

For the nuclear regulatory Commission.
John F. Stolz,
*Director PWR Project Directorate No. 6,
Division of PWR Licensing-B.*
[FR Doc. 86-28502 Filed 12-18-86; 8:45 am]
BILLING CODE 7590-01-M

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster Loan Area #2258;
Amdt. #3]

Declaration of Disaster Area Missouri; Change of Interest Rates

The above-numbered Declaration (51 FR 37532), as amended (51 FR 40099), and (51 FR 41887) is hereby further amended to change the interest rate for nonprofit, eleemosynary and similar organizations from 10.5 percent to 9.5 percent. Any loans approved to an organization in this group between October 1, 1986, and this date, will be automatically adjusted to reflect the new rate. All other information remains the same.

(Catalog of Federal Domestic Assistance
Programs Nos. 59002 and 59008)

Dated: November 13, 1986.

Alfred E. Judd,

*Acting Deputy Associate Administrator for
Disaster Assistance.*

[FR Doc. 86-28496 Filed 12-18-86; 8:45 am]

BILLING CODE 8025-01-M

STATE JUSTICE INSTITUTE

Institute Program Priorities, Conditions and Limitations on Awards; Policy Statement Availability

AGENCY: State Justice Institute.

ACTION: Notice.

SUMMARY: The State Justice Institute Act of 1984 (Pub. L. 98-620, Title II, sec. 203(f)) requires that interested parties be given notice and a reasonable opportunity to comment on Institute rules, regulations, guidelines and instructions prior to final issuance. Notice is hereby given that copies of a policy statement describing Institute

program priorities, conditions and limitations on awards, and application and review procedures is available for review and comment from the State Justice Institute at the address given below.

DATE: Comments from interested parties on the policy statement must be received no later than January 12, 1987.

ADDRESS: Copies of the policy statement are available from and comments should be returned to:

State Justice Institute, Superior Court of
the District of Columbia, Suite 5230,
500 Indiana Avenue, NW.,
Washington, DC 20001

FOR FURTHER INFORMATION CONTACT:
John B. Pickett, Acting Executive
Director, State Justice Institute at the
address given above; telephone (202)
628-0001.

John B. Pickett,

Acting Executive Director.

[FR Doc. 86-28478 Filed 12-28-86; 8:45 am]

BILLING CODE 6820-SC-M

Sunshine Act Meetings

Federal Register

Vol. 51, No. 244

Friday, December 19, 1986

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

FEDERAL ENERGY REGULATORY COMMISSION:

"FEDERAL REGISTER" CITATION OF

PREVIOUS ANNOUNCEMENT: 51 FR 44969, December 15, 1986.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: December 17, 1986, 10:00 a.m.

CHANGE IN THE MEETING: The following items have been added:

Item No., Docket Nos., and Companies

CAM-13—RM87-9-000, Confidential
Treatment of Records and Documents Filed
With the Commission

ER-1(A)—PL87—, Statement of Policy
on Phased Electric Rate Filings

RP-5—RP86-92-000 and 003, Northwest
Pipeline Corporation

Kenneth F. Plumb,

Secretary.

[FR Doc. 86-28616 Filed 12-17-86; 1:03 pm]

BILLING CODE 6717-02-M

FARM CREDIT ADMINISTRATION

Farm Credit Administration Board;
Special Meeting

SUMMARY: Notice is hereby given, pursuant to the Government in the Sunshine Act (5 U.S.C. 552b(e)(3)), of the

forthcoming special meeting of the Farm Credit Administration Board (Board).

DATE AND TIME: The meeting is scheduled to be held at the offices of the Farm Credit Administration in McLean, Virginia, on December 18, 1986, from 10:00 a.m. until such time as the Board may conclude its business.

FOR FURTHER INFORMATION CONTACT: Kenneth J. Auberger, Secretary to the Farm Credit Administration Board, 1501 Farm Credit Drive, McLean, Virginia 22102-5090 (703-883-4010).

ADDRESS: Farm Credit Administration, 1501 Farm Credit Drive, McLean, Virginia 22102-5090.

SUPPLEMENTARY INFORMATION: This meeting of the Board will be open to the public (limited space available). The matters to be considered at the meeting are:

1. Consideration of Final Regulations—
Regulatory Accounting Practices and
Requirements

Dated: December 16, 1986.

Kenneth J. Auberger,

Secretary, Farm Credit Administration Board.

[FR Doc. 86-28563 Filed 12-16-86; 4:39 pm]

BILLING CODE 6705-01-M

FARM CREDIT ADMINISTRATION

Farm Credit Administration Board;
Regular Meeting

SUMMARY: Notice is hereby given, pursuant to the Government in the Sunshine Act (5 U.S.C. 552b(e)(3)), of a change in the date of the forthcoming regular meeting of the Farm Credit Administration Board (Board).

DATE AND TIME: The meeting was scheduled to be held on January 6, 1987. The meeting has been rescheduled to be held at the offices of the Farm Credit Administration in McLean, Virginia, on January 15, 1987, from 10:00 a.m. until such time as the Board may conclude its business.

FOR FURTHER INFORMATION CONTACT: Kenneth J. Auberger, Secretary to the Farm Credit Administration Board, 1501 Farm Credit Drive, McLean, Virginia 22102-5090 (703-883-4010).

ADDRESS: Farm Credit Administration, 1501 Farm Credit Drive, McLean, Virginia 22102-5090.

SUPPLEMENTARY INFORMATION: Parts of this meeting of the Board will be open to the public (limited space available), and parts of the meeting will be closed to the public. Notice of the matters to be considered at the meeting will be published in the **Federal Register** before January 15, 1987.

Dated: December 16, 1986.

Kenneth J. Auberger,

Secretary, Farm Credit Administration Board.

[FR Doc. 86-28564 Filed 12-16-86; 4:40 pm]

BILLING CODE 6505-01-M

Corrections

Federal Register

Vol. 51, No. 244

Friday, December 19, 1986

This section of the FEDERAL REGISTER contains editorial corrections of previously published Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Parts 1064, 1102, 1106, 1108, and 1126

[Docket Nos. AO-231-A54 et al.]

