Free ISO 22000:2018 Internal Auditor Training

From Quality Asia Certifications Private Limited

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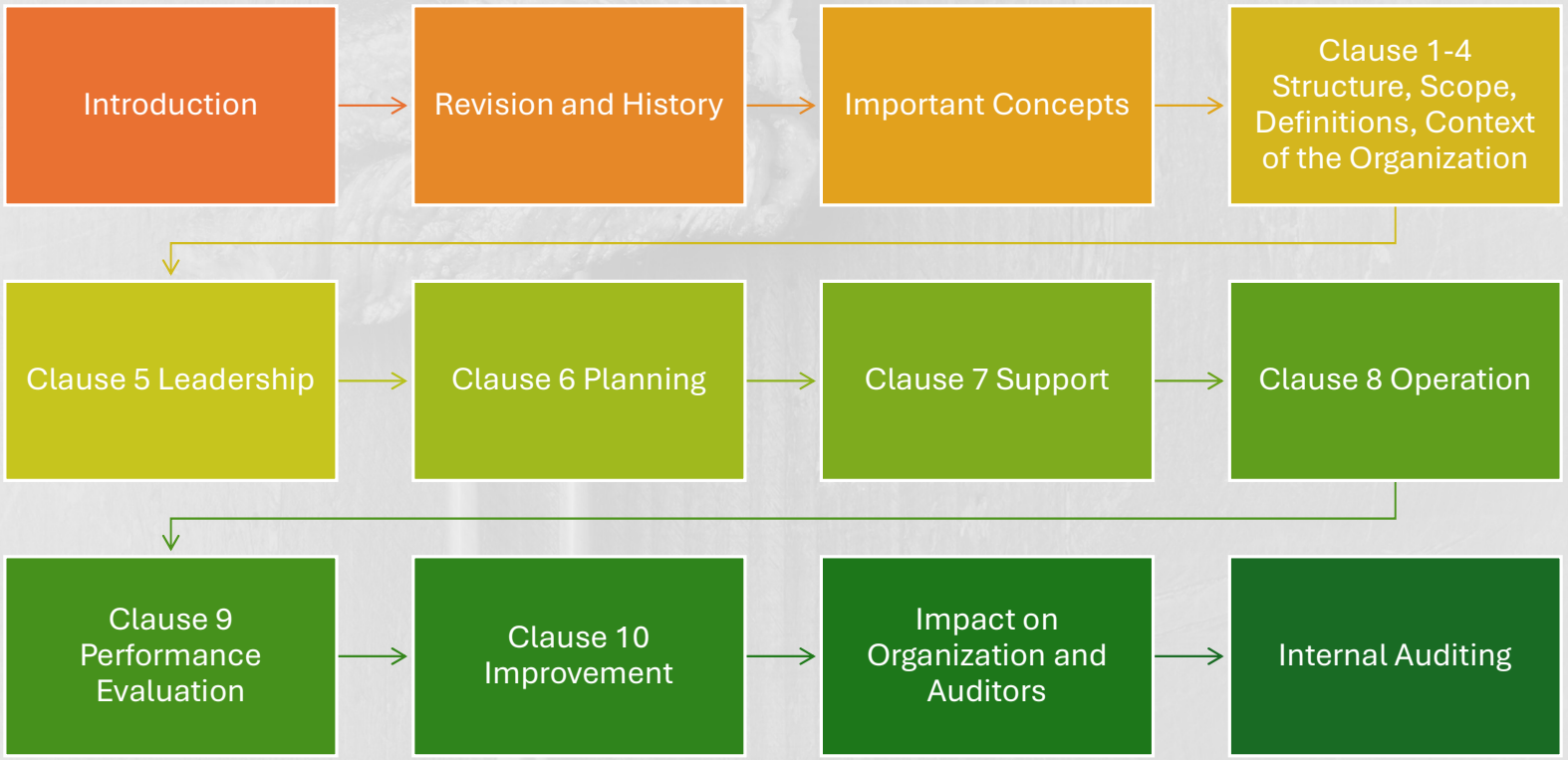
Structure of the Course



Objectives of the course

- Gain a comprehensive understanding of the requirements of the ISO 22000:2018 Food Safety Management System (FSMS) standard.
- Learn how to plan, conduct, and report internal audits effectively.
- Understand how to verify compliance with ISO 22000:2018 requirements.
- Foster a culture of food safety responsibility within the organization through effective communication and audit practices.

Outcomes

- Gain a solid understanding of ISO 22000:2018 requirements and its practical application.
- Develop the ability to plan, conduct, and report effective internal audits for the Food Safety Management System (FSMS).
- Identify opportunities for food safety performance improvement and ensure compliance with regulatory and organizational requirements.
- Enhance skills to support the organization’s continuous improvement in food safety management.
- Contribute to the organization’s readiness for external audits and ISO 22000:2018 certification

Trainer Introduction

- **Mr. Atul Suri**
- BE (Electrical), MBA
- Certified Lead Auditor:
  ISO 9001, 14001, 45001, 50001, 22000, 27001, 13485, and 26000
- BEE Certified Energy Auditor (CEA)
- Professional Experience:
  - 30+ Years in the industry, with a strong foundation in engineering and management.
  - 20+ Years as a seasoned Management Systems Auditor and Trainer, delivering expertise across multiple sectors.
- Worked with Various Top Notch Certification Bodies as a Lead Auditor and Reviewer like Quality Asia, Intertek, Apave, Moody International, IRQS, etc

About Quality Asia

QUALITY ASIA

Mission: To empower organizations with world-class quality standards and sustainable practices.

Vision: To be the leading provider of quality assurance and certification solutions in India.

NABCB accredited: Quality Asia is accredited by the National Accreditation Board for Certification Bodies (NABCB), which means that their certifications are recognized internationally.

Ethical Certifications: We are committed to providing 100% audit and compliance services, ensuring transparency and integrity in every certification we issue.

Comprehensive Expertise: We specialize in ISO 9001, ISO 14001, ISO 45001, and more, offering a full spectrum of certification services tailored to your organization's needs.

Free ISO Internal Auditor Training: We empower your team with free training, helping you build internal expertise and maintain compliance with international standards.

Global Reach, Local Touch: Serving clients across multiple Indian cities and international locations, we combine global expertise with personalized local service.

Commitment to Excellence: Our mission is to support businesses in achieving and maintaining their certification, unlocking new opportunities and improving operational efficiency.

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Monthly Training Programs	We offer a focused training session on a different ISO standard each month, ensuring continuous learning and up-to-date knowledge for your team.
Flexible Learning Options	Missed a session? No problem! Our training programs are available for later viewing through the Quality Asia School on our website, allowing you to learn at your own pace. Log on to our Quality Asia website.
Our Mission	We are dedicated to increasing awareness about ISO standards and enhancing internal auditor competence. Our goal is to uplift industry operational standards by empowering professionals with the knowledge and skills they need to drive excellence in their organizations.

ISO 22000 Food Safety Management System

What is food safety?

Food Safety
…. from farm to fork

- The assurance that food will not cause an adverse heath effect for the consumer (human or animal) when it is prepared and/ or consumed according to its intended use.

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ISO 22000 is...

- Food safety management systems - Requirements for any organization in the food chain
- Control and reduce any food/feed safety hazards identified for the end products delivered to the next step in the chain to acceptable levels
- Implementation of process approach, which incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking also in the food safety management part

Benefits of the ISO 22000

- **Enhanced food safety:** Ensures that food products are safe for consumption.
- **Regulatory compliance:** Helps organizations meet legal requirements.
- **Improved customer confidence:** Builds trust with consumers and stakeholders by demonstrating a commitment to food safety.
- **Operational efficiency:** Streamlines processes and reduces the risk of food safety incidents.
- **Market access:** Facilitates entry into new markets and improves competitiveness.

Revision and history of ISO 22000

- **First Edition (2005):** Introduced the Food Safety Management System (FSMS) framework, integrating HACCP principles and ISO's management system approach.
- **2018 Revision:** Updated to align with the High-Level Structure (HLS) for consistency with other ISO standards.
  - Aligned with the High-Level Structure (HLS) to ensure compatibility with other ISO standards like ISO 9001 and ISO 14001.
  - Enhanced focus on risk-based thinking and PDCA (Plan-Do-Check-Act) at both organizational and operational levels.
  - Clear differentiation between organizational and operational risks.
- **ISO 22000:2018/Amd 1:2024:** Amendment 1: Climate action changes

Food safety management system

HACCP

Hazard Analysis and
Critical Control Points

Prevention instead of reaction

ISO 22000 is based on the principles of HACCP

ISO 22000 Food Safety Management System

Key concepts and terms

Management System

- Set of interrelated or interacting elements of an organization to establish policies and objectives and processes to achieve those objectives.

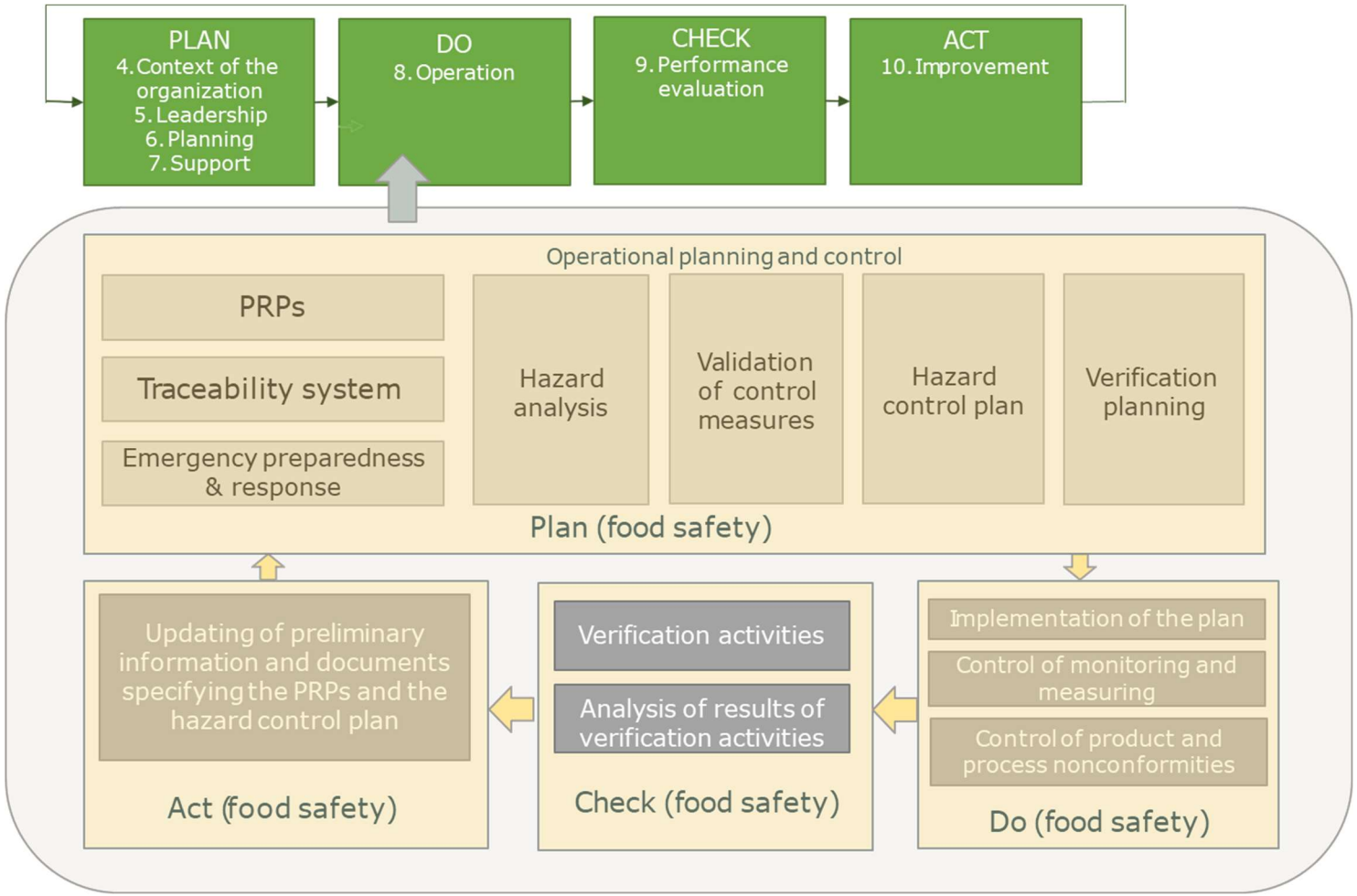
“Food” as per ISO 22000

- Any substance (or ingredient), whether processed, semi-processed or raw, which is intended for consumption (human and animal consumption).

The food chain

- Sequence of stages in the production, processing, distribution, storage and handling of a food and its ingredients, from primary production to consumption.

ISO 22000:2018 PDCA



Risk based thinking in ISO 22000

- Applied at organizational and operational levels

The ISO 22000 family

ISO 22000
Requirements for any organization in the food chain

ISO/TS 22002
Prerequisite programmes on food safety

Six parts: Food manufacturing, Catering, Farming, Food packaging manufacturing, Transport and storage, Feed and animal food production

ISO 22005
Traceability in the food and feed chain

ISO/TS 22003
Requirements for certification bodies

ISO 22000 structure

ISO 22000:2018 Requirements for any org	anization in the food chain
1 Scope	8. Operation 1. Operational planning and control 2. Prerequisite programmes (PRPs) 3. Traceability system 4. Emergency preparedness and response 5. Hazard control 6. Updating the information specifying the PRPs and the hazard control plan 7. Control of monitoring and measuring 8. Verification related to PRPs and the hazard control plan 9. Control of product and process nonconformities
2 Normative references	9. Performance evaluation 1. Monitoring, measurement, analysis and evaluation 2. Internal audit 9.3. Management review
3 Terms and definitions	10. Improvement 1. Nonconformity and corrective action 2. Continual improvement 3. Update of the FSMS
4 Context of the organization 1. Understanding the organization and its context 2. Understanding the needs and expectations of interested parties 3. Determining the scope of the FSMS 4. Food safety management system	
5 Leadership 1. Leadership and commitment 2. Policy 3. Organizational roles, responsibilities and authorities	
6 Planning 1. Actions to address risks and opportunities 2. Objectives of the FSMS and planning to achieve them 3. Planning of changes	
7 Support 1. Resources 2. Competence 3. Awareness 4. Communication 5. Documented information	

Why do we need such high Hygiene Standards?

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The COSTS of Poor Hygiene
• Food Poisoning Outbreaks & Sometimes Death • Customer Complaints • Pest Infestation • Wasted food (spoilage) • Closure of premises (loss of jobs) • Fines and costs of legal actions • Civil action taken by food poisoning victims • Loss of Profit

The BENEFITS of Good Hygiene
• One Satisfied Customer Leads to Another • A Good Reputation • Increased Business • Compliance with the Law • Longer Food shelf Life • Better Working environment • Higher Staff Morale • Increased Profits

Benefits of Serving Safe Food product

- Protects Employees and Customers
- Reputation and Repeat Business
- Better Service- Higher Profits
- Reduce Health Code Violations

By this You avoid;

- Legal fees
- Medical claims
- Lost wages
- Cleaning & Sanitizing costs
- Loss of food product- discarded
- Bad Publicity

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What is the primary role of an internal auditor in ISO 22000:2018 implementation?

- To develop the organization's food safety objectives
- To identify and report nonconformities within the FSMS
- To approve corrective actions and close audit findings
- To monitor Critical Control Points (CCPs) during production

Treemap | Bar

5 of 5

Show correct answer

Clause 4: Context of the organization

S. No.	Clause No.	Clause name
1.	4.1	Understanding the organization and its context
2.	4.2	Understanding the needs and expectations of interested parties
3.	4.3	Determining the scope of the food safety management system
4.	4.4	Food safety management system

4.1. Understanding the organization and its context

- The organization shall determine external and internal issues that are relevant to its purpose and that affect its ability to achieve the intended result(s) of its FSMS.
- The organization shall identify, review and update information related to these external and internal issues.

Context of the organization

- **External issues:** natural conditions, legislation, competition, technology, cultural and religious aspects, consumption patterns, food fraud…
- **Internal issues:** position in the food chain, infrastructure, competence, working conditions, access to resources, number and variety of customers…

4.2. Understanding the needs and expectation of interested parties

- To ensure that the organization has ability to consistently provide products and services that meet applicable statutory, regulatory and customer requirements with regard food safety, the organization shall determine:
  - the interested parties that are relevant to the FSMS;
  - the relevant requirements of the interested parties of the FSMS.
- The organization shall identify, review and update information related to the interested parties and their requirements.

Indian Law & FSSAI (Food Safety and Standards Authority of India)

- Established under the Food Safety and Standards Act, 2006
- Apex body for food safety and regulation in India
- Ensuring safe and wholesome food for human consumption

Legal Framework of FSSAI

- Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011
- Food Safety and Standards (Packaging and Labelling) Regulations, 2011
- Food Safety and Standards (Contaminants, Toxins, and Residues) Regulations, 2011
- **Enforcement:** Implemented by State and Central Authorities

Condition of License, Food Business Operators Shall:

- Display a true copy of the license galways granted in Form Cat a prominent place in the premises.
- Give necessary access to licensing authorities or their authorized personnel to the premises.
- Inform authorities about any change or modifications in activities.
- Employ at least one technical person to supervise the production process. The person supervising the production process shall possess at least a degree in science with Chemistry/ Biochemistry/ Food and Nutrition/ Microbiology or a degree or diploma in Food Technology/ Dairy Technology/ Dairy Microbiology/ Dairy Chemistry/ Dairy Engineering/ Oil Technology/ Veterinary Science/ Hotel Management & Catering Technology or any degree or diploma in any other discipline related to the specific requirement of the business from a recognized university or institute or equivalent.
- Furnish periodic annual return from 1st April to 31st March, within 31st May of each year. For collection/handling/manufacturing of milk and milk product, half-yearly return is also to be furnished as specified.
- Ensure that no product other than the product indicated in the license/registration is produced in the unit.
- Maintain factory's sanitary and hygienic standards and workers' hygiene as specified in Schedule-4 according to the category of food business.
- Maintain daily records of production, raw materials utilization, and sales separately.
- Ensure that the source and standards of raw material used are of optimum quality.

Condition of License, Food Business Operators Shall: (Contd.)

- Food business operator shall not manufacture, store, or expose for sale or permit the sale of any article of food in any premises not effectively separated to the satisfaction of the licensing authority from any privy, urine, sullage, drain, or place of storage of foul and waste matter.
- Ensure clean-in-place system (whatever necessary) for regular cleaning of machine & equipment.
- Ensure testing of relevant chemical and/or microbiological contaminants in food products in accordance with these regulations as frequently as required on the basis of historical data and risk assessment to ensure production and delivery of safe food through own or NABL-accredited/FSSAI-recognized labs at least once in six months.
- Ensure that as much as possible the required temperature shall be maintained throughout the supply chain from the place of procurement or sourcing till it reaches the end consumer, including chilling, transportation, and storage, etc.
- The Manufacturer/ Importer/ Distributor shall buy and sell food products only from, or to, licensed/registered vendors and maintain record thereof.

Other Conditions:

- Proprietors of hotels, restaurants, and other food stalls who sell or expose for sale savouries, sweets, or other articles of food shall put up a notice board containing separate lists of the articles which have been cooked in ghee, edible oil, vanaspati, and other fats for the information of the intending purchasers.
- Food business operator selling cooked or prepared food shall display a notice board containing the nature of articles being exposed for sale.
- Every manufacturer (including ghani operator) or wholesale dealer in butter, ghee, vanaspati, edible oils, solvent-extracted oil, de-oiled meal, edible flour, and any other fats shall maintain a register showing:
- Quantity of manufactured, received, or sold
    - Nature of oil seed used
    - Quantity of de-oiled meal and edible flour used
    - Destination of each consignment of substances sent out from the factory or place of business
    - The register shall be presented for inspection whenever required by the licensing authority.
- No producer or manufacturer of vegetable oil, edible oil, and their products shall be edible for license under this act unless they have their own laboratory facility for analytical testing of samples.

Other Conditions:

- Every sale and movement of stocks of solvent-extracted oil, 'semi-refined' or 'raw grade I,' edible groundnut flour, or edible coconut flour, or both, by the producer shall be a sale or movement of stocks directly to a registered user and not to any other person, and no such sale or movement shall be effected through any third party.
- Every quantity of solvent-extracted oil, edible groundnut flour, or edible coconut flour, or both, purchased by a registered user shall be used by them in their own factory entirely for the intended purpose and shall not be re-sold or otherwise transferred to any other person.
- Provided that nothing in this sub-clause shall apply to the sale or movement of the following:
    - Karanjia oil
    - Kusum oil
    - Mahua oil
    - Neem oil
    - Tamarind seed oil
    - Edible groundnut flour bearing the I.S.I. certification mark
    - Edible coconut flour bearing the I.S.I. certification mark
- No food business operator shall sell, distribute, offer for sale, dispatch, or deliver any edible oil for sale that is not packed, marked, and labeled in the manner specified in the regulations unless specifically exempted by notification in the official Gazette issued in the public interest by food safety commissioners in specific circumstances and for a specific period with reasons recorded in writing.

