

Verification activities for the regulatory requirements of the canning regulations

9 CFR 318.301/381.301 – Containers and Closures:

This section of the canning regulations requires that establishments ensure that empty containers and container materials are clean and free of structural defects and damage that may affect product or container integrity. Additionally, this section also specifies visual and physical examinations of closure or container defects are to be made, and that necessary corrective actions are to be performed when defects are found. You should verify that:

- a. the establishment has a statistical sampling plan for evaluating incoming containers and rejection actions, if needed,
- b. the establishment is following its statistical sampling plan,
- c. the establishment is ensuring that empty containers, roll stock for container forming, and lidding materials are clean and free from structural defects prior to filling,
- d. the establishment's empty container handling practices (e.g., conveying, unscrambling, denesting, manual handling) are adequate to prevent soiling and damage,
- e. the containers are free of damage after filling,
- f. the establishment is conducting container closure examinations,
- g. the containers and closures (after closure) are protected from damage which could cause defects likely to affect the hermetic condition of the container,
- h. corrective actions are taken in response to detection of improper container closure or damage,
- i. the containers are marked with a permanent, legible, identifying code mark per regulatory requirements, and
- j. the maximum time lapse between container closure and the initiation of the thermal process is 2 hours or less, unless otherwise approved.

Canning Regulations Example 1: *You are performing the 03D01 procedure at a canning facility, and have selected to verify §381.301(d)(1)(i). You decide to use the review and observation component for the post-retorting visual examination of the flexible pouches. You review the plant's written program for this examination. You determine the closure technician is to assess the container integrity of 10 containers at least every 2 hours of continuous production. All containers with defective seals are to be discarded. You proceed to where the closure technician is working. You look at the record and see hourly entries and that the first entry of the day showed there were some containers with seam defects. You see an entry indicating that all containers were held*

for further seam review and that the sealing machine had been adjusted. You see documentation that the closure tech continued to hold containers until the sealing machine was functioning properly. The entry also noted that all held product was held with a QC tag. You observe the closure tech select 10 containers. She carefully examines the seams and documents that no defects were found. You select 3 filled and sealed containers from the line and examine all seams, you observe no defects. This result is the same as what the QC tech had found. You go to the holding area and see a pallet with a QC hold tag as described on the record. You determine there is compliance with §381.301(d)(1)(i).

9 CFR 318.302/381.302 – Thermal Processing:

This section of the canning regulations requires that all product be produced by the establishment is produced according to a process schedule developed by a process authority. You should verify that:

- a. the establishment verifies that it has process schedules/documents from the processing authority on file for each product produced,
- b. the establishment ensures that no unauthorized changes are made to the process schedule in use (e.g., formulation, preparation, process equipment), and
- c. the establishment ensures that the products are prepared according to the formulation and procedures specified in documents that the processing authority has developed.

Canning Regulations Example 2: *You are performing the 03D01 procedure at a small canning operation, and have selected to verify §381.302(b)(2) using the review and observation component. You are verifying that the plant is not using any unauthorized product formulation changes. You go to the QC office and request the approved process schedules on file that are being used today. You note in the file that there are 2 different types of starch that may be used in the turkey chili formulation they are running currently. The process is different for each of the two types of starch they may use. You see that for the first starch, they need to use process schedule 023. You go to the formulation room and see they are adding bags of the first type of starch to make the turkey chili. You look at the formulation log and see they have used this type of starch in the product all day. You go to the retort area and see process schedule 023 posted. You ask the retort operator which process schedule he is using and he says he is only running the one posted on the wall today. You read the posted schedule and see that it matches the one you saw in the QC office. From this, you determine the operation is in compliance for §381.302(b)(2).*

9 CFR 318.303/381.303 – Critical Factors and the Application of the Process Schedule:

This section of the canning regulations requires that establishments ensure that the critical factors identified in the process schedule are measured, controlled, and recorded as specified in the process schedule. Factors that are often critical to process schedule

adequacy may include: maximum fill or drained weight; arrangement of pieces in the container; container orientation; product formulation; particle size; maximum thickness for flexible or semirigid containers during thermal processing; maximum pH; percent salt; ingoing nitrite level; maximum water activity, product consistency or viscosity; container filling sequence; minimum head space; retort conveyor or reel speed; steam/air ratio; and heating medium flow rate. You should verify that:

