بِسْمِ اللهِ الرَّحْمَنِ الرَّحِيمِ

UNDERSTANDING & INTERPRETING THE REQUIREMENTS OF ISO 22000: 2005

Institute of Food Science and Nutrition (IFSN)

University of Sargodha, Sargodha- Pakistan

CONTENTS

- **Key concepts in modern FSMS & ISO-22000**
- **General requirements**
- **Management responsibility**
- **Resource management**
- **Planning & Realization of Safe Products**
- **Comparison on the requirements of HACCP, ISO9001:2008, AND ISO22000:2005**
- **Understanding the requirements of ISO 22000: 2005 validation, verification & improvement of the FSMS**
- **Implementation Of ISO 22000: 2005**
- **Auditing Of ISO 22000**
- **Certification**

KEY CONCEPTS IN MODERN
FSMS & ISO-22000

FOOD FOR THOUGHT

INTRODUCTION

"It is a concept that is use for anything that gives you

a reason to stop and ponder."

- Global Burden of Diarrheal Diseases cause 2.2 million

deaths of all ages (WHO-2004 update).

- According to an estimation these food born diseases cost

about 5.6 – 9.4 billion US$ lost in work lose and medical expense.

Food for thought

FOOD SAFETY

(Food suitable & safe for human consumption)

Food safety

"It is a concept that food will not cause harm to its consumer when

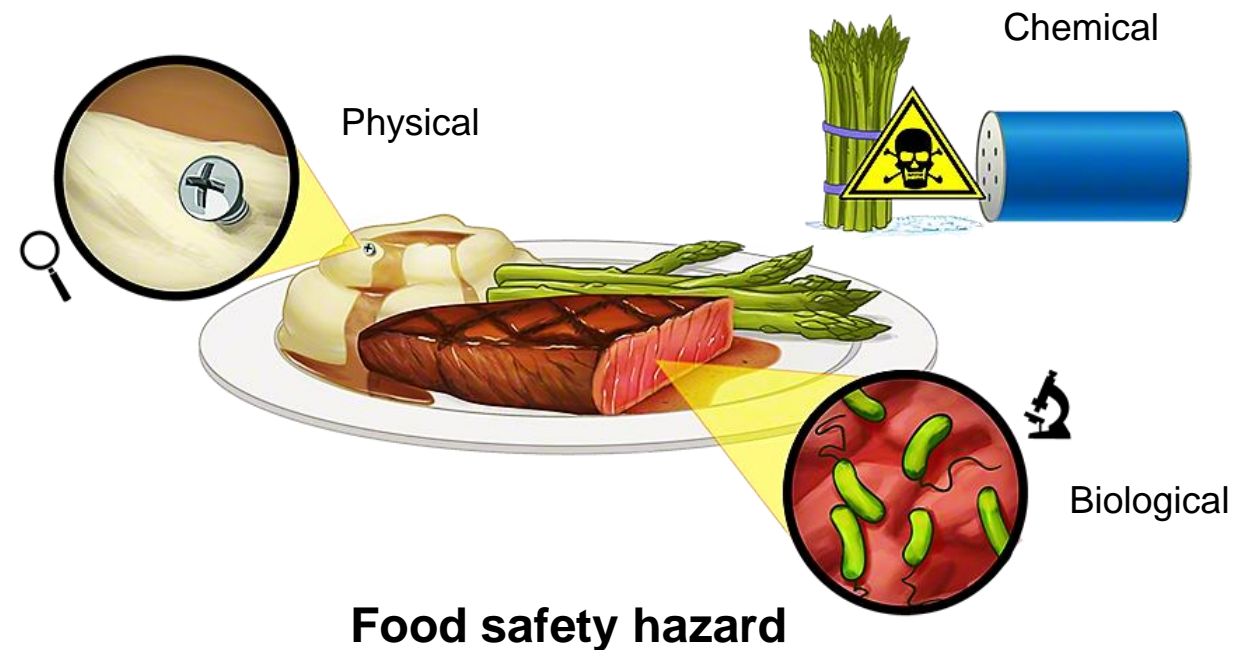it is prepared and eaten according to its intended use"

Suitable

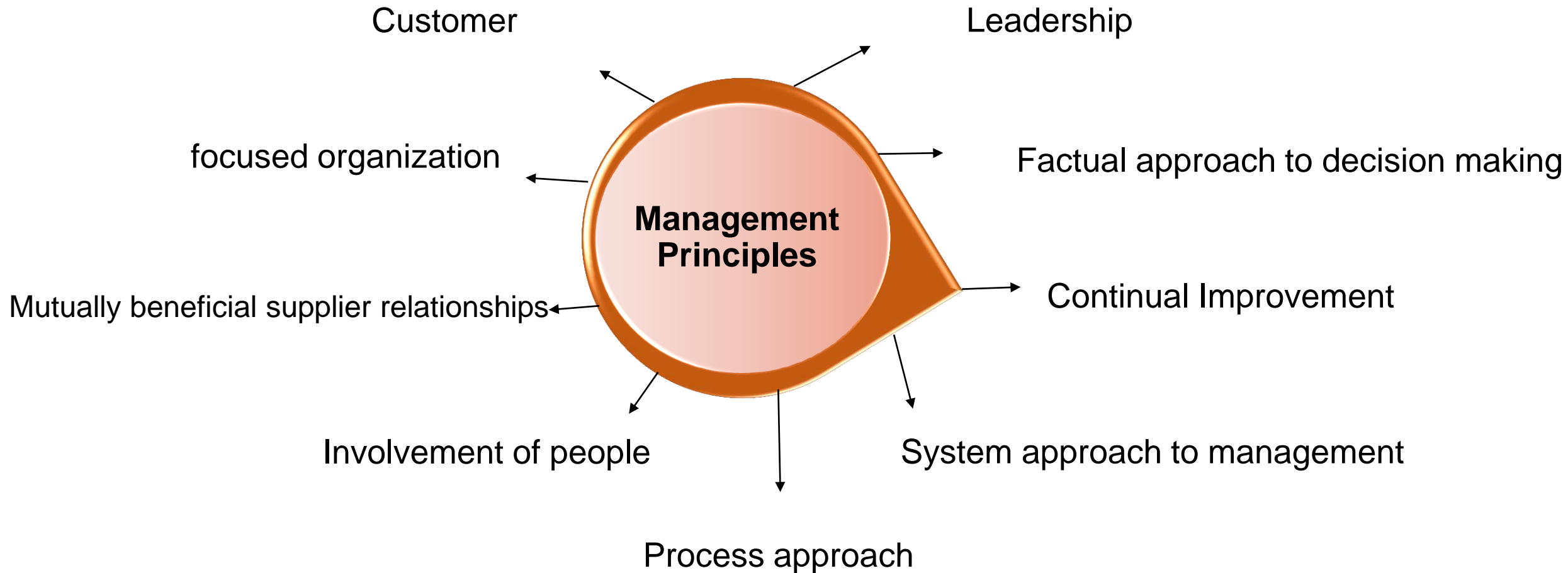- Produce under hygienic conditions.

- Appropriate for intended use

Safe

- Produce by applying all food

  safety requirements.

- Don't contain hazard at harmful

  level for human health

FOOD SAFETY HAZARD

"biological, chemical, physical agent or allergens in

food, or condition of food, with potential to cause an adverse health effect."

Chemical

Physical

Biological

Food safety hazard

FOOD MANAGEMENT SYSTEM

Customer

Leadership

focused organization

Factual approach to decision making

Management Principles

Mutually beneficial supplier relationships

Continual Improvement

Involvement of people
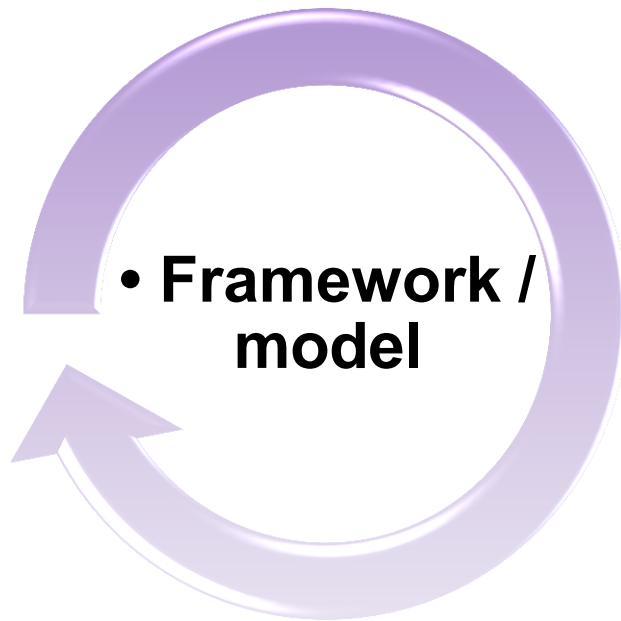
System approach to management

Process approach

FOOD MANAGEMENT SYSTEM

- **Framework / model**

- Policy

- Planning

- Implementation & operation

- Performance assessment

- Improvement

- Management review

FOOD SAFETY MANAGEMENT SYSTEM

- A set of interrelated or interacting elements (system) to establish

  policy & objectives & to achieve those objectives used to direct &

  control an organization with regard to FS.

i.   Meets food safety policy & objectives

ii.   Meets performance of "effectiveness"

iii.   Apply proven management principles.

