



Management of Change

Considerations for Effective Management of Change



Management of Change Presentation Outline

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Introduction



Introduction

Change

- Change is **ubiquitous** and constant in business today.
- Changes can be intentional or unintentional. Both types need to be managed.
- The **detrimental impact of change** to the business needs to be managed by effectively controlling hazards and risks
- Impact of these **significant** changes to food safety, safety and the environment needs to be considered.

Why Manage Change?

- Failure to manage change can result in serious illness, injury or fatality.
- We have an obligation to protect our customers, employees, assets and brands.
- It is a regulatory requirement to protect food safety, safety, occupation health and the environment.

Examples of Change Management Failure Consequences

- Fatality or injury of an employee or contractor due to an equipment failure
- Anaphylactic shock from undeclared allergens
- Cyberhacking resulting in the loss of intellectual property or confidential information

Potential Sources of Significant Change

- 1. Equipment Failure, Extraordinary Maintenance or Repair**
(e.g. “Midnight Plumbing” to complete production run)
- 2. Suppliers and Contractors**
(e.g. Material defects, modified services)
- 3. Corrective Action**
(e.g. Changes related to deviations or near misses)
- 4. Audit Finding / Improvement Opportunity**
- 5. Capital Expense Project**
(e.g. New Equipment, Changes to Utilities or Facility)
- 6. Improvement Project**
(e.g. Cost Savings Initiative, Recipe / Process Optimization)
- 7. Controls to Defend Emerging Threats**
(e.g. Emerging Pathogens, Bioterrorism / Food Defense, Cybersecurity)

Significant change can affect:

- Equipment
- Materials
- Processes
- Utilities
- Controls
- Prerequisite Programs
- Critical Control Points
- PLC programming or Software
- Regulatory Compliance

Significance of Change

- Determination of the significance of change is an important step in **risk management** and change management.
- The **Food Safety** hazard risk assessment and necessary controls are evaluated using HACCP principles.
- The **Safety and Occupational Health** hazard risk assessment and necessary controls are evaluated using HIRAC principles.
- The **Environmental** aspect risk assessment and necessary controls are evaluated using an Environmental Impact Study
- **Business risk management** principles can also be used to assess significance of change.



Scope of Change Management



Scope of Change Management

Define Scope of MOC

- It is important to define scope for management of change.
- Inappropriate definition of scope may generate program **overlaps** or program **gaps**, depending on the maturity of your Integrated Management Systems.
- It is useful to include “In Scope” and “Out of Scope” within the MOC procedure to help prevent potential overlaps and gaps.

“In Scope”

- Scope **must** include any significant change that has an impact on Food Safety, SHE or Regulatory compliance.
- The risk assessment and control principles of HACCP and HIRAC are used to determine what constitutes significant change (minimum scope).

“Out of Scope”

Depending on the maturity of your Integrated Management System you may consider the following to be out of scope:

- Unplanned changes **if** they are covered as deviations in Corrective Action procedures
- “Like for Like” maintenance **if** the same make and model number that was used in the equipment qualification is used in the maintenance repair
- CAPEX Projects **if** effectively managed by Engineering Qualification
- Changes to documentation **if** managed by Document Management procedures

Other Potential “ In Scope” Considerations

The MOC program can also be used to manage change involving:

- Information Systems
- Legacy Documentation such as:
 - Engineering Drawings
 - Equipment and Maintenance Registers
 - Manufacturing Specifications
 - Employee Training and Competency
 - Organization Charts



Organizational Structure and Competencies



Organizational Structure and Competencies

Organizational Structure and Competencies

- The **organization size, competencies and resource constraints** need to be considered in the development and maintenance of the MOC program.
- Small organizations with limited access to subject matter experts or hazard risk assessment experience may need to include qualified consultants.
- Larger organizations with multiple manufacturing sites provide complexities to change management that may challenge **timely** risk assessment, implementation planning and approval.