Milk in the Texas and Certain Other Marketing Areas; Order Amending Orders

Correction

In rule document 86-27870 beginning on page 44590 in the issue of Thursday, December 11, 1986, make the following corrections:

1. On page 44591, in the first column, in the sixth complete paragraph, third line, "or" should read "of".

§ 1106.52 [Corrected]

2. On page 44592, in the second column, in § 1106.52, the introductory text of paragraph (a)(6) was inadvertently omitted. After the fifth line insert the following:

* * * * *

(6) For a plant located in any of the following territory in the State of Texas, the adjustment shall be as follows:

* * * * *

3. On the same page, in the same column, in § 1106.52 (a)(7)(i), in the fifth line, insert "price" between "I" and "effective".

§ 1108.52 [Corrected]

4. On page 44592, in the third column, in § 1108.52 (a)(1)(iii), in the first line, "country" should read "county".

BILLING CODE 1505-01-D

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Parts 1065 and 1079

[Docket Nos. AO-178-A40, AO-86-A44, and AO-295-A37]

Milk in the Upper Midwest, Nebraska-Western Iowa, and Iowa Marketing Areas; Decision on Proposed Amendments to Tentative Marketing Agreements and to Orders

Correction

In proposed rule document 86-27871 beginning on page 44617 in the issue of Thursday, December 11, 1986, make the following correction:

On page 44628, the last paragraph of the first column and the first paragraph of the second column should have read as follows:

"The exceptions filed by Mid-Am, Gillette and Wells, except for Wells' legal interpretation of the new legislation, raise points that were fully considered in the recommended decision and therefore are denied. However, in further response to Mid-Am's exceptions, it must be noted that the 1.7-cent rate adopted was not based on the cost of moving packaged milk. As stated earlier, this rate is appropriate to reflect price alignment resulting from certain of the Congressionally mandated differentials. Also, there is no need demonstrated for an incentive to move milk from Norfolk to Omaha. The record does not indicate that the Omaha-area plants have experienced difficulty in obtaining milk supplies. With respect to the new legislation, the Food Security Act of 1985 does not prescribe the narrow approach to setting these new location adjustments that Wells thinks Congress intended.

With respect to proposals for a location adjustment at Norfolk, it would be inconsistent to adopt a minus location adjustment at Norfolk because Norfolk is part of the base zone. The mandated Class I differentials, which became effective May 1, 1986, were minimums intended by Congress to be applicable to the existing base zones as of that date. Accordingly, it would appear to be inappropriate to lower the Class I differentials at any location within that base zone during the two-

year period that the differentials were mandated under the 1985 Act."

BILLING CODE 3410-02-D

DEPARTMENT OF EDUCATION

[CFDA No. 84.116A]

Inviting Preapplications and Applications for New Awards Under the Comprehensive Program of the Fund for the Improvement of Postsecondary Education (FIPSE) for Fiscal Year 1987

Correction

In notice document 86-27927 appearing on page 44829 in the issue of Friday, December 12, 1986, make the following corrections:

1. In the first column, in the second paragraph, in the second line, "reapplications" should read "preapplications"; and
2. In the same column, in the third paragraph, in the second line, "preapplications" should read "applications".

BILLING CODE 1505-01-D

ENVIRONMENTAL PROTECTION AGENCY

[PP 5G3263/T533; FRL-3125-1]

Oxyfluorfen; Extension of Temporary Tolerance

Correction

In notice document 86-27658 beginning on page 44517 in the issue of Wednesday, December 10, 1986, make the following correction:

On page 44517, in the third column, under **SUPPLEMENTARY INFORMATION**, in the 15th line, the petition number should read "PP 5G3263". Also, the comma at the end of the line should be deleted.

BILLING CODE 1505-01-D

**SECURITIES AND EXCHANGE
COMMISSION****17 CFR Parts 210, 229, 239, 240, 249,
and 270**[Release Nos. 33-6676; 34-23789; 35-24236;
IC-15403; File No. S7-31-85]**Proxy Rules—Comprehensive Review***Correction*In rule document 86-25898 beginning
on page 42048 in the issue of Thursday,November 20, 1986, make the following
corrections:

1. On page 42052, in the third column,
the heading for paragraph "Q." should
read "*Item 9, Independent Public
Accountants*", and "Peer Review"
should be a subordinate heading.

§ 229.601 [Corrected]

2. On page 42057, in the table, line (3)
should read as set out below.

	Securities Act forms										Exchange Act forms				
	S-1	S-2	S-3	S-4	S-8	S-11	S-18	F-1	F-2	F-3	F-4	10	8-K	10-Q	10-K
(3) Articles of incorporation and by-laws.	X			X		X	X	X			X	X			X

3. In the same table, in footnote 2, the
seventh word should be "or", and in
footnote 3, "Forms S-4 of F-4" should
read "Forms S-4 or F-4".

§ 240.14a-3 [Corrected]

4. On page 42060, in the first column,
in the eighth line of § 240.14a-3(b)(10),
"of" should read "on".

§ 240.14a-101 [Corrected]

5. On page 42064, in the second
column, in § 240.14a-101, in the seventh

line of paragraph (b) of the instructions
to *Item 5*, "§ 240.14a-11" should be
removed.

6. On page 42070, in the second
column, in the fifth line of *Item 17*, "of
the security holders" should read "of its
security holders".

BILLING CODE 1505-01-D

Food Safety Inspection Service

Friday
December 19, 1986

Part II

Department of Agriculture

Food Safety and Inspection Service

9 CFR Parts 308, 318, 320, 327, and 381
Canning of Meat and Poultry Products;
Final Rule

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 308, 318, 320, 327, and 381

[Docket No. 81-013F]

Canning of Meat and Poultry Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: This rule revises the Federal meat inspection regulations and the Federal poultry products inspection regulations by adding a number of provisions covering thermally (heat) processed meat and poultry products packed in hermetically sealed containers. The rule strengthens controls over the canning of meat and poultry products and updates the regulations in accordance with technological advances in the canning industry. Further, it makes Department of Agriculture (USDA) requirements for canned meat and poultry products more consistent with Food and Drug Administration (FDA) requirements for most other canned foods. In addition, the rule is based on many of the principles of the international code of practice for canned foods developed by the Codex Alimentarius Commission of the World Health Organization/Food and Agriculture Organization.

This regulation will reduce the risk of public health hazards associated with improperly processed canned product; provide more uniform application of canning requirements by FSIS employees; reduce the number of product retentions by FSIS without compromising consumer safety; and foster the application of recognized good manufacturing practices.