- a. the critical factors specified in the process schedule are measured, controlled and recorded by the establishment to ensure that these factors remain within the limits used to establish the process schedule,
- b. all measurements are within limits used to establish the process schedule,
- c. the establishment ensures that the types of ingredients (hydrated vs. not hydrated, acidified vs. not acidified, blanched vs. not blanched, slow set vs. rapid set starch, etc.), as specified in the process schedule, are prepared or utilized in the product formulation, and
- d. the establishment ensures that the product is prepared according to the formulation specified in the process schedule, including but not limited to the specified amount and characteristics (e.g., pH, cure, water activity, viscosity, etc.) of each ingredient.

Canning Regulations Example 3: *You are performing the 03D01 procedure to verify the canning regulations at a canned chili establishment. You have selected to verify the requirement for §318.303. You review the process schedule on file to determine the critical factors specified for the product, and find that product formulation and use of hydrated beans are critical factors. You then proceed to observe the formulation procedures used by the establishment. You determine that hydrated beans were used and that all ingredients were incorporated in the amounts specified in the process schedule. You conclude that the establishment was in compliance with §318.303.*

9 CFR 318.304/381.304 – Operations in the Thermal Processing Area:

This section of the canning regulations requires that establishments ensure that the process schedule (or operating process schedule) for daily products, including minimum initial temperatures and operating procedures for the thermal processing equipment, is posted near the thermal processing equipment, or available to the thermal processing system operator and inspection program personnel. Additionally, this section also states that establishments shall have product traffic control to prevent product from bypassing the thermal process, that the initial temperature of the contents of the coldest container to be processed shall be determined and recorded, that timing devices shall be adequate to time applicable thermal processing operation functions or events, and that measurement of pH shall be conducted using potentiometric electronic instruments (pH meters) unless other methods are approved. You should verify that:

- a. the process schedules (or operating schedules) for daily production, including minimum initial temperatures and operating procedures for thermal processing equipment, are posted in a conspicuous place near the processing equipment,

- b. the establishment has a system in place for product traffic control to prevent product from bypassing the thermal processing operation,
- c. the establishment personnel are measuring the coldest container to be processed, and recorded at the time the processing cycle begins, to ensure that the temperature of the contents of every container to be processed is not lower than the minimum initial temperature specified in the process schedule,
- d. the establishment is following its written procedures on file for determining the initial temperature,
- e. measures are in place to prevent water from lowering the initial temperature below the prescribed minimum (if the establishment is placing containers in holding tanks or using water in the retort),
- f. there are adequate product traffic control procedures (e.g., heat sensitive indicators in each retort load) to prevent unprocessed product from bypassing the system,
- g. the establishment has accurate devices to time applicable thermal processing operation functions or events, such as process schedule time, come-up time, and retort venting, to assure that all such functions or events are achieved, and
- h. the establishment uses potentiometric methods that employ electronic instruments for making pH determinations when a maximum pH value is specified as a critical factor in a process schedule.

Canning Regulations Example 4: *You are performing the 03D01 procedure at a canned spiced ham establishment. You have selected to verify the requirements for §318.304(a). You review the process schedule on file. You then proceed to the retort area to determine if the process schedule is posted or available to the retort operator. You observe that the process schedule is posted and matches the process schedule on file. You conclude that the establishment was in compliance with §318.304(a).*

9 CFR 318.305/381.305 – Equipment and Procedures for Heat Processing Systems:

This section of the canning regulations requires that the equipment and procedures used for heat processing systems be adequate to deliver a thermal process to product that renders it commercially sterile. This regulation identifies specific criteria or parameters for the various instruments, controls, and components of the various types of thermal processing systems, including retort design. The establishment must have the various items addressed in this section of the canning regulations, including but not limited to: temperature indicating devices; temperature/time recording devices; pressure recording devices; steam controllers; air valves and supplies; water inlets and valves; steam inlets and spreaders; bleeders and condensate removal systems (including vents and mufflers); crate supports; stacking equipment; retort/reel speed timing; conveyor speed; heat distribution systems; drain valves; and circulation systems for the various types of

retort systems. Additionally, these regulations also address equipment maintenance, container cooling and cooling water, and post-process handling of containers. You should verify that:

- a. each retort system is installed, operated, and maintained as required,
- b. each retort system is equipped with at least one indicating temperature device that measures the actual temperature within the retort,
- c. the indicating temperature device, not the temperature/time recording device, is used as the reference instrument for indicating the process temperature,
- d. the mercury-in-glass thermometers meet the requirements specified,
- e. each thermal processing system is equipped with at least one temperature/time recording device to provide a permanent record of temperatures within the thermal processing system, and each retort is equipped with an automatic steam controller to maintain the retort temperature,
- f. all air lines connected to retorts designed for pressure processing in steam are equipped with a globe valve or other equivalent-type valve or piping arrangement that will prevent leakage of air into the retort during the process cycle,
- g. all retort water lines that are intended to be closed during a process cycle are equipped with a globe or other equivalent-type valve or piping arrangement that will prevent leakage of water into the retort during the process cycle,
- h. the steam inlet to each retort is large enough to provide steam for proper operation of the retort, and enter at a point to facilitate air removal during venting,
- i. steam spreaders, bleeders, stacking equipment, and divider plates are installed and used as per the regulatory requirements,
- j. vents are located in the portion of the retort opposite the steam inlet and designed, installed, and operated in such a way that air is removed from the retort before timing of the thermal process is started,
- k. vents are not connected to closed drain systems without an atmospheric break in the line,
- l. all instruments and controls are checked any time their functioning or accuracy is suspect,
- m. maintenance records and the annual thermal process system audit records indicate that the thermal process systems are functioning properly,

- n. recycled or reused container cooling waters are handled in systems that are designed, operated, and maintained so that there is no buildup of microorganisms, organic matter, and other materials in the systems and in the waters, and
- o. containers are handled in a manner that will prevent damage to the hermetic seal area.

Canning Regulations Example 5: *You are performing the 03D01 procedure in a canning establishment, and have selected to verify §318.305(b)(1)(viii) using the review and observation component. You notice that the bleeders on the horizontal still steam retorts are equipped with mufflers. You ask the retort room supervisor if the establishment has documentation on file that the mufflers do not impede the removal of air from the retorts. The retort room supervisor provides heat distribution data from a processing authority that the mufflers will not impede air removal from the retorts. You determine that the establishment is in compliance with §318.305(b)(1)(viii).*

Canning Regulations Example 6: *You are performing the 03D01 procedure at a canning facility, and have selected to verify §318.305(h), container cooling and cooling water. You chose to use the review and observation component. You request the written program from plant management for cleaning, replenishing with potable water, and measuring the residual chlorine.*

After review of the procedure, you determine that the plant's written program specifies that the residual chlorine will be measured at the discharge point of the canal with a colorimetric test kit every hour by a QC technician. The value specified is 2 ppm or above. You proceed to that location and observe the QC technician measure and record 2 ppm measurement at 0910. You determine the establishment is in compliance with §318.305(h).

9 CFR 318.306/381.306 – Processing and Production Records:

This section of the canning regulations requires that establishments obtain and record all information necessary to demonstrate that the product is prepared, processed and handled in a manner that is in compliance with the regulations for commercially-sterile, hermetically-sealed shelf stable product. The records required by this part of the canning regulations include, but are not limited to: date of production; product name and style; container code; container size and type; process schedule, including the minimum initial temperature; measurements made to satisfy the requirements for the control of critical factors; and recorded information and data associated with the particular type of thermal processing system used to process the product. You should verify that:

- a. establishment personnel record the date of production, product name and style, container code, container size and type, and the process schedule, including the minimum initial temperature,
- b. additional records are completed for the specific types of retorts in the establishment, and
- c. establishment personnel review and maintain production records.