Food Sample Test Report (Example)

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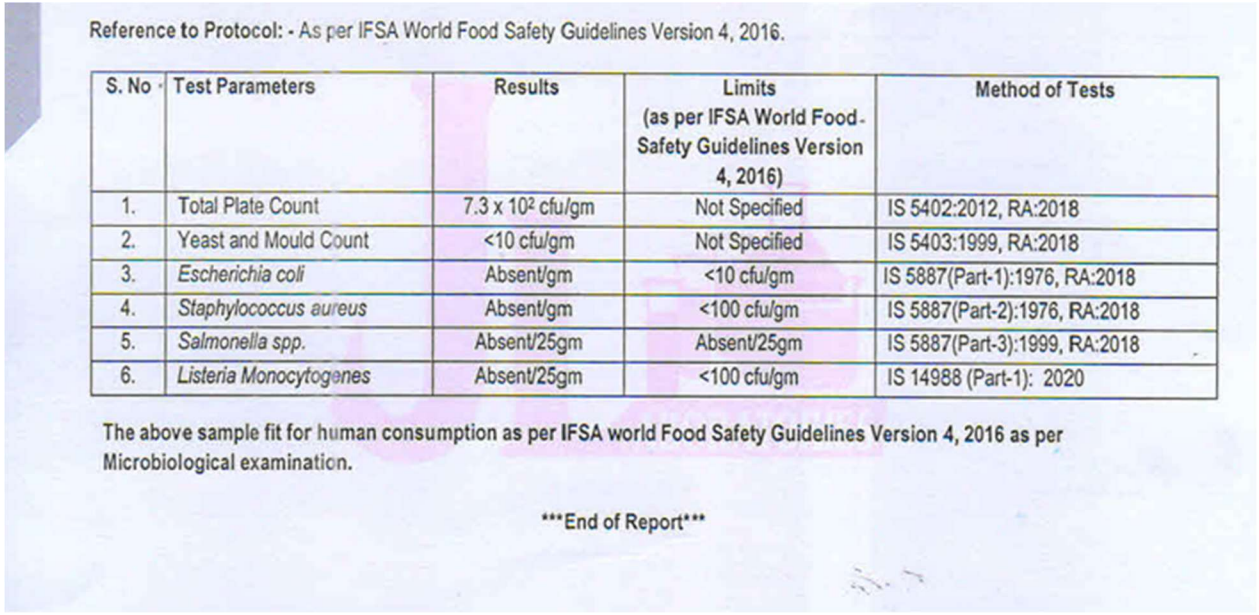


Reference to Protocol: - As per IFSA World Food Safety Guidelines Version 4, 2016.

S. No	Test Parameters	Results	Limits (as per IFSA World Food Safety Guidelines Version 4, 2016)	Method of Tests
1.	Total Plate Count	7.3 x 10^2 cfu/gm	Not Specified	IS 5402:2012, RA:2018
2.	Yeast and Mould Count	<10 cfu/gm	Not Specified	IS 5403:1999, RA:2018
3.	*Escherichia coli*	Absent/gm	<10 cfu/gm	IS 5887(Part-1):1976, RA:2018
4.	*Staphylococcus aureus*	Absent/gm	<100 cfu/gm	IS 5887(Part-2):1976, RA:2018
5.	*Salmonella spp.*	Absent/25gm	Absent/25gm	IS 5887(Part-3):1999, RA:2018
6.	*Listeria Monocytogenes*	Absent/25gm	<100 cfu/gm	IS 14988 (Part-1): 2020

The above sample fit for human consumption as per IFSA world Food Safety Guidelines Version 4, 2016 as per Microbiological examination.

End of Report

Interested parties

- Clients, consumers, employees, authorities, shareholders, professional associations, NGOs …
- They all have requirements that shall be identified.

4.3. Determining the scope of the food safety management system

- The organization shall determine the boundaries and applicability of the Food Safety Management System. (products, services, processes, production sites)

- The scope shall be documented and maintained up to date.

4.4. Food safety management system

- The organization shall establish, implement, maintain, update and continually improve a FSMS, including the processes needed and their interactions, in accordance with the requirements of this document.

Climate action changes

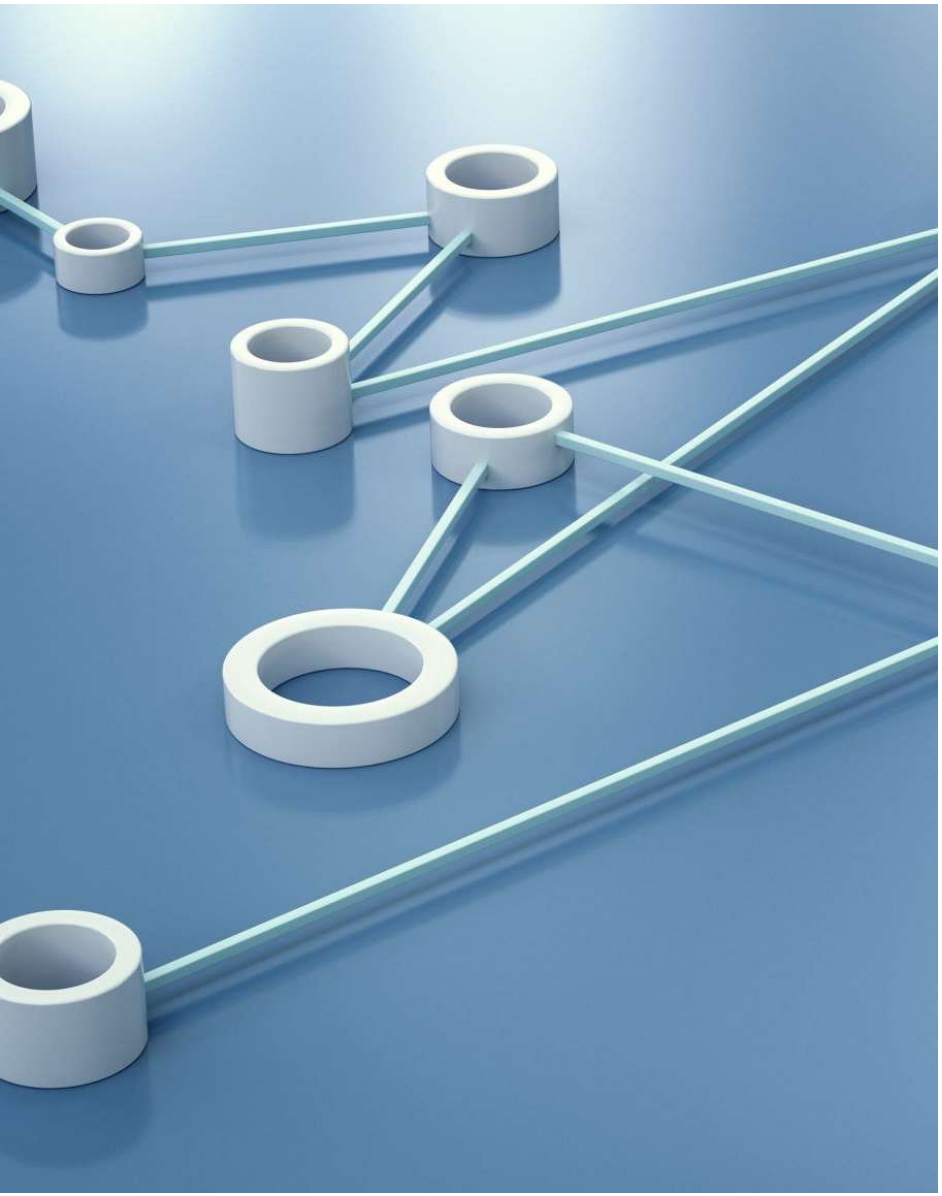
- **Amendment 1 to ISO 22000:2018 from February 2024**

CLIMATE ACTION CHANGES

- The organization shall determine whether climate change is a relevant issue (for its context)

CLIMATE ACTION CHANGES

- Interested parties can have requirements related to climate change



Recapitulation (Context of the organisation)

- Identify factors that impact the Food Safety Management System (FSMS), including regulatory, market, technological, and organizational influences.
- Recognize relevant stakeholders (e.g., suppliers, customers, regulatory bodies, employees) and their food safety-related needs and expectations.
- Establish the boundaries and applicability of the FSMS based on internal and external issues and the requirements of interested parties.
- Develop, implement, maintain, and continuously improve an FSMS to achieve food safety objectives and demonstrate continual improvement.

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Which of the following is an example of an external issue that can impact the FSMS?

- Changes in food safety regulations or supply chain disruptions.
- Lack of competence among internal staff.
- Equipment maintenance delays within the organization.
- Inadequate communication between production teams.

Treemap | Bar

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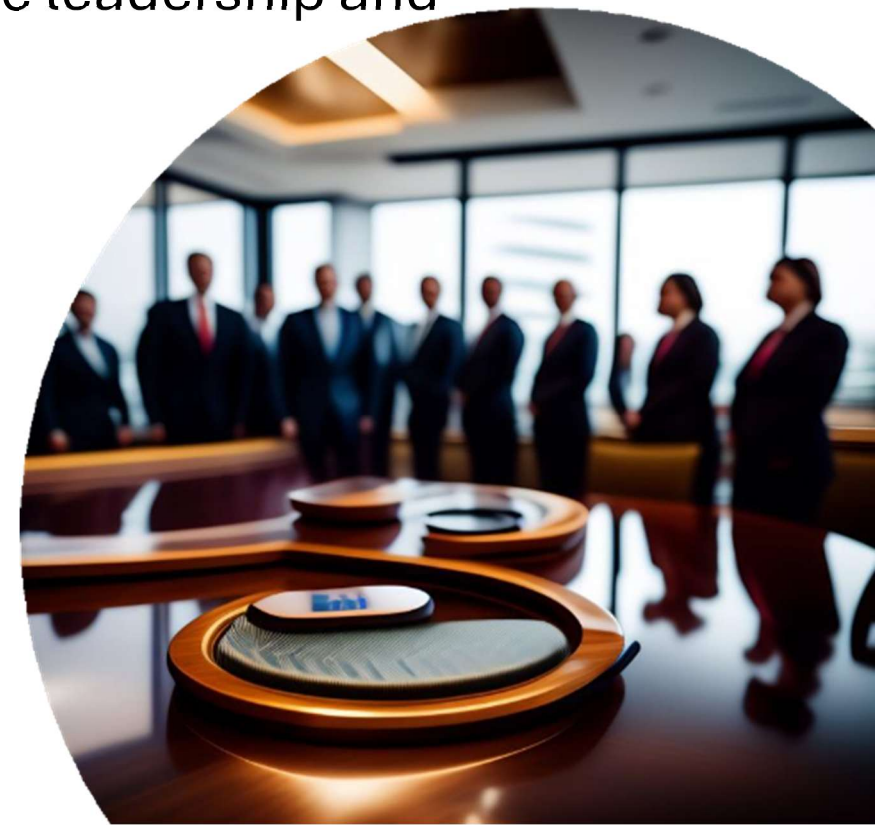
Show correct answer

Clause 5: Leadership

S. No.	Clause No.	Clause name
1.	5.1	Leadership and commitment
2.	5.2	Policy
3.	5.3	Organizational roles, responsibilities and authorities

5.1. Leadership and commitment

- The top management shall demonstrate leadership and commitment with respect to the FSMS.



Top management

- Ensure a food safety policy and objectives are established
- Provide resources
- Integrate food safety
- Communicate on food safety inside the company
- Supervise the FSMS
- Promote continual improvement

5.2. Policy

- Defines the direction of the company and serves as the visible evidence of the top management commitment
- Appropriate to the purpose and the context of the organization
- Provides a framework for setting and reviewing the food safety objectives
- Includes commitments:
  - to satisfy legal and client requirements;
  - for continual improvement
- The policy shall:
  - address internal and external communication
  - address the need to ensure competencies related to food safety

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The food safety policy

- Documented
- Communicated, understood and applied
- Available to interested parties, as appropriate

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5.3. Organizational roles, responsibilities and authorities

- Top management shall assign and communicate responsibilities and authorities for relevant roles
- There should be clarity about responsibilities and interfaces
- Responsibilities and authorities must be understood

Top management shall assign the responsibilities and authorities for…

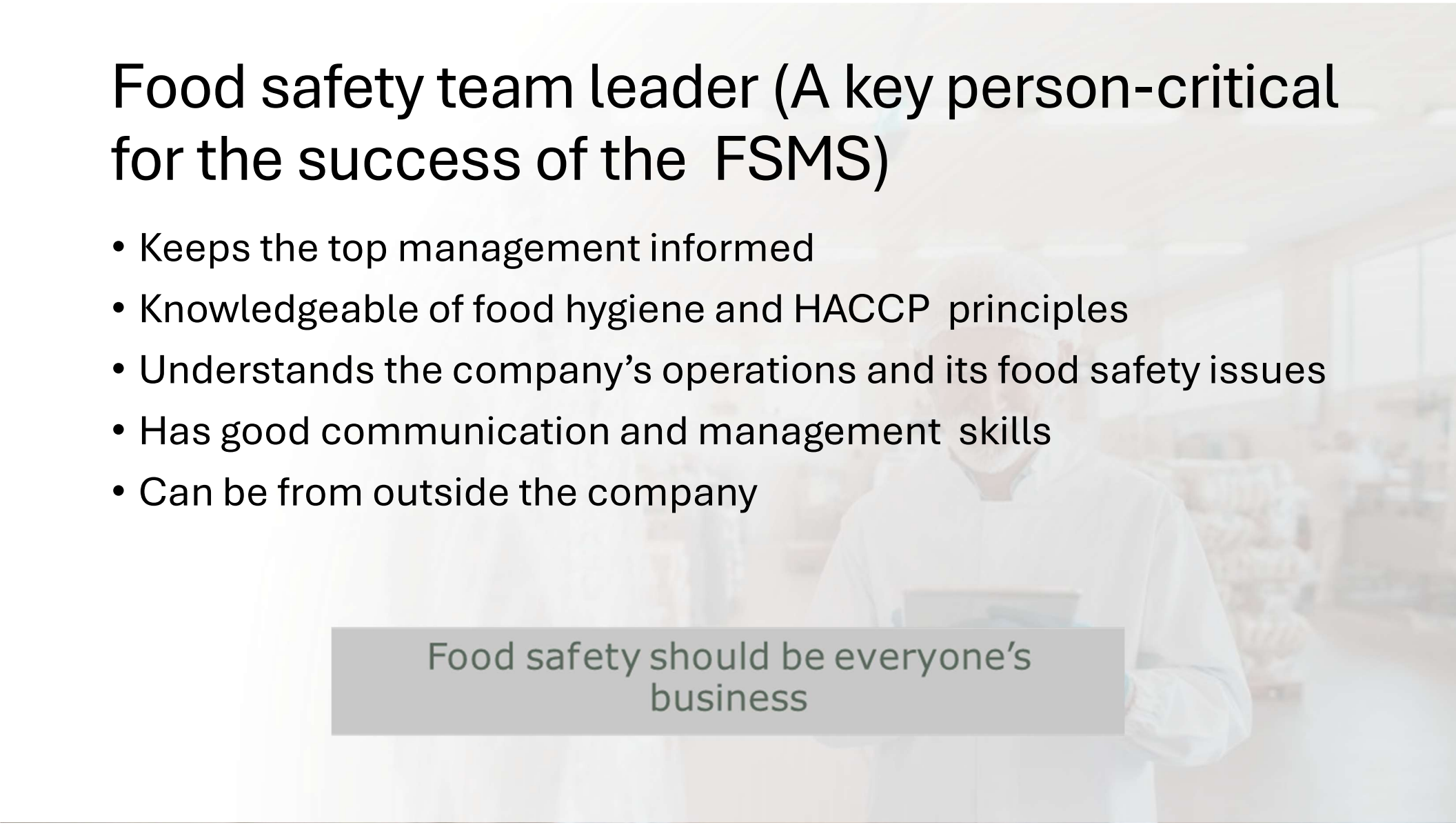
Ensuring	Reporting	Appointing	Designating
Ensuring that the FSMS conforms to the requirement of this document	Reporting on the performance of the FSMS to top management	Appointing the food safety team and the food safety team leader	Designating persons with defined responsibility and authority to initiate the document action(s).

Food safety team

- Responsible to coordinate, monitor and improve the FSMS
- Appointed by the top management
- Multi-disciplinary

Food safety team leader (A key person-critical for the success of the FSMS)

- Keeps the top management informed
- Knowledgeable of food hygiene and HACCP principles
- Understands the company's operations and its food safety issues
- Has good communication and management skills
- Can be from outside the company



Recapitulation (Leadership)

- Top management ensures the integration of the Food Safety Management System (FSMS) into the organization’s business processes.
- Drives continual improvement and alignment with strategic objectives.
- Develop and maintain a food safety policy that supports organizational goals, ensures compliance with regulatory requirements, and promotes safe practices.
- Assign roles and communicate responsibilities across the organization to ensure the effective implementation, maintenance, and improvement of the FSMS.

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Who is responsible for the establishment of food safety objectives?

Food Safety Team Leader	External consultants	Internal auditors	Top management

Treemap | Bar

5 of 5

Show correct answer

Clause 6: Planning

S. No.	Clause No.	Clause name
1.	6.1	Action to address risk and opportunities
2.	6.2	Objectives of the food safety management system and planning to achieve them
3.	6.3	Planning of changes

6.1. Actions to address risks and opportunities

- The organization shall determine risks and opportunities that need to be addressed to:
  - give assurance that the FSMS can achieve its intended result(s);
  - enhance desirable effects;
  - prevent, or reduce, undesired effects;
  - achieve continual improvement.

Risks (examples)

- Product counterfeiting
- Product alteration
- Theft or diversion
- Lack of competence
- …

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Opportunities (examples)

- New technologies
- Changes to processes
- Participation in groups, associations…

The organization shall plan…

- actions to address these risks and opportunities;
- how to:
  - integrate and implement the actions into its FSMS processes;
  - Evaluate the effectiveness of these actions

Address risks and opportunities

- Avoidance
- Mitigation
- Risk taking
- Acceptance

The actions taken by the organization to address risks and opportunities shall be proportionate to:

- the impact on food safety requirements;
- the conformity of food products and services to customers;
- requirements of interested parties in the food chain.

6.2. Objectives of the FSMS and planning to achieve them

- Consistent with the Food safety policy
- Considers applicable requirements (legal, customer, etc.)
- Measurable (whenever possible)
- Communicated
- Monitored and verified
- Updated
- Documented

Plan to achieve the objectives

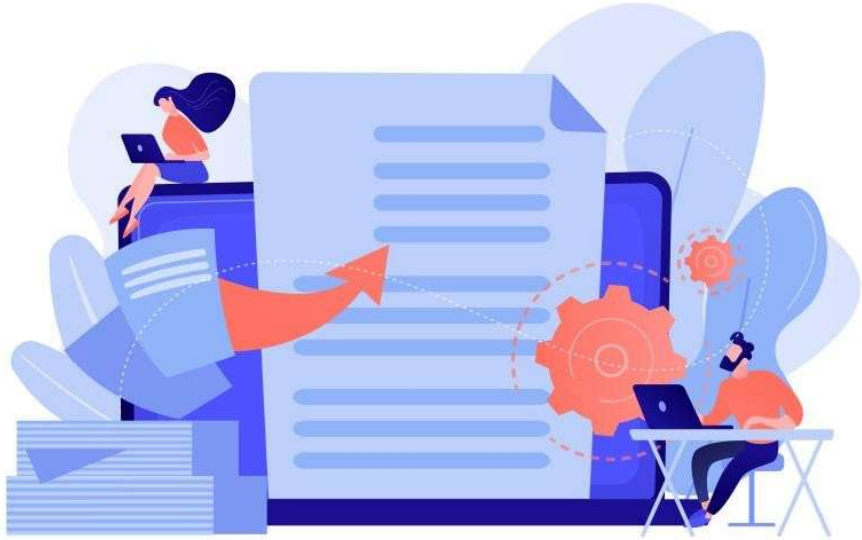
- What will be done?
- Resources required?
- Who is responsible?
- What are the deadlines?
- How to evaluate the results?

6.3. Planning of changes

- Changes shall be carried out and communicated in a planned manner
- Consider purpose and potential consequences
- Evaluate the impact and avoid unwanted effects
- Estimate resources and make them available
- Consider the allocation and re-allocation of responsibilities

Change management procedure

- Types of changes controlled by change management
- Responsibilities and authorities for managing, reviewing and approving changes
- Requesting a change
- Testing prior to implementation
- Dealing with unsuccessful changes
- Documentation prepared



Recapitulation (Planning)

- Identify and address risks and opportunities to ensure food safety.
- Establish measurable food safety objectives and plan actions to achieve them.
- Ensure planned changes are conducted systematically without compromising food safety.

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What type of objectives must be included as per Clause 6.2?

- Qualitative objectives only
- Verbal goals communicated to top management
- Production efficiency targets
- Measurable and monitored objectives

Treemap | Bar

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Show correct answer

Clause 7: Support

S. No.	Clause No.	Clause name
1.	7.1	Resources
2.	7.1.2	People
3.	7.1.3	Infrastructure
4.	7.1.4	Work Environment
5.	7.1.5	Externally developed elements of the food safety management system
6.	7.1.6	Control of externally provided processes, products or services
7.	7.2	Competence
8.	7.3	Awareness
9.	7.4	Communication
10.	7.5	Documented Information

7.1. Resources

- The organization shall determine and provide the resources needed for the establishment, implementation, maintenance, update and continual improvement of the FSMS.
- The organization shall consider:
  - the capability of, and any constraints on, existing internal resources;
  - the need for external resources.

7.1.2. People

- The organization shall ensure that persons necessary to operate and maintain an effective FSMS are competent (see 7.2).
- Where the assistance of external experts is used for the development, implementation, operation or assessment of the FSMS, evidence of agreement or contracts defining the competency, responsibility and authority of external experts shall be retained as documented information

7.1.3. Infrastructure

- The organization shall provide the resources for the determination, establishment and maintenance of the infrastructure necessary to achieve conformity with the requirements of the FSMS.
- Infrastructure includes, land, buildings and utilities, vessels, equipment (hardware and software), transportation, IT&C…

7.1.4. Work environment

- Provide and maintain the adequate work environment.

Human factors (social and psychological)	Physical factors
Non-confrontational	Temperature
Non-discriminatory	Humidity
Calm	Heat
Burnout prevention	Hygiene
Stress-reducing	Light
...	...

7.1.5. Externally developed elements of the FSMS

- Conformity with the standard
- Applicable to the specifics of the organization
- Adapted by the food safety team
- Retained as documented information

7.1.6. Control of externally provided processes, products or services

- Apply criteria for the evaluation, selection and monitoring of external providers
- Ensure that processes, products and services from external providers do not affect the ability to meet food safety requirements
- Communicate requirements to external providers in a suitable manner
- Retain documented information as evidence

Supplier (re)evaluation

- Criteria
- Records
- On a regular basis

7.2. Competence

- Determine the necessary competence
- Ensure the persons are competent
- Take action to acquire the necessary competence and evaluate effectiveness

- Ensure that the food safety team has the knowledge and experience required to develop and implement the FSMS
- Retain documented information as evidence

7.3. Awareness

- All relevant persons doing work under the company's control shall be aware of:
  - the food safety policy
  - the food safety objectives relevant to them
  - the individual contribution to the effectiveness of the FSMS and the benefits of improved food safety performance
  - the implications of not conforming to requirements

7.4. Communication

- The organization shall determine the internal and external communications relevant to the FSMS, including:
  - on what it will communicate;
  - when to communicate;
  - with whom to communicate;
  - how to communicate;
  - who communicates.
- The organization shall ensure that the requirement for effective communication is understood by all persons whose activities have an impact on food safety.

