

# PROCESS CONTROLS

## Developing Standard Operating Procedures for Food Manufacturing

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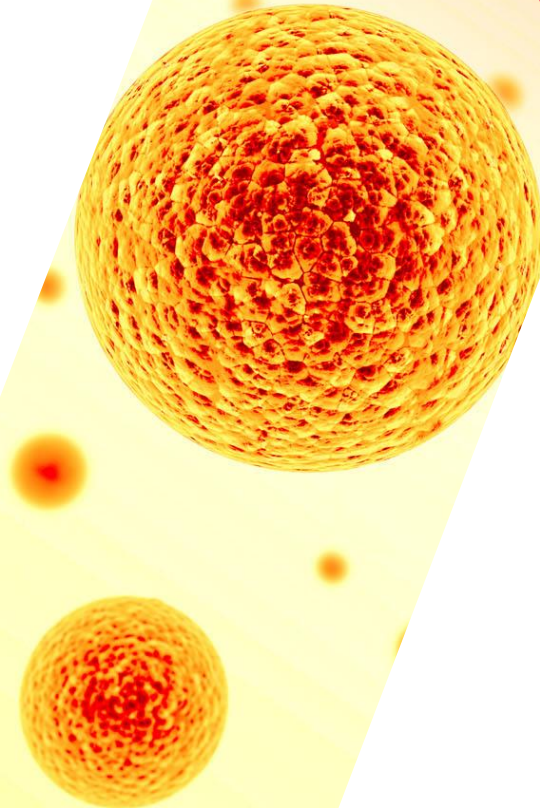
**Senior Food Microbiological and Food Safety Consulting**

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# AGENDA

- Definitions and Terms
- Regulatory Requirements
- Developing Standard Operating Procedures

# DEFINITIONS AND TERMS



# DEFINITIONS AND TERMS

- Hazard Analysis of Critical Control Points (HACCP)
  - A global standard developed as part of Codex Alimentarius to improve upon and synchronize international food standards, guidelines, and codes of practice to protect the health of consumers.
  - Required of juice and seafood (FDA) and meat (USDA) processors.
  - Supporting food safety programs are referred to as Pre-Requisite Programs.

# DEFINITIONS AND TERMS

- Hazard Analysis and Risk-based Preventive Controls (HARPC)
  - Created by the FDA and is written within Section 103 of FSMA (Food Safety Modernization Act) guidelines.
  - Requires that all food manufacturers and processing facilities operate with the strategies and guidelines in place.
  - Supporting food safety programs are referred to as Preventive Control Programs.

# DEFINITIONS AND TERMS

- A primary difference between HACCP and HARPC is within the Hazard Analysis.
  - HACCP – Biological, Chemical, Physical
  - HARPC – Biological, Chemical, Physical, Radiological, Intentional
- Foundational to the Food Safety Plan are the corresponding Standard Operating Procedures (SOPs).
- For each food safety program, there may be several SOPs, forms, and other supporting documentation.

# DEFINITIONS AND TERMS

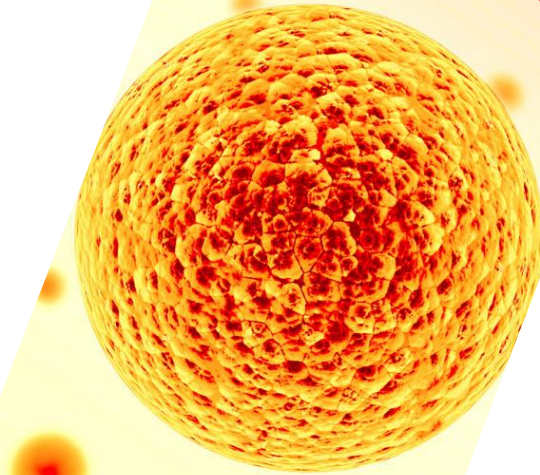
- Standard Operating Procedure (SOP)
  - A set of written instructions that document a food manufacturer's routine or repetitive activity.
  - Also referred as
    - Protocol
    - Job Instruction
    - Work instruction
- In food manufacturing, the term SOP is commonly used to Production, Manufacturing, and Support area processes, jobs, or activities.
- For all sanitation-related processes, jobs or activities, the term SSOP (Sanitation SOP) is reserved.