Canning Regulations Example 7: *You are performing the 03D01 procedure in a canning establishment that uses batch still retorts to verify §318.306(a). You decide to use the recordkeeping component.*

You proceed to the QC office and ask to see yesterday's production records. You review the records and see that they include the product name, container code, size and type and process schedule. Since the plant processes in steam with batch still retorts, you also verify that the records include: retort number; approximate # of containers per load; product IT; steam-on time/temp vent closed; start of process timing; time steam-off; and actual process time. The records also indicate that the temperature device/recorder was read at least once during process timing and the temperature was recorded. You determine that the plant is in compliance with §318.306(a).

9 CFR 318.307/381.307 – Record Review and Maintenance:

This section of the canning regulations requires that establishments prepare processing and production records associated with the production of commercially- sterile, hermetically-sealed shelf stable product appropriately, review the records in a timely manner, and maintain them for a minimum of three years (one year at the establishment and an additional two years at the establishment or other location). Additionally, these regulations also specify that records must be maintained by the establishment that identify the initial distribution of the finished product, and that all records be made available to inspection program personnel for review. You should verify that:

- a. entries on the records are made at the time the event occurs,
- b. establishment personnel (no later than 1 working day after the actual process) review all processing and production records to ensure completeness and to determine if all product adhered to the process schedule, and
- c. all records, including the temperature/time recorder charts and critical factor control records, are signed or initialed and dated by the person conducting the review.

Canning Regulations Example 8: *You are performing the 03D01 procedure in a canning establishment that uses batch still retorts. You select to verify compliance with a part of §318.307(a) which states “each entry on a record must be made at the time the specific event occurs, and the recording individual shall sign or initial each record form.” You decide to use the review and observation component.*

You proceed to the processing floor where the still retorts are located. You observe the retort operator venting retort # 1. You observe the posted process schedule and retort log and see that the date, IT, product code, and time steam-on has been recorded and that the retort operator has initialed the process record. You observe the vent operator close the vent and record the time that the vent was closed and the temperature of the retort. Based on your observation, you determine that the plant is in compliance with this part of §318.307(a).

On the following day, you proceed to the QC office and you ask to see the records from the previous day's production to verify if the plant reviewed the process records for the previous day's production. Using the recordkeeping component, you see that the responsible plant official signed the record indicating that he has reviewed all process records for retort #1. Based upon your records review, you determine that the plant is in compliance with this part of §318.307(a).

9 CFR 318.308/381.308 – Deviations in Processing:

This section of the canning regulations requires that whenever the actual process is less than the process schedule, or any critical factor does not comply with the requirements for that factor as specified in the process schedule, such events are considered deviations in processing, and that deviations are to be handled in a manner to prevent the distribution of under processed product. These regulations specify the requirements for handling deviations identified either in-process or through records review. You should verify that:

- a. establishment personnel detect all deviations,
- b. establishment personnel handle process deviations in accordance with these regulations, whether identified in-process or through records review,
- c. the establishment only reprocesses or repacks product with a process schedule authorized by the processing authority,
- d. deviations in a continuous retort, including, but not limited to, emergency stops (jams or breakdowns) or temperature drops, are handled according to regulatory requirements, and
- e. the establishment's process deviation file contains full records regarding the handling of each deviation, including at a minimum, the appropriate processing and production records, a full description of the corrective actions taken, the evaluation procedures and results, and the disposition of the affected product.

9 CFR 318.309/381.309 – Finished Product Inspection:

This section of the canning regulations is designed to ensure that only safe and stable product is shipped in commerce. This regulation specifies the finished product inspection procedures that the establishment must follow, including the handling of abnormal containers, to ensure that only normal-appearing, hermetically-sealed containers of product that are commercially sterile and shelf stable are distributed in commerce. You should verify that:

- a. the establishment has finished product inspection procedures that are in compliance with these regulations,
- b. the establishment has documented procedures in place for finished product inspection,

