Prerequisite Programs: GMP’s, SOP’s, SSOP’s

HACCP Does Not Stand Alone
- Must be built on existing food safety programs
  - Prerequisite Programs...
- Definition of Prerequisite Programs: Procedures, including Good Manufacturing Practices, that address operational conditions providing the foundation for the HACCP system

HACCP Does Not Stand Alone
- Prerequisite programs are necessary to provide basic operating conditions essential for the safe production of food
GMP’s, SOP’s. and SSOP’s

Definitions
- **GMP** = Good Manufacturing Practice
- **SOP** = Standard Operating Procedure
- **SSOP** = Sanitation Standard Operating Procedure

Prerequisite Programs
- “…essential component of an establishment’s operations and are intended to keep low-risk potential hazards from becoming serious enough to adversely impact the safety of foods produced”

from HACCP: A Systematic Approach to Food Safety
Prerequisite Programs

1. Provide basic environmental and operating conditions necessary for production of safe, wholesome food
2. Should be well-documented with written standard operating procedures (SOP’s)

Prerequisite Programs

3. Should be revised and reviewed as needed
4. Can include objectives other than food safety

Prerequisite Programs

*Primary Company Goal:

To produce a safe and clean quality product
HACCP vs. Prerequisites

- Food safety
- Specific
- Deviation = serious consequences

- General operations
- Multiple lines/areas
- Deviation may not be serious

What are GMP's?

- GMP=Good Manufacturing Practice
- GMP's are the minimum sanitary and processing requirements necessary to ensure the production of wholesome food.
- GMP’s build people, equipment, process, and the environment into the production process

GMP’s

- Are broad and general in nature
- Are also referred to as cGMP’s (current Good Manufacturing Practices)
Where do the GMP Requirements Come From?

- Food, Drug & Cosmetic Act (FDCA), 1938
  - Gave regulatory power to FDA over foods
  - Requirements for GMP's are listed in 21 CFR 110
  - Section 402(a)(4) of FDCA contains provisions for “adulterated”

The FDA and GMP’s

1969 GMP’s 1st established
- Covered food processing, handling and storage
- Specific GMP’s developed

1986 Revised GMP’s into “umbrella” GMP’s (21CFR110), the cGMP’s
- Left several specific GMP’s untouched
  - Thermally processed low-acid foods
  - Acidified foods
  - Bottled drinking water

cGMP’s

21CFR110 Category

Subpart A – General Provisions
110.3 Definitions
110.5 Current good manufacturing practices
110.10 Personnel
110.19 Exclusions

Subpart B – Buildings and Facilities
110.20 Plant and grounds
110.35 Sanitary operations
110.37 Sanitary facilities and controls
GMP’s, SOP’s, and SSOP’s

**cGMP’s**

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>21CFR110</td>
<td>Category</td>
</tr>
<tr>
<td>Subpart C</td>
<td>Equipment and Utensils</td>
</tr>
<tr>
<td>110.40</td>
<td></td>
</tr>
<tr>
<td>Subpart E</td>
<td>Production &amp; Process Controls</td>
</tr>
<tr>
<td>110.80</td>
<td>Processes and Controls</td>
</tr>
<tr>
<td>110.93</td>
<td>Warehousing and Distribution</td>
</tr>
<tr>
<td>Subpart G</td>
<td>Defect Action Levels</td>
</tr>
<tr>
<td>110.110</td>
<td>Natural or unavoidable defects in food for human use that present no health hazard</td>
</tr>
</tbody>
</table>

**Personnel**

- **Education**
- All employees should be aware of GMP’s
- Information at hiring
- Training prior to beginning work
- Periodic training for all employees

- **Disease control**
- People that are ill should not be working with food
- Return to work policy
- Open lesions or infected wounds
GMP’s, SOP’s, and SSOP’s

Personnel
- Personal cleanliness in production area
- Clean outer garments
- Wash hands
- Remove jewelry
- Storage of personal belongings
- No chewing gum or smoking
- Hair nets and beard nets

Hair Net and Beard Net

Clean Outer Clothing
GMP’s, SOP’s, and SSOP’s

**Building and Facilities**

- Grounds and area outside should be clean, well drained and free of waste
- Cafeteria or lunch area

**Design to prevent cross contamination**

- Raw Materials
- Cooler
- Processing
- Shipping
- Office
- People

**Equipment and Utensils**

- Design and construction of equipment
  - Easily cleaned
  - Metal contamination
- Instruments for control of temperature or pH must be accurate (regularly calibrated)
Production and Process Controls

- Some may be GMP's while other controls may be in HACCP plan
  - Food safety hazards
  - Level of occurrence or severity
- Raw materials and other ingredients
- Manufacturing operations