FOOD SAFETY MANAGEMENT SYSTEM

FSMS

Well established

Documented

Continually improved / update

And its resultant products are safe,

Preventive approach,

Science based approach.

FOOD SAFETY MANAGEMENT

1. **Science Based Approach**

- Developing countries are now implementing different types of science based decisions in their day to day work.

   Example: Science based activities

1. Implement HACCP system,

2. Establish acceptable daily intake of chemical additives

3. Estimate maximum allowable exposure level to pestici

4. Use labels to warn consumers about allergens.

5. Risk analysis (by cooperation of stakeholders)

FOOD SAFETY MANAGEMENT

1. **Preventive Approach**

• Involve reaction / inspection

• Preventive approach is already well establish within industries.

Preventive approach include.

    1. Basic good practices / PRPs
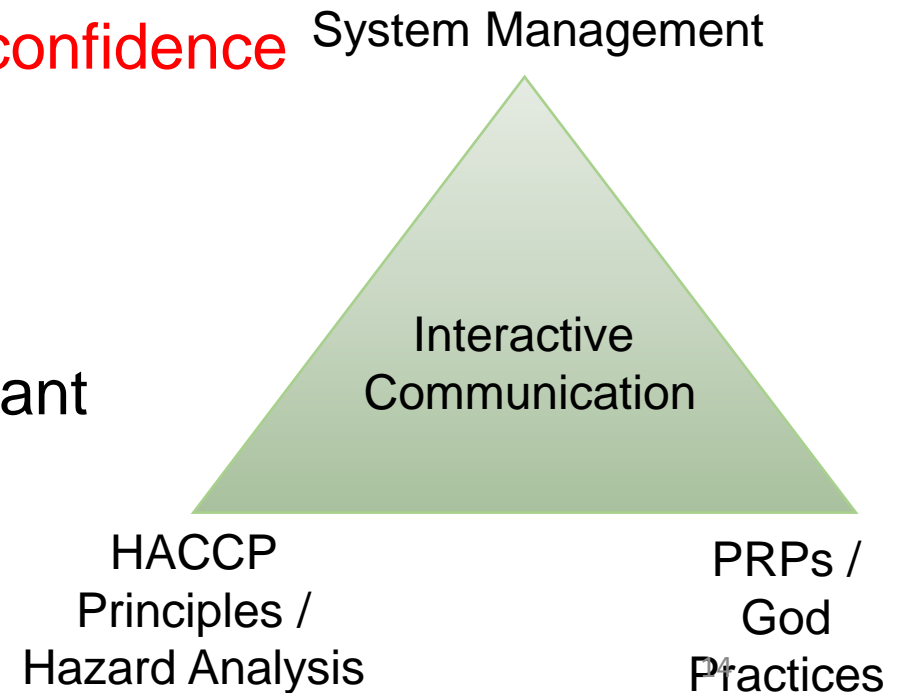
    2. HACCP

    3. Suppliers program

      (so that processors are certain about safety of their components).

FSMS --- ISO22000

- Provides a basis to design & implement a fundamentally sound FSMS.

- Represents the latest step in the evolution of FS systems beyond HACCP.

- Harmonizes national FS standards to ensure confidence through out the food chain.

Requirement

- Interactive communication is one of the important requirement of ISO22000.

System Management

Interactive Communication

HACCP Principles / Hazard Analysis

PRPs / God Practices

FSMS --- ISO22000

Structure

I.   Food chain approach

II.   Process approach

III. Continual improvement
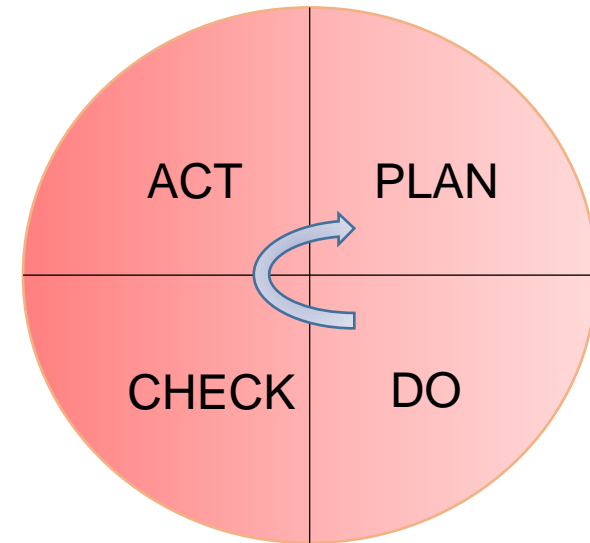
FSMS --- ISO22000

History

- ➢ 1946 – ISO founded

- ➢ 1959 – HACCP Principles by Pillsbury Co., for NASA

- ➢ 1971 _ HACCP takes official notice internationally

- ➢ 1980 – WHO reporting on HACCP

- ➢ 1983 – WHO Europe recommends HACCP

- ➢ 1991 – Codex includes HACCP in codes

- ➢ 1993 – Codex issues HACCP guidelines

- ➢ 1997 – Codex issues revised document

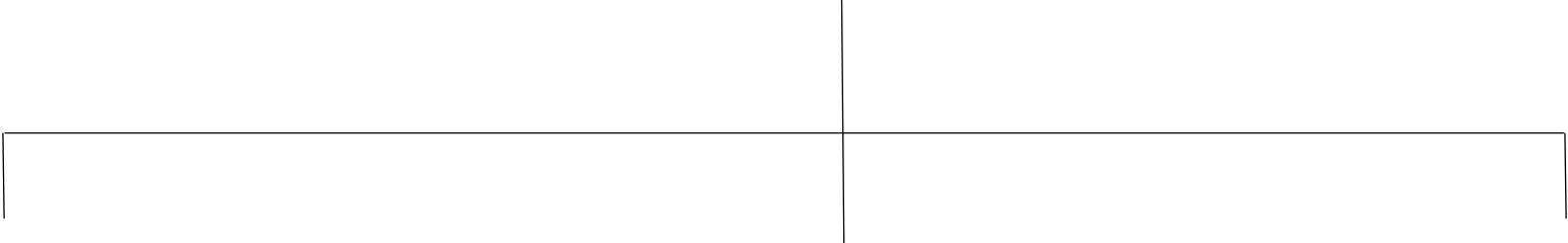- ➢ 2001 – TC 34 starts drafting ISO 22000

- ➢ 2005 – ISO 22000 adopted on 1st Sept

FSMS ISO-22000
GENERAL REQUIREMENTS

REQUIREMENT OF FSMS

- The FSMS is require because of three major purposes,
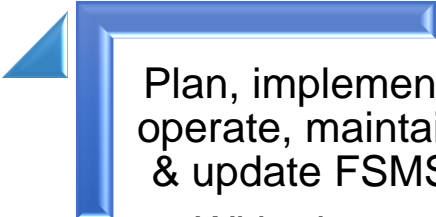
To ensure hazard free safe food at consumption time.

Consistently provide safe food

Use internal and external resources to fulfill the requirement

WHAT IS THE REQUIREMENT ?