External communication

- Establish, implement and maintain *effective* communications with customers, consumers, external providers, authorities and others.

- Assign responsibilities and authorities for external communication (regarding food safety)
- Retain documented information

Internal communication

- An effective system to communicate inside the company on food safety matters.

- The food safety team shall be informed in a timely manner about changes that may have an impact on food safety

7.5. Documented Information

- FSMS documentation includes:
  - the documents required by ISO 22000;
  - documents not required by the standard but necessary for the FSMS;
  - documents required by authorities or customers.

Creating and updating documents

- Identification and description
- Format and media
- Review and approval

Control of documented information

Availability
In a suitable format, where and when needed

Protection
From improper use, alteration, loss of integrity, unwanted disclosure

Control of changes
Identify current version

Retention and disposition
Retention period shall exceed product shelf life

Access
Who can make changes to documents and who is only allowed to view

Recapitulation (Support)

- Provide adequate resources for the effective FSMS.
- Ensure competent personnel to maintain food safety processes.
- Establish and maintain necessary infrastructure for FSMS.
- Provide a suitable work environment to ensure food safety.
- Control externally developed components of the FSMS.
- Ensure external processes, products, and services meet food safety requirements.
- Ensure personnel are competent based on education, training, or experience.
- Ensure staff are aware of food safety policies, objectives, and roles.
- Establish internal and external communication for FSMS.
- Create, maintain, and control documented information for FSMS.

Scan the QR or use link to join

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What is mandatory under Clause 7.3 (Awareness)?

- Employees must know their roles and the importance of food safety
- Awareness programs should be focused on top management
- Annual awareness surveys must be conducted
- Staff must communicate food safety policies to customers

Treemap | Bar

5 of 5

Show correct answer

Clause 8: Operations

S. No.	Clause No.	Clause name
1.	8.1	Operational planning and control
2.	8.2	Prerequisite programmes (PRPs)
3.	8.3	Traceability system
4.	8.4	Emergency preparedness and response
5.	8.5	Hazard Control
6.	8.6	Updating the information specifying the PRPs and the hazard control plan
7.	8.7	Control of monitoring and measuring
8.	8.8	Verification related to PRPs and the hazard control plan
9.	8.9	Control of product and process nonconformities

8.1. Operational planning and control

- Establish criteria for the processes
- Control the processes according to criteria
- Keep documented information to prove that the processes have been carried out as planned

Change management

- Control planned changes
- Review unintended changes
- Act to mitigate any adverse effects

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Outsourcing

Control outsourced processes

8.2. Prerequisite programmes (PRPs)

- Basic conditions and activities that are necessary within the organization and throughout the food chain to maintain food safety.

The organization shall establish, implement, maintain and update PRPs to facilitate the prevention and/ or reduction of contaminants in the products, product processing and work environment.

Prerequisite programmes

- Appropriate to the organization
- Approved by the food safety team
- Applicable to the whole production system or to a specific process/ product

Prerequisite programmes

- When selecting and/or establishing PRP(s), the organization shall ensure that applicable statutory, regulatory and mutually agreed customer requirements are identified. The organization should consider:
  - Applicable part of the ISO/TS 22002 series;
  - Applicable standards, codes of practice and guidelines

What to consider when establishing PRPs?

Construction, buildings and utilities	Premises, workspace and employee facilities	Air, water, energy and associated utilities	Pest control, waste disposal and sewage
Equipment	Supplier approval	Reception, storage, dispatch, transportation and handling of products	Prevention of cross-contamination
Cleaning and disinfection	Personal hygiene	Product information/ consumer awareness	Others (e.g., food defense, bioterrorism)

PRPs for food manufacturing - Construction and layout of buildings

- Buildings shall be designed, constructed and maintained for food processing operations (considering the hazards and the potential sources of contamination)
- Durable construction
- Locations close to waste dumps, flood plains and heavy vegetated areas should be avoided
- Clear identification of boundaries
- Roads, parking spaces, yards shall be maintained

PRPs for food manufacturing - Layout of the premises and workspace

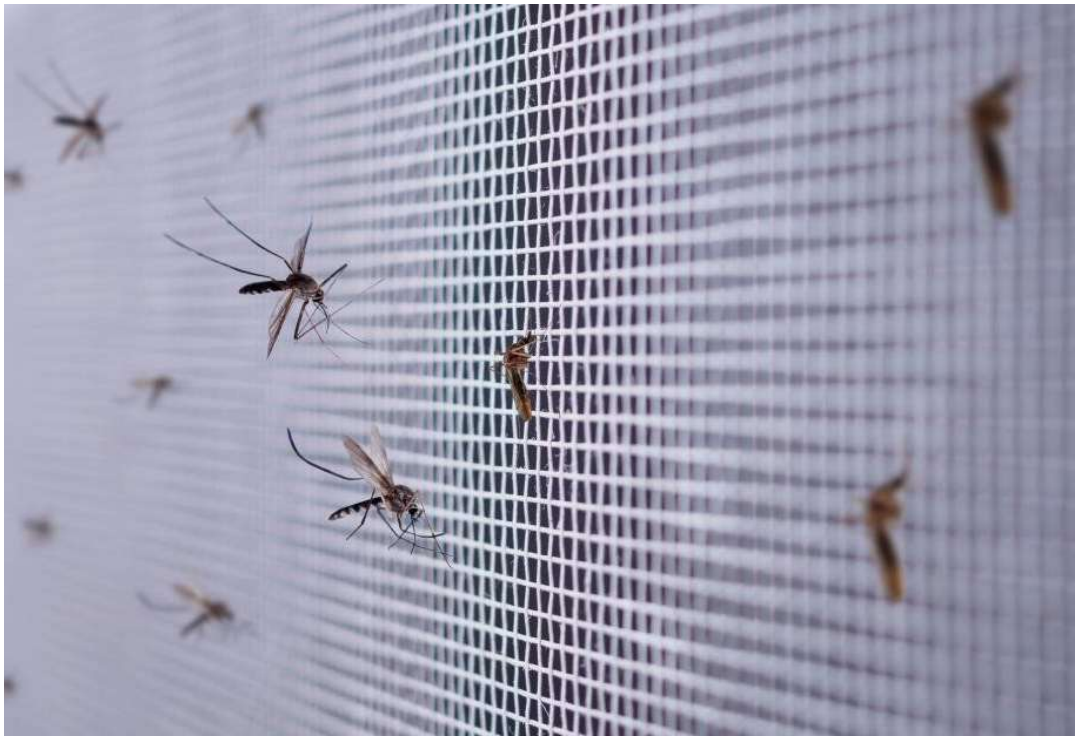
- Sufficient space.
- Protection against contamination.
- Consider the logical flow (materials, products, personnel).
- Separation between raw and processed areas.

PRPs for food manufacturing - Layout of the premises and workspace

- Washable/ cleanable walls and floors.
- Standing water on the floor avoided
- Ceilings and overhead fixture shall prevent the
- accumulation of dirt and condensation.
- Walls, floors, ceilings, doors shall be non-corrosive, impervious, non-absorbent and constructed of durable materials.

PRPs for food manufacturing - Layout of the premises and workspace

- Screened windows and roof vents.
- Closed/ screened external doors (self closing).
- Equipment positioning shall allow for cleaning, sanitizing, maintenance and inspection.



PRPs for food manufacturing - Layout of the premises and workspace

- Laboratory facilities shall not open directly to the production area.
- Temporary/ mobile premises and vending machines shall be designed, located, constructed and operated to prevent the harborage of pests and the contamination of the food products.

PRPs for food manufacturing - Layout of the premises and workspace

- Storage areas shall be dry and ventilated protected from dust, condensation, waste. Segregation between raw materials, work in progress and finished products.
- Storage areas shall allow for cleaning and maintenance activities.
- Chemicals, cleaning products, hazardous substances shall be stored separately.

PRPs for food manufacturing - Water supply and boiler chemicals

- Sufficient potable water supply.
- Water quality testing.
- Separate system for non-potable water.
- Water filters shall be changed/ maintained.
- Water storage facilities shall prevent contamination.
- Seawater (if used) shall be from an approved source.
- Ice or steam shall be obtained from potable water.
- Boiler chemicals shall be approved and stored securely

PRPs for food manufacturing - Air quality and ventilation

- Define the requirements for air filtration, microbiology and humidity.
- Monitoring systems shall be in place wherever air temperature or humidity are critical for the process.

PRPs for food manufacturing - Air quality and ventilation

- Sufficient air exchange.
- The design shall not allow the flow of air from contaminated areas to clean areas (air pressure differentials).
- Quality monitoring for air supply.

PRPs for food manufacturing - Compressed air and other gasses

- The systems shall be designed, constructed and maintained to prevent contamination.
- Food contact gases shall come from an approved source.
- The organization shall define its requirements for filtration, humidity and microbiology.

PRPs for food manufacturing - Lighting

- Sufficient for the activity performed.
- Should not alter the color of the food.
- Light bulbs and fixtures shall be protected in case of breakages.

PRPs for food manufacturing – Waste disposal

- Waste shall be identified, collected, removed and disposed of in a manner that prevents the contamination of the product and of the production areas.

PRPs for food manufacturing – Waste management

- Designated areas for waste containers.
- Waste segregation.
- Leak-proof and easy to clean containers.
- Daily waste removal.
- Attention to printed packages, labelled or trademark materials that are disposed of.

PRPs for food manufacturing – Drains and drainage

- Sufficient capacity.
- Accessible for cleaning.
- Direction shall not be from a contaminated area to a clean one.

PRPs for food manufacturing – Equipment

- Designed and constructed to facilitate cleaning, disinfection, maintenance.
- Constructed of durable materials.
- Hygienic design.
- Pipes and ducts cleanable, drainable and with no dead ends.
- Product contact surfaces designed for food use.

Cleaning programmes for the plant, the equipment and utensils.

PRPs for food manufacturing – Equipment maintenance

- Preventive maintenance programme.
- Maintenance activities shall not contaminate food.
- Food safety related maintenance requests shall be prioritized.
- Food grade lubricants and heat transfer fluids.
- Maintenance personnel shall be trained in the product hazards associated with their activities.

PRPs for food manufacturing – Purchasing

- Control the process of purchasing materials with an impact on food safety.
- Ensure that suppliers are capable to meet requirements.
- Verify the conformance of incoming materials.

PRPs for food manufacturing – Selection and management of suppliers

- Process for the selection, approval and monitoring of suppliers.
- Supplier audits
- Request for documentation (e.g. certifications)

PRPs for food manufacturing – Requirements for incoming materials

- Check delivery vehicles before and during unloading.
- Inspect, test, verify the products prior to acceptance or use.
- Documented procedure for managing non- conforming materials.
- Access points to bulk material receiving lines must be identified, capped and locked.

PRPs for food manufacturing – The prevention of cross-contamination

- Programmes to prevent, control and
- detect contamination:
  - microbiological
  - allergen
  - physical

Microbiological contamination

- Hazard assessment.
- Control measures:
  - separation of raw from finished or ready- to-eat products;
  - barriers, walls, separate buildings;
  - access controls for personnel;
  - traffic patterns;
  - air pressure differentials.

Allergen

- Allergens shall be declared.
- Products shall be protected from unintended allergen cross-contact.
- Rework containing allergens shall only be used for products that contain the same allergen or after a process that removes or destroys allergenic material.
- Training of employees on allergen control measures

Physical contamination

- Avoid brittle materials (glass, hard plastic).
- Keep records of glass breakages. Possible control measures:
  - covers over equipment or containers;
  - shatterproof light bulbs;
  - screens, sieves, filters, magnets;
  - metal detectors or X-ray.

PRPs for food manufacturing – Cleaning and sanitizing

- Cleaning and sanitizing programmes to ensure that the food processing equipment and the environment are kept in a hygienic condition.

PRPs for food manufacturing – Cleaning and sanitizing agents and tools

- Agents and chemicals:
  - appropriate,
  - food grade,
  - identified,
  - stored separately,
  - used according to specifications.
- Tools and equipment:
  - hygienic design,
  - proper maintenance.

PRPs for food manufacturing – Cleaning and sanitizing programmes

- Cleaning programmes established and validated including:
  - what to clean;
  - methods (Cleaning in Place vs. Cleaning out of Place);
  - substances;
  - frequency;
  - responsibilities;
  - post-clean and pre-start-up inspections.

Validation vs. Verification

Validation – to confirm that a control measure will achieve the intended results.

Verification – to confirm (with objective evidence) that requirements have been fulfilled.

PRPs for food manufacturing – Cleaning in place (CIP)

- Define and monitor the parameters for Cleaning in Place systems.

PRPs for food manufacturing – Monitoring sanitation effectiveness

- The organization shall monitor its cleaning and sanitation programmes to ensure that they are suitable and effective.

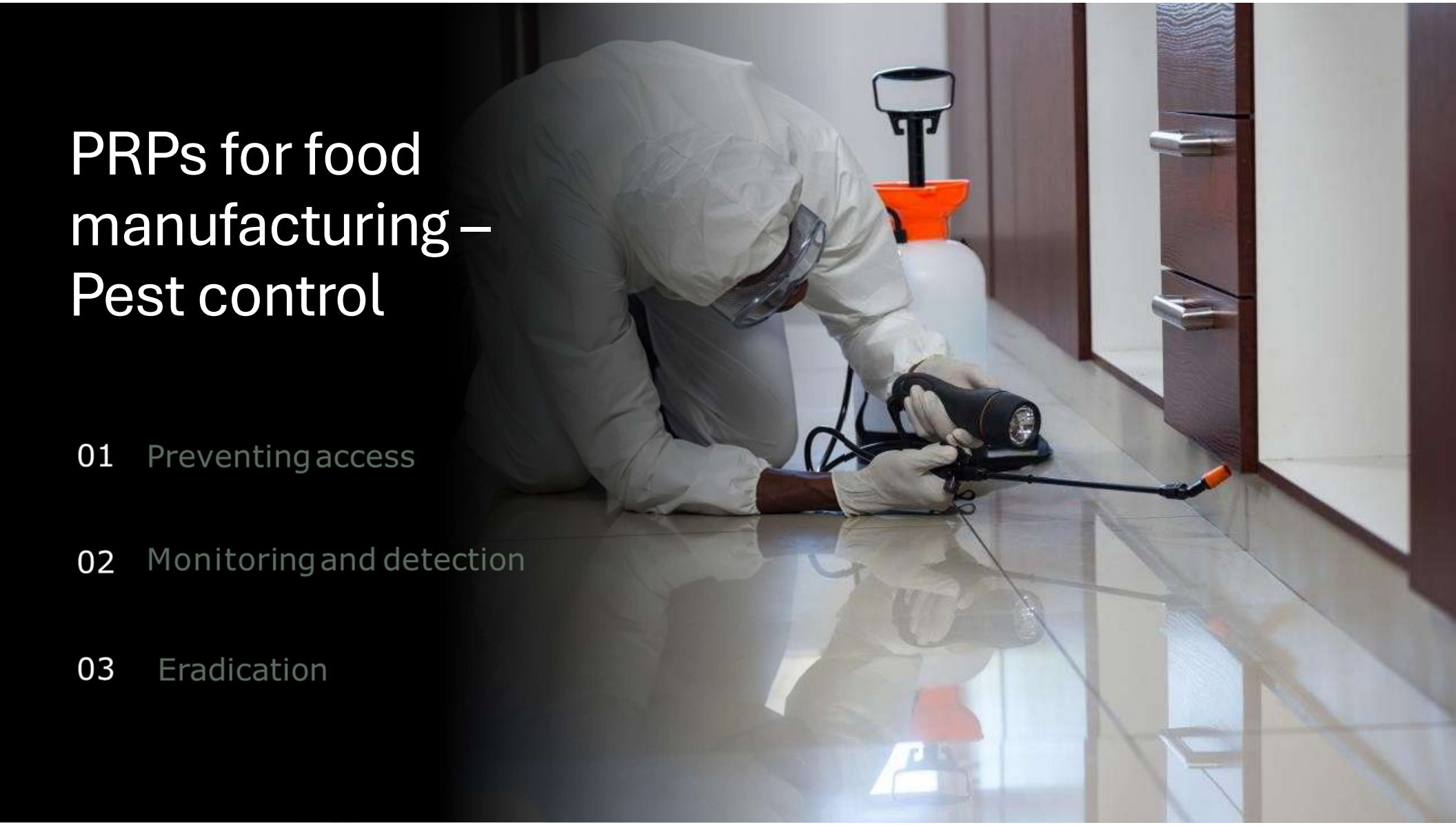
PRPs for food manufacturing – Pest control

- Nominated person to manage pest control activities.
- Licensed/ approved pest contractors.

PRPs for food manufacturing – Pest control

- Pest management programme(s) including:
  - pests targeted,
  - plans,
  - methods,
  - frequency,
  - inspections,
  - training requirements,
  - chemicals approved.

PRPs for food manufacturing – Pest control



01 Preventing access

02 Monitoring and detection

03 Eradication

PRPs for food manufacturing – Personnel hygiene and employee facilities

- Define, document and enforce rules for personal hygiene and behaviors, proportional to the hazards.

PRPs for food manufacturing – Personnel hygiene facilities and toilets

- Sufficient and accessible hand washing facilities.
- Sinks should be of stainless steel (or another non-corrosive material) and they shall not be hand operated.
- Hand washing sinks separated from those for food use and equipment cleaning-stations.
- Sufficient toilets, clean and properly maintained.
- Employee hygiene facilities shall not open directly onto production, packing or storage areas.
- Changing facilities located to minimize the risk of contaminating workwear.

PRPs for food manufacturing – Staff canteens and designated eating areas

- Located to minimize the risk of cross- contamination.
- Managed in a hygienic condition.
- Staff shall consume and store food only in designated areas.

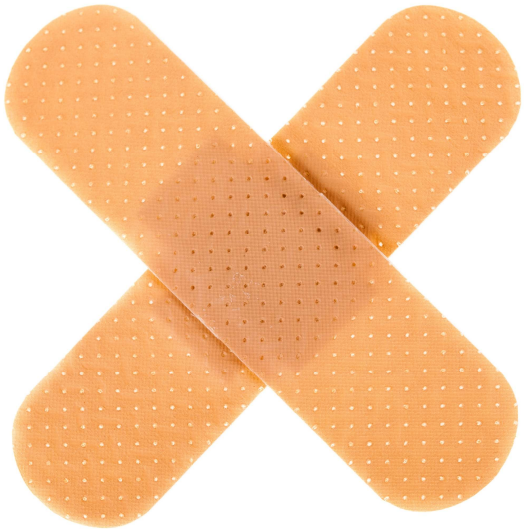
PRPs for food manufacturing – Workwear and protective clothing

- Suitable to the work and designed to prevent contamination.
- Avoid buttons and external pockets.
- Hair, beards, moustaches covered.
- Gloves kept in good condition (avoid latex).
- Workwear laundered to standards at suitable intervals.

PRPs for food manufacturing – Health status

- Medical testing in accordance with the provisions of the legislation. Prior to employment and regular testing.

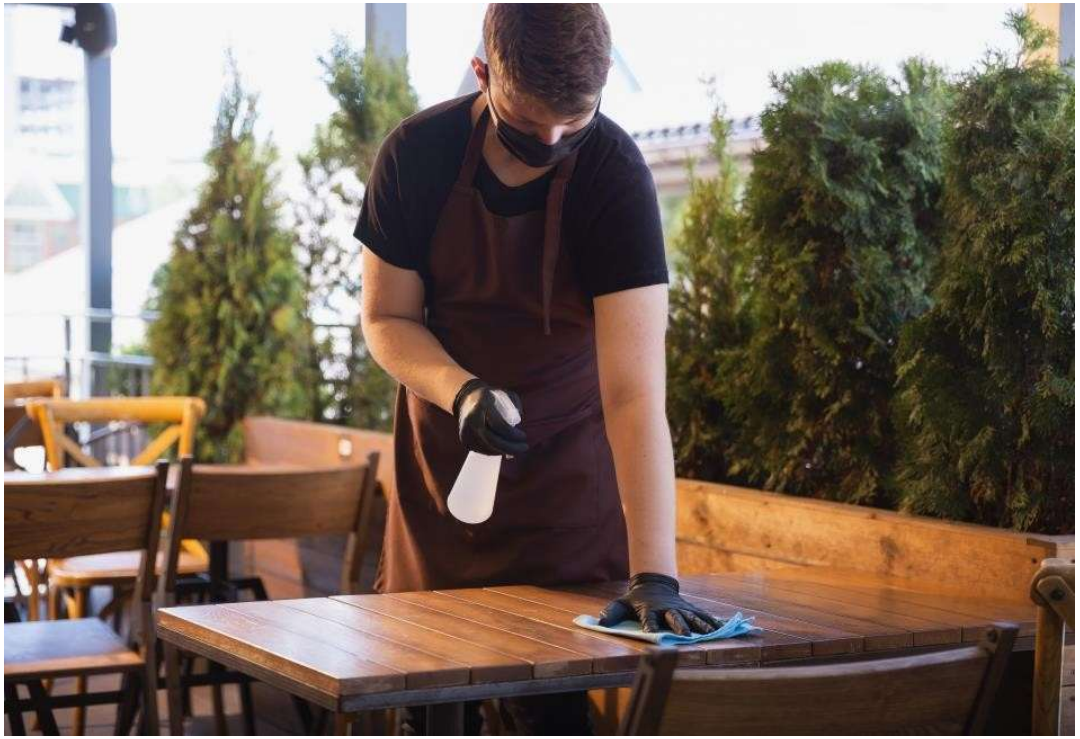
PRPs for food manufacturing – Illness and injuries



- Conditions shall be reported.
- Wounds and burns must be covered with dressings (colored, metal detectable).
- Lost dressings must be reported.