EFFECTIVE DATE: June 19, 1987, except for: § 318.305(h)(3) and § 381.305(h)(3), concerning the recycling and reuse of container cooling water, which are effective December 21, 1987; and § 318.310 and § 381.310, concerning the training of supervisors, which are effective December 19, 1988.

FOR FURTHER INFORMATION CONTACT: Mr. Bill Dennis, Director, Processed Products Inspection Division, Meat and Poultry Inspection Technical Services, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, (202) 447-3840.

SUPPLEMENTARY INFORMATION:**Executive Order 12291**

FSIS has determined that this rule is not a major rule under Executive Order 12291. It will not result in an annual effect on the economy of \$100 million or

more; a major increase in costs or prices for consumers, individual industries, Federal, State and local government agencies or geographic regions; or have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Effects on Small Entities

FSIS has determined that this rule does not have a significant economic impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act, Pub. L. 96-354 (5 U.S.C. 601). The facilities and equipment provisions of this rule reflect current "state-of-the-art" conditions in the canning industry and are not expected to impose any significant regulatory burden on small plants, in part, because most federally inspected canning establishments are not small entities. FSIS solicited comments from small plants that, because of unusual circumstances, would have to make large capital outlays in order to comply with the proposed rule. No comments on this aspect were received.

Background

The Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*) require the Secretary of Agriculture to administer an inspection program that assures consumers that meat and poultry products distributed in commerce are wholesome, not adulterated, and properly marked, labeled, and packaged. Consistent with that, on April 12, 1984, the Department published in the *Federal Register* a proposed rule titled, "Canning of Meat and Poultry Products" (49 FR 14636-72). The primary purpose of the proposal was to revise USDA regulations over the canning of meat and poultry products and update them in accordance with technological advances in the industry. The proposed regulations would replace existing USDA regulations governing the processing and production of thermally processed meat and poultry products packed in hermetically sealed containers.

The original comment period was to have ended July 1, 1984; however, because of the length and complexity of the proposal, several trade associations requested additional time to study the proposal and submit comments. FSIS therefore published a notice in the *Federal Register* (49 FR 28252) on July 11, 1984, granting an extension of the comment period to September 10, 1984. Because the July 11 notice contained

additional information clarifying the types of products covered by the proposed rule, two trade associations requested an additional 30 days to study the proposal and submit comments. On September 10, 1984, FSIS again published a notice in the *Federal Register* (49 FR 35507) extending the comment period to October 10, 1984.

Before 1984, a decade of experience had proven the need for revising USDA's canning regulations. In 1971, botulinum toxin was found in canned chicken vegetable soup packed by a processing plant under USDA inspection. That incident raised questions within USDA about the effectiveness of existing canning regulations and inspection procedures. Then, in 1974 one person died from botulism attributed to a canned food packed under USDA inspection—the first reported death involving a USDA-inspected product. These incidents led to an indepth departmental review of USDA controls governing the canning of meat and poultry products. As a result of the review, the Department concluded that its regulations and inspection procedures were, in many ways, outmoded in terms of the technological changes taking place in the canning industry. In particular, the regulations did not fully address all the critical control points in the processing of meat and poultry products. Thus, in 1975 USDA decided that its canning regulations needed complete revamping. However, because of the urgency of the matter, the Department issued instructions and guidelines to canning establishments and USDA employees as an interim measure. These publications addressed many of the critical control points in canning operations.

On September 17, 1976, the Department published in the *Federal Register* a proposed rule to update its regulations for canned meat and poultry products (41 FR 40156). The proposal incorporated the existing regulations as well as the requirements in the interim instructions and guidelines. It also included certain generally recognized good manufacturing practices employed by the industry and contained in FDA regulations. The FDA regulations had been issued in January 1973 as Part 128b, "Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers," (21 CFR Part 128b). Part 128b was later recodified as Part 113 (21 CFR Part 113).

The public comment period on USDA's 1976 proposal ended on January 15, 1977. During the comment period, 13 written comments on the proposal were received. Commenters generally agreed

that the canning regulations needed revision, but they also believed that the 1976 proposal was not comprehensive. Upon review, USDA concurred and withdrew the proposal.

After this decision, the Department continued using its interim instructions and guidelines as a basis for ensuring that consumers were receiving a safe and wholesome product. In 1980, the task of drafting a new regulatory proposal was initiated. On September 18, 1981, the Department received a petition from the National Food Processors Association (NFPA) urging "early publication of a proposed regulation governing thermal processing of canned meat and poultry products, and prompt issuance of a final regulation taking into account the comments received." NFPA argued that the issuance of a regulation would strengthen consumer protection, reduce the cost of USDA inspection of meat and poultry processing plants, and provide fairer, more specific, and less burdensome processing rules governing canned meat and poultry products. USDA continued its work on a proposal and on April 12, 1984, issued a new notice of proposed rulemaking (49 FR 14636).

Discussion of Comments

FSIS received 16 comments on the April 1984 proposed rule. Six were from canning establishments; 7 were from trade associations of which 3 were requests for an extension on the comment period; 1 was from a consulting laboratory; 1 was from a foreign canning establishment; and 1 was from a foreign government meat inspection service. Most of the comments were technical in nature and were directed toward specific sections of the proposed regulations. Some of the comments, however, were of a general nature and affected the scope of the proposed regulations. The following discussion will first address the general comments and will then respond to the specific comments on a section-by-section basis.

General Comments

Types of Products Covered by the Rule

Four commenters argued that the final rule should not cover "keep-refrigerated" products because, by definition, these products are not shelf stable (commercially sterile). One commenter suggested that, if regulations are necessary, keep-refrigerated products should be covered in a separate rulemaking procedure. This commenter also pointed out that a separate rule could be directed

specifically to product formulation, proper heat treatment, and proper refrigeration after processing.

FSIS agrees that keep-refrigerated products should not be included in the same rule as shelf stable products and has revised the final rule to exclude this class. The Agency will consider issuing regulations covering keep-refrigerated products at a later date, and there will be no further discussion of this subject hereafter.

One of the four commenters also argued that acidified low acid products should be excluded from the final rule because many of the requirements in the proposed rule are excessive if applied to these products. Another stated that the requirements were excessive but also believed that it is not inappropriate to include acidified low acid foods in a regulation covering low acid products because both are commercially sterile. If acidified products are retained in the final regulation, this commenter suggested incorporating additional language pertaining to the necessary controls for such products. The commenter also noted that comments should then be solicited on the revision.