Following are the some requirement,
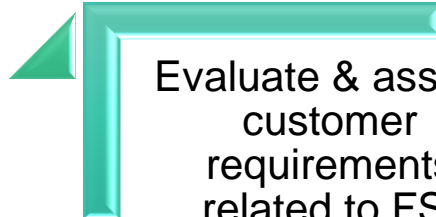
Plan, implement, operate, maintain & update FSMS
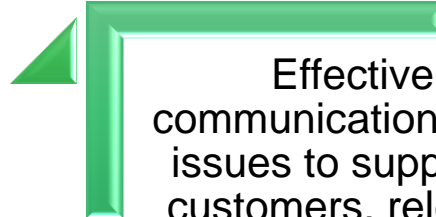
With aim to provide safe food to consumer.
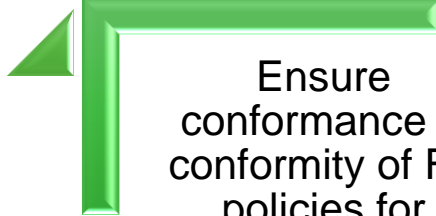
Comply with applicable FS regulations.

Evaluate & assess customer requirements related to FS,

& try to fulfill them to enhance customer satisfaction.

Effective communication of FS issues to suppliers, customers, relevant interested parties in the food chain

Ensure conformance & conformity of FS policies for interested parties.

Seek certification to FSMS

FSMS ISO22000 : 2005

Documentation requirement

- More than twenty six types of documents required by ISO 22000:2005

- Twenty eight mandatory records required by ISO 22000:2005

- Documents needed by the organization to ensure effective development, implementation and updating of the FSMS

Scope of FSMS

1. Product   2. Processes   3. Production1

EXPECTATION OF ISO22000 FSMS

EXPECTATION

Identify, evaluate & control the FS hazard of product In such a way that it will not cause any harm to consumer on consumption.

Communicate information about development, implementation and updating of the FSMS throughout the organization, to ensure the FS required by this International Standard .

Communicate appropriate information throughout the food chain regarding FS issues related to its products.

Evaluate periodically, and update when necessary, the FSMS system reflects the organization's activities and use the most recent information on the FS hazards subject to control.

FSMS ISO22000

Outsourcing

- Is the process organization needs for its FSMS but chooses to have it performed by an external party.

- Need to ensure control over all outsourced processes that may affect end product conformity.

- Control shall be identified and documented within the FSMS

OUTSOURCING

FSMS ISO22000

External Competencies

- It is used to developed, implemented, monitored, maintained and

  updated FSMS in compliance with ISO 22000 requirements.

- Externally developed combinations of PRPs and

  HACCP plans can be used.

DOCUMENTATION

Document

- Information & its supporting medium e.g. record, specification,

  procedure, drawing, report, standard

- Medium can be hard copy / soft copy, etc.

Record

- Document stating results achieved.

- Provides evidence of activities performed.