- c. the establishment has an incubator, when incubation is used, with an accurate recorder, accurate thermometer, a means for air circulation within the incubator, and a means to prevent unauthorized entry into the incubator,
- d. the establishment's container incubation program, when applicable, complies with required time, temperature, range, sampling program, identification of product requiring incubation, checks, and records,
- e. the establishment (when it uses a reduced incubation rate) has controls that include incoming container and closure examinations, packer's end double seam examinations, handling of filled and sealed containers, retort traffic control container cooling practices, recordkeeping and records review, and procedures for ensuring the container soundness of finished lots,
- f. the establishment (when it uses a reduced incubation time) has adjusted the amount of product incubated (a percentage of the total lot rather than a single container for still retorts or 1 per 1000 containers for continuous retorts) and has narrowed the temperature range for incubation (e.g., from $\pm 5^{\circ}\text{F}$ to $\pm 2^{\circ}\text{F}$),
- g. the establishment (when it ships product without incubation) has a letter from its process authority stating that its HACCP plan, QC program(s), and/or process schedule(s) adequately provide for product safety and stability,
- h. establishment personnel are performing incubation checks,
- i. incubator records are maintained as required, and
- j. abnormal containers are handled according to regulatory requirements.

Canning Regulations Example 10: While performing the 03D01 procedure for canned chili to verify compliance with §318.309(d). You review the establishment's written program for handling finished product inspection. Based upon your review, you determine that the establishment is shipping product without incubation because it has a letter from a process authority indicating that the establishment has programs in place to ensure container integrity and stability. Therefore, you conclude that the establishment is in compliance with §318.309(d).

9 CFR 318.310/381.310 – Personnel and Training:

This section of the canning regulations requires that all operators of the thermal processing systems within the establishment and all container closure technicians are under the direct supervision of a person who has successfully completed a school of instruction that is generally recognized as adequate for properly training supervisors of canning operations. You should verify that:

all operators of thermal processing systems and container closure technicians are under the direct supervision of a person who has successfully completed a

school of instruction that is generally recognized as adequate for properly training supervisors of canning operations

9 CFR 318.311/381.311 – Recall Procedures:

The purpose of this part of the canning regulations is for the establishment to ensure that it has prepared and maintains a current recall procedure for all canned product they produce that are covered by the canning regulations. You should verify that:

the establishment has prepared and maintains current procedures for the recall of all canned product covered by the canning regulations

Noncompliance with the Canning Regulations

The following are examples of 03D01 noncompliance with the canning regulations.

Noncompliance Example 1: While performing the review and observation component of 03D01, you observe the temperature indicating device (MIG) on several vertical still steam retorts. The MIG on one retort has divisions that are readable to 2°F. **The MIG must be readable to 1°F so the establishment is not in compliance with §318.305(a)(1)(i).**

Noncompliance Example 2: The plant is using a process schedule from the neighboring establishment for its Vienna sausages with broth. *“Process schedules used by an establishment shall be developed or determined by a processing authority.”* This is noncompliance with §318.302(b)(1) because **the process schedule is not from a processing authority.**

Noncompliance Example 3: The plant is using frozen meatballs in its spaghetti and meat balls in a can. The formulation, as written and given to the process authority, specified fresh meatballs. *“Any change in product formulation, ingredients, or treatments that are not already incorporated in a process schedule and that may adversely affect either the product heat penetration profile or sterilization value requirements shall be evaluated by the establishment’s processing authority. If it is determined that any such change adversely affects the adequacy of the process schedule, the processing authority shall amend the process schedule accordingly.”* You determine there is noncompliance with §318.302(b)(2) because **there is no process schedule for frozen meatballs in the formulation.**

Noncompliance Example 4: You rotate into a canning assignment and ask to see the process schedule for chicken noodle soup. The plant says all its process schedules are kept at the headquarters plant in another state. *“...process schedules shall be maintained on file by the establishment...”* You determine there is noncompliance with §381.302(c)(2) because **the process schedule is not on file at the establishment.**

Noncompliance Example 5: One of the canned products was formulated with uncured pork. The processing schedule was established for cured pork. *“Any change in product formulation, ingredients, or treatments that are not already incorporated in a process schedule and that may adversely affect either the product heat penetration profile or*

sterilization value requirements shall be evaluated by the establishment's processing authority. If it is determined that any such change adversely affects the adequacy of the process schedule, the processing authority shall amend the process schedule accordingly." You determine there is noncompliance with §318.302(b)(1) because **the product could be underprocessed. There is no processing schedule for uncured pork.**

