traditional approach
- Did not address issues in real-time; actions to late

Shift to ”Checking”

SQF Code – Section 13.2.1.3

13.2.11 Cleaning and Sanitation

13.2.11.1 The methods and responsibility for the cleaning of manufacturing and storage areas, staff amenities and toilet facilities shall be documented and implemented.

13.2.11.2 Provision shall be made for the effective cleaning of processing equipment, utensils and protective clothing.

13.2.11.3 Suitably equipped areas shall be designated for cleaning product containers, utensils and cleaning staffs protective clothing. Racks and containers for storing cleaned utensils and protective clothing shall be provided as required.

13.2.11.4 Pre-operational hygiene and sanitation inspections shall be conducted by qualified personnel to ensure manufacturing and storage areas, staff amenities and sanitary facilities and other essential areas are clean.

13.2.11.5 The responsibility and methods used to verify the effectiveness of the cleaning procedures shall be documented and implemented. A verification schedule shall be prepared.

What is the Pre-operational Check?

- Based on Key Assumption
- If the conditions of production are right – production of safe food is assured
- Issues happen in a moment in time
- Should be checked and addressed in that moment and prior to impact

What is the Pre-operational Check?

- Conditions – hygiene, SOP's, times, temperatures etc
- Formal checks of the conditions determined to produce safe food
- Many be general or specific requirements
- Basic on the insight that things right before production not detection afterwards

Character of Pre-operational Check

- Focused on checking and not auditing
- Based on specific production window, production line, batch run
- Takes place before production commences
- High frequency
- Corrective actions can be managed locally and in real time
- Very specific in terms of requirements
- Integrated fully into normal operational activities – not separate or above
- Owned by operational personnel – ideally

What should be included in a Pre-operational Check?

- What is essential for safe food production – and nothing more (Risk Assessment)
- What is clearly measureable
- What can be reasonably addressed or corrected at that time

What should be included in a Pre-operational Check?

- Hygiene standards – general plant area (floors, walls, drains, pumps, brushes/pads, foot-baths)
- PRP's (pest control, housekeeping, roof, doors/ windows, air handling system, building)
- Personal hygiene standards
- Hygiene standards – equipment, utensils, cleaning standards

What should be included in a Pre-operational Check?

- Processing (tanks/silos, pumps/valves, vacuum breakers, retort charts, pasteurizer charts)
- Employee practices (illness/open lesions, jewelry, restricted areas, foot baths, use of hand tools/utensils, training programs)
- Labelling and other legal requirements
- Records (cleaning and sanitation, SSOPs/GMPs, compliance with scheduled sanitation program, violations/corrective actions, score)

The Power of “Positive Release”

- Pre-operational checks are most potent when coupled with Positive Release
- Operation affirmation that conditions have been met and production can commence
- Should be policy based and approved senior management
- A “No run” policy should be adopted
- Formal sign-off and release
- Escalation procedure also required
- For continuous process a system of “Permit to continue” can be used

Corrective Actions

- Should by definition be capable of being managed locally
- Can be addressed in real time
- Full scale CAPA process not required
- Procedure for recurring issues should be in place

Checklists

- Essential element and core to success
- Should be well designed and easy to use
- Cover the scope of what is required
- Define the requirement and actions to be taken if relevant
- Include the positive release workflow
- Reviewed regularly and controlled as a formal document

Checklists – audit type

Audit Record

Checklist

No.	Requirement	Response	Comments / Observations	File	Corrective Action
	Hygiene room				
	No unneeded items - Sort	3 - 3 pt			No
	All items in correct location - Set	3 - 3 pt			No
	Knives cage locked- Set	3 - 3 pt			No
	Sockets & switches intact & clean - Shine	3 - 3 pt			No
	No condensation build up - Standardise	3 - 3 pt			No
	General -Specify issue - General	3 - 3 pt			No
	Line 3				
	No unneeded items - Sort	2 - 2 pt	FC crates sitting in label holder on line 3 / had these removed issue closed line 3	image.jpeg	No
			Green crate sitting on conveyer / this was line 4 who left these there as line 3 was not running today..	image.jpeg	No
	All items in correct location - Set	2 - 2 pt	Cover from scannem on floor / had operater remove this line 3 issue closed	image.jpeg	No
	PPE dispenser clean & items segregated - Shine	3 - 3 pt			No
	No product / meat on the floor - Shine	3 - 3 pt			No
	Equipment surface clean,no label residue - Shine	2 - 2 pt	Mondini panel on line 3 Mondini is very grubby / have highlighted this to AnnMarie she will speak to line isdue closed no one running this line today..	image.jpeg	No

Checklists – monitoring type

Monitoring Record

Date 21/07/2015

Record

Batch No	OPEN / CLOSE	Date / Time	Line No	Product Description Correct?	Label Code HM - (Enter) (259.099 - 1162.01)	Use By Date	UBD (DOP+8)	Bar Code (Enter) - 20475.01)
06201023	OPEN	21/07/2015 15:11	Line 6	CORRECT	1162	28 jul	CORRECT	20475
0620123	OPEN	21/07/2015 15:16	Line 6	CORRECT	1162	28 jul	INCORRECT	20475

Checklists – monitoring type

Checklists – positive release type

Verification & Release

Visual Inspection

Requirements	Conducted By	Result
Crust Freezer- Inspect internal surfaces including 1) Walls 2) Fans (Attach Photographic)	Ramazan Kumru	Pass
Crust Freezer - Inspect parts after cleaning including 1)Baskets (Attach Photographic)	Ramazan Kumru	Pass
TVI Slicer - Inspect all surfaces (Attach Photographic)	Ramazan Kumru	Pass
TVI Slicer - Inspect parts after cleaning including Conveyor belts 1) Blade 2) White plastic parts 4) Accessorie rack (Attach Photographic)	Ramazan Kumru	Pass

ATP Test Result

Sample Point	Reading	Result
Crust Freezer - Internal surface 1) Walls	0.00	Pass
Crust Freezer - Baskets	0.00	Pass

Checklists – positive release with photo

How does the process work?

- 1. Risk assess and determine what is required (HACCP)
- 2. Prepare SSOP's and other relevant policies
- 3. Prepare schedules
- 4. Identify and train auditors
- 5. Define requirements / specifications / criteria
- 6. Define corrective actions
- 7. Create checklists
- 8. Conduct checks and review adequacy of system