PRPs for food manufacturing – Personal cleanliness

- Wash (+ sanitize) hands.
- Refrain from sneezing or coughing over materials or products.
- Fingernails clean and trimmed.



PRPs for food manufacturing – Personal behaviour

- A policy to describe the behaviors required.
- Aspects to consider:
  - smoking, chewing, eating in designated areas;
  - nail polish, false nails, false eyelashes not allowed;
  - pencils not carried behind the ear;
  - consideration to the risks posed by jewellery and personal effects;
  - personal lockers;
  - storage of cigarettes, medicines, lighters and other personal items

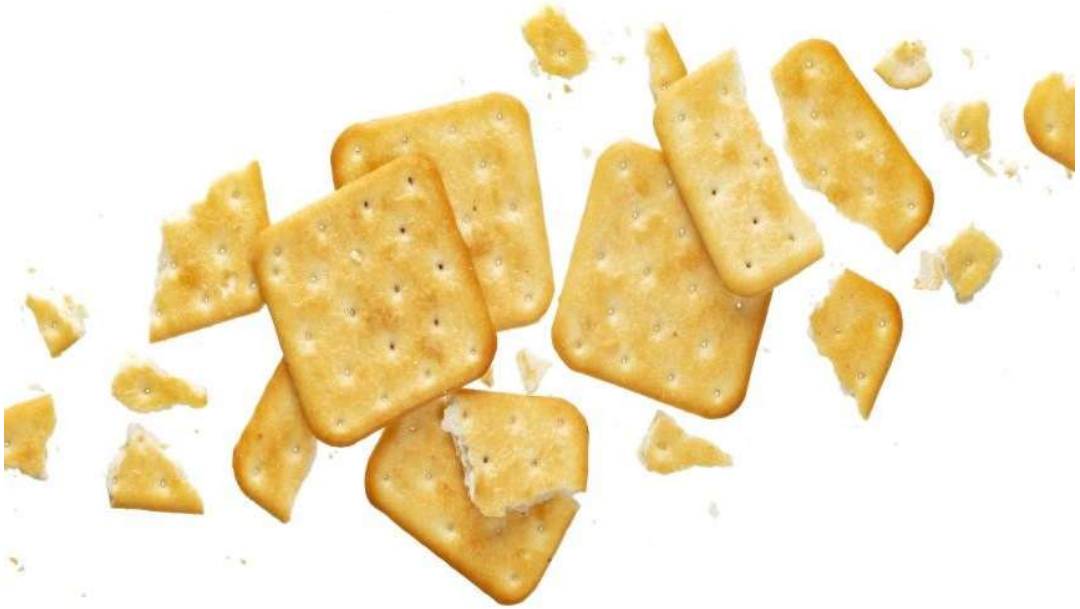
PRPs for food manufacturing – Rework

Nonconforming or returned products that are suitable for reprocessing.

- Stored, handled and used so that product safety, quality, traceability and regulatory compliance are maintained.

PRPs for food manufacturing – Rework

- Protected from contamination.
- Labelled and identified for traceability.
- Records retained on rework classification and reasons for rework designation.
- Segregation, labelling and identification for allergen control.
- Specify conditions, methods for rework usage.



PRPs for food manufacturing – Product recall

- Products that fail to meet safety requirements shall be identified, located and removed.
  - Maintain a list of all key contacts to be used in case of a recall.
  - Investigate the safety of other products manufactured in similar conditions.
  - Consider the need for public warning.

PRPs for food manufacturing – Warehousing

- Products and materials shall be stored in clean, dry, well-ventilated spaces; protected from dust, condensation, fumes, odors or other forms of contamination.

PRPs for food manufacturing – Warehousing

- Temperature, humidity and other environmental conditions must be controlled.
- Waste and chemicals stored separately.
- Segregation of non-conforming materials.
- Stock rotation systems (e.g. FIFO, FEFO).
- Diesel or gasoline forklifts shall not be used in product storage areas.

PRPs for food manufacturing – Vehicles, conveyances and containers

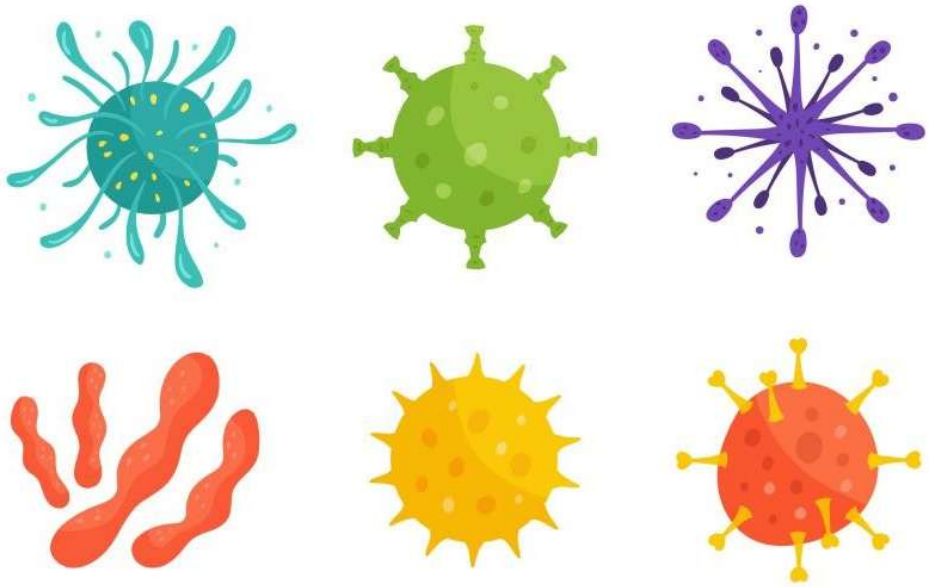
- Clean and in a condition consistent with requirements.
- Cleaned between loads, when used for food and non- food transport.
- Shall provide adequate protection against damage and environmental conditions.
- Appropriate loading and unloading procedures.
- Bulk containers for food use only.

PRPs for food manufacturing – Product information and consumer awareness

- Provide information to consumers so that they understand its importance and can make informed choices.

PRPs for food manufacturing – Food defense

- The process to ensure the security of food and drink from all forms of intentional malicious attacks, including ideologically motivated attacks leading to contamination.
- Assess the hazard to products posed by potential acts of sabotage, vandalism or terrorism and implement control measures.



PRPs for food manufacturing – Bioterrorism

- TACCP – Threat Analysis and Critical Control Points.
- Access control – identify, map and control sensitive areas.
- HR Security.
- Control of suppliers and contractors.

What is Food Poisoning ?

- An unpleasant illness which normally happens within 1 to 36 hours of eating contaminated or poisonous food.
- Symptoms:
  - Abdominal Pain
  - Diarrhea
  - Vomiting
  - Fever

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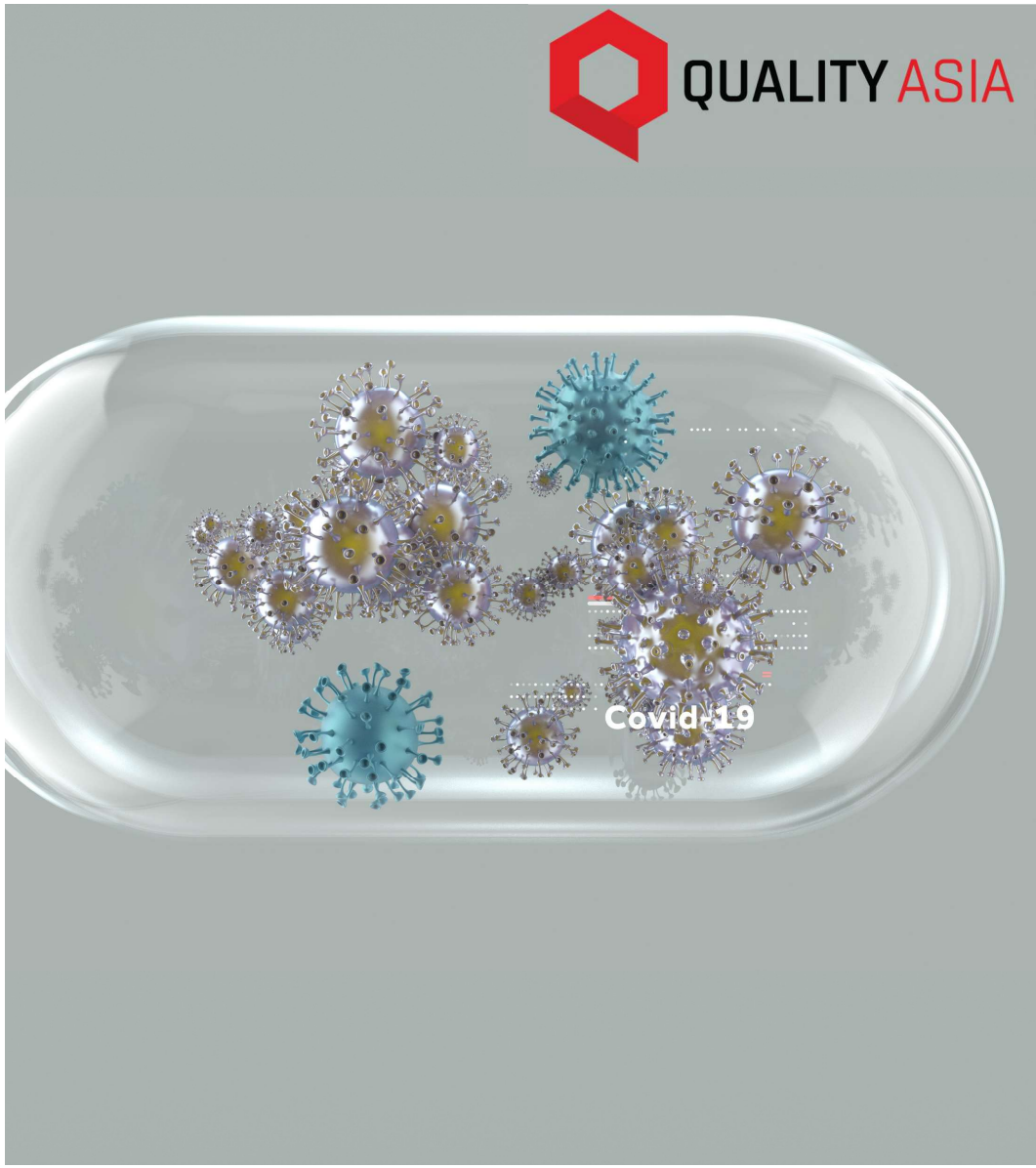
What are the Main Causes of Food Poisoning ?

- Bacteria or their poisons
- Viruses
- Chemicals
- Metals
- Poisonous Plants
- BACTERIAL FOOD POISONING CAN BE FATAL & IS THE MOST COMMON CAUSE OF FOOD POISONING

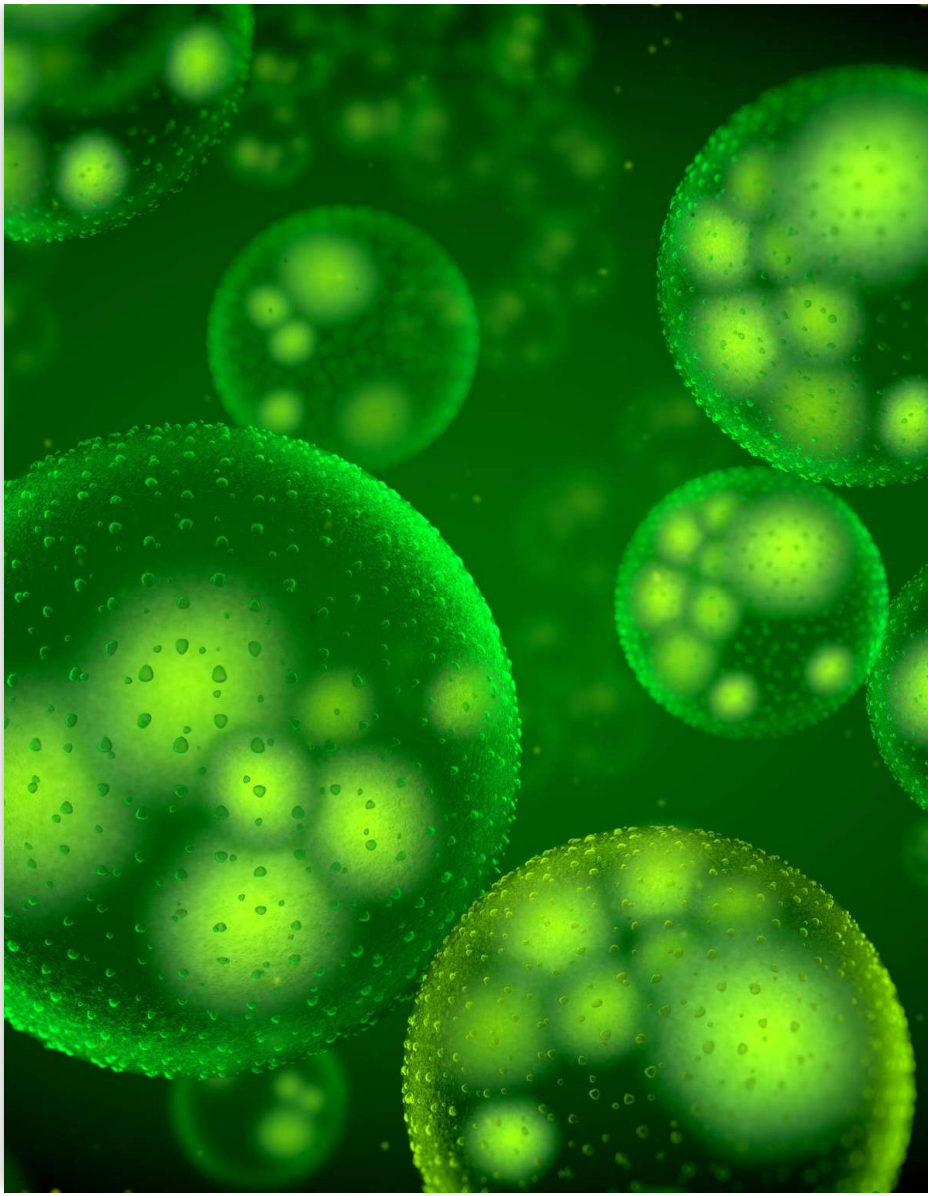
Different Types of Bacteria

- FOOD POISONING BACTERIA
  - Cause Illness
  - Can not be detected by taste or smell
  - Very Harmful due to difficulty to detect
- FOOD SPOILLAGE BACTERIA
  - Can be detected (when in high numbers) by smell, taste or even colour & texture of food
  - Relatively Harmless because of ease of detection



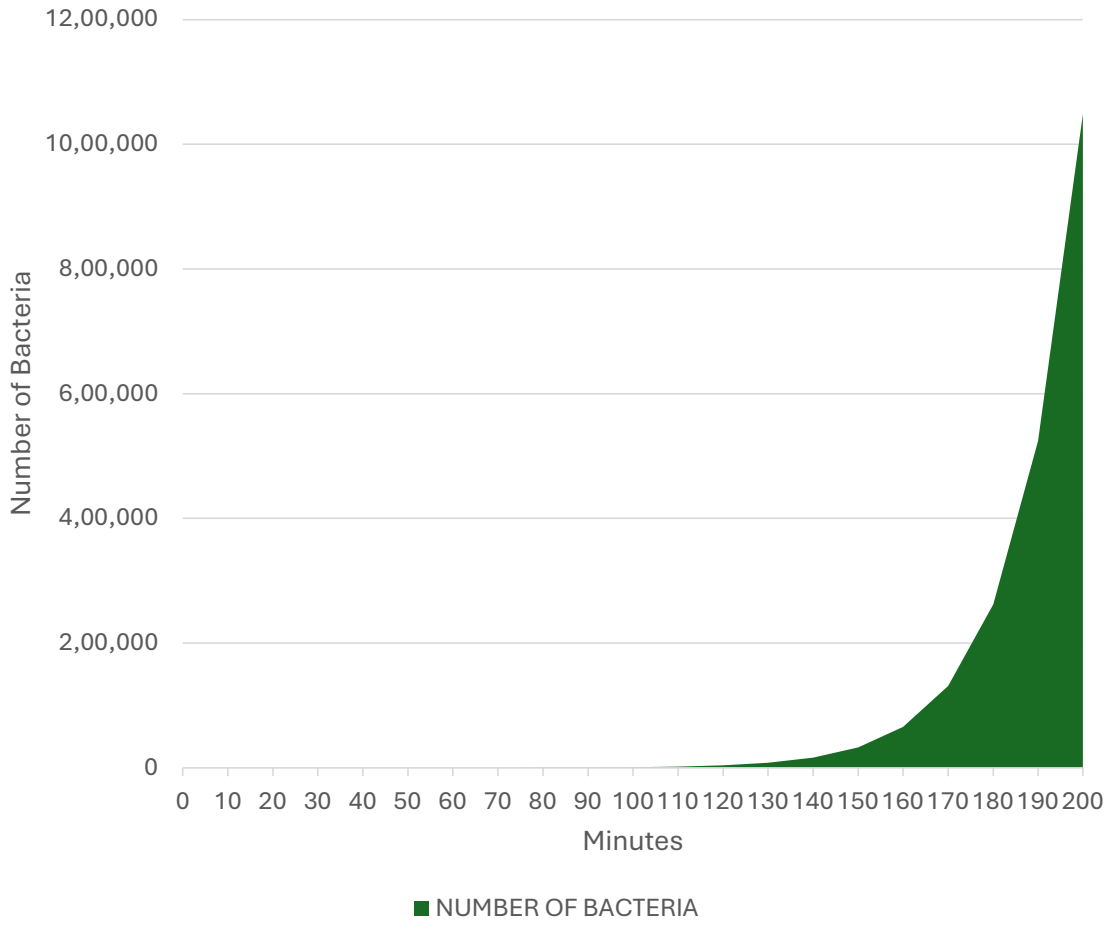
How Bacteria Grow

- Bacteria reproduce by splitting in two
- Under ideal conditions bacteria can divide in two every :10 minutes
- One bacteria can become 1,000,000 in 3 hours & 20 minutes



Growth of Bacteria

- THIS IS CALLED EXPONENTIAL GROWTH



Conditions for Bacterial Growth

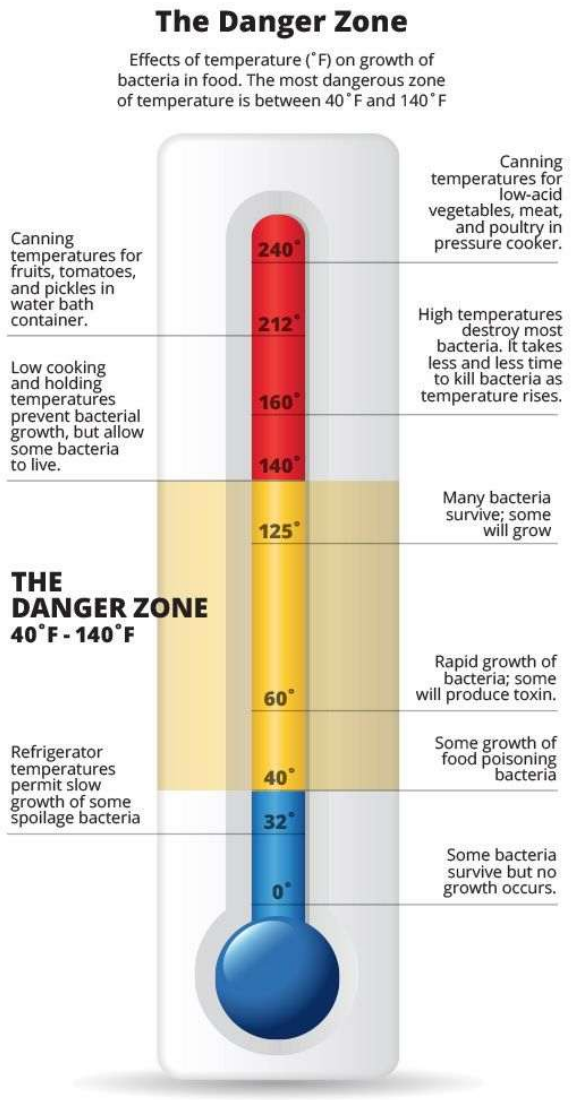
FOOD

WARMTH

TIME

WATER

The Temperature ‘DANGER ZONE’ for Food



HEAT

e.g., Cooking, Pasteurisation

IRRADIATION

e.g. X-Rays, Gamma Rays

CHEMICALS

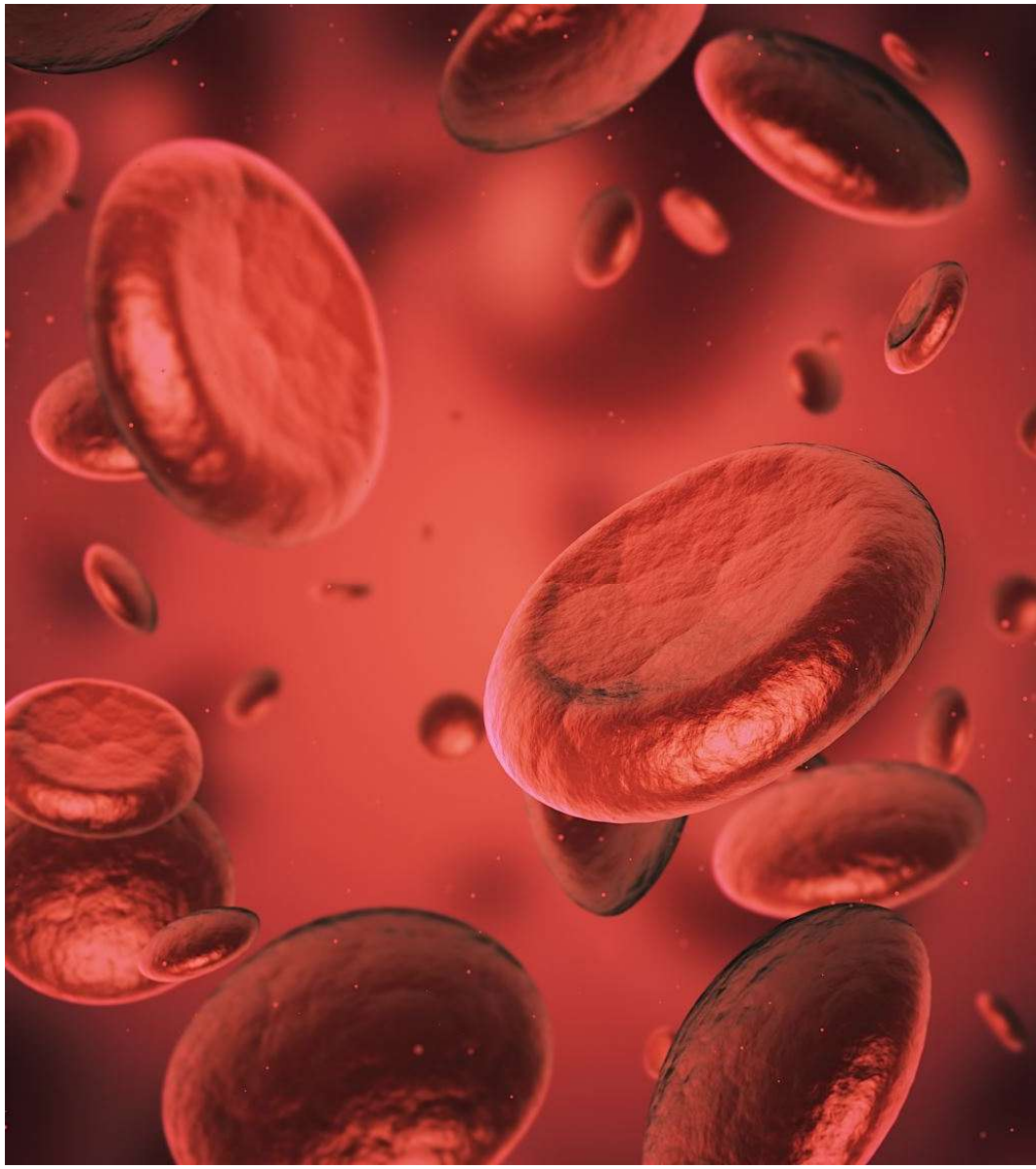
e.g. Preservatives, Salt, etc.