# DEFINITIONS AND TERMS





# REGULATORY REQUIREMENT REVIEW



# REGULATORY REQUIREMENT REVIEW

- Why Have Written SOPs?
  - Regulatory Requirement
    - Whether follow HACCP or HARPC, all food safety program SOPs must be written and documented.
  - Other Benefits of Written SOPs
    - SOPs serve as the basis for implementing an effective program to include employee training as well as a tool for on-the-floor coaching and development.
    - SOPs identify control points, as well as their limits, in order to control and validate the process. Corrective actions and preventative actions can be identified in order to address each.
    - SOPs can be used to establish time, labor, and material requirements for a job or task.
    - SOPs are used as checklists by Internal Audit Team members when auditing the factory's programs and procedures.

# REGULATORY REQUIREMENT REVIEW

- Food Safety Modernization Act (FSMA) Requirements
  - Facilities must have a written Food Safety Plan
    - Hazard Analysis of Critical Control Points (HACCP)  
or  
Hazard Analysis of Risk-based Preventive Controls (HARPC)
  - Food Safety Plan must include the following elements:
    - Hazard analysis to determine hazards that are likely to occur
    - Determination of Critical Control Points
    - Development of control measures to significantly minimize or prevent the hazard
    - Monitoring
    - Corrective Actions
    - Verification
    - Associated records and documentation

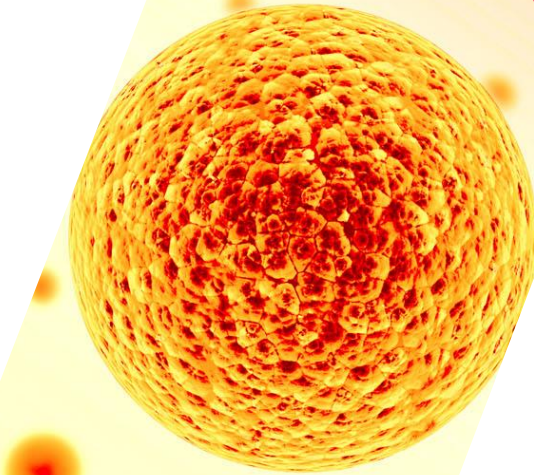
# REGULATORY REQUIREMENT REVIEW

- FSMA Required Preventive Control Programs
  - Manufacturing Process
  - Allergen Control
  - Sanitation
    - Sanitation of food contact surfaces
    - Sanitation of utensils and equipment
  - Recall Plan

# REGULATORY REQUIREMENT REVIEW

- FSMA Required Preventive Control Programs
  - Other Programs “As Needed”.
    - Good Agricultural Practices / Good Manufacturing Practices
    - Environmental Monitoring Program
    - Supplier Monitoring
    - Pest Control
    - Employee Training
    - Personal Hygiene
    - Storage and Distribution

# KEY SECTIONS OF STANDARD OPERATING PROCEDURES



# KEY SECTIONS OF SOPs / SSOPs

- Title Section / Page
  - Clearly identifies the procedure name, an identification number, date of issue and / or revision, the name of the applicable factory, division, and department to which the SOP applies.
- Table of Contents (Optional)
  - A Table of Contents is helpful for quick reference and location of specific information, changes, or updates.
  - A Table of Contents is especially important for lengthy or detailed SOPs / SSOPs.
- Objectives / Introduction / Purpose
  - This section will describe the intention for the SOP / SSOP and allows the reader to better understand not only the “how” but the “why” as well.

# KEY SECTIONS OF SOPs / SSOPs

- Responsibilities
  - List of accountabilities for all stakeholders, detailed by position.
- Definitions
  - This section includes a list of terms, phrases, words, or acronyms, and their applicable meanings. Since the reader will already have some knowledge of the task or equipment, only uncommon or unfamiliar terms should be defined.
  - For example: In a “*Salmonella* Testing SOP”, *Salmonella* may not need to be defined as the reader should be familiar with the term. However, for the reader of an “Environmental Monitoring Program SOP”, *Salmonella* may be unfamiliar and require definition.
- Materials
  - Where necessary, list the materials, equipment, checklists, and supporting documents required to complete the activity or task.



