Purpose and Objectives

- **Purpose of Module 4**
  - Provide an understanding of key sections of FSIS canning regulations

- **Performance Objectives**
  - Become familiar with main sections of regulations
  - Familiarization with and effective use of current FSIS Directive 7530.2
Regulations for canning and canned products are contained in:

- 9 CFR 431.1 through 431.12
§431.1 - Definitions

- **Canned Product**: meat or poultry product with water activity >0.85 which receives a thermal process either before or packaging in hermetically sealed container.

- **Thermal Process**: Heat treatment necessary to achieve shelf stability as determined by Processing Authority.

- **Abnormal Container**: Container with any sign of swelling, product leakage, or any evidence that contents of unopened container may be spoiled.
Definitions (cont’d.)

- **Initial Temperature** (I.T.): measured in coldest container at start of thermal process
- **Process Temperature** (PT): minimum maintained temperature of heating medium
- **Process Time** (Bₜ): intended time containers exposed to heating medium in retort while at or above PT
- **Come-up Time** (CUT): elapsed time in minutes at start of Bₜ until retort reaches required PT
§431.2 Examination and Cleaning of Empty Containers

- Closure examinations for rigid containers (cans)
  - Visual examinations
  - Teardown examinations
- Closure examinations for glass containers
  - Visual examination
  - Closure examination and tests
Examinations of Empty Containers and Closures (con’t.)

- Closure examinations for semirigid and flexible containers
  - Visual examination
  - Physical tests
- Container coding
- Handling of containers after closure
§431.3 Thermal Processing

- Process Schedules (PS)
  - Developed by a Processing Authority (PA)
- Source of process schedules
- Submittal of process information
  - Any changes to PS evaluated by PA
§431.4 Critical Factors

- Container orientation
- Product formulation
- Maximum thickness of flexible containers
- Retort reel speeds
§431.5 Operations in the Thermal Processing Room

- Posting of processes
- Process indicators and traffic control
- Initial temperatures
- Timing devices
- Measurement of pH
§431.6 Equipment and Procedures for Heat Processing Systems

- Instruments and controls common to different systems
  - Indicating temperature devices
  - Mercury-in-glass thermometers
  - Other devices
  - Temperature recording devices
  - Chart-type devices
  - Steam controllers
  - Air valves/water valves
• Instruments and controls common to different systems (con't.)
  • Pressure processing in steam
    – Batch still retorts
      » Recommended venting schedules
    – Batch agitating retorts
    – Continuous rotary retorts
    – Hydrostatic retorts
• Pressure processing in water
  – Batch still retorts
  – Batch agitating retorts
• Pressure processing in steam-air mixtures
• Atmospheric cookers (batch, continuous)
• Other systems
• Equipment maintenance
• Container cooling and cooling water
• Post-process container handling
§431.7 Processing and Production Records

- Processing in steam
  - Batch still retorts
  - Batch agitating
  - Continuous rotary
  - Hydrostatic retorts
• Processing in water
  • Batch still retorts
  • Batch agitating
• Processing in steam-air mixtures
• Processing in other systems (e.g., cascade or water spray)
• Atmospheric cookers (batch, continuous)
§431.8 Record Review and Maintenance

- Process records
- Automated process monitoring and recordkeeping
- Container closure records
- Distribution of product
- Retention of records
§431.9 Deviations in Processing

- HACCP plan that addresses microbial hazards
- Procedures for handling deviations if microbial hazards occur
- Deviations identified in-process
- Deviations identified through record review
§431.10 Finished Product Inspection

- Incubation of shelf stable canned product (if applicable)
  - Incubator
  - Incubation temperature
  - Product requiring incubation
  - Incubation samples
  - Incubation time
Finished Product Inspection (con’t.)

- Incubation checks and records
- Abnormal containers
- Shipping
- Container condition
  - Normal containers
  - Abnormal containers
Additional Parts

- §431.11 Personnel and Training
- §431.12 Recall Procedure
Verification Activities in Canning Operations That Choose to Follow the Canning Regulations
If the establishment elects not to address hazards associated with microbiological contamination in its HACCP plan, the decision is the hazard is NRLTO.

Any records required by regulations in 9 CFR 431 and establishment’s associated process documentation would be required to be kept under 9 CFR 417.5(a)(1).
HACCP Verification Task

- Select specific production
- Use RK, RO, or both components
- Verify monitoring, corrective action, verification, and recordkeeping requirements at all CCPs (if any) and execution of any prerequisite programs
- Verify canning regulations relevant to the specific production (see Dir. 7530.2, IV)
- Verify 1 or more other canning regulations
Verify that:

- Process schedule posted
- Correct process schedule used
- No formulation, equipment, or treatment changes
- I.T. measured and recorded
- All critical factors met
- Deviations appropriately handled
Verify that:

- Required processing information recorded
- Only normal containers selected for incubation (if applicable)
  - Establishment reviewed all processing and production records no later than one working day after actual process
  - §417.5(a)(3) requirements met if HACCP plan addresses any chemical or physical hazards
Corrective Actions

- If microbial hazards are addressed with canning regulations, corrective actions must meet per §431.9
- If a deviation is not handled according to §431.9, it is a regulatory noncompliance
- Unforeseen hazards must be addressed according to §417.3(b)
- If chemical or physical hazards are addressed as CCPs, corrective actions for deviations from critical limits must meet §417.3(a)
If inspection personnel have concerns about the establishment’s corrective actions, they should contact their supervisor and request assistance.
Noncompliance with Part 431 canning regulations should be addressed by issuance of Noncompliance Record (NRs) and/or retention of suspect product.

When an establishment addresses microbiological hazards using the canning regulations, IPP document noncompliance with applicable canning regulation and also §417.5(a)(1).
Key Points

- **Must** = requirement
- **Should** = recommendation
- Part 431 sections include definitions and address requirements for:
  - Containers and closures
  - Thermal processing
  - Critical factors
  - Operations in the thermal processing area
Part 431 also addresses requirements for:

- Equipment and procedures for heat processing systems
- Processing and production records
- Record review and maintenance
- Deviations in processing
- Finish product inspection
- Personnel and training
- Recall procedures
Key Points (con’t.)

- IPP must ensure that their assigned facility complies with applicable sections of regulations
- Design and application of recommended thermal process is critical to finished product safety
- Installation, operation, instrumentation, maintenance, and validation of thermal processing systems is critical to finished product safety
Key Points (con’t.)

- Proper handling of thermal process deviations and affected product is critical to finished product safety.
- Proper handling of abnormal containers (e.g., swollen, leaking, evidence of spoilage), whether in incubation or found elsewhere, is critically important.
Key Points (con’t.)

- When performing HACCP Verification tasks for specific production of canned foods, IPP verify HACCP plan implementation (Directive 5000.1) AND

- Verify compliance with canning regulations relevant to specific production and one or more general canning regulations (Directive 7530.2)
Questions?