Basic Roles and Responsibilities

Basic Roles and Responsibilities

- **Change Initiator**
 - Initiates the change request, supplies information to the MOC Coordinator and presents the MOC Request to the committee
 - Acts as the Project Manager to drive all Implementation Plan actions
- **MOC Coordinator**
 - Completes the change request and preliminary hazard risk assessment
 - Works with the Change Initiator and Subject Matter Expert to develop the Implementation Plan
- **Subject Matter Expert**
 - Provides expertise as needed on hazards and controls

Basic Roles and Responsibilities (Continued)

- **MOC Committee**

- Reviews completed change requests
- Critiques the hazard risk assessment and implementation plan.
- Denies any change request that cannot properly control hazards
- Provides MOC approval to proceed with the implementation plan
- Provides final approval to close the MOC

- **MOC Action Verifier**

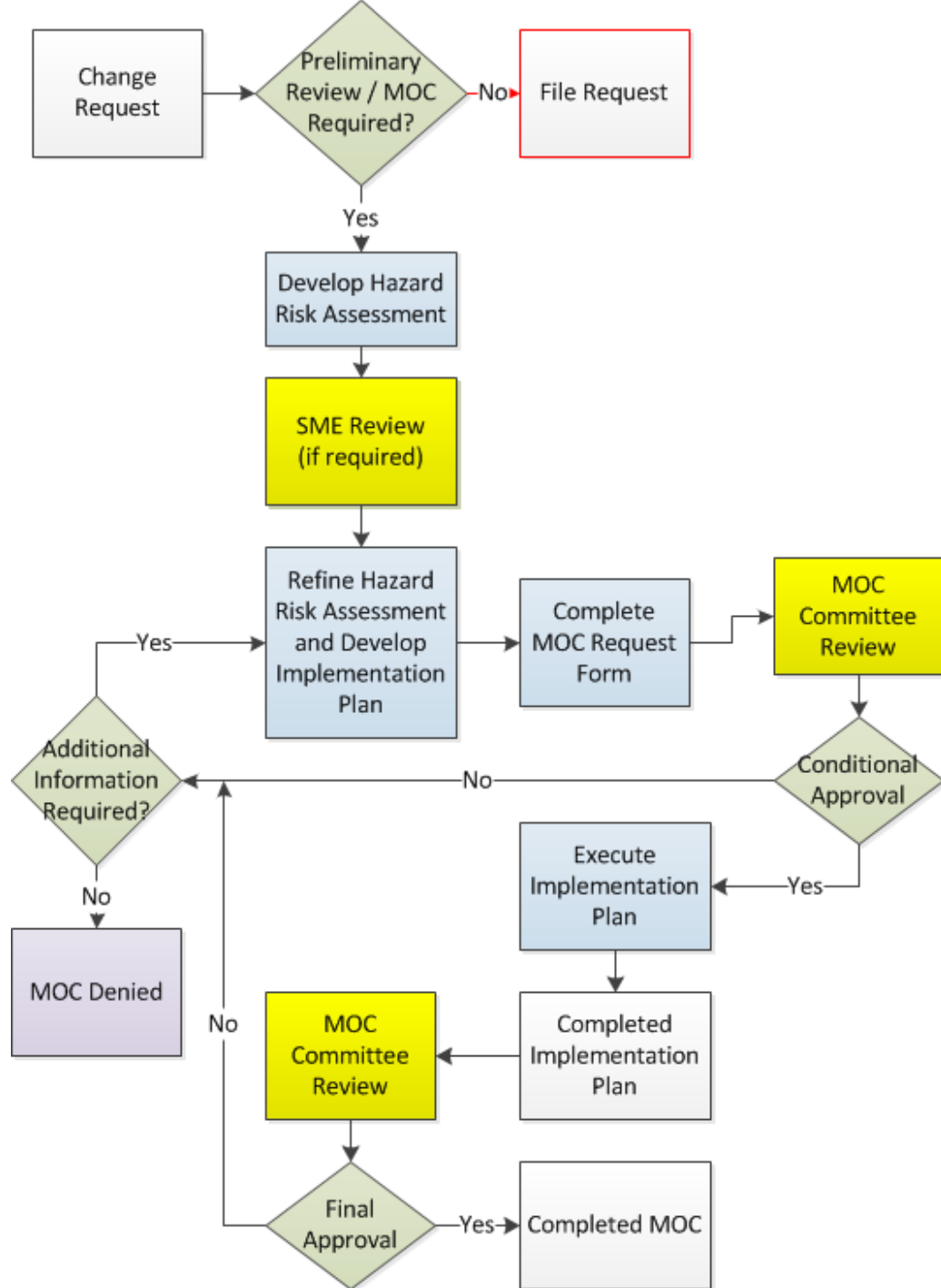
- Determines that a specific MOC action is effectively implemented
- Is a member of the MOC committee