FSIS agrees with the second commenter that it is appropriate for the final rule to include both low acid and acidified low acid canned products because both types of products are packaged in hermetically sealed containers and are intended to be shelf stable at room temperature. Like low acid canned products, acidified low acid canned products that are improperly processed can represent a major public health threat. Thus, acidified low acid products should be subject to the same stringent controls as low acid products. FSIS believes, however, that the rule is adequate to cover acidified low acid products and does not believe that additional language is necessary at this time.

The Use of Mandatory (Shalls) Versus Advisory (Shoulds) Statements

Four commenters expressed concern that the proposed rule contains only mandatory statements and noted that FDA regulations sometimes include advisory statements that are intended as recommended good manufacturing practices. They objected to USDA's use of mandatory statements in instances where FDA uses advisory language, arguing that advisory statements provide a flexibility that makes technological advances possible without the cumbersome procedure of amending the regulations. They also argued that USDA should not make advisory statements or recommendations mandatory.

One commenter also pointed out that basic canning principles are the same for meat and nonmeat products. The commenter urged uniformity between FDA and USDA regulations so that schools that train industry personnel in canning technology and procedures can use the same textbooks and other materials for employees in meat and nonmeat plants.

FSIS generally agrees with these arguments. For the most part, it has incorporated advisory statements or recommended practices in specific subsections of the regulations recommended by the commenters. FSIS believes, however, that it is necessary to retain mandatory language in certain instances to take into account the experience gained since the FDA regulations were adopted. These cases are addressed under the discussion of comments on specific subsections.

Request To Rescind Bulletins Relating to Canned Meat and Poultry Products

Three commenters pointed out that a final rule should supersede all existing FSIS bulletins and notices relating to canned products, and one also argued that the final rule should eliminate the need for future FSIS notices pertaining to canning. FSIS agrees that existing bulletins and notices relating to canned meat and poultry products can be rescinded and intends to rescind them after the effective date of this final rule. FSIS may find it necessary in the future, however, to issue additional instructions to field personnel regarding the implementation of the canning regulations, and these instructions could be issued as FSIS notices or directives.

Confidential Information

Noting that the proposed rule would have required that certain documents containing trade secrets be made available to inspectors, five organizations expressed concern that such confidential information might be copied and removed from plants. The commenters requested that the final rule indicate clearly that inspectors may not remove such materials unless the removal is justified and is authorized by FSIS supervisory personnel.

FSIS is concerned about maintaining the confidentiality of trade secrets—an issue that involves all aspects of inspection and is not restricted to canning establishments. Because confidentiality is a general issue, the Agency has issued FSIS Directive 4735.6, which addresses the safeguarding of confidential business information of all establishments and provides sufficient guidance on this matter.

Terminology

The proposed rule contains references to both FSIS program employees and inspectors. Several commenters urged that the final rule not include both terms and that uniform terminology be used throughout.

FSIS has examined all sections of the proposed rule and has found that the term "program employee" is used in almost all cases. The term "inspector" is used only in conjunction with routine inspection procedures in which other FSIS employees are not normally involved and indicates to establishments the appropriate FSIS employee to whom information should be provided. The term "inspector" has been retained in such instances.

Clarifications

Minor editorial changes have been made for clarity, but the changes do not alter the requirements.

Specific Comments

The following discussion deals with comments on specific subsections of the proposed rule. Subsections have been added and deleted from the proposal on the basis of some of the comments, and the final rule has been recodified to reflect these changes. In some instances, it was also necessary to relabel and transfer subsections within sections because of suggested changes accepted by FSIS.

Sections 318.300 and 381.300 Definitions

Two commenters suggested that the final rule include a definition of abnormal containers and also proposed the wording. FSIS has accepted the suggestion, and a definition of an abnormal container has been added to the final rule. In order to accomplish this inclusion, the definition appears in subsection (a) of §§ 318.300 and 381.300, and the other definitions have been recodified accordingly.

(a) *Acidified low acid product.* Five commenters said that the requirement to acidify products within 24 hours after the completion of the thermal process is unnecessarily restrictive. One suggested modifying the time requirement with the phrase "unless data are available to indicate that a longer time period is safe and appropriate." Some commenters also argued that the designated processing authority should be given the responsibility for determining the acidification time period. FSIS agrees with these suggestions and has modified the final rule accordingly.

(b) *Bleeders.* One commenter suggested that the definition include

condensate as a possible discharge. FSIS concurs and has added condensate to the list of discharges.

(c) *Come-up time.* Six commenters suggested that the point at which come-up time ends be defined as the start of process timing. Another suggested qualifying "venting time" with the phrase "if applicable." These suggestions have been incorporated in the final rule.

(f) *Critical factor.* Three commenters stated that the proposed definition was too general and recommended that it be revised to indicate that a critical factor affects the adequacy of the process schedule. This change has been made. An explanatory phrase has also been added to indicate that critical factors are established by processing authorities.

(g) *Designated authority.* Four commenters noted that more than one designated authority can be used and suggested that this fact be acknowledged by inserting "(s)" after the words "person" and "organization." FSIS concurs and has revised the subsection accordingly. One commenter also pointed out that the term "processing authority" is more widely used in the industry and suggested that this term be substituted for "designated authority" throughout the final rule. FSIS agrees, and the term "designated authority" has been changed to "processing authority" and recodified as subsection (q). Language indicating that the processing authority is designated by the establishment has been retained.

(h) *Gross headspace.* Six commenters requested that the definition be changed to allow measurement of gross headspace from the flange of unsealed cans. They pointed out that this procedure is a widely accepted industry practice. FSIS agrees and has included this measurement in the definition.

(i) *Semirigid container.* Two commenters believed that the definition could be misinterpreted to include drawn-aluminum containers and suggested that the definition be revised. The Agency disagrees. It was intended that the definition be comprehensive enough to include some of these containers because new types of drawn-aluminum containers are considered semirigid. For example, thinly drawn aluminum trays have recently been developed for packaging shelf stable, low acid meat and poultry products. FSIS wants to make it clear, however, that the definition is not intended to include traditional drawn-aluminum containers currently being used to process shelf stable products such as those with pull tops used to pack Vienna sausages.

Flexible container. Two commenters pointed out that strict interpretation of the proposed definition could include large, rectangularly-shaped cans. They suggested that the adverb "significantly" be added before the verb "affected" to clarify the intent of the definition. FSIS concurs and has made this addition.

