ASIFOOD

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Short Term Training Course (STTC)
"Safety and Quality in Innovative Food Production Systems"

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Lecture 11:

Auditing in Food Processing Industries

Auditing in Food Processing Industries

Quality Audit Systems in Food Safety Management Systems

- A systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively to achieve objectives
- Typically performed at defined intervals (monthly, annual, biannual)
- Any failure in their proper implementation may be published publicly and may lead to a revocation of quality certification

Objectives Of Quality Audit

- Food manufacturers commonly use audits as an effective mechanism to verify compliance with GMP regulation (GMP).GMP audits have two important goals
  - Audits are intended to verify that manufacturing and Control systems are operating under a state of control.
  - Audits permit timely correction of potential problems that may otherwise result in higher quality loss (cost).

Types Of Quality Audit

The quality audit system is mainly classified in three different categories:

i Internal Audit
ii. External Audits
iii. Regulatory Audit

In food industries all three audit system may be used to carry out

1. Product manufacturing audit
2. Plant sanitation/GMP audit
3. Product Quality audit
4. HACCP audit

Internal Audit

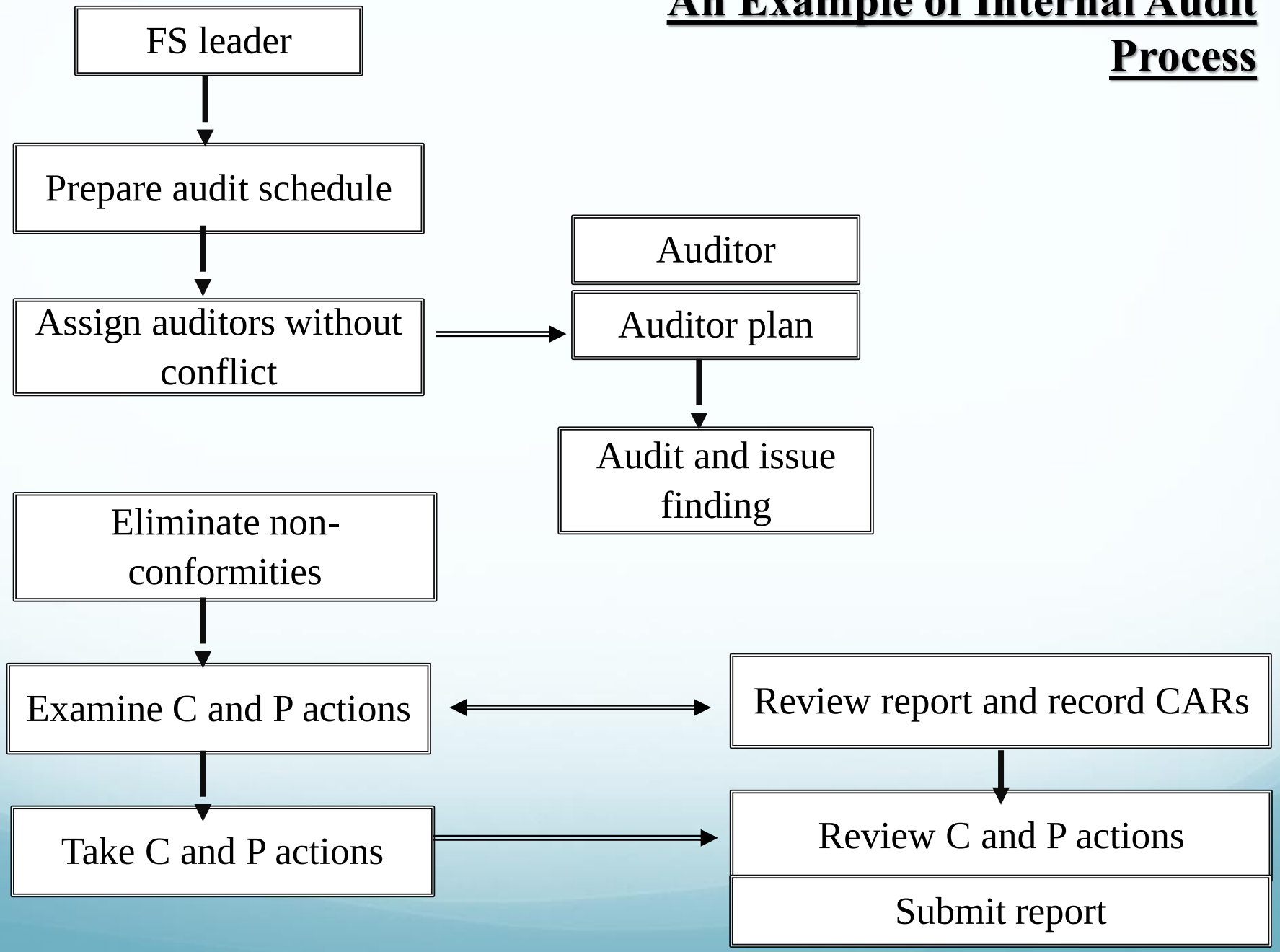
Purpose of Internal audit:-

- To ensure that adequate Quality systems are maintained
- To asses compliance with the C-GMP’s and firms standard operating procedures (SOPs)
- To achieve consistency between manufacturing and testing facilities
- To identify problems internally and Correct problems prior to a external or regulatory audit.

Types Of Internal Audit

	Tier One	Tier Two	Tier Three
Carried out by:-	Interdepartmental heads, staffs of other department inside company	Local Quality assurance Group	Corporate Compliance Group and External Consultant
Purpose:-	Require Short time and Focus is on house keeping and documentation	Require Longer period and more focus on system than housekeeping	More focusing for asses the readiness of regulatory audit
Frequency:-	More often	Less	Less than tier two
Qualification:-	Receive Some basic training	More exclusive training	Highly trained and experienced or specialist with the expert knowledge of GMP

An Example of Internal Audit Process



External Audit

Purpose of External Audit:-

- Ensuring that requirements are well understood