Basic Workflow



Basic Workflow





More Clarity on MOC Requests and the Implementation Plan



Work Aid for the Change Initiator

Change Affect Questionnaire

- Defines those systems, processes or elements impacted by the change
- Used to trigger discussion of the change hazard risk assessment and hazard / aspect control strategy with the Subject Matter Expert (as needed) and the Management of Change Committee
- Helps define the MOC actions / tasks in the implementation plan

Change Affect Questionnaire

Does the change impact any of the following?

- **Material Risks / Controls**
(Ingredients, Packaging, Chemical)
- **Formula / Label**
- **Methods**
(e.g. Hydration, Batching, Mixing, Analytical)
- **Prerequisite Programs**
(e.g. Traceability, Sanitation, Maintenance, Calibration)
- **Critical Control Points**
(e.g. Thermal Process, Container Integrity, HACCP Record)
- **Equipment Controls**
(e.g. Manual Controls, PLC Programming, Equipment Function, Alarms)

Change Affect Questionnaire (Continued)

Does the change impact any of the following?

- **Status of Validated Equipment**
(e.g. Controls, Cleaning, Microbiological)
- **Utilities**
(e.g. Steam, Water, Air, Electricity)
- **Safety Hazard Controls**
(e.g. Guarding, Interlocks, Lockout, Required PPE)
- **Environmental Aspects and Controls**
(e.g. Containment Devices, Environmental Discharge)
- **Documentation**
(SOP's, SSOP's, Instructions)
- **Training / Competencies**



Implementation Plan

Implementation Plan

- Considers the impact of the change to QFS, SHE and Regulatory requirements
- Defines the specific actions / tasks necessary to manage the change
- All actions / tasks are assigned owners, due dates and verifiers
- All critical actions / tasks need to be completed before the “change” is allowed for general operation or product consumption



Management of Change Documentation Systems

Management of Change Documentation Systems

- Spreadsheets can be used effectively for small organizations with a single manufacturing site
- Database systems are more appropriate for larger organizations or organizations with multiple manufacturing sites:
 - MS Access Database Applications
 - Intelex
 - Trackwise
 - TraceGains

Challenges to Effective Change Management

- Ensure **all employees** have a basic understanding of change management requirements and procedures. Consideration needs to be given to employee turn-over and new hires.
- Materials, goods and services from suppliers and contractors are included “in scope” of the MOC process. **Suppliers and contractors** must understand the requirements of change management and communicate significant change **before** the change is made.

Challenges to Effective Change Management (Continued)

- **All changes** are risk-assessed for their significance against existing FS and SHE controls (at minimum).
- Workflow **user friendly** and can be executed in a **timely** fashion.
- Management of change should be **proactive** and evaluate both intrinsic and extrinsic changes to the business. These may not be just the standard scope of food safety and safety but also include **significant threats** to the business. We are challenged to be more diligent to new external threats to the business.

Suggestions

- Train all employees to a basic level of change management and empower them to be potential change initiators. This encourages MOC “pull” from the change initiator instead of a “push” from the MOC committee.
- Use a balanced approach to create a program that can be resourced sustainably.
- Develop FS and SHE competencies to enable an effective succession plan for the MOC committee.
- Communicate, Inform, Train...repeat!



Questions?