(k) *Incubation tests.* One commenter suggested that the definition be revised to indicate that samples of product are tested. FSIS has not accepted this suggestion because entire lots are sometimes tested; the proposed definition allows for both possibilities.

(l) *Initial temperature.* Five commenters suggested rewording the proposed definition to permit various methods of measurement, including measurement of unsealed containers. One suggested that FDA language be adopted. FSIS has made the definition in the final rule more general than the proposed definition to permit a variety of methods to be used, but has not adopted the FDA definition, which is too specific regarding methodology.

(m) *Low acid product.* Four commenters objected to the inclusion of a specific time requirement for measuring pH after thermal processing. FSIS has concluded that the use of a time period in the definition is indeed inappropriate because low acid products are not subjected to an acidification process. Thus, the pH of low acid products, by definition, is above 4.6 at all times during thermal processing and storage. For that reason, the time element has been eliminated in the final rule.

(n) *Maximum pH.* Two commenters suggested revising the definition to make the time when pH is measured flexible. Still another commenter suggested that the term be deleted because it provides no additional information. FSIS agrees that inclusion of the term is not needed and has deleted this definition from the final rule.

(p) *Process schedule.* One commenter suggested that the phrase "as specified by the designated authority" be added to the end of the definition. In the final rule, the definitions of the terms "critical factors" and "thermal process" indicate that these two factors are specified by the designated processing authority. Because the process schedule is made up of the two factors, FSIS believes that it would be redundant to add the suggested phrase to the definition of process schedule. The proposed definition, however, has been modified to reflect the elimination of keep-refrigerated products from the final rule.

(u) *Shelf stability.* Two commenters suggested that the term "commercial sterility" be substituted for the term "shelf stability," arguing that commercial sterility is widely used in the industry. FSIS has retained the terms "shelf stability" and "shelf stable" in the final rule. The Agency believes that these terms are more definitive than the suggested revision and are understandable to industry and consumers alike. The definition given in the final rule makes it clear that the terms are synonymous with commercial sterility and commercially sterile.

(v) *Sterilization temperature.* One commenter suggested that an "(s)" be added to the phrase "minimum temperature" because some process schedules list more than one processing temperature. Two commenters also suggested qualifying that phrase by adding "of the heating medium" to clarify the definition. FSIS concurs with these comments and has made the suggested changes.

A commenter suggested that subsection (w), "sterilization time," be called "process time." FSIS has accepted this change (see item (w) below). For consistency, subsection (v), "sterilization temperature," has also been redesignated as "process temperature" and recodified as subsection (o).

(w) *Sterilization time.* Six commenters recommended numerous changes in wording to make the definition applicable to different retort systems. In keeping with these suggestions, FSIS has simplified the definition so that it will be comprehensive enough to cover all processing systems. One commenter also suggested "sterilization time" be renamed "process time" to conform to industry usage. FSIS concurs. Subsection (w), "sterilization time," has been redesignated as "process time" and recodified as subsection (p) of the final rule.

(x) *Thermal process.* Two commenters suggested substituting the term "commercially sterile" for "shelf stable." FSIS has rejected these comments. (See discussion of comments to the definition of the term, "shelf stability.") Another commenter requested that an "(s)" be added to the words "time" and "temperature" because some process schedules list more than one time and temperature. FSIS concurs and has made the suggested change.

The same commenter recommended that a third item—any other factors specified by the processing authority—be added to the list of factors quantified. FSIS has rejected this comment as redundant because such wording is included in the definition of "critical

factor", and that definition is incorporated in the definition of "process schedule."

(y) *Venting.* One commenter recommended that the phrase "and low temperature areas" be inserted after the word "air" in the proposed definition. FSIS believes that this addition would be redundant and thus has not accepted the suggestion.

Other Comments

One commenter suggested that a definition of an indicating temperature device be added to the final rule. This recommendation has not been accepted because §§ 318.305(a)(1) and 381.305(a)(1) give examples of these devices. Those subsections have been drafted in general terms to include devices that exist today or that may be developed in the future.

Another commenter suggested that the term "qualified individual" be substituted for "closure technician" throughout the final rule. The term "closure technician" appears only in §§ 318.301 and 381.301; thus, this recommendation is addressed under §§ 318.301(b)(1) and 381.301(b)(1).

Sections 318.301 and 381.301 Containers and Closures

(a) Examination and cleaning of empty containers.

(1) Four commenters recommended the addition of language to indicate that the section will not require the examination of all empty containers. One suggested adding the phrase "in accordance with an appropriate sampling plan."

FSIS agrees and has modified the final rule to clearly indicate that a 100% examination of empty containers, closures, and flexible rollstock is not required. The intent of this requirement is to increase the assurance that empty containers are clean and free of structural defects. Therefore, the Agency has added an advisory statement indicating that an examination based on a statistically-drawn sample of containers, closures or flexible rollstock would be acceptable. In addition, one of the four commenters suggested using the word "evaluated" rather than "examined" and making such evaluations a recommended practice. FSIS rejects both suggestions. The Agency has documented a significant number of spoilage incidents that were directly attributable to container manufacturing defects. Also, in the absence of any compelling reason put forth by the commenter to change the word "examined" to "evaluated", the suggested word change was not accepted.

Another commenter suggested qualifying the phrase "free from structural defects" with the clause "which may affect product or container integrity." While the commenter did not provide a rationale, the Agency believes the recommendation was meant to exclude those defects of containers, closures, and flexible pouch rollstock that are not likely to affect the integrity of the product or the hermetic condition of a filled and sealed container. FSIS agrees and has incorporated the proposed wording into the final rule.

(2) One commenter asked whether this subsection precludes the use of jumble storage bins for cans. It does not, but FSIS recommends against the use of this type of storage because it increases the possibility of damaging containers.

(3) Three commenters said that the language relating to methods of cleaning was too restrictive and would preclude alternative cleaning methods. One commenter suggested that the following wording be substituted: "Prior to filling, rigid containers shall be cleaned appropriately to prevent incorporation of foreign matter into the finished product." FSIS has accepted this language except that the word "appropriately" has been deleted as unnecessary and "prior to" has been rejected as too vague. The sentence in the final rule now reads "Just before filling, rigid containers shall be cleaned to prevent incorporation of foreign matter into the finished product."

(b) Closure examinations for rigid containers (cans).