# KEY SECTIONS OF SOPs / SSOPs

- Safety
  - Includes a list of any personal injury or loss of life warnings, such as Confined Space. This section should explain what will happen if the procedure is not followed or is followed incorrectly.
- Procedure(s)
  - Each process, task, or step to be taken, in sequence will be listed in this section.
  - Multiple processes or sub-processes may either be (1) included in one SOP / SSOP or (2) a stand-alone SOP / SSOP.
- Training
  - List the training requirements for the SOP / SSOP as well as the frequency of training (ie: one-time, annually).

# KEY SECTIONS OF SOPs / SSOPs

- Additional Documentation
  - Identify any forms that are to be used and any reports to be written in conjunction with the SOP. Also identify the data and record storage location and duration.
- Compliance Verification and Validation
  - Verification will include a periodic review of the SOP / SSOP and the corresponding activities.
    - *Are we doing what we say we are doing?*
  - Alternatively, validation will include a periodic review of the records, reports, and other documentation.
    - *Are the goals of the SOP / SSOP being accomplished?*
  - All deviations should be reported, trended, and a corrective action / preventative action plan developed to address each opportunity.

# KEY SECTIONS OF SOPs / SSOPs

- References
  - List of all cited regulatory, company, or facility references.
- Approvals and Signatures
  - Includes the signatures and signature dates of those individuals who prepared and approved the SOP.
  - Electronic signatures are acceptable for SOPs maintained on a computerized database.
- Document Revision History
  - List of all reviews, updates, and revisions made to the SOP / SSOP.

# EXAMPLE FORMAT

SOP Template.doc

# STANDARD OPERATING PROCEDURES

Content

Development

Reviews and Revisions

Document Control

Employee Access

# SOPs / SSOPs CONTENT

- SOPs and SSOPs should be clearly worded so as to be readily understandable by a person knowledgeable with the general concept of the procedure.
- Use diagrams, flow charts, pictures, and computer screen shots to help to break up long sections of text and to briefly summarize a series of steps for the reader.
- Care must be taken to include all necessary information without becoming too detailed.

# SOPs / SSOPs CONTENT

- Examples
  - Step 4. Rinse thoroughly with warm water.
  - Step 4. Rinse thoroughly with warm water and boosted pressure. Use the blue hose fitted with a 2-4 gpm, 15 degree fan spray nozzle.
- **Remember ...**

The SOP / SSOP is to be written for the employee, not the author.

# SOPs / SSOPs DEVELOPMENT

- Initial Draft
  - Subject Matter Expert (SME) prepares written draft of procedure.
- Verify Accuracy
  - SME “walks” through the procedure, on the floor, taking into consideration to all key parameters (ie: time, equipment speed, sample location,...).
  - Conduct an area / equipment expert review. This should be with a foreman, floor lead, equipment expert, primary line operator, ...
  - Update and refine.
- Finalize and Approve
  - Add pictures, computer screen shots, diagrams, flow charts, ...
  - Submit through the company’s approval process.