Where do Bacteria come From ?

- PEOPLE
- PESTS
- AIR
- WATER
- ANIMALS & BIRDS
- RAW FOOD
- SOIL & WASTE

Food Poisoning Bacteria

- SALMONELLA
  - Symptoms : Vomiting, Diarrhoea, Abdominal Pains, Fever
  - Incubation Period : 12-36 hours
  - Duration of Illness : 1-8 days
  - Source : All raw foods of animal origin, poultry in particular. Humans can be carriers.
- STAPHYLOCOCCUS AUREUS
  - Symptoms : Vomiting, Abdominal Pains
  - Incubation Period : 1-7 hours
  - Duration of Illness : 6-24 hours
  - Source : Human Nose, throat, skin, hair, boils, styes, septic cuts



Food Hygiene is..

PROTECTION of food from risk of contamination by bacteria, poisons, viruses & foreign bodies.

PREVENTION of bacteria present in food multiplying to numbers that would result in illness of people or result in premature spoilage of food.

DESTROYING any harmful bacteria in the food by proper cooking or processing

CONTAMINATION is the presence of any OBJECTIONABLE MATTER in food. This may be bacterial or physical, e.g. glass, wood, metal, etc.

Food Contamination

PHYSICAL, Examples :
• Dead Insects (sometimes live) • Paper & Cardboard • Plastic, Metal, Plasters, • Cleaning Materials, String, • Rodent hair & droppings, • Sweet Papers, Pen Tops, Grease, • Glass, Cigarette Ends, and so on…

PHYSICAL, Examples :
• Dead Insects (sometimes live) • Paper & Cardboard • Plastic, Metal, Plasters, • Cleaning Materials, String, • Rodent hair & droppings, • Sweet Papers, Pen Tops, Grease, • Glass, Cigarette Ends, and so on…

High Risk Foods

- Some foods are higher risk than others because they present a better growth opportunity for Food Poisoning bacteria (and viruses) than others.
- EXAMPLES :
  - ALL COOKED FOODS - Already cooked, will not be cooked again, also free from competition,
  - FOODS CONTAINING RAW INGREDIENTS (or FOODS normally eaten RAW or PART COOKED) - e.g. Mayonnaise, Rare Steak, Shellfish.

High Risk Foods

Food	High Risk?
Cooked Meat	Yes
Apple	No
Cooked rice	Yes
Milk, Cream, etc.	Yes
Fresh meat	No

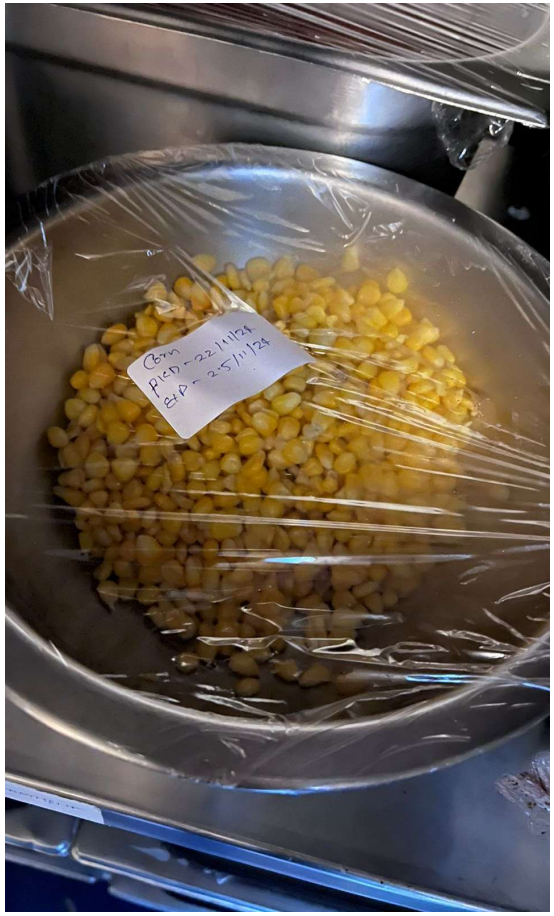
- A HIGH-RISK FOOD is one which SUPPORTS THE GROWTH OF BACTERIA and is INTENDED FOR CONSUMPTION WITHOUT FURTHER TREATMENT THAT WOULD DESTROY SUCH BACTERIA, e.g., Cooking.

Best Practices - Kitchen

Best practices

Colored chopping board and knife

Date tagging



Good hygiene practice

Hygiene rule code - FSSAI

For Restaurant

Hygiene rule code - FSSAI

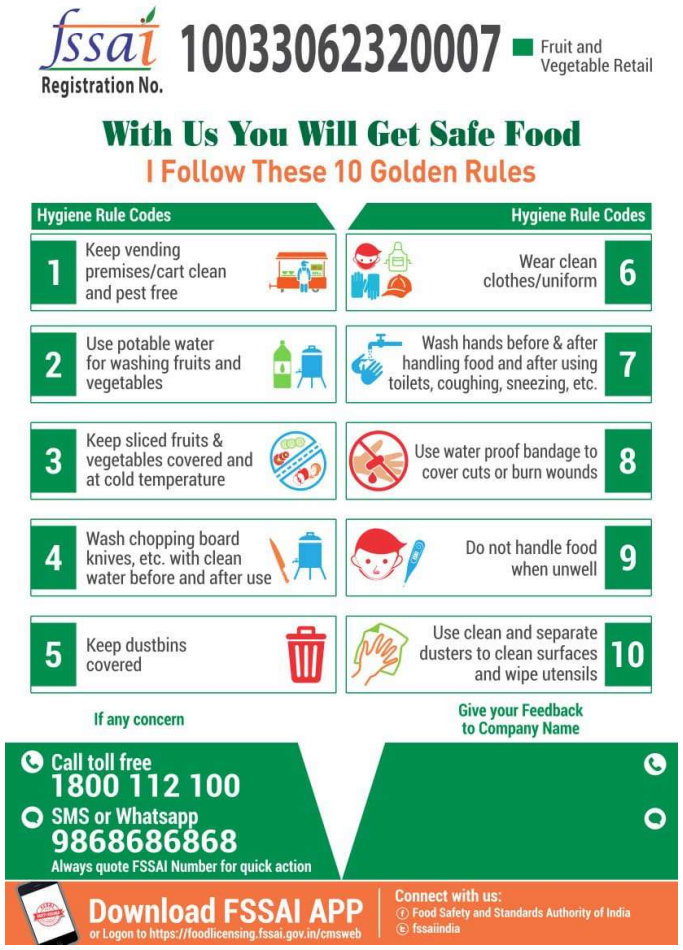
For Meat Retail

Hygiene rule code - FSSAI

For Street Vendor

Hygiene rule code - FSSAI

For Fruit and Vegetable vendor



FSSAI guidelines for handling and disposal of used cooking oil

Guidance Note No.: 06/2018

HANDLING AND DISPOSAL OF USED COOKING OIL

SUMMARY

The practice of reheating cooking oil or using the same cooking oil for frying is common. Cooking oil is often repeatedly used by topping it up with fresh oil. Generally, big food businesses involved in the manufacturing of fried foods dispose of their used cooking oil (UCO) for industrial purposes (soap manufacture, etc.) but sometimes it finds way to small food vendors at cheap prices. At household level or by road-side vendors, the UCO is discarded in an environmentally hazardous manner blocking the sewerage and drainage systems. Therefore, in order to safeguard public health, FSSAI has notified the limit of Total Polar compounds to be not more than 25% beyond which the oil is unsafe for human consumption. This guidance note outlines the Standard Operating Procedure (SOP) for safe handling and disposal of UCO for the benefit of consumers as well as small and big Food Business Operators (FBOs).

KEY TAKEAWAYS

- Avoid repeated use of cooking oil for frying.
- At household level, oil once used for frying foods should be filtered and may be used for curry preparation in order to make it economical.
- Used Cooking Oil should be consumed in a day or two. It should not be stored for longer period as the rate of deterioration is higher in used oil.
- Discard Cooking Oil when blue-grey smoke appears ortough foam is formed or oil becomes dark and murky or the consistency of oil changes.
- Discard cooking oil having developed Total Polar Compounds (TPC) of more than 25%.
- Do not dispose of the discarded oil in drains/sewerage systems.
- UCO should be discarded in an environment friendly way preferably by providing it to the authorized UCO aggregators/collection agencies.
- In order to dispose small quantities of used cooking oil at household level, mix the oil with

8.3. Traceability system

- Establish a traceability system that allows to go one step back and one step forward.
- It shall address at least:
  - the relationship between the lots of received materials, ingredients and intermediate products to the end products;
  - the distribution of the end-product;
  - reworking of materials/ products.

Traceability system

- A traceability system should be: verifiable, cost-effective, practical to apply, results oriented.
- Retain documented information as evidence of the traceability system for a period that covers at least the shelf life of the product.
- Verify and test the effectiveness of the traceability system.

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8.4. Emergency preparedness and response

Procedures to respond to emergency situations that can have an impact on food safety

Emergency preparedness and response

- Respond to emergency situations.
- Reduce the consequences.
- Test the procedures.
- Review and update the procedures and arrangements, as necessary.

8.5. Hazard control

1

Conduct a hazard analysis

To identify food safety hazards

2

Assess the hazards

Considering likelihood of occurrence and severity

3

Implement and monitor controls

To prevent or reduce the hazards to acceptable levels.

Preliminary steps to enable the hazard analysis

Raw materials, ingredients and product contact materials

Identify statutory and regulatory requirements

Maintain documented information on each raw material, ingredient or product that comes into contact with food

Characteristics of end products

Identify and statutory and regulatory requirements

Maintain documented information on the characteristics of end products

Intended use

Consider and document the intended use and any reasonably expected mishandling or misuse. As applicable groups of consumers/ users shall be identified.

Flow diagrams

Establish, maintain and update flow diagrams for the products or product categories. Confirm on-site the accuracy of the flow diagrams.

Description of the processes

Layout of premises, equipment, PRPs, process parameters, controls, external requirements, any variations due to seasonal changes or shift patterns

Hazard identification and determination of acceptable levels

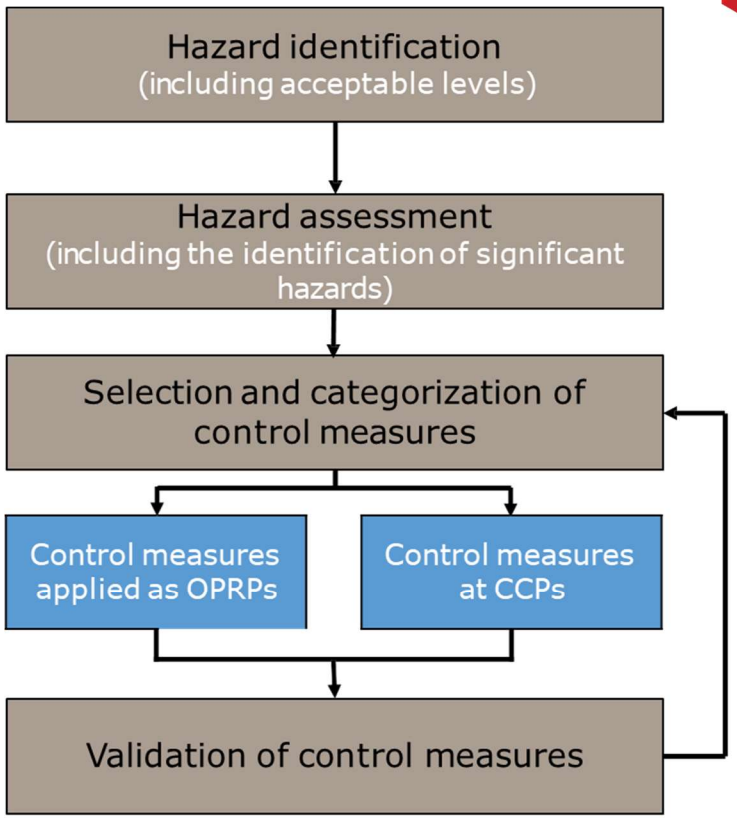


Illustration of the hazard analysis process
(source ISO 22004:2014)

Hazard identification

- Identify and document all food safety hazards that are reasonably expected to occur, depending on the type of product, the type of process and the environment.
- Hazards:
  - Chemical
  - Microbiological
  - Physical
  - Allergens

Hazard identification

Process step	Hazard category (C, M, P, A)	Hazard description
Reception of flour	M	Bacillus mesentericus. Bacillus cereus. Molds. GMOs
	C	Pesticides. Cleaning chemicals. Lubricants. Fuels
	P	Dead insects. Metals. Wood. Stones
	A	Cross contamination with allergens
Storage of flour	M	Yeasts (Saccharomyces cerevisiae, Rhodotorula). Molds (Aspergillus, Penicillium). E-coli
	C	Pesticides. Cleaning chemicals
	P	Dead insects. Pests. Foreign matter
	A	Cross contamination
Sieving the flour	M	…
	C	…
	A	…
	P	…

Acceptable levels

- Determine the acceptable level in the end
- product of each food safety hazard identified.
- Acceptable level = a level of hazard in the end product that shall not be exceeded in order to ensure food safety.

Process step	Hazard category	Hazard description	Acceptable level
Reception of flour	P	Metals	3mg/ kg
	M	GMOs	0

Hazard assessment

- Purpose: to identify significant hazards for which it is essential to act to prevent their occurrence or to reduce them to acceptable levels.

Impact/Probability	Probable (3)	Possible (2)	Improbable (1)
High impact (3)	9	6	3
Medium impact (2)	6	4	2
Low impact (1)	3	2	1

Hazard	Impact	Probability	Level
Contamination with Bacillus mesentericus	2	2	4 - Medium

Selection and categorization of control measures

- Select and apply appropriate control measures to prevent or to reduce to acceptable levels the significant food safety hazards.
- Control measures are to be managed at CCPs (Critical Control Points) or as OPRPs (Operational Prerequisite Programmes).

CCP vs. OPRP

- CCP (Critical Control Point) – step in the process at which control measures are applied to prevent or reduce a significant food safety hazard to an acceptable level and defined critical limit(s) and measurement enable the application of corrections.
- OPRP (Operational Prerequisite Programme) – control measure or combination of control measures applied to prevent or reduce a significant food safety hazard to an acceptable level and where action criterion and measurement or observation enable effective control of the process and/ or product.

OPRPs (Operational Prerequisite Programmes) ≠ PRPs (Prerequisite Programmes)

CCP vs. OPRP

CCP	OPRP
-Step in the process where control measures are applied.	-Control measures or combination of control measures.
-Allows to establish critical limits.	- No critical limits.
- Allows measurements (precise).	-Measurement or observation (less precise and more subjective).
- Corrections can be applied.	- Action criterion.

The decision tree (CCP or OPRP?)

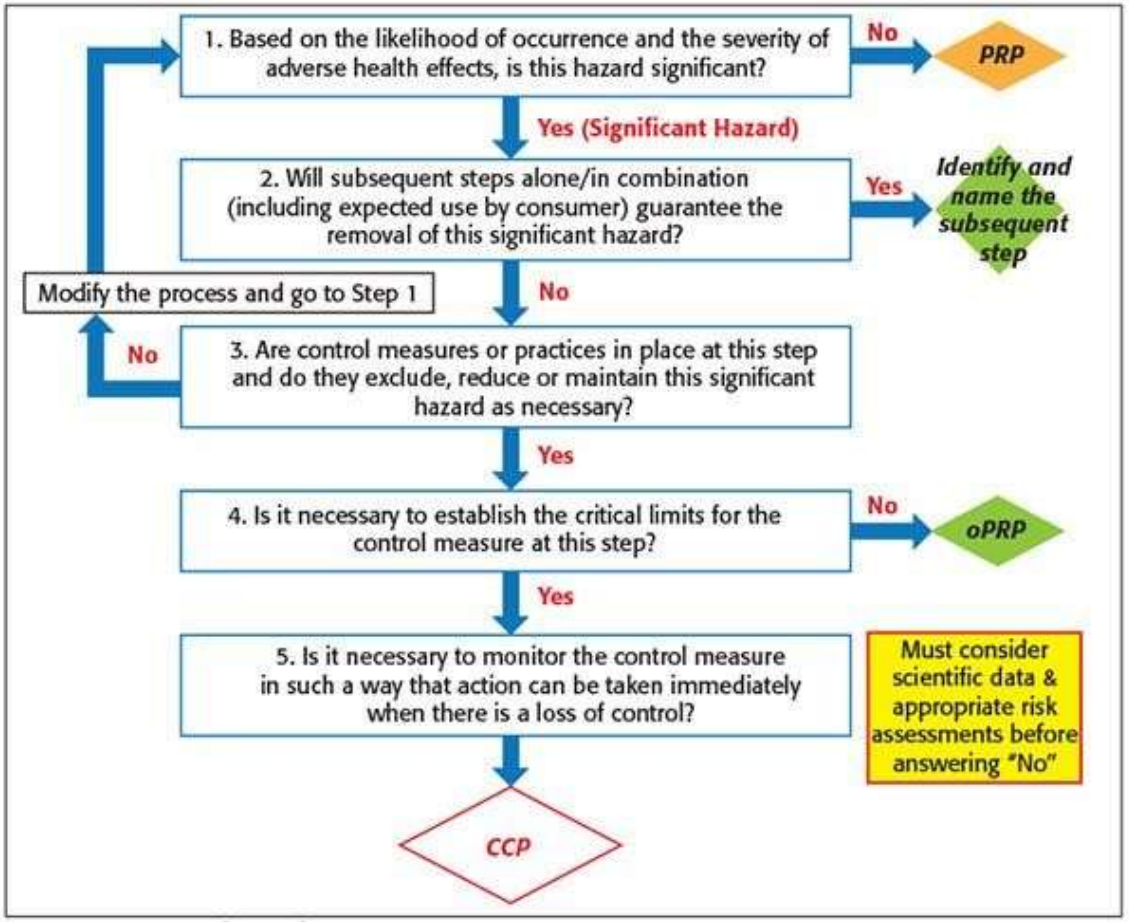
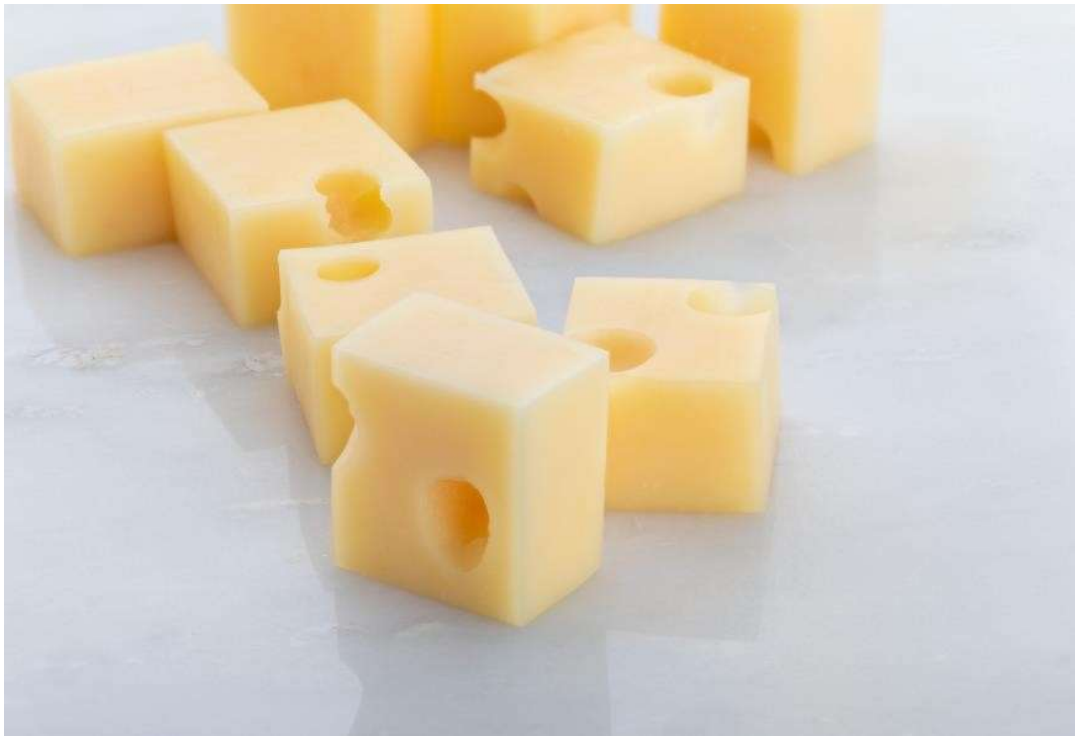


Figure 1: Coca-Cola/Michigan State Decision Tree

Validation of control measure(s) and combinations of control measures

- Validation is intended to ensure that the control measure(s) and combinations of control measures are capable to achieve the results expected.
- To validate = to obtain evidence that a control measure (or a combination of control measures) will be capable to control effectively a food safety hazard.