- Enabling reduction of in-house QC testing of raw materials
- Reducing the risk of failure
- Carried Out by a company on its vendors or sub contractors
- External auditors have experience of GMP and as well as regularly audited by their certification body

Regulatory Audit

Purpose of Regulatory audit:-

- Networking and confidence-building between national inspection authorities
- Development of quality systems plan
- Work towards global harmonization of GMP principles
- Carried out by regulatory bodies such as US FDA, national regulatory bodies
- Failure of regulatory audit: withdrawal of a manufacturing or import/export license
- After regulatory audit, a formal report will be delivered

What is to be audited:-

5 P's

Premises

Primary materials

People

Procedures

Processes defined and Recorded

- **Plant facilities-**floors, walls, ceilings, windows for more effective food safety environment
- **Employee Hygiene-**how employee's hygiene may affect food safety risk should be observed
- **In-process control-** food safety and sanitation policy, raw materials, operation conditions
- **Pest control-**to be outsourced from a trained firm and record should be kept

Role of GMP Audits in Q.A And Q.C programme

- GMP audits find objectionable condition that is unknown to responsible production , QC ,QA or management personnel.
- The auditor will see whether such actions are frequent or not .From this he can signal other GMP problems.

- Audits may be effective in:
  - changing SOPs, modifying manufacturing equipment or procedure
  - upgrading equipment or procedure
  - Improving employee training programme
  - Developing new or revised documentary system

Selecting Audit teams

Limitations of Personnel audit

- Experience and knowledge, which is individual.
- Emphasize on familiar issues as well as particular area

- Team is required to **cover many different systems and large amount of data.**
- Composition of team will vary **depending upon the nature and scope of the audit**
- Leader is usually a senior auditor who has extensive knowledge of the firm's operations and exhibit strong leadership qualities.

Reporting Audit Finding

- Audit reports should contain complete details of the problem detected.
- Corrective action is taken to eliminate problems and to measure the overall adequacy of the audit program uses reports

There are two important reporting phases:-

1) Preliminary reports during the audit
2) Final report to the management

Conti….

Preliminary reports during the audit:

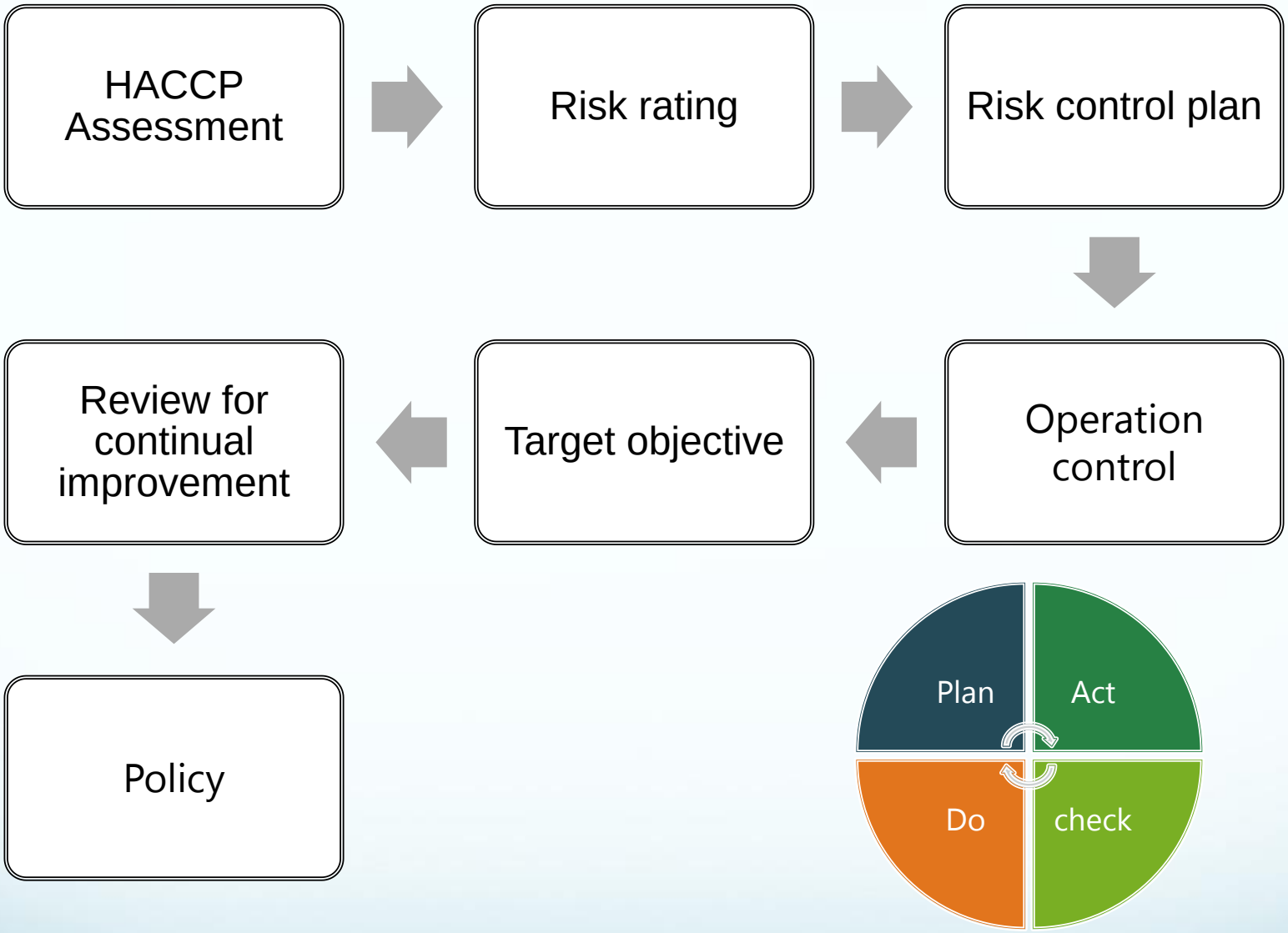
1) Benefits can be gained from having dialogues with employees

2) Finding is communicated with affected personnel.

3) Discussion may help the employees to learn why problems happened.

Final report to the management

- Management must review the final reports and determine what steps need to be taken to eliminate deficiencies.
- Management should sincerely encourage detection of problems and express appreciation for being able to improve quality operations.
- The audit reports may be shared with manger supervisor who may discuss finding with employees.
- The workers and supervisory personnel should be given the opportunity to explain their views and ideas about the audit findings.



FSMS-Critical Control Audit Trail ("Process" and "PDCA" Approach to enable "Value Added" Assessment

A complete ISO 22000:2005 audit documents for a Catering Services

No.	Process Description	Interfaces/ Communication					Key Resources
		Mgt/ F and B	Purchasing	Kitchen	Sale	Cust Svc	
1.	Menu design						Human, Database
2.	Purchase Ingredients						Human, Database, Fax
3.	Receiving Inspection						Human, Weight M.
4.	Storage						Human, Cold/Dry, Trolley
5.	Ingredients Preparation						Human, Crockery, Utensils, Oven
6.	Sales / Taking Orders						Human Database
7.	Cooking and packaging						Human, Crockery, Utensils, Oven, Packaging material
8.	Pre-serving inspection						Human
9.	Delivery						Human, Transport