DOCUMENTATION

FSMS documentation shall include,

1. Food safety policy & related objectives.

2. Documented procedures and records required by FSMS.

3. Documents to ensure effective development, implementation and updating of FSMS.

DOCUMENTATION

Documented procedure

Establish

Documented

Implemented

Reviewed
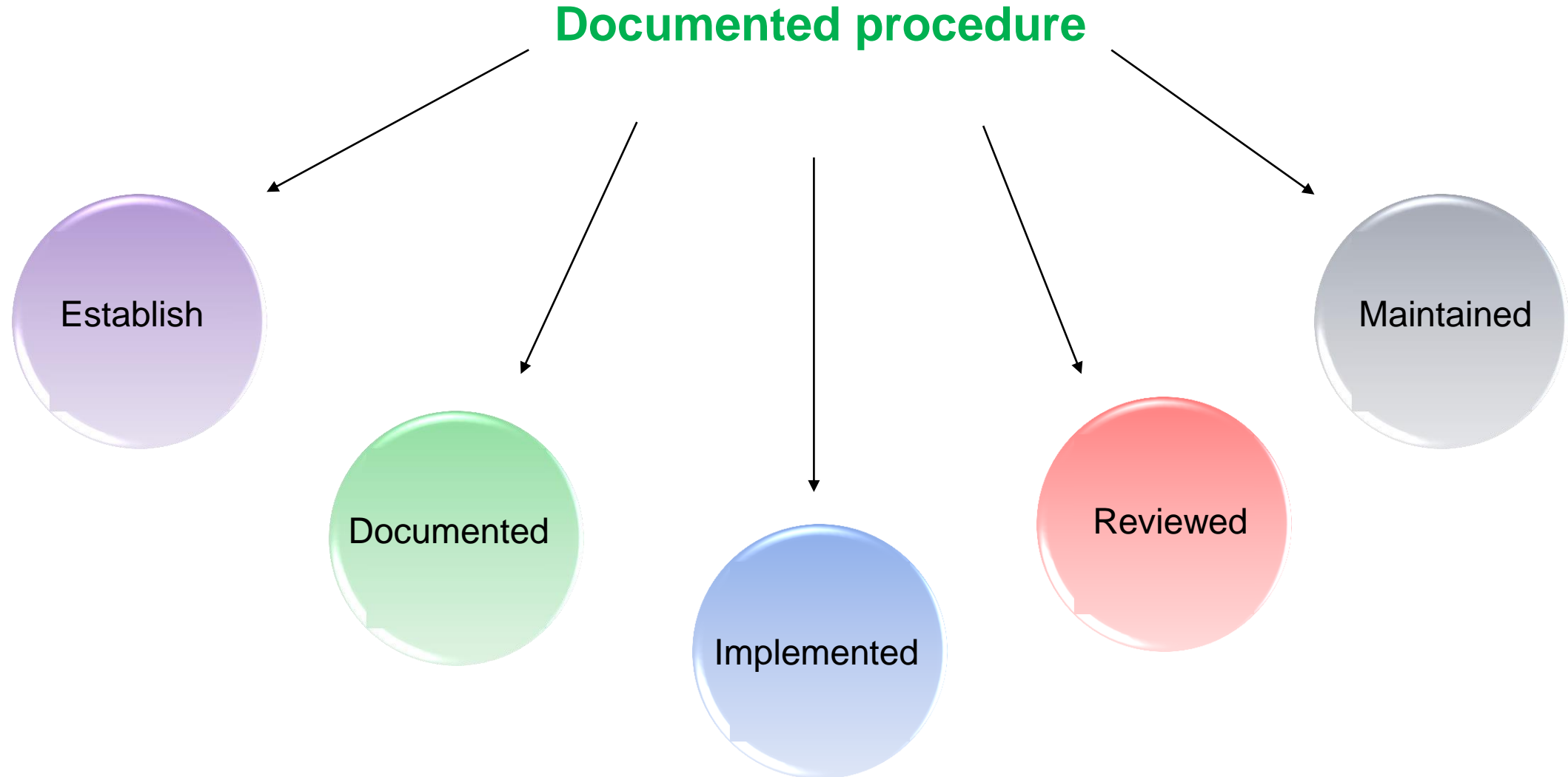
Maintained

COMPULSORY DOCUMENTED PROCEDURE

control of documents

Control of records

corrections

Corrective actions

Handling of potentially unsafe products

withdrawals

Internal audit
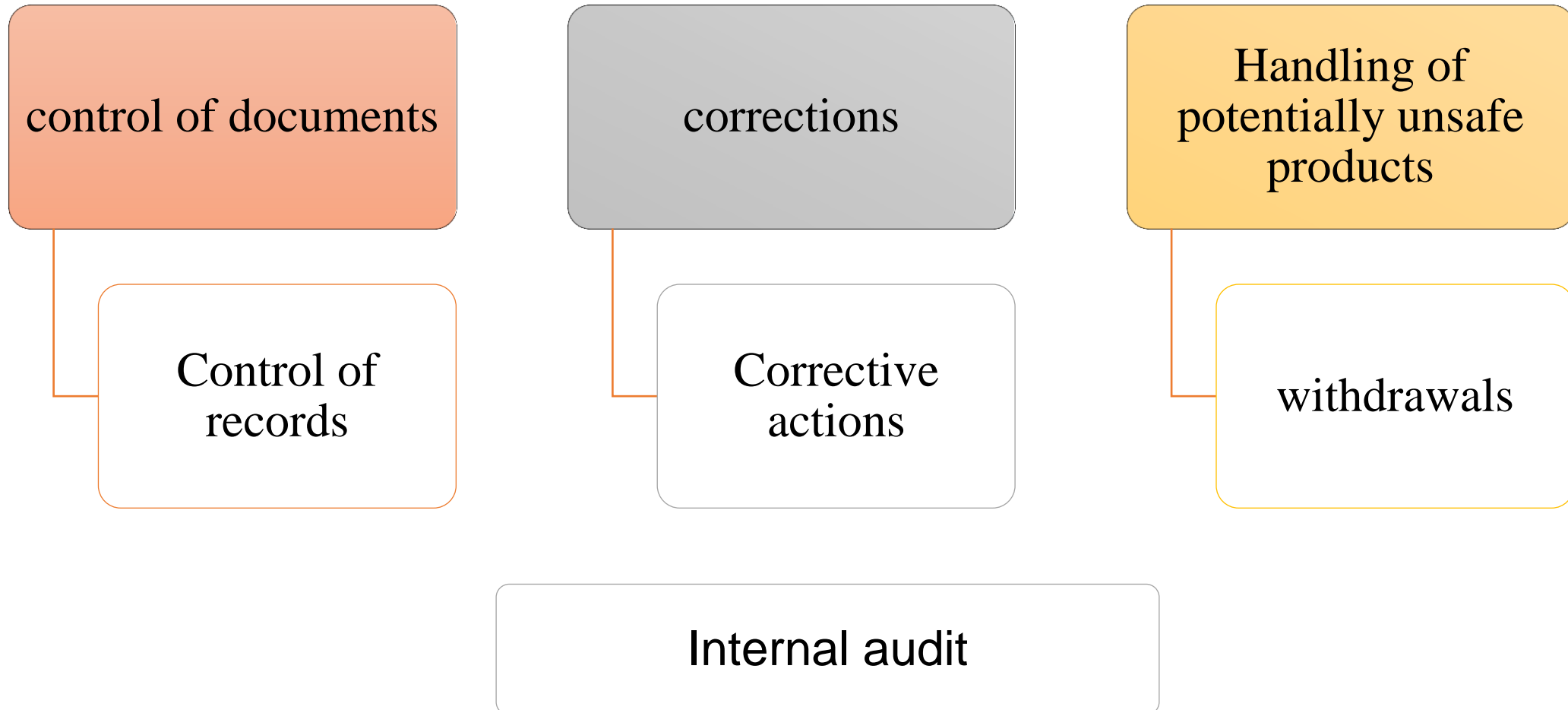
DOCUMENTATION

Policy

- Follow FSMS guidelines.

Documentation purpose

1. Identify and maintain appropriate documents (procedure / SOP, etc)

2. Documents must be available, when and where required, and can be in any form or medium (paper, electronic, sample or picture) suitable to the needs of the organization

3. Maintain records of evaluation, verification, validation, etc

Objective

- Establish system to support FSMS policy.

DOCUMENTATION

Purpose to control document

- Ensure the availability of the latest information to carry out &

  satisfy the latest requirements

Approval

- Approve from higher authorities before distribution.

- In case of review and update, re-approve the

  document and again distribute it as before.

DOCUMENTATION

Availability of document

- Ensure relevant document should be available at point of use.

- Should be in right language understand by operator.

Identification

- Document should be easily identified, e.g. by its tittle.

- Right information should be in there that is easy to rea

RECORDS CONTROL

Record provides evidence of

- Conformity to requirements

- Effective operation of FSMS

Records shall remain

Legible, readily identifiable and retrievable.

Documented procedure required to define control needed for

- Identification, Storage, protection, retrieval, retention time & disposition

FSMS ISO-22000
MANAGEMENT RESPONSIBILITY

MANAGEMENT RESPONSIBILITY

1- Management commitment

2- Food safety policy

3- Food safety management system

1.4- Responsibility and authority

1.5- Food Safety team leader

1.6- Communication

- **External communication**
- **Internal communication**

7- Emergency preparedness and response

8- Management review

- **General**
- **Review input**
- **Review output**

Management Commitment

- Top management – the person or group of people who directs and controls the organization at the highest level"

- Evidences of commitment to include awareness & leadership initiatives linked to
  - The development and implementation of the FSMS
  - Continually improving its effectiveness

- By;
  - Showing food safety is **supported by the business objectives** of the organization
  - Communicating to the organization the **importance of meeting the requirements**
  - Establishing the **food safety policy**
  - Conducting **management reviews**
  - Ensuring the **availability of resources**

Food Safety Policy

- Top management – define, document and communicate its food safety policy

- Ensure that the Food Safety Policy

1. Appropriate to the **role** of the organization in the **food chain**
2. Conforms with both **statutory** and **regulatory requirements**
3. Communicated, implemented and maintained at all levels of the organization
4. Reviewed for continued **suitability**
5. Adequately addresses **communication**
6. Supported by **measurable objectives**

FSMS Planning

▪ Top management ensure that

1. Planning continues even after the FSMS is implemented

2. Management reviews are planned

3. Any changes to the FSMS are also Planned

Responsibility & Authority

- Top management ensure that
  - Responsibilities and authorities are **defined** and **communicated** within the organization
  - To ensure the **effective operation** and **maintenance** of the FSMS

- All personnel - responsibility to **report problems** with the FSMS to **identified person**(s).

- Designated personnel - defined responsibility and authority to **initiate and record actions**.

Food Safety Team Leader

- Central to the FSMS of the organization

- The responsibility and authority

  - To **manage** a food safety team and **organize** its work
  - To ensure **relevant training** and **education** of the food safety team members
  - To ensure that the FSMS is **established, implemented, maintained** and **updated**
  - To **report to the organization's top management** on the effectiveness and suitability of the FSMS

Communication

Internal communication

- **The organization**
  - Establish, implement and maintain **effective arrangements** for communicating with personnel on issues having an impact on food safety

  - Ensure that the food safety team is **informed in a timely manner** of changes

- **Food Safety team**
  - Ensure that information is included in the **updating of the FSMS**

- **Top management**
  - Ensure that **relevant information** is included as input to the management review

Communication

External communication

- **The organization**
  - To ensure that **sufficient information** on issues concerning food safety is available **throughout the food chain**
  - Establish, implement and maintain **effective arrangements** for communicating with
    - Suppliers and contractors
    - Customers or consumers
    - Statutory and regulatory authorities
    - Other organizations that have an impact on FSMS

- Designated personnel - defined responsibility and authority to **communicate externally** any information concerning food safety

- Information obtained through external communication - included as **input to system** updating and management review

Emergency Preparedness & Response

- The organization should be aware of
  - Potential emergency situations e.g. fire, energy failure, flooding, environmental contamination, weather-related events, vehicle accidents, bioterrorism & sabotage, etc.

- When developing the organization's capacity to respond to emergencies, consider the following:

  - Plan, train, trial, revise plan

Management Review

General

- Top management - **review** the organization's FSMS at planned intervals

- To ensure its **continuing** suitability, adequacy and effectiveness

- Include **assessing opportunities** for improvement and the need for change to the FSMS, including the food safety policy

- Records of management reviews **maintained**

Management Review

Review input

The input to management review include

- Follow-up actions from previous management reviews
- Analysis of results of verification activities
- Changing circumstances that can affect food safety
- Emergency situations, accidents and withdrawals
- Reviewing results of system-updating activities
- Review of communication activities, including customer feed-back, external audits or inspections

Management Review

Review output

The output from the management review include **decisions and actions** related to

- Assurance of food safety
- Improvement of the effectiveness of the FSMS
- Resource needs
- Revisions of the organization's food safety policy and related objectives

FSMS ISO-22000
RESOURCE MANAGEMENT

RESOURCE MANAGEMENT

1- Human Resources

2- Infrastructure

3- Work Environment

Human Resources

- The organization shall

  - **Identify** the necessary **competencies for personnel** whose activities have an impact on food safety,
  - **Provide training** to **ensure** personnel have the **necessary competencies**
  - **Ensure** that personnel responsible **for monitoring, corrections** and **corrective actions** of the FSMS are trained
  - **Evaluate** the **implementation** and the **effectiveness**
  - **Ensure** that the personnel are **aware of the relevance** and **importance** of **their individual activities** in contributing to food safety
  - **Ensure** that the **requirement for effective communication is understood** by all personnel whose activities have an impact on food safety
  - **Maintain** appropriate **Records of training** and **actions**

Infrastructure

- Includes fields, buildings, process equipment, utilities, surrounding areas and supporting services

- Maintenance

- Can overlap with PRPs

Work Environment

- Include measures to prevent contamination, work place requirements, protective work wear equipment, and the availability & location of employee facilities