Raw Materials

- Inspection at receiving
  - Damaged boxes
  - Foreign material
  - Temperature
  - Letters of guarantee
- Prevention of contamination during storage
- Purity of ingredients (Letter of Guarantee, LOG, or Certificate of Analysis, COA)

Manufacturing Operations

- Refrigerated foods kept at 40°F or less
- Frozen foods maintained in a frozen state
- Hot foods kept above 140°F
- Time and temperature
- Chemical or physical hazards
GMP’s, SOP’s, and SSOP’s

Writing a GMP

Prepare a written document describing policies or procedures employees are expected to follow

Example:

Primary Company Goal:
To produce a safe and clean quality product
1. Every employee must practice adequate personal hygiene.
2. Each employee will take a bath or shower prior to starting work.

Writing a GMP

Can employee read and in what language?
Recommended to include a training component for certain procedures such as handwashing
Example
Handwashing

1. Use water as hot as the hands can comfortably stand.

Handwashing

2. Moisten hands, soap thoroughly, and lather to elbow.

Handwashing

Handwashing

4. Rub hands together, using friction for 20 seconds.

Handwashing

5. Rinse thoroughly under running water.

Handwashing

6. Dry hands, using single-service towels or hot-air dryer.

GMP’s, SOP’s, and SSOP’s
Writing a GMP

Include employee signature indicating agreement and understanding of GMP’s

Employee Agreement

I Will Trybetter have read the above GMPs and agree to adhere to them to the best of my ability and will alert another person when he/she is not following these practices.

Employee Signature Will Trybetter

Example Training:

Name of Trainee: __________________________
Trained By: __________________________
1. The undersigned has been shown how to do all of the above steps. *Initials of trainee and date*
2. The undersigned has performed the above steps 3 times with supervision. *Initials of trainee and date*
I have been trained on the items above that I initialed.

Employee Signature __________________________ Date __________________________

Date of Retraining is: __________

________________________
What are SOP’s?

- SOP’s are descriptions of specific tasks to be carried out in a particular operation
- SOP’s work with GMP’s to support your HACCP plan

SOP’s

- SOP’s are used in conjunction with GMPs to train employees.
- An SOP is one person’s job or one task.

SOP’s

An SOP defines:
1. Who is doing the job or task. WHO
2. The purpose for doing the job or task. WHY
3. Identifies what the job or task is. WHAT
4. Identifies steps for completing the job or task. HOW
GMP’s, SOP’s, and SSOP’s

SOP’s

5. Identifies the frequency it is performed.
6. Specifies the critical time limits for the job or task.
7. Identifies what corrective action must be taken if the job or task is performed incorrectly.

Are SOP’s Different than GMP’s?

GMP’s
- A set of procedures to be carried out by a plant to prevent adulteration of food
SOP’s
- A set of explicit instructions on how to carry out a specific operation

Example
SOP: Receiving Perishable Items

1. Immediately with each shipment, receiving clerk measures product internal temperature using a calibrated thermometer and checks date for product age (see procedures for measuring temperature)
2. Inspect for off-odors and appearance
**SOP: Receiving Perishable Items**

3. Visually inspect packaging for mishandling and exposed surface for foreign objects
4. Check for Letter of Guarantee or Certificate of Analysis
5. Record status of shipment in receiving log

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**SOP: Receiving Perishable Items**

6. Reject product that has been mishandled or has been opened or broken
7. Reject product with a temperature over 44°F
8. Place items in the appropriate storage areas (see storage of items)

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**What was missing from the Example SOP?**

- **Purpose**
- **What is done with rejected product?**
- **May need more detail to describe how the SOP is conducted**
Sanitation Standard Operation Procedures (SSOPs)

- USDA-FSIS mandates SSOPs for Meat and Poultry Operations
- Address the pre-operational and operational sanitation procedures to prevent “direct product contamination or adulteration”

SSOPs

- Developed by the facility/company
- Must address pre-operational sanitation and operational sanitation
- FSIS will verify that the plan is working
- Plant needs to update SSOPs to reflect changes in equipment and facilities

1. Pre-operational sanitation
   - Procedures must result in clean facilities, equipment and utensils
   - SSOPs include:
     - Detailed descriptions of equipment disassembly and re-assembly
     - Details of cleaning and sanitation steps
GMP’s, SOP’s, and SSOP’s

2. Operational Sanitation
   - Equipment cleaning during production
   - Employee hygiene
   - Product handling in raw and cooked product areas

3. Implementing and Monitoring
   - Specific employees specified for pre-operational and operational checks
   - Methods
     - Organoleptic
     - Chemical
     - Microbiological

4. Corrective Actions
   - When deviations occur the plant must take corrective actions to prevent direct product contamination
   - Corrective actions must be predetermined
   - All activities associated with corrective actions must be recorded