- Validation ≠ Verification



Validation methods

- Reference to technical or scientific literature.
- Use of previous validation studies or historical knowledge of the of the performance of control measure(s).
- Use of experimental data that is scientifically valid.
- Collection of data during the operation of the entire production process.
- Mathematical modelling.
- Surveys.
- Documented information on the validation method and results.

What is HACCP?

- Problems
  - Foodborne diseases
  - Market access – importance of food safety all along the food-chain
- Solutions
  - Food safety system that focuses on preventing problems before they occur
  - Industry-led programme used to improve and verify food safety
- Answer

Hazard	Danger to health
Analysis	Investigation of the hazard
Critical	Crucial for containment
Control	Handling of conditions
Points	Position in the process

What is HACCP?

Science-based, internationally accepted food safety system

Can be applied to all segments of the food chain

HACCP

Focused on hazard identification and prevention

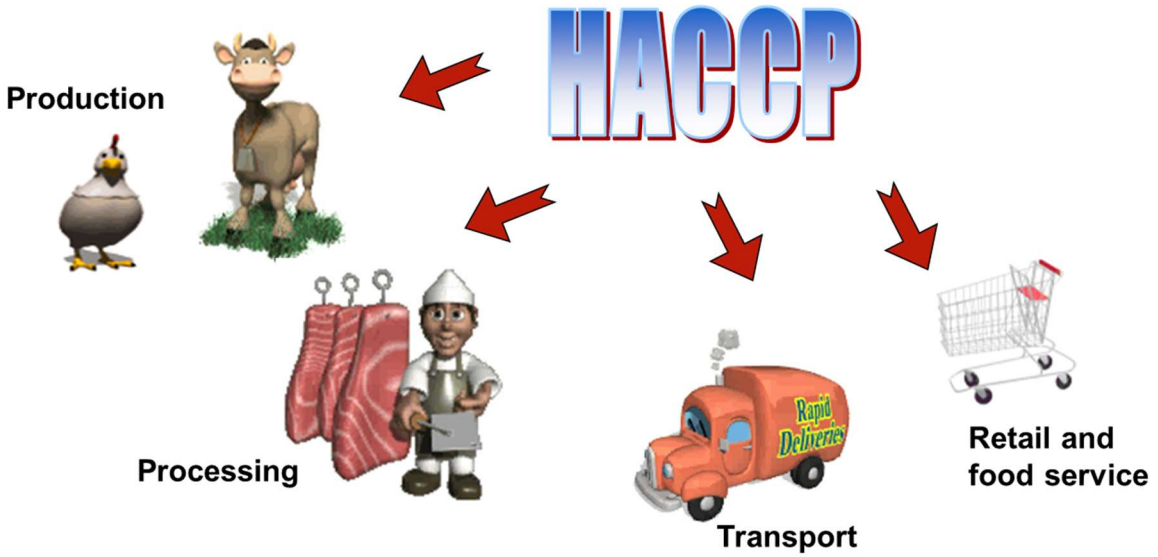
Addresses chemical and physical hazards

Why adopt HACCP?

- A properly functioning HACCP system will result in the production of safer food.
- Benefits:
  - Improved food safety
  - Increased market access
  - Protection against liability
  - Drive for continuous improvement
  - Enhanced process control

Where can HACCP be used?

- HACCP can be used in any food sector from production to retail



HACCP principles (Hazard Analysis and Critical Control Points)

Principles of HACCP
Conduct a hazard analysis
Identify critical control points (CCPs)
Establish critical limits
Monitor critical control points
Establish corrective actions
Establish verification procedures
Establish record keeping procedures

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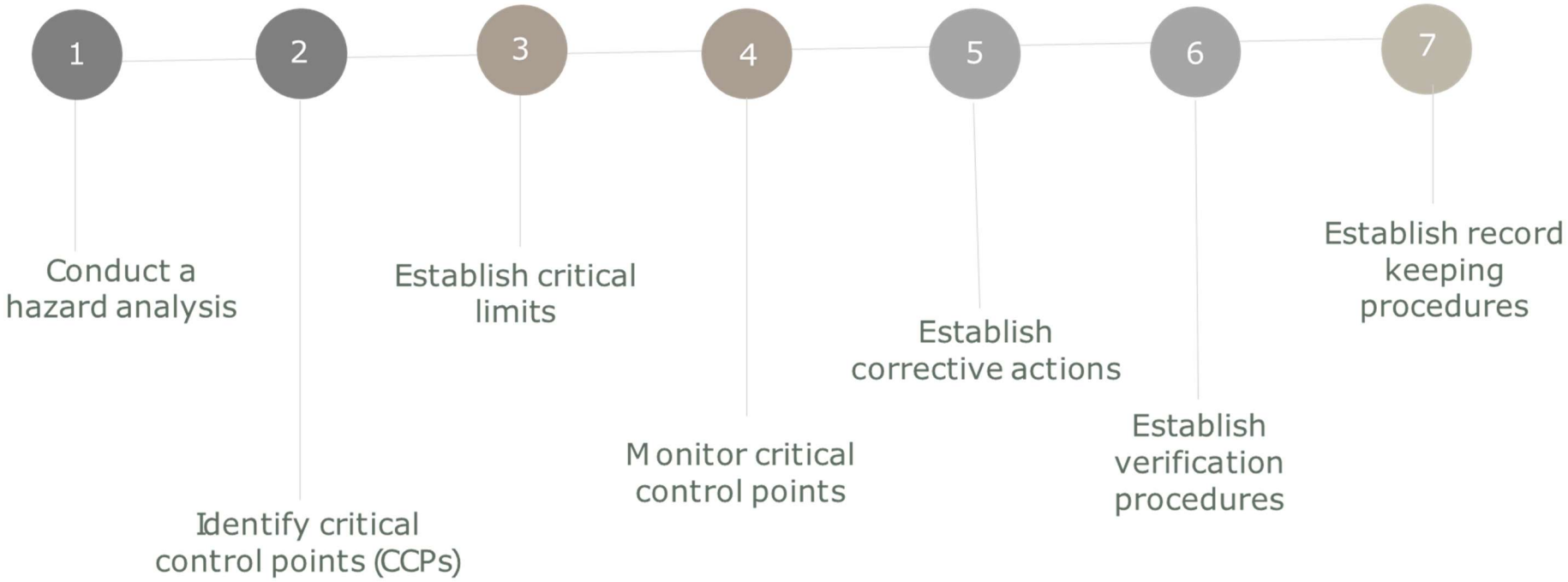
HACCP principles

(Hazard Analysis and Critical Control Points)



Implementing HACCP

- Preliminary Steps for the introduction of a HACCP System
  - Gathering the resources and information needed
- Seven principles of HACCP in action
  - Completion of all steps will result in a properly functioning HACCP plan

Preliminary steps

- Assemble the HACCP team
  - Group of people that will oversee the implementation and maintenance of the HACCP programme
  - Multi-disciplinary (i.e. production, sanitation, management, etc.)
  - Including a HACCP-trained person
- Description of products and identification of intended use and consumers
  - Full description of the product(s) being manufactured under the programme
  - Product information assists with hazard analysis
  - Which group(s) will be consuming the food product
  - Where will the product be sold
  - How will it be prepared

Development and verification of process flow diagram(s)

- The flow diagram should
  - Outline all processing steps
  - Include all processing steps
- The plant schematic should
  - Outline where all of the processing steps occur
  - Display the movement of products, people and waste

Grouping of products

- Decide whether products can be grouped using process categories
  - Slaughter – all species
  - Raw product – ground/not ground
  - Thermally processed – commercially sterile
  - Heat/not heat treated – shelf stable
  - Fully cooked – not shelf stable
  - Heat treated but not fully cooked – not shelf stable
  - Product with secondary inhibitors
- Further categories for grouping can be commodity group, hazards, etc.
- Products in the same process category may be covered by the same HACCP plan

Principle I - Conduct a hazard analysis

- Evaluate information regarding potential hazards associated with the manufacturing process and ingredients
- Determine which hazards are significant to food safety
- Consider:
  - Probability of occurrence
  - Severity of consequences

Principle II - Identify Critical Control Points (CCPs)

- A CCP is a point, step or procedure at which a control measure has to be applied to prevent, eliminate or reduce a food safety hazard
- CCPs are not necessarily located where the hazard occurs, they may be located at a subsequent step
- Some hazards cannot be controlled by the operator

Principle III - Establish Critical Limits (CL)

- What is a critical limit?
  - The maximum and/or minimum value to which a parameter must be controlled at a CCP
  - The critical limit separates acceptability from unacceptability
  - The critical limit must be clearly defined and measurable

Principle IV - Establish monitoring procedures

- Monitoring: Is the process of conducting a planned sequence of measurements to determine if a CCP is under control. Monitoring results must be recorded
- If monitoring shows that critical limits are not met, then the process is out of control and the food may be unsafe.

Principle V - Establish corrective actions

- Corrective actions are pre-determined measures that have to be implemented when monitoring indicates that a deviation has occurred.
- Corrective actions must:
  - Regain control of the process
  - Locate and segregate affected product
  - Determine disposal of affected product
  - Prevent a recurrence

Principle VI - Establish verification procedures

- Validation
  - Ensures that the HACCP plan is complete and valid
  - Ensures that the plan is effective in achieving expected food safety outcomes
- Ongoing verification
  - Ensures that the HACCP plan is working effectively
  - Confirms that the plan is operating according to written procedures
- Auditing
  - Overall review of the HACCP plan
  - To be performed whenever any changes occur that could affect the hazard analysis or alter the HACCP plan

Principle VII - Establish record keeping procedures

- Record keeping must be complete and accurate and includes:
  - Documentation pertaining to all steps, including the HACCP principles
  - Appropriate record storage procedures
  - A logbook to keep track of changes

HACCP system – Summary

- HACCP systems consist of two elements
- **Prerequisite Programmes**
  - Implemented prior to HACCP plans
  - Control of the overall plant environment
  - Control factors not directly related to food (e.g. water quality, transportation and storage, plant sanitation, employee training)
- **HACCP plans**
  - Implemented following pre-requisite programmes
  - Tailored to a certain product or process
  - Control factors directly related to food production

Hazard control plan (HACCP/OPRP plan)

- Establish, implement and maintain a hazard control plan.

Step in the process	Hazard	Control	CCP or OPRP	Critical limit or Action criterion	Monitoring				Corrections
					Monitoring procedure	Monitoring frequency	Procedure/ records	Who is responsible	
Thermal treatment	Survival of pathogens Salmonella (M)	Pasteurization	CCP	72°C, 15 sec	Automated monitoring	Continuous	Procedure … Automated record keeping	…	Flow valve for recirculation of milk

For CCP – Critical limit (measurable)

For OPRP – Action criterion (measurable or observable)

Monitoring systems at CCPs and for OPRPs

- A monitoring system includes:
  - measurements or observations;
  - methods or devices;
  - calibration of devices;
  - monitoring frequency;
  - responsibilities and authorities.

Actions when critical limits or action criteria are not met

- Corrections and corrective actions to ensure that:
  - potentially unsafe products are not released;
  - the cause of the nonconformity is identified;
  - the parameters controlled at the CCP or by the OPRP return within the critical limits/ action criteria;
  - recurrence is prevented.

8.7. Control of monitoring and measuring

- The monitoring and measuring methods and equipment must be adequate.

- Monitoring and measuring equipment:
  - calibrated or verified (with records);
  - adjusted and re-adjusted, as necessary
  - identified;
  - safeguarded from adjustments that would invalidate results;
  - protected against damage and deterioration.

Monitoring and measuring software

- The software used for monitoring and measuring must be validated.

- Commercial off-the-shelf software is considered sufficiently validated

8.8. Verification related to PRPs and the hazard control plan

- Establish, implement and maintain verification activities.
- Verification to confirm that:
  - PRPs are implemented and effective;
  - the hazard control plan is implemented and effective;
  - hazard levels are within acceptable levels;
  - input to the hazard analysis is updated;
  - other actions determined by the organization are implemented and effective.

Verification

- Audits, inspections, product testing, documents review…

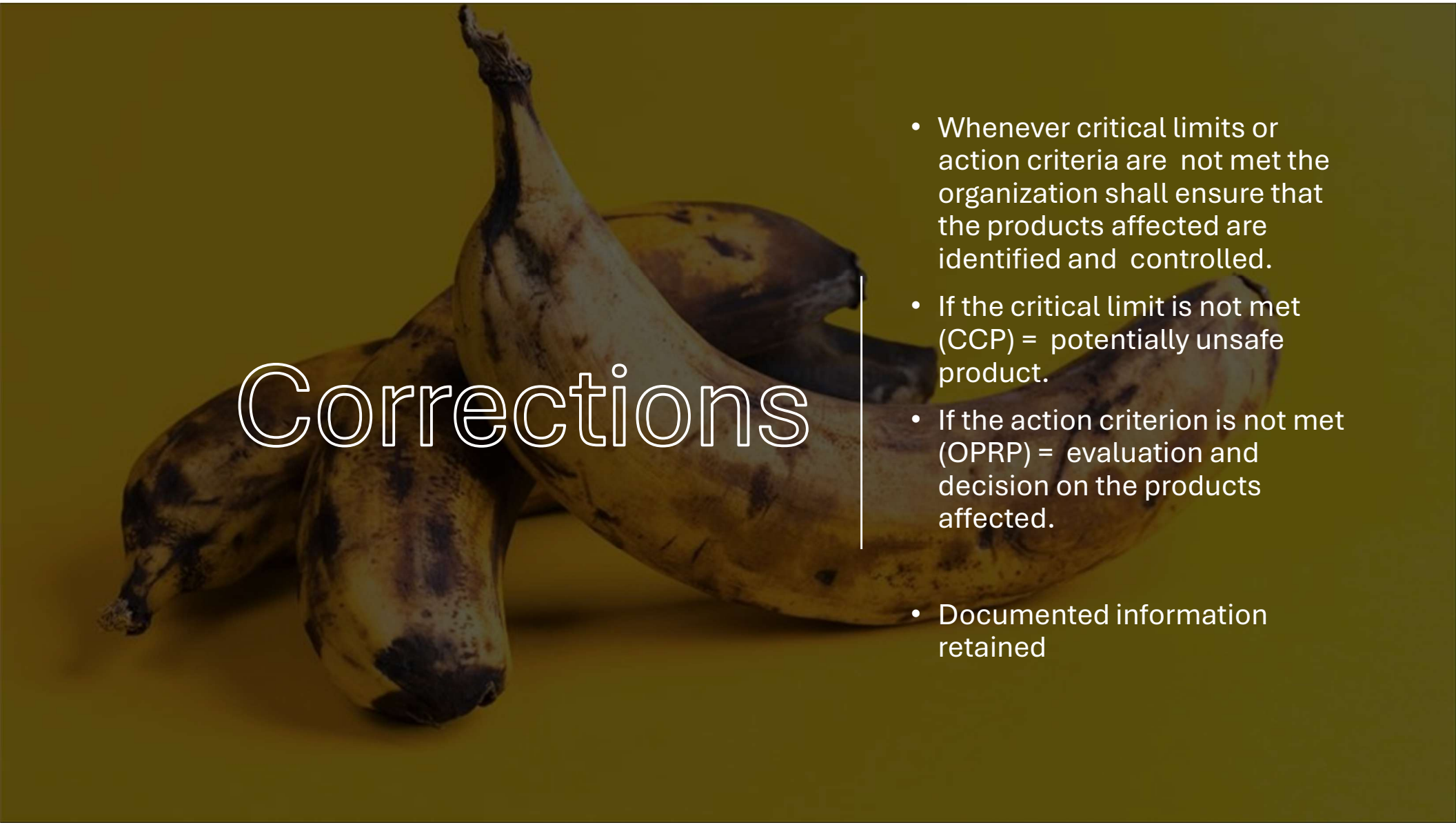
- Documented information + objectivity.

8.9. Control of product and process nonconformities

- Nonconformities: Situations when critical limits at CCPs and/ or action criteria for OPRPs are not met.

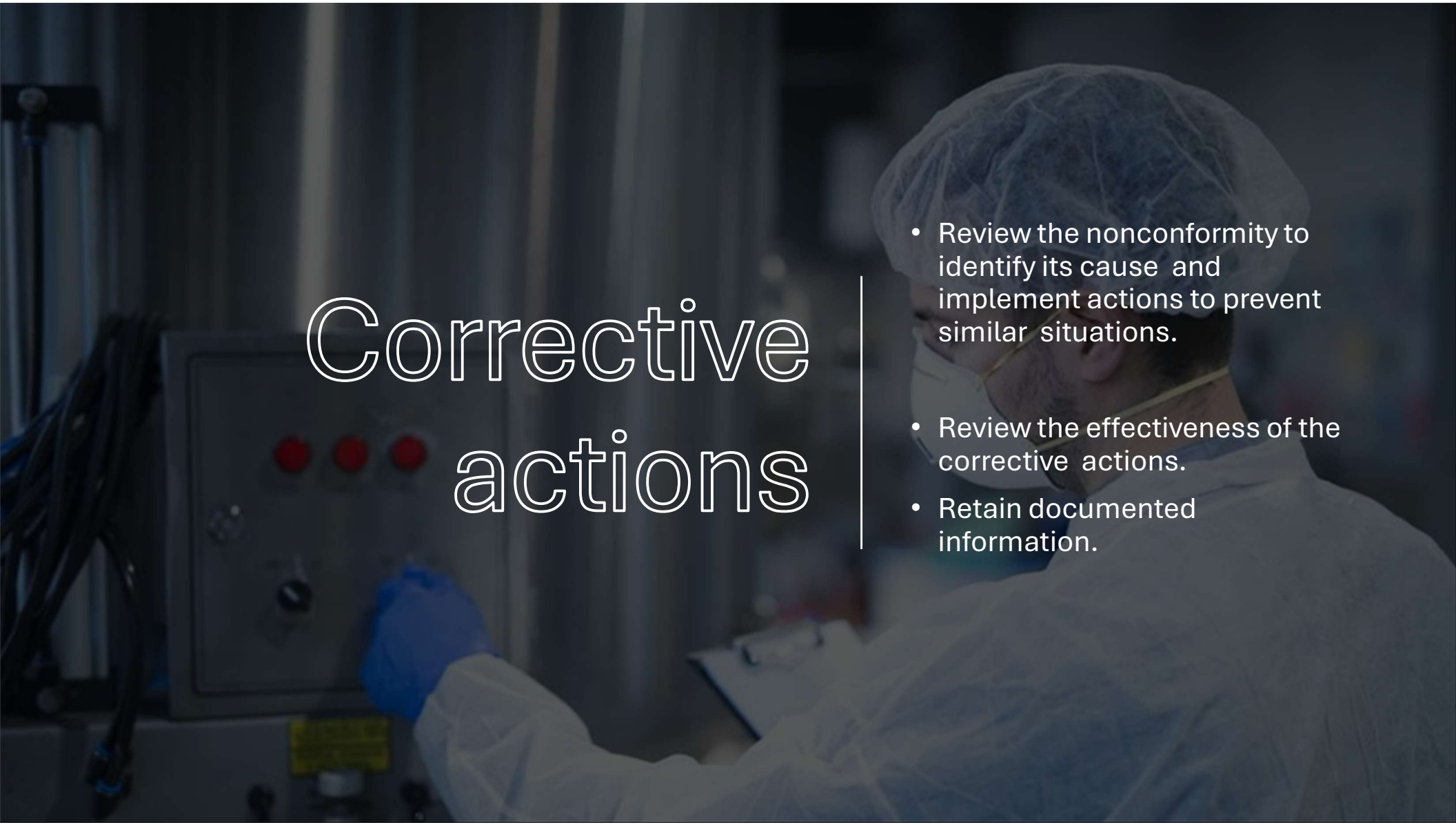
- Correction – deals with the effects of a nonconformity.

- Corrective action – deals with the cause of the nonconformity.



Corrections

- Whenever critical limits or action criteria are not met the organization shall ensure that the products affected are identified and controlled.
- If the critical limit is not met (CCP) = potentially unsafe product.
- If the action criterion is not met (OPRP) = evaluation and decision on the products affected.
- Documented information retained



Corrective actions

- Review the nonconformity to identify its cause and implement actions to prevent similar situations.
- Review the effectiveness of the corrective actions.
- Retain documented information.

Nonconforming vs. Unsafe

- A nonconforming product may be unsafe for consumption, or not.

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Potentially unsafe products

- Potentially unsafe products shall be prevented from entering the food chain (with conditions).
- Products affected by a nonconformity must be evaluated.

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Evaluation for release

If the nonconformity relates to a CCP (critical limit not met) – the product will not be released.

Options: reprocess, repurpose, destroy or dispose.

If the nonconformity relates to an OPRP (action criterion not met) – the product can be released if:

- there is evidence that controls have been effective;

-there is evidence that the combined effect of controls maintains the hazard within acceptable levels; or

-sampling, analysis or other verification activities demonstrate that the affected products conform to the acceptable levels for the hazard in question.

Withdrawal/ recall

- The organization must be able to ensure the timely withdrawal/ recall of lots of end products that have been identified as potentially unsafe.