- Maintenance

- Can overlap with PRPs

FSMS ISO-22000
PLANNING & REALIZATION OF SAFE PRODUCTS

Planning & Realization of Safe Products

1. Prerequisite Programmes (PRPs)

2. Preliminary steps to enable hazard analysis

3. Hazard Analysis

4. Establishing the PRPs

5. Establishing the HACCP Plan

6. Updating preliminary information and documents specifying PRPs

7. Verification Planning

8. Traceability System

PRP

Basic conditions & activities necessary to maintain a hygienic environment throughout food chain suitable for production, handling & provision of safe end products and safe food for human consumption

PRPs

Shall establish, implement & maintain PRPs for Food Safety hazards

PRPs shall be

- Appropriate to the needs

  (size, nature & type of products / operations)

- Implemented across entire production system

- Approved by FS team

ESTABLISHING PRPs

Consider,

- Statutory & regulatory requirements

- Customer requirements

- Recognised guidelines

- Codex Principles & Codes of Practices

- Relevant Standards national/ international/ sector

PRPs Consideration

- Purchased material management – raw materials, ingredients, chemicals, packaging

- Supplies management _ water, air, steam and ice

- Waste disposal management (incl sewage)

- Products handling – storage, transportation

- Cleaning + sanitization Pest control

- Personnel hygiene

PRELIMINARY STEPS TO HAZARD ANALYSIS

- Food Safety Team

- Product Characteristics – Raw Materials

- Product Characteristics – End Products

- Intended Use

- Flow Diagrams

- Process Steps & Control Measures

- Hazard Analysis

HAZARD ANALYSIS

HACCP PRINCIPLES

The seven principles of HACCP are:

1. Conduct a hazard analysis.
2. Determine the critical control points (CCPs).
3. Establish critical limits.
4. Establish monitoring procedures.
5. Establish corrective actions.
6. Establish verification procedures.
7. Establish record-keeping and documentation procedures

HAZARD IDENTIFICATION & DETERMINATION OF ACCEPTABLE LEVELS

- Need to identify ALL FS hazards reasonably expected to occur

  Identification shall be based on :

- Preliminary info & data collected

- Experience

- External info incl. extent possible, epidemiological & other historical data

- Info from food chain on FS hazards relevant to safety of end & intermediate products + food for consumption

HAZARD ASSESSMENT

Shall conduct to determine whether its elimination / reduction

to acceptable levels is essential to

- production of safe food

- Enable defined acceptable levels to be met

HACCP Plan

Plan shall be documented Each identified CCP shall include :

- FS hazards to control

- Control measures

- Critical limits (CL)

- Monitoring procedures

- Correction & CA if CL exceeded

- Responsibilities & authorities

- Records of monitoring

Identification of CCPs

For each hazard controlled by HACCP plan, CCPs shall be identified for control measures identified

Determination of CL for CCP

- Determine CL for monitoring of each CCP
- Establish CL to ensure identified acceptable
- level of FS hazard in end product is NOT exceeded
- CL shall be measurable
- Document rationale for CL
- Support by instructions / specifications and / or education & training any CL based on subjective data

System for monitoring of CCPs

- Establish monitoring system for each CCP to demonstrate control

- System shall incl. all scheduled measurements / observations relative to CL

Shall consist of relevant procedures, instructions and records covering :

- Measurements / observations providing results within adequate time frame Monitoring devices used
- Applicable calibration methods
- Monitoring frequency
- R & A related to monitoring & evaluation of monitoring results
- Record requirements & methods

Verification Planning

Shall define purpose, methods, frequencies & responsibilities

for verification activities Verification shall confirm :

- PRPs implemented

- Input to HA continually updated

- PRPs & elements within HACCP plan implemented & effective

- Hazard levels within identified acceptable levels

- Other procedures required implemented and effective

- **Recorded &Verification**

- Results communicated to FS team If verification based on testing of

  end product samples, any NC lot to be handled as potentially

  unsafe

Traceability System (TS)

- To identify product lots & link to raw materials, processing & delivery records To identify incoming material from immediate suppliers & initial distribution route of end product

- Maintain TS records for defined period in line with regulatory & customer requirements

COMPARISON ON THE REQUIREMENTS OF HACCP, ISO9001:2008, AND ISO22000:2005

Similarities

- HACCP
- ISO22000

Similarities of HACCP and ISO22000:2005

- Both are focus on **food safety requirements**.

- Both are considered as modern scientific and systematic approach to **hazard identification** & **Food Safety Management**.

- HACCP Principles are the part of ISO 22000.

- Both requires the supporting **PRPs** to function.

- Both emphasize on **competent FSM team.**

- Both uses **Hazard Analysis** as the key to an effective FSMS.

Similarities of HACCP and ISO22000:2005

- Both requires **all hazards** that may be reasonably expected to occur in the food chain, including hazards that may be associated with the type of process and facilities used, are identified and assessed.

- Both focuses on Food Safety controlling **identified hazards** through:

  - Prevention

  - Elimination

  - Reduction

  - Mitigation

DIFFERENCES

- HACCP
- ISO22000

Differences between HACCP and ISO22000

HACCP

- HACCP is considered as a tool to **assess hazards** & establish control systems.

- HACCP focused purely on food safety.

- HACCP is part of ISO 22000 FSM.

- HACCP uses the two groups of **control measure** that includes:

    - Pre requisite measures (PRPs)

    - Critical control point (CCPs)

Differences between HACCP and ISO22000
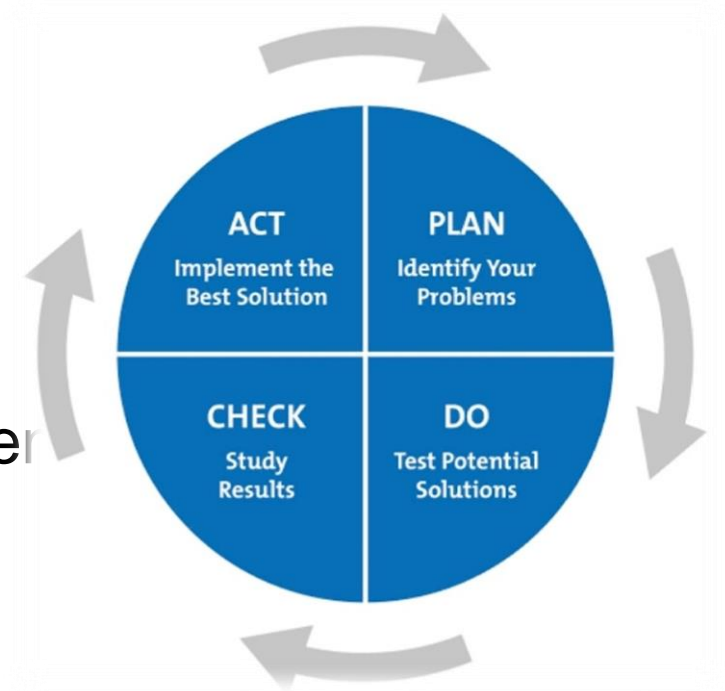
ISO22000

- ISO 22000 is a **structured management system** that completely involves the
  - Interactive communication
  - System management
  - Pre-requisite programs
  - HACCP principales.
- **Operational PRPs** are unique to ISO 22000.
- ISO 22000 focuses on very **specific verification** of control measure combinations

Differences between HACCP and ISO22000

ISO22000

- ISO 22000 has clear specific requirements:

    • Traceability System

    • Corrections & review of corrections carried out

    • Internal Audit

    • Management Review.

- ISO involves the **PDCA cycle** = Continual improvemen

Similarities

- ISO9001
- ISO22000

Similarities between ISO9001 and ISO22000

- Both uses the **P-D-C-A Approach**.

- ISO 9001 also considers FS aspects in its Quality focus.

- ISO 22000 = ISO 9001 + HACPP

- Legal requirements are important consideration for the Quality Management

  System and Food Safety Management System.