Noncompliance Example 6: While performing the 03D01 procedure for canned chili to verify the requirement for supporting documentation, you review the requirement for §318.303. You reviewed the process schedule on file to determine the critical factors specified for the product, and found that product formulation, meat chunk size of $\leq \frac{1}{4}$ inch, and use of hydrated beans are critical factors. You then proceeded to observe the formulation procedures used by the establishment and determined that hydrated beans were used and that all ingredients were incorporated in the amounts specified in the process schedule. However, you observe that the meat chunk size is about $\frac{1}{2}$ inch. **The meat chunk size exceeds that critical limit specified in the process schedule.**

Noncompliance Example 7: While performing the 03D01 procedure for canned chili to verify the requirement for supporting documentation, you review the records associated with compliance with §318.309(d). You review the establishment's written program for handling finished product inspection. Based upon your review, you determine that the establishment complies with §318.309(d) by incubating one container from each load of the vertical still retorts for at least 10 days at 95 ± 5 F. When conducting the review and observation component, you observe that all sample containers are removed from the incubator at 10 days of incubation and temperature of the incubator is 89 F. **You conclude that the establishment is not in compliance with §318.309(d).**

Noncompliance Example 8: You are conducting the 03D01 procedure in a canning establishment that uses batch agitating retorts and decide to verify compliance with §318.306(a)(2). That regulation requires recording the reel or retort speed and the functioning of the condensate bleeder. You proceed to the processing area where the retorts are located and observe the retort operation. You examine the retort log and determine that although the reel speed of the retort has been recorded, the function of the condensate bleeder has not. **You conclude that there is non-compliance with §318.306(a)(2).**

Noncompliance Example 9: You are conducting the 03D01 procedure in a canning establishment that uses batch agitating retorts and decide to verify compliance with §318.307(c) using the Rk component. You go to the QC office and ask to see the container closure records. You review the container closure records. They include the results of container closure examination. However, the record does not include the signature or initials of the container closure technician, as required. **You determine that the plant is not in compliance with §318.307(c).**

Noncompliance Example 10: Today, February 1, 2005, you are conducting the 03D01 procedure in a canning establishment that uses batch agitating retorts and decide to verify compliance with §318.307(e). You proceed to the QC office and ask to see the processing records for the batch agitator retort for June 1, 2004. The QC technician informs you that they only keep records on-site for 6 months, all other records are stored off-site at their corporate office. **You determine that the plant is not in compliance with §318.307(e).**

Noncompliance Example 11: While performing the 03D01 procedure for canned chili to verify the supporting documentation, you review the requirement for §318.304. You review the process schedule on file. You then go to the retort area to determine if the process schedule is posted or available to the retort operator. You observe that the process schedule is posted and matches the process on file. However, you observe that the container IT is below that specified in the process schedule for the process. **You determine that the plant is not in compliance with §318.304(c).**

Noncompliance Example 12: While performing the 03D01 procedure, you verify the canning regulatory requirement §318.305(b)(1)(vii)(b). You are familiar with this establishment, and you know that divider plates are not normally used in the steam batch still retorts for small production orders. The majority of product was retorted with the hydrostatic systems. Today you observe stacking of layers in the crate using divider plates in the vertical still retort when verifying this procedure. You request documentation that the venting procedure allows air to be removed from the vertical still retort before timing of the thermal process is started. Plant management could not provide documentation in the form of heat distribution data with the use of divider plates. **You determine noncompliance with §318.305(b)(1)(vii)(b) exists.**

Noncompliance Example 13: While performing the 03D01 procedure, you request the maintenance procedures for the periodic cleaning and sanitizing of the container cooling water recycling system. You also request the water quality standards (microbiological, chemical, or physical) record for the monitoring procedure. The QC manager provides a cleaning and sanitizing procedure. The procedure specifies water quality standards for recycled water, but does not include the sampling frequency, sample site location, and corrective action when the water quality standards are not met. **You determine that noncompliance with §318.305(h)(3)(iii)&(iv) exists.**