Withdrawal/recall

- Withdrawal/ recall procedures(s):
  - initiation of the withdrawal/ recall;
  - notification of interested parties;
  - responsibilities;
  - handling of recovered products + products still in stock;
  - investigation and documented information to be retained.

- Verify the effectiveness of withdrawals/ recalls (e.g. mock recalls) and retain documented information.

Recapitulation (Operations)

- Plan, implement, and control operations to ensure food safety.
- Establish, implement, and maintain PRPs to control food safety hazards.
- Implement a traceability system to identify product batches and their status.
- Plan responses to food safety emergencies and test the plan regularly.
- Establish control measures for food safety hazards through HACCP and PRPs.
- Keep hazard control plans and PRPs up to date based on changes.
- Monitor and measure processes to ensure food safety effectiveness.
- Verify that PRPs and hazard control plans are effective.
- Manage nonconformities to prevent unsafe products from reaching consumers.

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What is a best practice for monitoring Critical Control Points (CCPs) as part of the HACCP plan?

- Relying on manual monitoring of CCPs without regular verification
- Establishing real-time monitoring methods with documented results
- Performing corrective actions before the monitoring step is complete
- Verifying CCPs only during annual external audits

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5 of 5

Show correct answer

Clause 9: Performance evaluation

S. No.	Clause No.	Clause name
1.	9.1	Monitoring, measurement, analysis and evaluation
2.	9.2	Internal audit
3.	9.3	Management review

9.1. Monitoring, measurement, analysis and evaluation

- The organization shall determine:

✓ what to monitor and measure;

✓ how to monitor and measure (i.e. methods);

✓ when to monitor and measure;

✓ when to analyze and evaluate the results;

✓ who will analyze and evaluate the results.

KPIs (Key Performance Indicators)

Analysis and evaluation

- The data and information collected through monitoring and measuring, the results of verification activities and the results of audits shall be analyzed and evaluated.

- The results of the analysis and the resulting actions shall be retained as documented information.

9.2. Internal Audit

- The organization shall conduct internal audits of the FSMS at planned intervals.
- The purpose of the internal audit is to determine whether the FSMS:
  - conforms to requirements;
  - is effectively implemented and maintained.

ISO 19011 - Guidelines for auditing management systems

Internal audit programme

- When planning the internal audits consider:
- the importance of processes;
- changes in the FSMS;
- the results of monitoring and measuring;
- previous audits.

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For each internal audit

- select competent and impartial auditors;
- develop an audit plan (to include at least the audit objectives, scope and criteria);
- generate an internal audit report;
- implement corrections and corrective actions for the findings, as necessary;
- Inform the food safety team and the management on the results;
- retain documented information as evidence (programme, plans, reports, etc)

9.3. Management review

- The top management shall review the FSMS at planned intervals.
- Input elements:
  - status of actions from previous reviews;
  - changes;
  - the performance and effectiveness of the FSMS;
  - adequacy of resources;
  - emergency, incident, withdrawal/ recall;
  - requests, complaints, relevant communications received;
  - opportunities for improvement.

Management review

- Output elements:
  - decisions and actions for continual improvement;
  - updates and changes to the FSMS
- Documented information retained as evidence.

Recapitulation (Performance Evaluation)

- Monitor, measure, and evaluate the performance of the FSMS.
- Conduct internal audits to ensure FSMS compliance and effectiveness.
- Review FSMS performance and suitability at planned intervals.

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Who is responsible for ensuring that internal audits are conducted effectively?

- External food safety consultants
- Top management
- Internal auditors appointed by the organization
- Food safety team leader only

Treemap | Bar

Next question

5 of 5

Show correct answer

Clause 10: Improvement

S. No.	Clause No.	Clause name
1.	10.1	Nonconformity and corrective action
2.	10.2	Continual improvement
3.	10.3	Update of the food safety management system

Management of nonconformities

- React – to control and correct the situation and deal with the consequences (correction).
- Review the nonconformity to determine its cause. Implement corrective actions.
- Review the effectiveness of the corrective actions. Retain documented information.

Continual improvement

- The organization shall improve continually the suitability, the adequacy and the effectiveness of its FSMS.

Update of the FSMS

- The FSMS must be continually updated.
- The food safety team shall evaluate the FSMS at planned intervals.

Recapitulation (Improvement)

- Identify, correct, and prevent recurrence of nonconformities.
- Continuously improve the effectiveness of the FSMS.
- Update FSMS to reflect changes, improvements, and lessons learned.

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What tool is most commonly used for identifying continual improvement opportunities?

- Financial audits
- Management reviews and performance data analysis
- Competency evaluations for internal auditors
- Supplier inspection reports

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5 of 5

Show correct answer

Certification for organizations

- achievable for **any organization**
- following an **initial certification audit**
- valid for **3 years**
- annual **surveillance audits**

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Audits: Definition, Principles, and Types

Audit

- “Systemic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.”

- Alternative Definitions:
  - Impartial documented activity
  - Follows written checklists and documentation
  - Uses examination of audit evidence to determine the existence of objective evidence
  - Verifies that applicable processes of a QMS have been identified and are effectively controlled.

Reasons for Conducting Audits

- To examine the Food Safety Management System for Improvements
- To ensure ISO 22000, and all other standards, are being complied with.
- To determine compliance or non-compliance
- To meet regulatory requirements
- To enable certification

Effective Audits - Requirements

- Timely access to facilities, documents and personnel, including top management
- Defined auditing procedures
- Support/involvement of management
- Competent audit team
- Impartial and objective audit team

Type of Audit

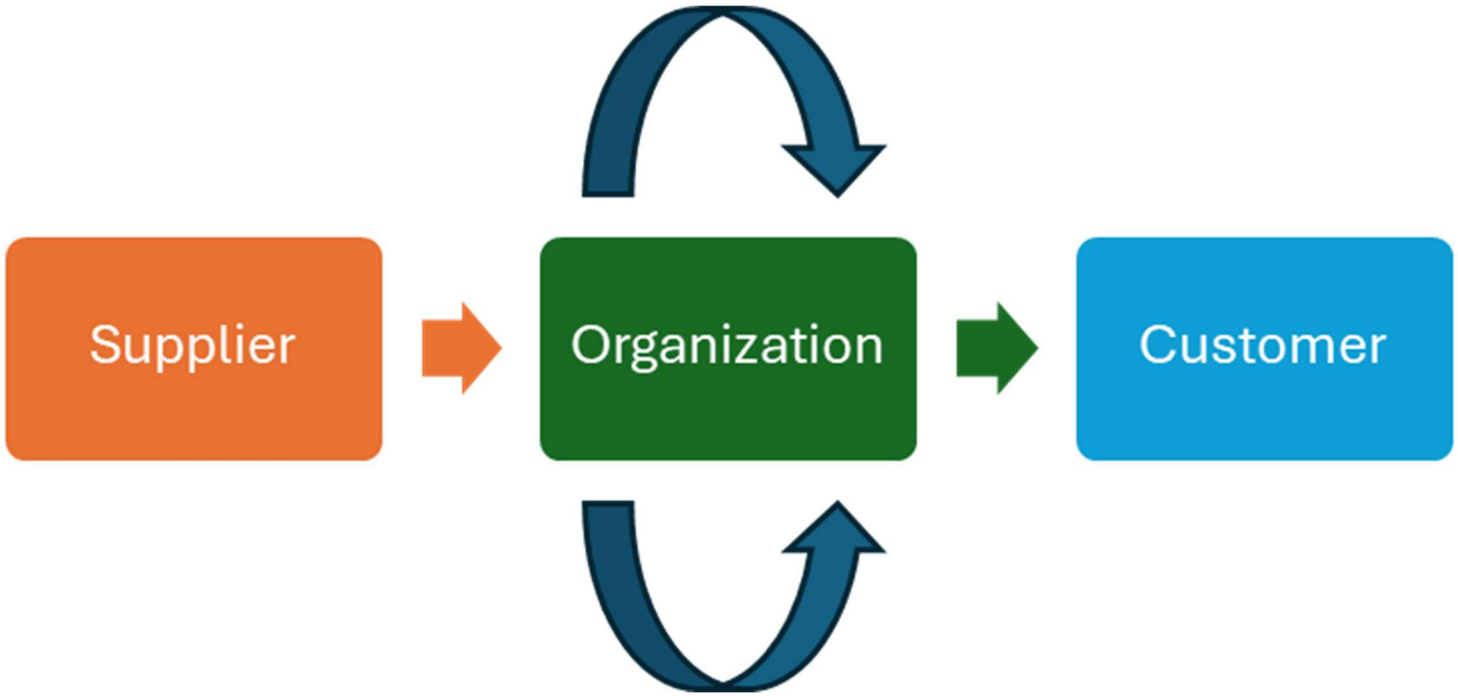
First Party Audits

Second Party Audits

Third Party Audits

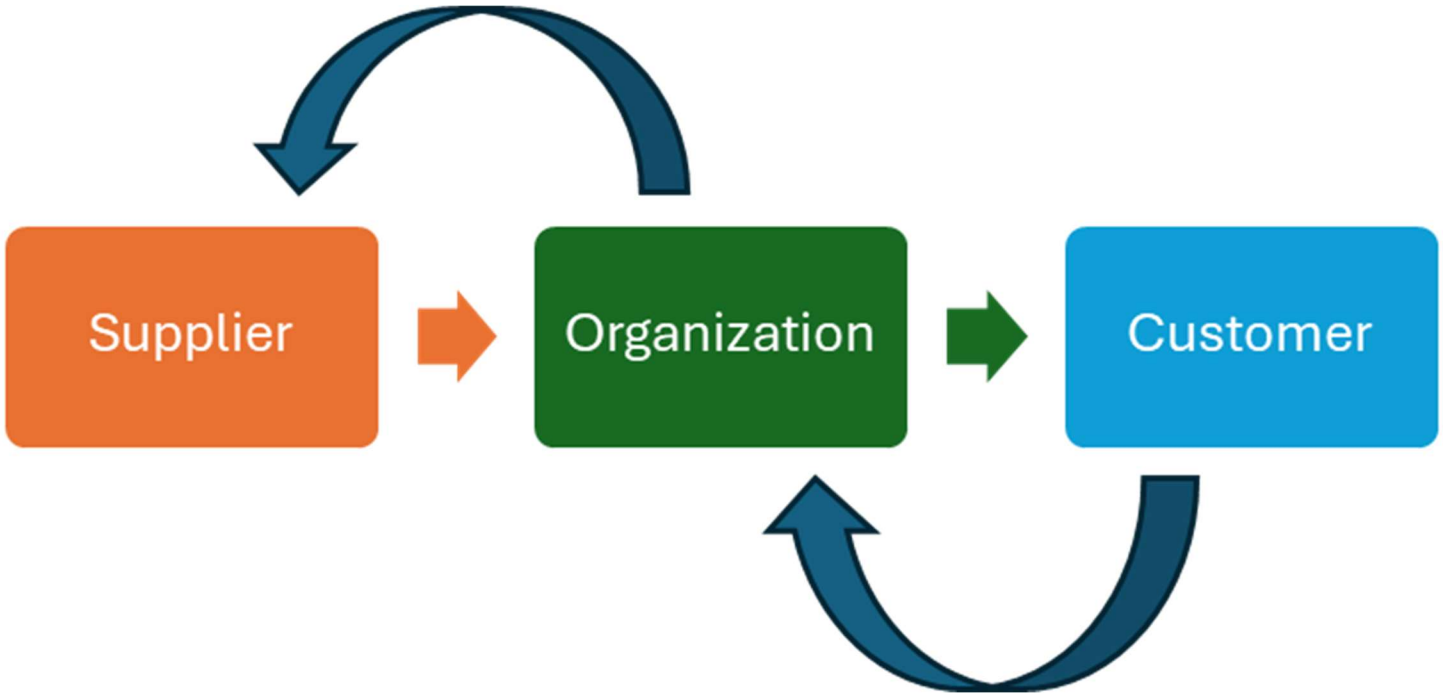
First Party Audit

- Internal audits
- Performed within an organization
- Auditors have no vested interest in the area being audited



Second Party Audit

- Performed by Customers on suppliers
- Before or after awarding a contract



Third Party Audit

- Performed by an audit organization independent of the customer-supplier relationship
- Free from any conflict of interest

Audit participants

Client – Organization or person requesting the audit

Auditor – A Person who conducts the audit

Auditee – Organization or individual being audited

Client, responsible for..

- Initiates audit
- Determines audit purpose and scope
- Provide resources
- Receives the audit report
- Determine the report distribution

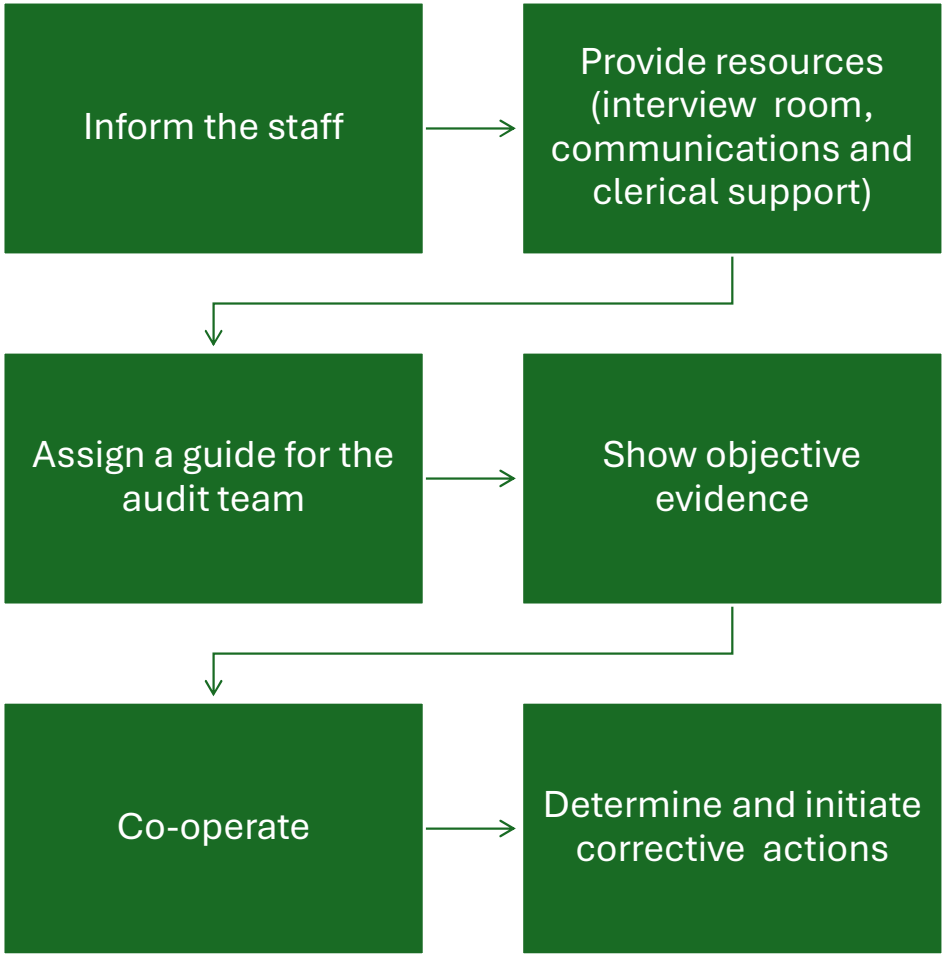
Auditor, responsible for…

- Understand the purpose, scope and audit criteria.
- Plans the audit
- Perform the audit
- Collect audit evidences
- Analyze audit evidences
- Reports the audit
- Follows up the action on audit findings

Lead auditor, responsible for...

- Balance the strength and weaknesses of team members
- Manage the audit process
- Represent the audit team
- Lead the audit team
- Prepare and complete the audit report

Auditee, responsible for...



Audit participants - 2

Technical Expert – a person who provides specific knowledge or expertise to the audit team.

Observer – a person who accompanies the audit team but does not audit.

Guide – a person appointed by the auditee to assist the audit team.

Phases of an Audit

Phases of an Audit

- Planning
- Preparation
- Performance
- Reporting and Follow Up

Planning the Audit Stage

- Frequency and timing
- Responsibility
- Criteria
- Scope
- Methods
- Duration

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Planning Internal Audits

Frequency and timing:	Based on status and importance
Responsibility:	Competent auditor with technical knowledge
Criteria:	Organization's own procedures, specifications, documents, etc. Internal Standards e.g., ISO 22000:2018
Scope:	A process An area of the company, e.g. distribution, Quality control, servicing
Duration	Depends on the size of the scope

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Planning Second Party Audits

Frequency and timing:	As determined by the organization
Responsibility:	Competent auditor with technical knowledge
Criteria:	Contractual obligations Organization's management system ISO 22000 or other agreed standards
Scope:	The entire facility An area of the company, e.g. a product line
Duration	Depends on the size of the scope

Planning third Party Audits

Frequency and timing:	Responsibility:	Criteria:	Scope:	Duration
• As determined by the accreditation	• Qualified auditor with technical knowledge & experience	• ISO 45001 or other standards	• Entire organization • Management system operations as defined by applicable standard	• Depends on accreditation requirements

Audit Procedure

- External audits are usually agreed in advance with the auditee and carefully planned, however ‘unannounced audits’ may be carried out by the Certification Bodies or Customers and their representatives as a policy or when there is some justification for such an audit

Activities Prior to the Audit

Create audit program and audit plan and notify the auditee

Arrange audit logistics

Prepare audit checklist

Audit preparation

Notify person to be audited and agree to a date and time

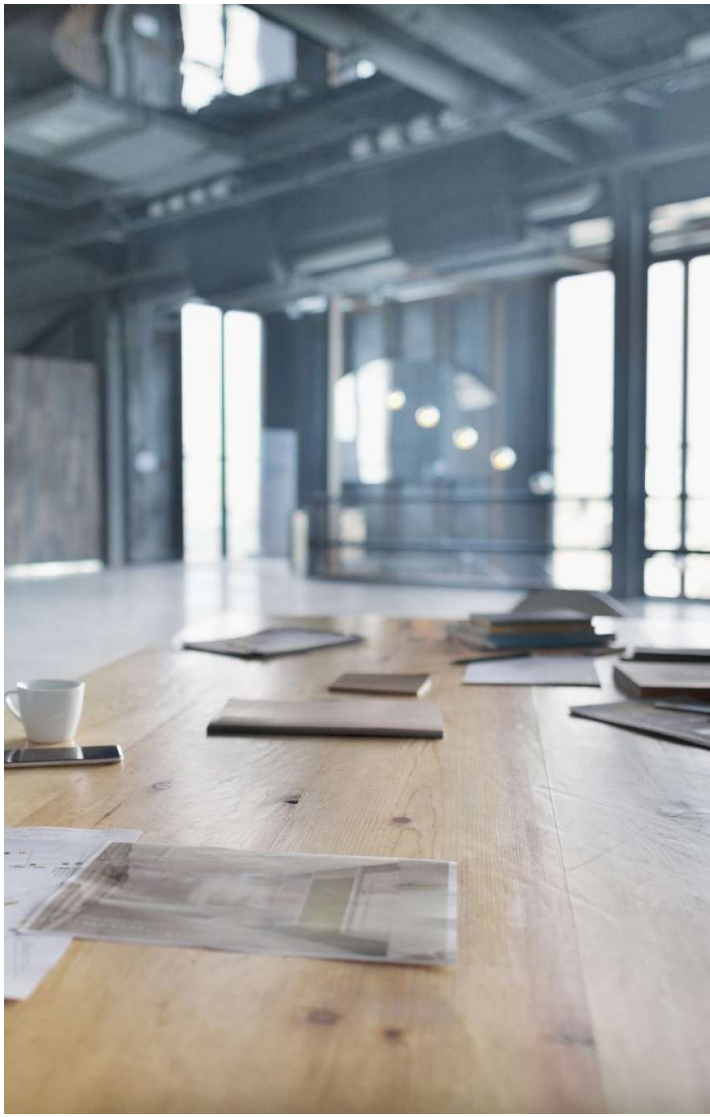
Review documents: procedures, forms, previous reports, corrective action requests, work instructions, etc.