Similarities between ISO9001 and ISO22000

- Both have the " **Management** "component in the system requirements:

Corrective Actions

Management Review

Internal Audit

Objectives
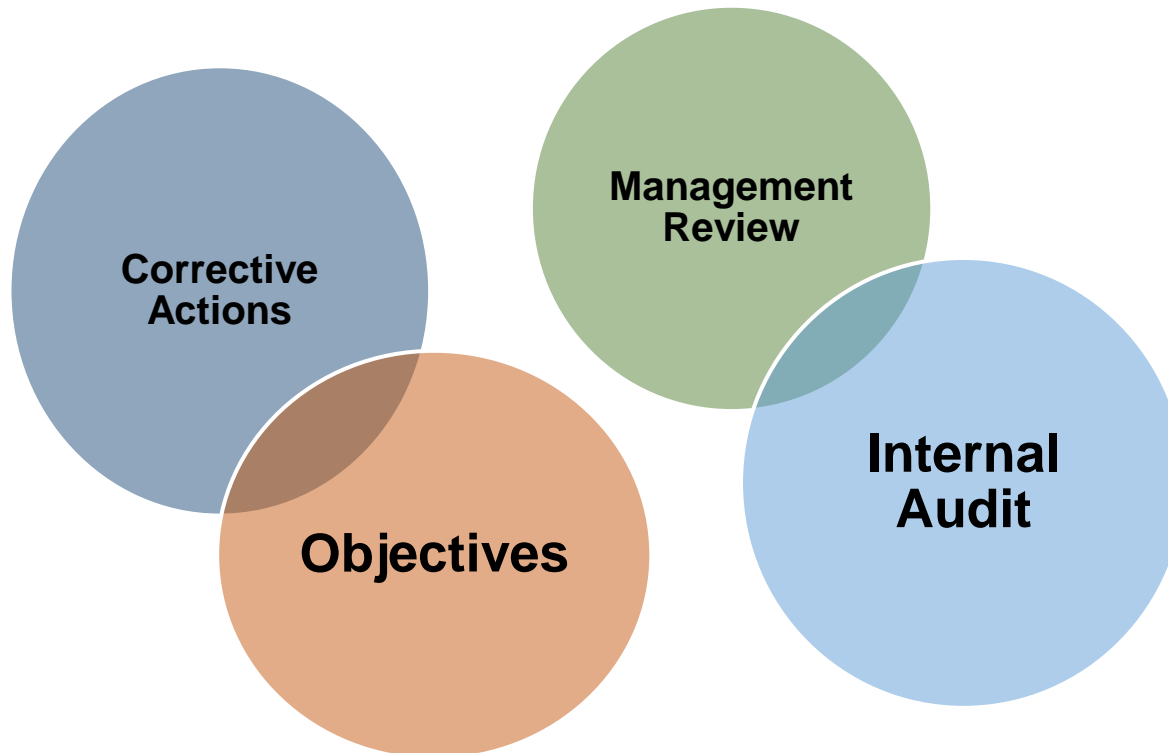
Differences between ISO9001 and ISO22000

ISO9001

ISO 9001 does not require :

- PRPs

- Operational PRPs

- HACCP Plan – Hazard Analysis &

   CCPs.

- Food Safety Team

- Withdrawals

- Evaluation of individual

   verification results

ISO22000

ISO 22000 does not require :

- Quality Manual

- Customer focus

- Customer Property

- Customer related processes

- Design & development

- Purchasing

- Quality Plan

- Customer satisfaction monitoring

- Preventive action

UNDERSTANDING THE REQUIREMENTS OF ISO 22000: 2005

VALIDATION, VERIFICATION & IMPROVEMENT OF THE FSMS

VALIDATION

- Validation is the confirmation through the provision of objectives evidence that the requirements for a specific **intended use** or application have been fulfilled.

- Obtaining evidence that the elements of the HACCP plan are effective.

- That element of **verification** focused on collecting and evaluating scientific and technical information to determine whether the HACCP plan when properly implemented will effectively control the hazards.

- The act of **confirming** that a product or service meets the requirements for which it is intended.

VERIFICATION

- Verification is the confirmation through the provision of objective evidence that **specific requirements** have been fulfilled.

- The application of the methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan.

- Those activities other that determine the **validity** of the HACCP plan and that the system is operating according to the plan.

- The act of **determining** whether products and services conform to specific requirements.

IMPROVEMENT OF THE FOOD SAFETY MANAGEMENT SYSTEM (FSMS)

Validation of the FSMS

Validation activities include: -

- Reference to validations carried out by others, to scientific literature, or to historical knowledge.

- Experimental trials to stimulate process conditions,

IMPROVEMENT OF THE FOOD SAFETY MANAGEMENT SYSTEM (FSMS)

Validation of the FSMS

BCP hazard data collected during operating conditions that are:

- Statistically designed surveys.

- Mathematical modelling .

- Use of a guide approved by competent authority.

IMPROVEMENT OF THE FOOD SAFETY MANAGEMENT SYSTEM (FSMS)

Verification of the FSMS

- Verification - "ongoing" & "periodic" .

- **Ongoing verifications** use methods, procedures or tests separate from, and in addition to those used in monitoring.

- Verification activities include: -

  - Reviewing monitoring records.

  - Reviewing deviations & their corrections or corrective actions, handling of affected product.

  - Calibrating thermometers or other critical measuring equipment.

IMPROVEMENT OF THE FOOD SAFETY MANAGEMENT SYSTEM (FSMS)

Verification of the FSMS

- **Visually** inspecting operations to observe if control measures are under control.

- **Analytically** testing or auditing monitoring procedures.

- **Randomly** collecting & analysing samples of in-process or end product.

- **Reviewing customer** or consumer complaints to determine whether they relate to the   performance of the control measures or reveal the existence of unidentified or need for additional control measures.

IMPROVEMENT OF THE FOOD SAFETY MANAGEMENT SYSTEM (FSMS)

Evaluation of Verification Results

- Individual verification results be recorded & communicated to FS team which performs the "Verification planning".

Analysis of results of Verification Results

- Verification results provided to FS team to enable analysis of verification activities.

IMPROVEMENT OF THE FOOD SAFETY MANAGEMENT SYSTEM (FSMS)

Improvement of the FSMS

Continual improvement includes:

- Communication – favourable environment for improvement.

- Validation and verification activities and further actions after evaluation and analysis of their results lead to improvement.

IMPROVEMENT OF THE FOOD SAFETY MANAGEMENT SYSTEM (FSMS)

Improvement of the FSMS

Updating the food safety management system

- FS team receives inputs from different sources & evaluate and analyse them.

- Outputs from FS team - inputs for management review, updating of the FSMS etc.

IMPLEMENTATION OF
ISO 22000: 2005

INTRODUCTION

- ISO 22000 can be implemented by any organization in the food chain

- Organizations achieved ISO 22000 certification, 20 in japan

- In January, 2009_ 500 certification in APO member countries

REASONS FOR IMPLEMENTING

- **Realization:** Can be used a as tool for improvement
- **Legal & Liability:** to meet regulatory compliance / avoid litigation
- **Customer-driven:** requirements form potential / existing customer
- **Market focus:** reputation of enterprises
- **Pressure:** directive from main markets

BENEFITS OF IMPLEMENTATION

➢Reduced cost of sales

➢Lower risk of liability

➢Improved overall performance

GENERIC APPROACH

- Demonstrate a commitment to food safety
- Support the establishment of a complete FSMS
- Define the scope & boundaries of FSMS
- Plan the establishment of organization FSMS
- Document FSMS responsibilities & authorities
- Appoint FS organization team leader
- Appoint FS organization team
- Establish FS communication arrangements
- Provide competent FS personnel
- Provide training and awareness programs

CONT…

- Provide infrastructure and work environment
- Establish PRPs
- Perform a FS hazard analysis
- Specify acceptable hazard levels
- Select measures to control hazards
- Establish OPRPs
- Prepare HACCP plan
- Establish a product lot traceability system
- Identify and correct nonconforming product
- Evaluate data and take corrective actions

Project Plan

1. **Management awareness & commitment**
- Executive briefing for management team
- Establish / Redefine management responsibility and FS team

2. Develop and Document system
- Refine activities relating to PRPs
- Establish / Refine OPRPs / HACCP plan
- Prepare / improve FSMS documentations

CONT…

3. Implement and Monitor system

• Control measures & implement FSMS

• Train and coach staff

• Monitor and improve FSMS

4. Audit, Review & improve system

• Train an coach internal audit o FSMS

• Conduct management review

• Review findings, update and improve FSMS

CONT…

5. Prepare for certification

- Select certification body
- Conduct pre-assessment by independent party
- Achieve ISO 22000 certification

EXPERIENCE OF AN ORGANIZATION

- Reduction in metal contamination incidents achieved, as a result of enhancing their HACCP process and using the conclusions from HACCP study to convince senior management team to invest money in upgrading screens, sieves and metal detection equipment