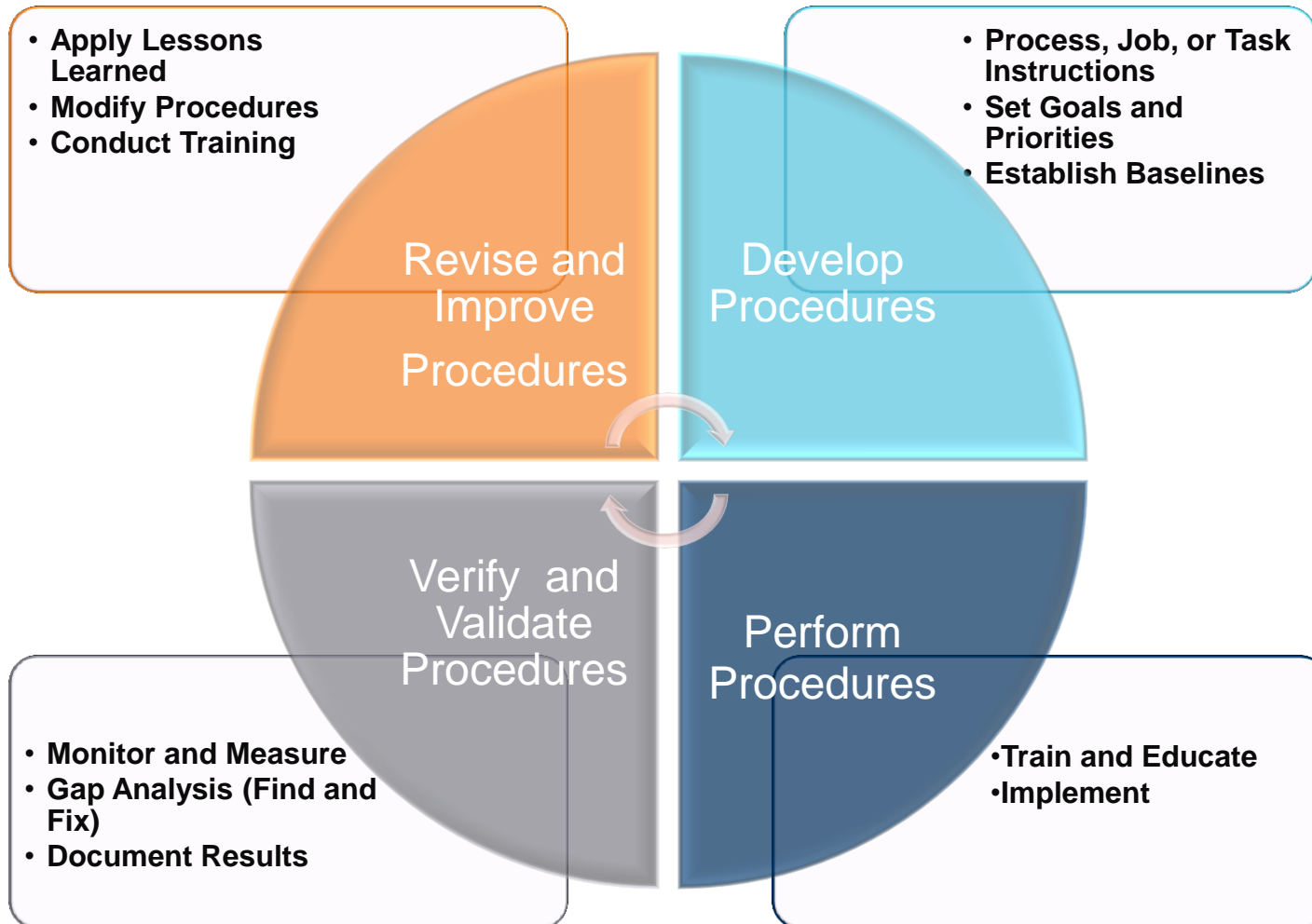


# SOPs / SSOPs REVIEWS AND REVISIONS

- All SOPs / SSOPs must be continuously improved.
- Improvements should be actively sought and changes often made. These improvements can come from:
  - Audits (Internal, Customer, 3<sup>rd</sup> Party)
  - Regulatory Visits / Regulation Changes
  - Customer Complaints
  - New Equipment / Processes / Products
  - Seasonal Production Fluctuations

# SOPs / SSOPs REVIEWS AND REVISIONS

- Continuous Improvement Cycle (Deming Circle)



# SOPs / SSOPs DOCUMENT CONTROL

- Company must have a process of initiating, updating, changing and expiring company documents.
- Document Archiving
  - Short Term
    - Generally <6 months
  - Long Term
    - Shelf Life or 2 years (which ever is longer) + 1 year
    - Additional considerations include local, state, and federal regulations as well as customer requirements.

# SOPs / SSOPs ACCESS

- Easy employee access to each SOP and SSOP is a must.
- Access can mean either a printed document or electronic access.
- If a printed manual is used, procedures and practices must be in place that ensure the manual is controlled and that the updates current.

# FOOD SAFETY MAGAZINE REFERENCE

For the full article ...

[FSM101113ProcessControl.pdf](#)

<http://www.foodsafetymagazine.com/magazine-archive1/december-2013january-2014/food-plant-sops-the-backbone-of-your-food-safety-system/>

# Covance

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# The End... And Thank You!