(1) *Visual examinations.* One commenter requested that the definition of closure technician be expanded in the first sentence to include his/her designee. FSIS understands this need; however, if the comment is accepted as received, untrained individuals could be designated by the establishment to perform the duties of the closure technician. Therefore, a definition of a closure technician has been included in §§ 318.300 and 381.300. The definition provides for the establishment to designate any individuals to perform the duties of the closure technician provided such individuals have been identified by the establishment as being properly trained.

One commenter urged that the time interval between required visual examinations be changed from 30 minutes to 60 minutes. Two other commenters argued that requiring visual examinations every 30 minutes should be made a recommended practice. While it is the establishment's responsibility to visually examine cans for defects, the time interval between

examinations is dependent upon such factors as production volumes, line speeds, and equipment. Therefore, FSIS has accepted the latter suggestion and has incorporated language offered by one of the commenters into the final rule.

Two commenters also suggested that the first sentence of the subsection be reworded to indicate that the entire external can surface must be examined, including the double seams formed by each closing machine head. FSIS has accepted this suggestion and has incorporated it into the final rule. For clarification, FSIS has also added the requirement that such examinations must be performed on at least one container from each closing machine head and that the observations, along with any corrective actions taken, must be recorded by the closure technician.

Another commenter suggested that the phrase "container closure technician" be replaced by "qualified individual." Although the individual performing such functions should indeed be properly trained and supervised, FSIS has rejected this comment because the use of such a phrase would raise questions about appropriate qualifying criteria and who serves as the qualifying authority. Furthermore, a definition for a closure technician has been added to the final rule. The Agency believes that the definition would allow an establishment ample latitude in designating individuals to perform those activities required by this section.

(2) *Teardown examinations of double seams.* One commenter urged that the entire subsection be reserved and remain open for comment and modification until the industry position is finalized through the Can Manufacturers Institute/National Food Processors Association (CMI/NFPA) Container Integrity Task Force.

FSIS has rejected this comment because the Agency considers closure examinations for rigid containers a critical part of this rule and one that cannot be held in reserve. The requirements of this subsection are consistent with FDA regulations and Codex recommendations and are considered the minimum measures that must be taken by establishments to ensure container integrity. Once the CMI/NFPA Container Integrity Task Force completes its work, FSIS will evaluate the contents of this subsection to determine if changes are necessary.

Four commenters argued that the requirement that a seam teardown be conducted at least every 4 hours or within a coding period is excessive if, for example, the code changes by retort load. FSIS has accepted this comment

and has revised the final rule to delete the reference to coding period.

Two commenters argued that can manufacturers' specifications are only guidelines and should not be considered as rigid "go" or "no-go" situations. The commenters suggested that the term "guidelines" be used in place of "specifications." FSIS agrees with this comment and has added the term "guidelines" to the final rule but has also retained the word "specifications" to indicate clearly that the guidelines are intended to be actual dimensional measurements of the various double seam components.

Three commenters argued that double seam teardown examinations of the can manufacturer's end (i.e., the end of the container completed by the can manufacturer) should not be required after the containers are filled and sealed when: (1) Double seam teardowns are conducted on the can manufacturer's end during incoming empty can inspection; or, (2) cans are self-manufactured (i.e., made by the official establishment) and the can plant records are made available for review. The commenters offered wording to clarify this requirement in the final rule. FSIS has accepted these comments and the substance of the proposed wording and has revised the final rule accordingly.

One commenter requested that FSIS consider the possibility that an ink code could be applied to the manufacturer's end of the can. FSIS has accepted this comment and has revised the subsection to distinguish between the "packer's end" and the "manufacturer's end" of the container. The "packer's end" is the end closed by the official establishment after the container is filled.

In addition to the above changes, FSIS has included in the final rule a good manufacturing practice recommendation using the word "should" which states that additional teardowns on the "packer's end" should be conducted at the beginning of production, immediately after a can jam, and after a closing machine adjustment.

(i)(a) *Micrometer measurement.* Five commenters recommended that only the maximum and minimum seam measurements be recorded. FSIS has accepted this recommendation and adjusted the language of the final rule accordingly. Can seam dimensions found to be within the manufacturer's specifications indicate that a double seam has been properly formed. However, dimensional measurements that approach or are beyond the upper or lower limits established by the manufacturer are a signal of a potential problem. Therefore, the Agency believes

that while it is critical to record the maximum and minimum values, the recording of other values is unnecessary. One commenter correctly pointed out that seam measurements should be taken at least one-half inch from the side seam juncture. This language has been incorporated in the final rule. The same commenter suggested modifying the language to clarify that the measurement is applied to cylindrical cans. This suggestion has been accepted. In addition, the commenter proposed that the optional measurements and calculations of overlap be deleted as they may give inaccurate results because of container variables and other double seam characteristics. FSIS has accepted this recommendation and deleted the optional measurements.

Four commenters recommended that the measurement of end plate or cover thickness be deleted because the measurement is needed only for the calculation of overlap. FSIS agrees and has deleted the requirement from the final rule.

(i)(b) *Seamscope or seam projector.* One commenter recommended that optional measurements be deleted. FSIS has accepted this recommendation because these optional measurements are not considered critical when evaluating double seams by the micrometer method. The commenter also suggested adding wording to indicate that the measurement applies to cylindrical containers. This suggestion has been adopted.

(ii) *Seam tightness.* One commenter recommended changing the wording of the subsection to "... shall be stripped to assess the degree of wrinkle or otherwise evaluated to assess seam tightness." The commenter argued that complete pressure ridges are not always obtained in the case of certain closing machines or containers. While FSIS agrees with this argument, it believes that, at a minimum, the seams must be stripped to determine the degree of wrinkling. Moreover, the Agency believes the phrase "or otherwise evaluated to assess seam tightness" is ambiguous and unacceptable as an alternative to stripping the seam. Therefore, the language in the final rule has been revised to reflect the need to strip the seam.

(iii) *Side seam juncture rating.* One commenter suggested the substitution of more precise language concerning the rating of the juncture of cans having side seams. This suggestion has been incorporated into the final rule.

(iv) *Examination of rectangular and square containers.* One commenter said

that it is premature for FSIS to attempt to establish fixed measurement points on irregular-shaped containers and recommended that the paragraph be deleted. In its place, the commenter suggested amending certain other subsections to include general methods of measuring noncylindrical containers.