- Greater and more widespread understanding of food safety issues across the company, through enhanced internal communication arrangements

- A widely understood corrective actions process

CONT…

- More effective change in management system

- Enhanced focus on the Real CCPs, enabling better control measure management

- Approach to conducting management reviews and managing improvement programmes

- More visible and widely understood reporting relationships, document control mechanisms and record control mechanisms

- A control measure validation approach which gives confidence in the food safety controls implemented

AUDITING OF
ISO 22000

DEFINITION

"Systematic, independent & documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled"

Types of Audits:

Depending on the interrelationships that exists among the participants

1) **Internal audit**

• First party audit

2) **External audit**

• Second party audit

• Third party audit

AUDIT PARTICIPANTS

- Client
- Auditee
- Audit team
- Auditor
- Team leader
- Technical experts

AUDITING IN ISO 22000

Requirements relating to audit:

- Top management shall ensure that the organization continually improve the effectiveness of the FSMS through the use of internal audits

- The input to management review shall include information on external audits

INTERNAL AUDIT
(PART OF VERIFICATION)

- Include procedures or methods, frequency and person responsible for performing the activities

For internal audit:

- Observe audit principles
- Competent and independent auditors

Details of internal audit:

- Documented procedure
- Planned interval
- Audit programmes
- Responsibilities and requirements
- Actions for non-conformities
- Follow up verification

IMPLEMENTING AUDIT

ISO 19011: 2002

• Guidelines on Q / EMS auditing

5 Principles of auditing:

1. Ethical conduct
2. Fair presentation
3. Do professional care
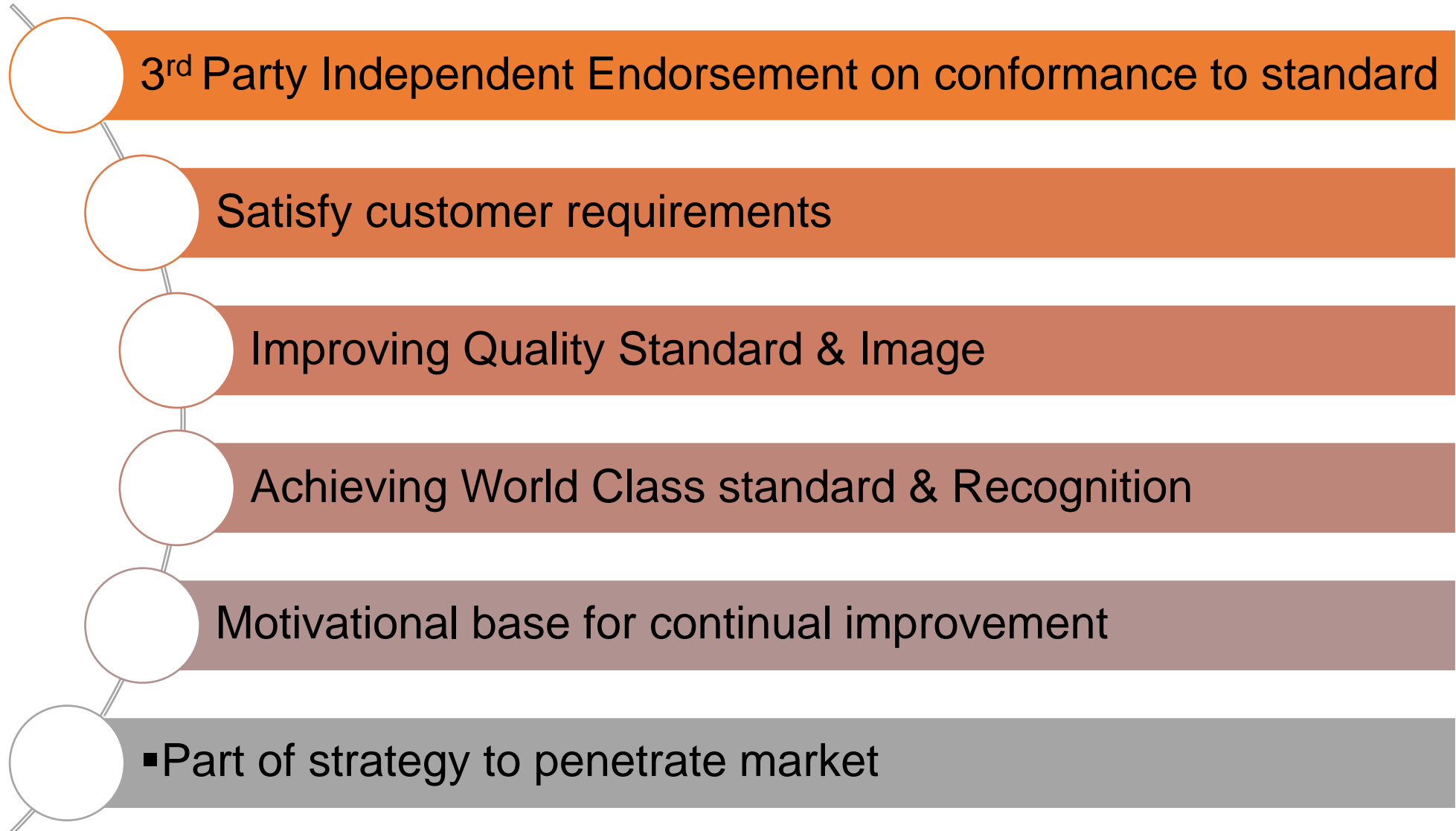4. Independence
5. Evidence_ based approach

CERTIFICATION

Accreditation Body

- Accreditation bodies provide accreditation to certification bodies

- Monitored by IAF (International Accreditation Forum)

Certification Body

- Certification Bodies provides Certification / Registration services to

  clients wishing to be ISO 22000, etc certified

- Monitored by AB(Accreditation Body)

Purpose of Certification ?

3rd Party Independent Endorsement on conformance to standard

Satisfy customer requirements

Improving Quality Standard & Image

Achieving World Class standard & Recognition

Motivational base for continual improvement

- Part of strategy to penetrate market

# Benefits of Certification

Amongst the many benefits are :

- Conform to customer requirements

- For image building

- To reduce the number of audits by customers

- Conformance to the standard requirements

- Valuable input towards continual improvement

- Overcome Trade Barrier

Guidelines for CB (ISO 22003)