A complete audit documents for a Catering Services ISO 22000:2005 “Process Approach” Audit Timetable

Time	Auditor A	Auditor B
	Opening Meeting	
	Management	
	Site walk-through	
	Kitchen	Purchasing
		Customer Service
	Lunch	
	Auditors’ interim meeting	
	Process Step 1 (Menu design/ planning)	Process Step 6 (Sales and taking order)
	Auditors’ review	
	Closing meeting	

A complete audit document for a Catering Service ISO 22000:2005 "Process Approach" audit checklist

S/N	Requirements	Remark		
1.	All logistic records maintained? How?	Y	N	
2.	All duties and responsibilities of the personnel clearly defined?			
3.	Are records of education/ skills maintained?			
4.	Do acceptance request and criteria conform to customer request?			
5.	Are supplier checked for approval of stock?			
6.	Are inventory list of stock available?			
7.	Does the department have a procedure to handle stock need, inspection, reject and storage?			
8.	Does the department keep record of all information?			
9.	Effective handling of stock segregation, identification and traceability?			
10.	Are procedure for preparing food in place?			
11.	Maintaining of working environment cleanliness?			
12.	How disposed of garbage/leftover is handle.			
13.	Is there any procedure to monitor general health condition of personnel?			
14.	Are performance data controlled/ maintained?			
15.	Availability of customer order/ product			
16.	How do you preserve/ protect product after preparation and prior to delivery?			
17.	How do you identified/ traced products to correct customer?			
18.	Are records of customer feedback/ complaint monitored/ maintained?			

Example of an HACCP audit Programme

Organization :

Standard :

Assessment date :

Scope :

Lead auditor :

Auditor :

Time		Opening meeting
	LA	• HACCP team • Product description and intended use • Flow diagram and on-site verification
	A	Review of HACCP Plans • Hazard analysis • Critical Control Points • Critical Limits • Monitoring • Correction Action

	LA	Audit of process and storage facilities • Confirmation of process flows • Verification of critical limits, critical control points, monitoring system and correction action • Product identification • Cleaning and sanitation • Personal hygiene practice • Pest control
	A	Reviewing of documentation records • Cleaning and sanitation programme • Pest control • Equipment maintenance and calibration • Verification of HACCP system and review of verification records
		Reviewing of documentation and records • Training • Health screening • Personal hygiene practice • CCP monitoring and corrective action records • Product traceability and recall procedure
		Preparation of audit
		Closing meeting

Corrective action request and audit reporting

Supplement Documents

- ISO 19011:2002
- International CODEX-General Principles of Food Hygiene
- EUREPGAP- General Regulation Fresh Fruit and Vegetables

Legal compliance and conformance with ISO standards

- In general, nonconformance can be found in both adequacy and site audits
- If a nonconformance is found, then corrective action request (CAR) should be raised specifying the nonconformance conditions
- The auditors should perform the audit following the guidelines given ISO 19011

Legal compliance required by ISO standards

- If legal compliance to certain legislations required by the ISO standards, it shall be audited and the auditor shall ensure that he is competent to perform such audit

Legal compliance not covered by the ISO standards

- Any legal non-compliance found by the auditor should be raised as an observation for legal matters which are outside the scope of the audit.
- The auditor may not have sufficient legal knowledge to audit certain legal compliance.

Classification of Non-conformance

Scheme 1	Scheme 2
Critical • If non-conformance can lead to a massive product recall • Related to food safety	**Category1** • Where a total element or a significant part of an element of the FSMS is missing
Major • Deficiencies such as omission of documented FSMS element • Gross nonconformance with FSMS elements	**Category 2** • Where there are significant number of minor deficiencies occurring in a FSMS element.
Minor • Omission of a control point in HACCP program	**Category 3** • Where there is a single deficiency found in a FSMS element.

An example of an HACCP Audit report

S/N	Audit finding	Clause No	Category
01	Personnel responsible for overall food safety, review and approval of any changes in process, formulation, equipment was not defined	1	Minor (Category 2)
02	Following were noted in the Hazard analysis: i. Not all possible causes were identified. ii. Not all potential hazards were correctly identified iii. Not all control resources were correctly identified	6	Minor (Category 2)
03	The entire HACCP Plan need to be improved to ensure the correct potential hazard, causes, right control measure were identified.	10	Minor (Category 2)

" Let food be thy medicine and medicine be thy food"

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धन्यवाद

Terima Kasih

Grazie

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