Because of the variety of container types, FSIS agrees that it may be unwise to specify fixed measurement points for noncylindrical containers. Rather than amending other subsections as suggested by the commenter, FSIS has combined proposed subsections (b)(2)(iv) and (v) into a single subsection covering the examination of all noncylindrical containers. The combined subsection appears as subsection (b)(2)(iv) in the final rule. The intent of the commenter's suggested wording has been incorporated into this new subsection.

(v) *Examination of "D"-shaped and irregular-shaped containers.* This subsection has been combined with subsection (b)(2)(iv) and appears as subsection (b)(2)(iv) in the final rule. See comments under subsection (iv) above.

(c) *Closure examinations for glass containers.*

(1) *Visual examinations.* One commenter urged that the subsection be revised to require that visual examinations be conducted with sufficient frequency to ensure proper closure and that the requirement that these examinations be conducted at least every 30 minutes of continuous closing operation should be made a recommended practice. FSIS has accepted this comment and has incorporated this language into the final rule. An appropriate time interval between visual examinations will vary with production volumes, line speeds, and the like. Therefore, while the final rule will require visual examinations of glass containers, it will be the establishment's responsibility to determine the appropriate time interval that will ensure proper closure.

Another commenter suggested that the visual examinations be conducted of the entire container as well as the closure. FSIS agrees with this comment and has added language to the final rule to require that in addition to examining the closure, the container closure technician shall examine the entire container for defects likely to affect the hermetic condition of the container.

For consistency with the requirements of subsection (b)(1) in §§ 318.301 and 381.301, FSIS has added a requirement to this subsection that when closure defects are observed, corrective actions, such as adjusting or repairing the

closing machine, shall be taken and recorded.

(2) *Closure examinations and tests.* One commenter questioned whether or not the closure examinations must be conducted before or after retorting. FSIS believes it is the responsibility of the establishment to determine whether a particular test is performed before or after thermal processing, and the final rule has been revised accordingly. Language indicating when additional closure examinations should be made has also been added for consistency with subsection (b)(2) above.

(d) *Closure examinations for semirigid and flexible containers.*

(1) *Heat seals—(i) Visual examinations.* One commenter argued that it is not necessary to record normal observations but only the type and number of defects. This comment is addressed at the beginning of the discussion of §§ 318.306 and 381.306.

One commenter argued that the adoption of this subsection should eliminate the need for MPI Bulletin 75-4. As stated in the General Comments section of this preamble, FSIS intends to rescind all MPI bulletins and notices on thermal processing after the effective date of this final rule.

Another commenter stated that the subsection could be interpreted as requiring 100 percent visual inspection of containers before and after thermal processing and requested that a statistical sampling be allowed. FSIS agrees with this comment and has revised the final rule to allow the use of appropriate sampling procedures. The intent of this requirement is to increase the assurance that semirigid and flexible containers are properly sealed and free of obvious defects. Therefore, the Agency has added an advisory statement indicating that an examination based on a statistically-drawn sample of containers would be acceptable.

Another commenter suggested that the term "closing machine" should be changed to "sealing machine." FSIS has accepted this comment and revised the final rule accordingly.

(ii) *Physical tests.* One commenter urged that the subsection be revised to indicate that physical tests shall be conducted with sufficient frequency to ensure consistent and reliable hermetic seals and that such tests should be conducted at intervals not to exceed 2 hours.

FSIS concurs with this comment and has revised the final rule accordingly because the change would make this subsection more uniform with other subsections that deal with physical examinations of containers. Also, for

uniformity, FSIS has added a requirement to the final rule that the establishment's acceptance guidelines for each test performed shall be on file and shall be available for review by Program employees.

One commenter suggested that the term "burst strength" test be changed to "pressurization/hold" test, while a second commenter stated that the bond strength test is not necessary after thermal processing. FSIS has not accepted these comments because the tests are given in the final rule only as examples and are not intended to represent all possible tests that could or should be used to ensure the integrity of the hermetic seals.

(iii) Because of the revisions made to subsections (d)(1)(i) and (d)(1)(ii), subsection (d)(1)(iii) of the proposal has been deleted from the final rule.

(2) One commenter suggested that this subsection be revised by adding the phrase "plus any additional measurements specified by the container manufacturer." FSIS agrees because these new types of containers may require additional measurements, beyond those required for double seams on metal containers, to assess the adequacy of the double seams. The same commenter also recommended that the subsections be expanded to include flexible containers with double seams. While FSIS is not aware of any flexible containers with double seams, this fact does not preclude their development. Therefore, this suggestion has been accepted.

(e) *Container coding.*

Three commenters argued that the product name should not be required in the code mark if it is lithographed or printed on the container. FSIS agrees with this comment and has added language to the final rule to indicate that the code mark need not identify the product if the product name is lithographed or printed elsewhere on the container.

One commenter suggested that the phrase "each hermetically sealed container of low-acid processed food" be substituted for the word "container." FSIS has rejected this comment because the Agency believes that the word "container", as used in this rule, applies only to the immediate container (defined in §§ 301.2(xx) and 381.1(b)(22)) of hermetically sealed low acid and acidified low acid product.

Another commenter suggested that the phrase "as a minimum" be added to the second sentence to allow the packer the option of including additional information in the code. FSIS agrees and

has incorporated this phrase into the final rule.

(f) Handling of containers after closure.

(1) Five commenters argued that the proposed subsection contains vague requirements that may hinder normal operations if inspection personnel misinterpret it. The commenters requested that the subsection be either deleted or revised to make the requirements advisory. FSIS agrees in part with this comment and has made the second sentence of the subsection advisory. FSIS has retained the mandatory language in the first sentence, however, because the Agency believes that it is essential to protect containers and closures from damage that could affect the hermetic seal.

(2) One commenter argued that this subsection should be deleted because the commenter considers the time lapse between closure and the start of thermal processing a question of product quality rather than product safety. FSIS rejects this position because holding unprocessed products for extended periods may cause adulteration. There have been several documented incidents of incipient spoilage in canned products resulting in illnesses from staphylococcal enterotoxin. Holding product for an extended period of time could allow the growth of *Staphylococcus* and the production of enterotoxin.

Sections 318.302 and 381.302 Thermal Processing

Sections 318.302(b) and 381.302(b) Establishing process schedules.