- Certificate issued for period of 3 years normally

- Surveillance audit maximum period 12 monthly Audit team shall be competent

- Confidentiality assured Must follow the audit guidelines

- Must be capable of managing the certified client

Types of Audit

- Initial

- Surveillance
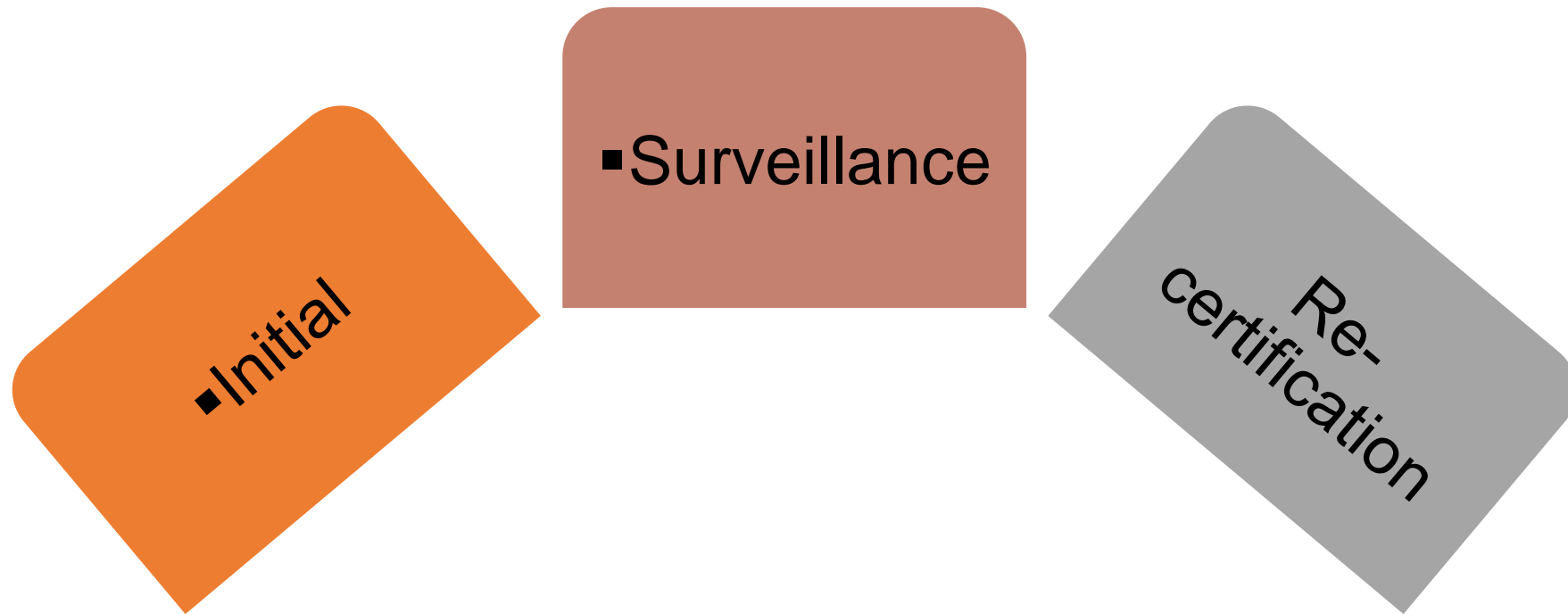
- Re-certification

Re-certification

Not to exceed 3 years from last initial / recertification audit

Stage 1 audit not required if no significant changes to FSMS or regulations

Technical Expert

As there are many different activities related to the food industry, audits carried out may require the use of technical expert

Role of technical expert to provide technical guidance to the auditor
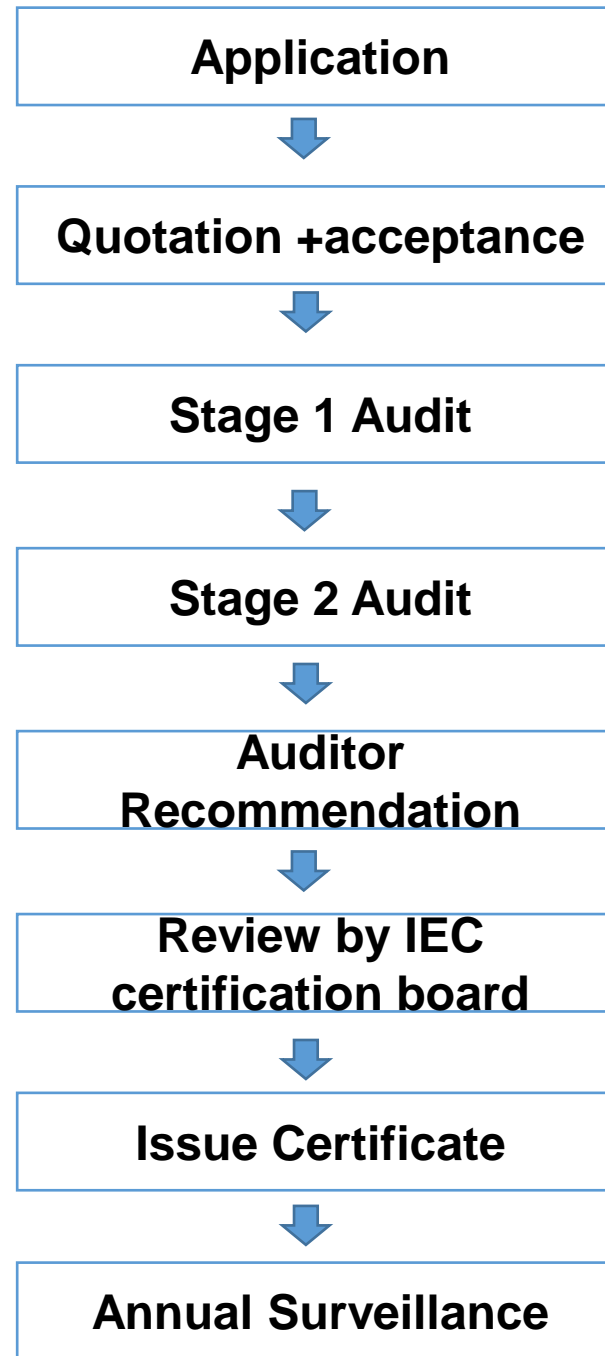
2 - Stage Audit

Stage 1

- Audit shall be at site

- Determine readiness of the organization to proceed to S2

- Provide info for planning of S2 audit

- No NCR issued at this stage

- Observations highlighted to bridge the gap as part of the report

- Need to proceed to S2 within 6 months

Stage 2

- Shall be at site(s)

- Shall audit sufficient no. of staff

- Top management

- Operational staff

- Decision for certification based on info & evidence from S1 & S2

- NCRs issued

Certification process

Application

↓

Quotation +acceptance

↓

Stage 1 Audit

↓

Stage 2 Audit

↓

Auditor Recommendation

↓

Review by IEC certification board

↓

Issue Certificate

↓

Annual Surveillance

IEC / UKAS CERTIFICATION

Sample of Certification / Accreditation Mark

COMMON NONCONFORMITIES DETECTED IN FSMS

- General overview
- Where can NC arise?
- Common nonconformities
- Prerequisite Programmes (PRPs)
- Control of nonconformity
- Control of Monitoring & Measuring
- FSMS verification
- Verification results

GENERAL OVERVIEW

With reference to the P-D-C-A cycle

- PLANNING – generally not a problem

- DOING – most of the problems arises here

- CHECKING –problems with incompetent FS team

- ACTION –problems with incompetent FS team

Where can NC arise?

- Practically anywhere in the FSMS.

- Most are related to PEOPLE factor

  Lack of understanding

  Lack follow up/ monitoring

- Where Top management commitment is weak we see/ expect

  more problems

  Only want to have a certificate

  Not willing to invest

  No training budget.

COMMON NONCONFORMITIES

1: Statutory & Regulatory Requirements

- SRR not determined
- SRR not updated
- SRR not complied
- SRR importing country not determined.

2: Effective communication

- FS issues not fully understood by operators.
- Customer FS requirements not effectively communicated.

3 :Top Management Commitment

- Lack of Top Management involvement with the FSMS

- FS related complaints take a long time for decisions by Top Management

- Results not clearly defined and/ or communicated

4: FS Team & FS Team Leader

- Weak FS Team Leader not able to manage the FS Team

- FS Team members not clear on the role & responsibility

- Records not updated to demonstrate that FS team has the required knowledge & experience.

- External communication

- Records of communication not maintained.

- FS requirements from SRR &customer not available.

5: Competence, Awareness and Training

- Records of training not properly maintained

- Not all personnel responsible for monitoring, corrections are adequately trained

- No evaluation carried out to review the effectiveness of the trainings or actions taken to improve competencies.

Prerequisite Programmes (PRPs)

❖ **Personnel Hygiene**

Operators do not understand why (during operation) they need to :

- wash their hands
- Wear hair net
- Wear face mask
- Refrain from wearing jewelry etc

Hand wash facilities not adequate / appropriate

- Use of hand operated tap
- Poor hand drying facilities e.g. Use of toilet paper
- Use of soap instead of liquid soap

❖ **Pest control**

Pest appears on the day of audit
- Birds
- Ants on production lines
- Flies
- Mosquitoes
- Cockroaches
- Lizards
- Wasp

Sign of pest presence & not action taken
- Feather at storage area
- Pest droppings

❖ **Maintenance of building & machinery**

- Cracks / damages on ceilings & walls

- Damaged floorings

- Paint work peeling – Wall / Machinery

- Grease oozing from moving parts

- Cobwebs

- Plenty of dust around ventilation outlets

- Damaged window / ventilation screens

CONTROL OF NONCONFORMITY

Corrections:
- no record maintained
- inadequate records maintained to allow for traceability purposes.

Corrective actions (CA)

- CA not initiated when critical limit exceeded
- not all CA recorded
- CA not effective.

CONTROL OF MONITORING & MEASURING

- Equipment not calibrated / verified

- Equipment not suitably identified on

- calibration status (especially after internal verification)

- Internal verification records poorly

FSMS verification

- Internal audits carried out are not effective.
- Results of verification activities including monitoring records not adequately reviewed.
- Verification does not include external audit feedback.

Verification Result

- Records of verification results – not all maintained

- Verification results not all communicated to FS Team for follow up analysis and actions