Prepare/review/update checklists

Brief auditor/team

Arrange for Audit Logistics

- Travel and accommodation
- Safety and security considerations
  - Personal Protective Equipment (PPE)
  - Location and/or Camera Permit
- Need for a Guide
- Translators
- Facilities
  - Working area, conference room, internet, printer, tea/coffee and working lunch



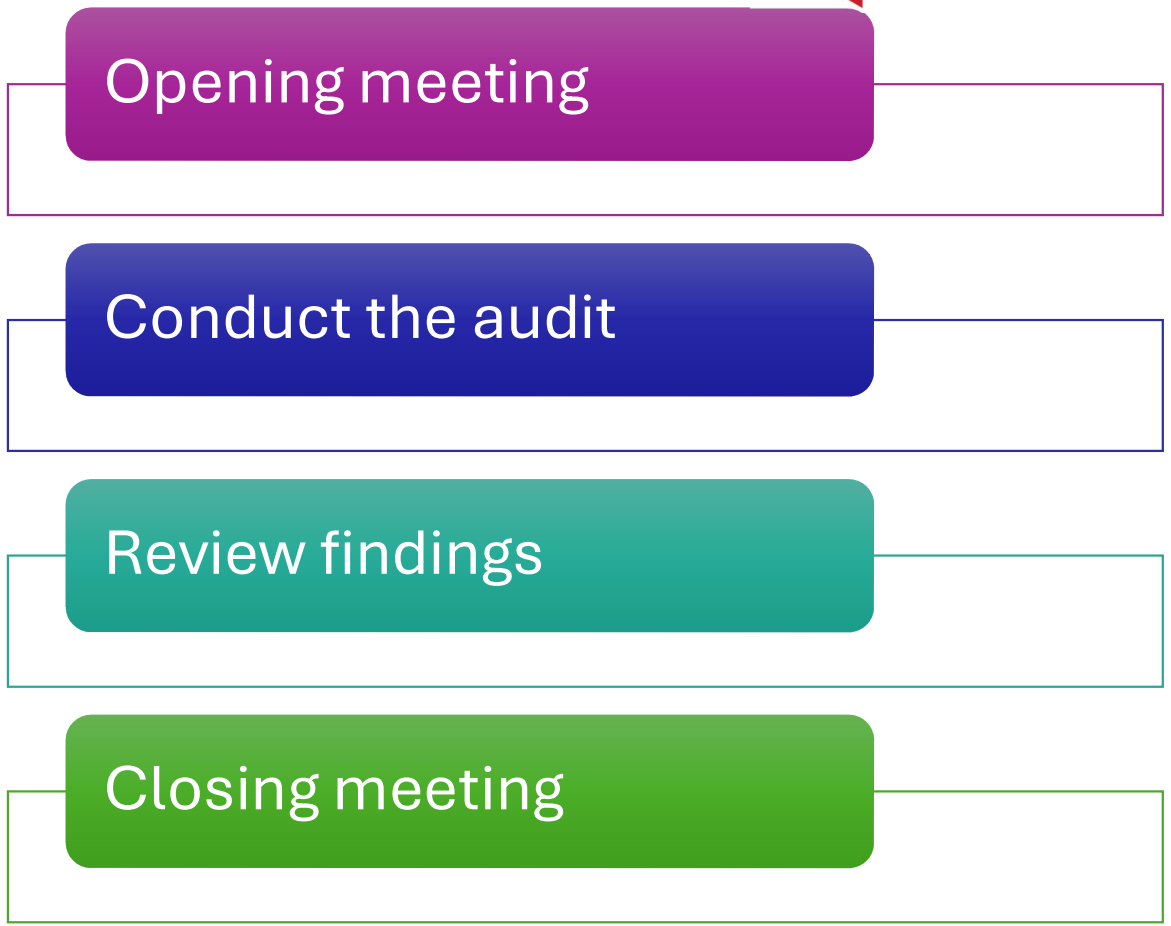
Audit Checklist

The Checklist	The Purpose of the Checklist	Risks of the Checklist
• To be used as a working document and as a record • Tool to audit company processes, not standard • Should follow the natural process of the organization	• To provide guidance to the auditor • To ensure that the audit scope is covered (processes, activities) • To reinforce the objectives and scope of the audit • To act as a record	• Too focused on a single area • Insufficient information included to evaluate conformance in interviews • Not customized to reflect company's practices

Sample Checklist

Audit Checklist		Assessment No.
Specification	Location	Date
REQUIREMENT	SPEC	OBSERVATIONS
		Sheet of form QA1

Audit Performance



Opening Meeting

- Introduce auditors or audit team
- Discuss audit scope and process
- Explain reporting and follow-up procedures
- Necessary for:

  a) Good communication

  b) Co-operation

  c) Openness

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The Auditor must:

- Deal with top management
- Understand the key issues in the organization
- Focus on the critical processes
- Audit for business improvement
- Meet the area representative first
- Always talk to those performing the task
- Explain the purpose of the visit
- Be calm, polite, reassuring
- Never talk down
- Never act superior
- Speak clearly and carefully

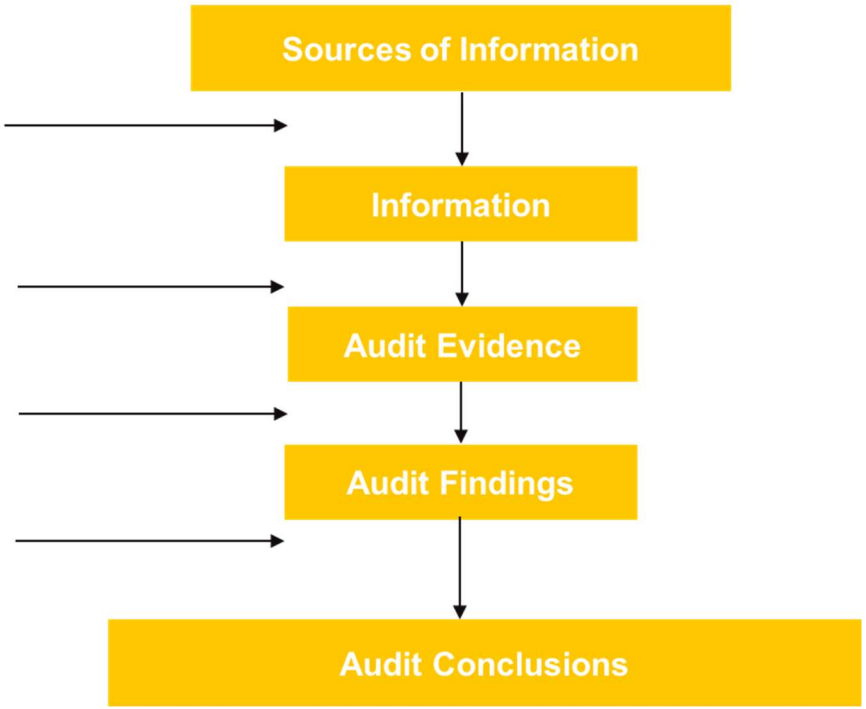
The Auditor Process

Gathering & selecting
(by document review, interviewing,
observing, etc.)

Verification

Comparison with audit criteria

Review



Obtaining objective (audit) Evidence

May be gathered from:

- Interviews with people
- Observation of activities
- Interactions between functions, activities, processes
- Measurement of processes and programs
- Documents/records
- Data summaries, reports from other sources (e.g., customer feedback)

- People:
  - Does anyone understand the systems and documentation?
  - Are the employees competent?
  - Is there co-operation?
  - Are there any system problems?

Obtaining objective (audit) Evidence (Continued)

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- Observation of activities
  - Are the processes efficient? Effective?
  - Are things in logical sequence?
  - Are the interactions between processes defined?
  - What is the significance of links between processes?
  - Can inputs and outputs be identified?
- Measurement of processes and programs
  - Capacity of processes
  - Product measurement
  - Accuracy
  - Dependability
  - Cycle times
  - Resource utilization
  - Productivity

Obtaining objective (audit) Evidence (Continued)

Documents/records

- Issue status?
- Complete and concise?
- Condition?
- Legibility?
- Identity?
- Approval?
- Availability?

Data summaries

- Customer feedback
- Vendor analysis
- Internal Audits
- Financial measurements
  - Preventive, appraisal and failure cost analysis (Cost of quality)
  - Cost of nonconformity

Examine objective Evidence

Examine:

- Documents/data
  - Fully complete
  - Accurate data
  - Check for authorization
  - Review analysis of data
- Physical Evidence
- Environmental Conditions

Establish:

- Extent of conformity/nonconformity
- Nature for nonconformity
- Sample: According to the amount and variety of evidence

Use the Checklist

- To record conformity/nonconformity
- To track where you are and manage time
- To control the pace of the audit and manage auditee personalities
- To ensure all areas are covered
- To make notes for follow-up in other areas
- For future reference

Questioning Techniques

Who?

What?

When?

Where?

Why?

How?

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Controlling the Audit

- Insist that people being questioned answer for themselves
- Do as little talking as possible
- Do not let others dictate the pace
- Rephrase misunderstood questions
- Give compliments
- Say, “Thank you”
- Be aware of hidden agendas and emotional blackmail

Some Basic Issues

- Establish that the company is demonstrating control over the operation
- Involve management in the audit process
- Observe work progression when possible
- Evaluate physical objective evidence
- Examine inputs and outputs
- Make comprehensive notes

Some Basic Rules

Seek verification

- Do not assume people will lie, but seek to verify statements if necessary

Do not accept pre-prepared samples

- Choose your own

General Principles of Auditing

- **Integrity –** the foundation of professionalism
- **Fair presentation –** the obligation to report truthfully and accurately
- **Due professional care –** the application of diligence and judgment in auditing
- **Confidentiality –** security of information
- **Independence –** the basis for the impartiality of the audit and objectivity of the audit conclusions
- **Evidence-based approach –** the rational method for reaching reliable and reproducible audit conclusions in a systematic audit process

Auditor's Personal Attributes

Ethical – Fair, truthful, sincere, honest and discreet

Open-minded – willing to consider alternative ideas or points of view

Diplomatic – tactful in dealing with people

Observant – actively observing physical surroundings and activities

Perceptive – aware of and able to understand situations

Versatile – able to readily adapt to different situations

Tenacious – persistent and focused on achieving objectives

Decisive – able to reach timely conclusions based on logical reasoning and analysis

Self-reliant – able to act and function independently whilst interacting effectively with others

General knowledge and skills of Management System Auditors

- Audit principles, procedures and methods
- Management system and reference documents
- Organizational context
- Applicable legal and contractual requirements and other requirements that apply to the auditee
- Discipline and sector-specific knowledge and skills of management system auditors

Generic Knowledge and Skills of Audit Team Leaders

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Audit team leaders should be able to:

- Balance the strengths and weaknesses of the individual audit team members
- Develop a harmonious working relationship among the audit team members.
- Plan audits and effectively use audit resources
- Manage the uncertainty of achieving audit objectives
- Protect the health and safety of the audit team members including compliance with the requirements
- Organize and direct the audit team members
- Provide direction and guidance to auditors-in-training
- Prevent and resolve conflicts as necessary
- Represent the audit team
- Lead the audit team to reach the audit conclusions
- Prepare and complete the audit report

Good Practices for Auditors

- Introduce self and/or audit team
- Ensure agenda is understood
- Keep to agenda
- Keep control of the audit and time
- Avoid arguments
- Listen
- Keep records
- Remain polite, calm, professional

Audit Review

- Conduct a private review when the audit is finished
- Interim or “end of the day” reviews (or both) may be appropriate
- Review and complete checklists
- Study and compare notes (team)
- List nonconformities

Analyzing Results

Review if:

- The deficiency is an isolated error or a breakdown of a system
- Auditee is aware of the problem
- The deficiency has been reported before

Closing Meeting


Explain/discuss the findings


Obtain agreement


State overall degree of conformity


Mention the positive points

Internal audits	Second party audits	Third party audits
• Informal • Constructive • System improvement	• Contracts at stake • Reports used as future reference • More emotional situation than first party audit meeting • Be prepared to be challenged	• Contracts at stake • Reports used as future reference • More emotional situation than first party audit meeting • Be prepared to be challenged

Non-conformance management in first party audits

- **Identification**: Auditors identify non-conformities against the organization's internal procedures or ISO requirements.
- **Recording**: Non-conformances are documented in the audit report.
- **Corrective Action**: The organization takes corrective actions to address root causes and prevent recurrence.
- **Verification**: Follow-up audits or reviews ensure actions are implemented effectively.
- **Purpose**: Improve internal systems, ensure compliance, and prepare for external audits.

Non-conformance management in second party audits

- **Identification**: Non-conformities against agreed terms, product specifications, or food safety requirements are identified.
- **Reporting**: Issues are communicated to the supplier formally.
- **Corrective Action**:
  - The supplier is required to provide a Corrective Action Plan (CAP) within a specified timeline.
  - Actions include root cause analysis, corrective measures, and preventive actions.
- **Verification**: Follow-up audits or supplier reviews are performed to verify corrections.
- **Purpose**: Ensure suppliers meet contractual obligations and quality standards.

Non-conformance management in third party audits

- **Identification**: Non-conformities are classified as:
  - Major: Systematic failures or high-risk non-compliance.
  - Minor: Isolated issues that don't pose significant risk.
- **Reporting**: Non-conformities are included in the audit report and communicated to the auditee.
- **Corrective Action**:
  - Auditees must submit an action plan with root cause analysis, corrective actions, and preventive measures.
  - A timeline is set to resolve major non-conformities (often 30-90 days).
- **Verification**:
  - Major non-conformities require evidence submission and/or re-audit.
  - Minor non-conformities are checked during the next surveillance audit.
- **Purpose**: Achieve certification, regulatory compliance, or demonstrate conformity to standards.

Nonconformance Statement

A short statement describing the nonconformity including:

- What - The issue in question
  (a statement of nonconformity)

- Why - What the statement is raised against?
  (the requirement, or specific reference to the requirement)

- Objective Evidence - The objective evidence found
  (the objective evidence observed that supports statement of nonconformity)

Nonconformance report

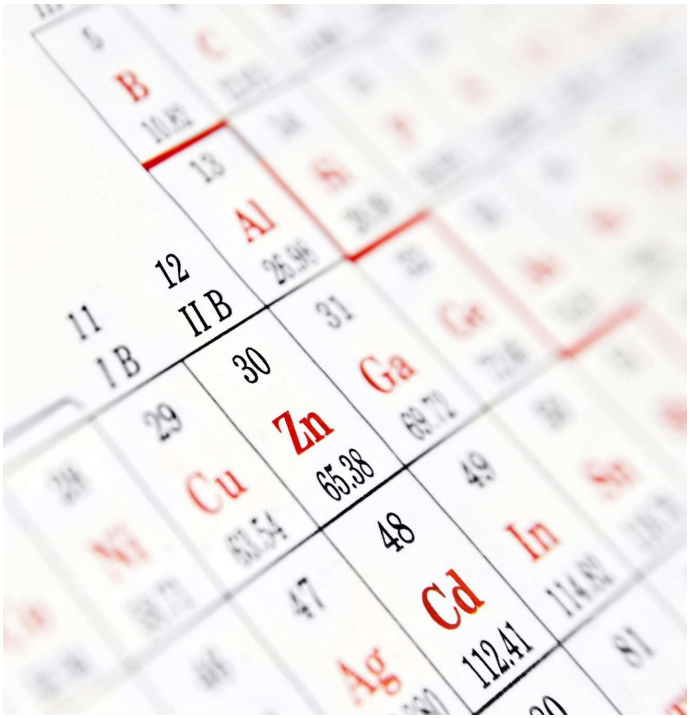
- Used to report non-conformity audit findings
- Must be factual
- Must be understandable and traceable
- Raise non-compliances on completion of an audit
- Allow the auditee to implement corrective action prior to the closing meeting
- The auditee is requested to sign signifying an understanding and acceptance of the non-compliance

Wording of NC report

- It is important when preparing and wording NC-Report's to take care and ensure it is justified
- Failure to achieve clear information will invite challenge of the findings at the closing meeting
- This will be particularly important in areas where the emphasis has changed with respect to the requirements in order that they will be clearly understood, i.e.
  - Management Commitment
  - Competence
  - Communication
  - Continual Improvement

Example of Nonconformance Statement

- **A statement of nonconformity:**
  - The system for monitoring the temperature of perishable food products during storage was not effectively implemented.
- **The requirement, or specific reference to the requirement:**
  - ISO 22000:2018 Clause 8.5.1 - Control of Food Safety Hazards "The organization shall establish and implement monitoring activities for critical control points to ensure food safety requirements are met.
- **The objective evidence observed that supports statement of nonconformity:**
  - No temperature monitoring records were retained for perishable food storage between January 10-12, 2024, in Warehouse Section A.



Audit Reporting

The audit report should include:

- Auditors, contracts, scope
- Overall conclusions
- Deficiencies, observations, supporting objective evidence
- Follow-up details

Exclude from Report:

- Confidential information given in interviews
- Matters not raised or discussed at the closing meeting
- Subjective opinions – use only verifiable facts / objective evidence
- Ambiguous statements
- Antagonistic words or phrases

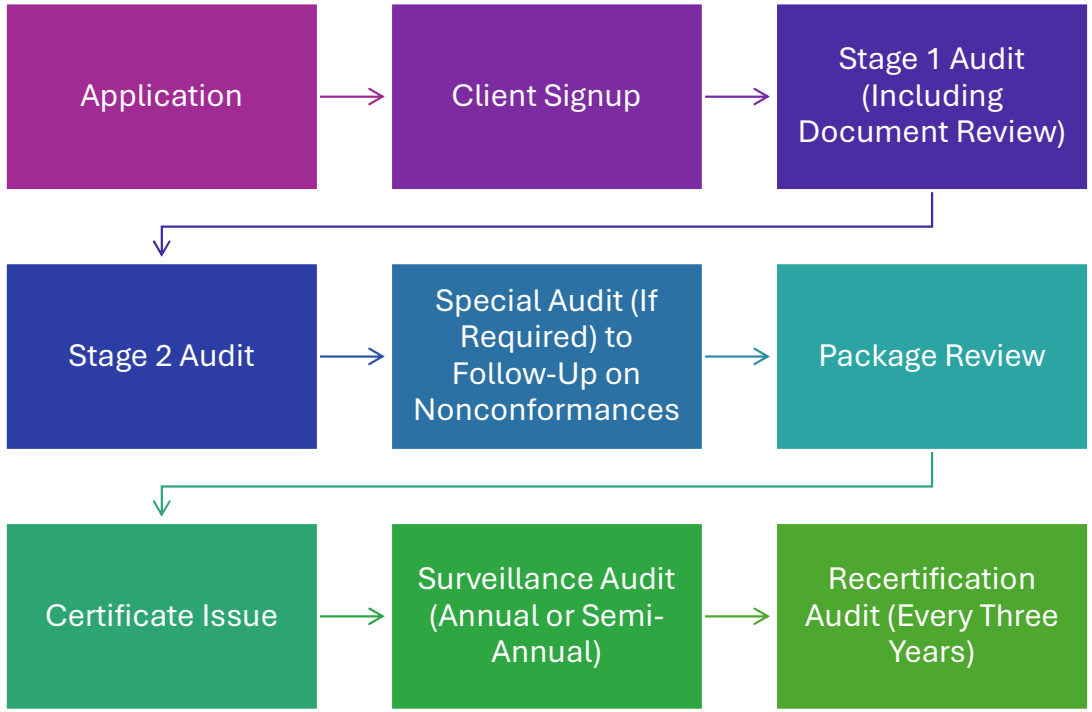
Audit Reporting

- Description of audit aim, purpose and scope
- Number of non-compliances and summary of audit findings
- Description of good points and any main concerns
- Description of the identified opportunities for improvement
- Recommendations made because of audit findings

Audit Follow-Up

- Verify that action(s) are implemented
- Ensure short- and long-term effectiveness
- Record follow-up details & objective evidence reviewed
- Sign off forms

Registration Process Flow



Certifications and Internal Auditor Trainings offered

- We offered certifications and internal auditor training for -
  - ISO 9001 (QUALITY MANAGEMENT SYSTEMS)
  - ISO 14001 (ENVIRONMENT MANAGEMENT SYSTEMS)
  - ISO 45001 (OCCUPATIONAL HEALTH & SAFETY MANAGEMENT SYSTEMS)
  - ISO 50001 (ENERGY MANAGEMENT SYSTEMS)
  - ISO 27001 (INFORMATION SECURITY MANAGEMENT SYSTEMS)
  - ISO 22000 (FOOD SAFETY MANAGEMENT SYSTEMS)
  - ISO 13485 (MEDICAL DEVICES QUALITY MANAGEMENT SYSTEMS)
  - ISO 26000 (SOCIAL ACCOUNTABILITY MANAGEMENT SYSTEMS)

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Our Accreditation

- At Quality Asia Certifications, our commitment to excellence is validated through our prestigious accreditations.
- We are proud to be recognized by leading national and international accreditation body, including **NABCB (National Accreditation Board for Certification Bodies), IAF Accredited** ensuring the highest standards of quality and compliance.
- Our accreditations reflect our rigorous adherence to industry standards and our dedication to providing reliable and trustworthy certification services. These credentials are a testament to our expertise and our unwavering commitment to delivering value to our clients.
- Proud BNI (Business Network International) Member

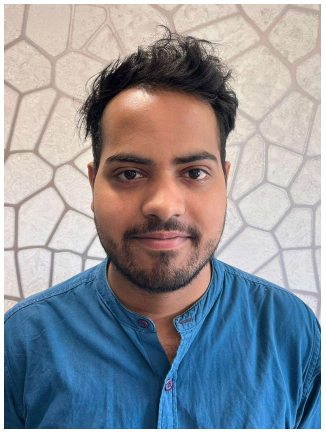
MEMBER OF MULTILATERAL IAF RECOGNITION ARRANGEMENT

NABCB QM-085

LEADERSHIP TEAM

			
Mr Atul Suri	**Mrs. Seema Suri**	**Mr Samarth Suri**	**Ms Palak Ahuja**
Lead Auditor & Reviewer	**Director - Accreditations**	**Managing Director**	**GM - Certifications**
Responsible for Leading Teams of Auditors and Establishing Excellence in Auditing Operations	Responsible for Maintaining Accreditation Status and Heading Audit Review and Certification Decision Process	Responsible for Marketing & Promotions, and ensuring Right Visibility of the Certification Body	Responsible for Heading and Managing Certification and Operations and Ensuring Client Success through Certifications

CORE TEAM

			
Mr Parveen Singh Negi	**Mr Sagar Mahour**	**Team of Auditors**	**Team of Executives**
Business Development Head	**Quality Assurance Officer**		
Responsible for Heading Sales Teams and Ensuring Customer Acquisition in the Most Ethically Right Manner	Responsible for compliance with accreditation standards, manages documentation and audits, assists in training programs, and supports marketing and operational excellence initiatives.	Responsible for Conducting Ethical and Quality Rich Audits, enabling Organizations to Understand and Upgrade their Systems and Processes	Responsible for Managing the Shows behind the scenes

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Training Information and Evaluation

Training Material will be provided to you through mail.

Training Evaluation, a google form link is provided to you through mail.

Training Feedback is the part of the Training evaluation form, please provide your valuable feedback.

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Quality Asia School and Free Training program updates...

- **Quality Asia School: Explore comprehensive training programs on various ISO standards: https://www.qualityasia.in/qasia-school.php**
- **Join our WhatsApp channel for convenient access to live training sessions: https://whatsapp.com/channel/0029VamtSmnJ93wcEDIsrT1Z**
- **Free Internal Auditor Training Calendar: Explore upcoming training sessions on various ISO standards, including ISO 14001, on our website: https://www.qualityasia.in/training-calendar.php**

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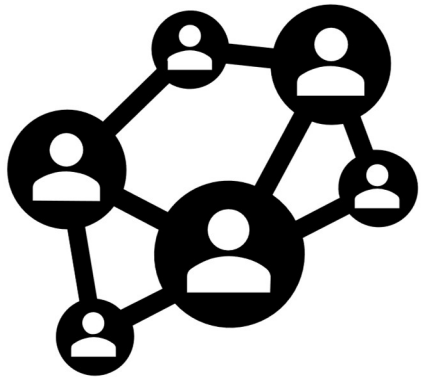

Thank You.