Four commenters expressed concern that subsections (1) and (2) were too specific regarding procedures that must be followed to develop process schedules. One argued that the work of processing authorities is not within the scope of the regulation. All offered alternative versions for subsections (1) and (2). For example, two commenters suggested that the subsections be combined in the following general statement: "The establishment through its designated authority shall develop a process schedule for each of its canned meat products. Complete records concerning all aspects of the determination of the process schedule, including any associated incubation tests, shall be prepared and retained by the designated authority. These records shall be made available by the establishment upon request of the Administrator."

Two of the four commenters also addressed the proposed requirement that the processing authority evaluate the adequacy of the process schedule if

any change is made in product formulation, ingredients, or treatments. One argued that the requirement should apply only to changes not already covered by the process design. The other suggested that any changes that may affect the adequacy of the process schedule could be verbally described to the processing authority, who could assess the significance of the change.

FSIS has revised subsections (1) and (2) to take into account the substance of most of the comments. The subsections have been condensed to reflect the general comments that the proposed subsection was too specific regarding the development of the process schedule. For clarity, a new subsection (3) has been added to the final rule; the subsection incorporates the provisions of subsection (2) of the proposed rule regarding maintenance of process data and the availability of the data to the Administrator of FSIS. However, FSIS rejects using the phrase "... shall be prepared and retained by the designated authority." The Agency's regulatory authority does not extend over work performed by independent processing authorities. Therefore, it is incumbent upon the establishment to make available, upon request, all records associated with the development or determination of a process schedule.

Sections 318.302(c) and 381.302(c) Submittal of process information.

Three commenters argued that it was an unnecessary burden to require establishments to provide inspectors with copies of process schedules and related documentation and suggested that the requirement be reworded to indicate that the establishment shall make available to the inspector for review a copy of the letter or other written communication from the processing authority recommending process schedules and associated critical factors.

FSIS agrees that copies of letters or other written communications from the establishment's processing authority need not be provided to the inspector but may be maintained on file by the establishment provided that the inspector has easy and ready access to them for review. The establishment, however, must provide the inspector with a list of process schedules for each product and each container size so that the inspector can monitor the firm's processing operation effectively. The list must include any alternate process schedules recommended by the firm's designated processing authority as well as any critical factors associated with the process schedule. Letters or other written communications maintained on

file by the establishment would be used to verify the list of schedules provided.

Two commenters urged that establishments not be required to submit process schedules to the inspector for experimental products not intended for sale or distribution. FSIS agrees with this comment and has revised the final rule to reflect this concern. However, when experimental product is packed, the inspector must be informed of such work and all experimental product must be clearly marked and cannot be distributed in commerce. The commenters also suggested that the phrase "the retort venting procedures for pressure processing in steam or steam air" be replaced by "the retort come-up operating procedure." FSIS concurs with the commenters because the recommended change is more inclusive and covers other thermal processing systems besides those that use steam or steam/air under pressure.

Sections 318.303 and 381.303 Critical Factors and the Application of the Process Schedule

One commenter recommended that the list of critical factors be deleted from the final rule, arguing that the list is not complete and does not reflect the most common critical factors related to thermal process schedules.

FSIS has retained the list of critical factors in the final rule because the rule states that the items are given only as examples. FSIS is aware that there may be additional critical factors identified by processing authorities, but the Agency believes those included in the list are representative of factors associated with thermal processing. If additional factors are identified in a process schedule, the establishment must also measure, control, and record those factors to ensure that they remain within the limits specified in the process schedule.

A second commenter suggested that the air-flow rate and forced recirculation flow rate listed as critical factors for steam/air retorts be combined as the heating medium flow rate. FSIS has accepted this suggestion because the term is considered to be more encompassing than either "air-flow rate" or "forced recirculation flow rate."

Another commenter suggested that the maximum thickness of semirigid containers not be listed as a possible critical factor because, the commenter argued, the shape and contour of semirigid containers are not affected by the enclosed product and because the maximum thickness will not affect the process schedules. Again, the items in the list are given only as examples of

critical factors. In the case of semirigid containers for which laminants are used as closures, it is possible that container thickness could be affected by thermal processing. In those cases, maximum thickness could be a critical factor. Thus, FSIS has retained the example in the final rule, although the Agency recognizes that it would not apply to all container types.

*Sections 318.304 and 381.304
Operations in the Thermal Processing Area*

(a) Posting of processes.

One commenter suggested that the rule be revised to allow the posting of operating processes instead of the process schedules recommended by the designated processing authority. FSIS has accepted this suggestion with the understanding that operating process schedules are more stringent than process schedules recommended by processing authorities.

Another commenter suggested that the phrase "retort operating procedures" be substituted for "venting procedures (where applicable)." Presumably, the comment was meant to make the rule apply to all types of retort systems rather than to steam retorts only. FSIS recognizes this need and has modified the language of the final rule to include all necessary operating procedures.

(b) Process indicators and retort traffic control.

One commenter argued that the use of process indicators should not be required for products in flexible containers that can be visibly identified as processed.

FSIS believes that this comment was meant to pertain to keep-refrigerated products, which have been removed from the final rule. The Agency is not aware of any transparent flexible containers currently in use for shelf stable meat and poultry products. If they are in use, process indicators are still appropriate as an added safeguard. Therefore, the proposed language has been retained in the final rule.

(c) Initial temperature.

A commenter argued that this subsection should not apply to canned cured meat products because the initial temperatures of such products generally do not vary before thermal processing. The commenter states that the requirement should be applied only to products for which initial temperatures are specified in the process schedule.

Although it may be true that the initial temperatures of some products do not vary, FSIS nevertheless considers the product initial temperature to be an essential part of all process schedules and requires that it be included in the

schedules. The initial temperature must be monitored, controlled, and recorded frequently enough to ensure that it is never lower than the minimum initial temperature specified in the process schedule.

Four commenters asked that the word "thermometer" be replaced with the phrase "temperature-measuring device" to allow the use of temperature measuring devices such as resistance temperature devices and thermocouples. While FSIS understands the basis for this comment, after further consideration, the Agency has deleted reference to temperature measuring devices, including thermometers. It is the establishment's responsibility to select the equipment and methods necessary to properly determine product initial temperature as defined in §§ 318.300 and 381.300.

(d) Process timing.

For clarity, this section has been renamed "timing devices" in the final rule.

One commenter suggested that the reference to the use of digital clocks should contain a distinction between those that display seconds and those that do not. In the case of digital clocks that display seconds, the commenter argued that the 1-minute safety factor is not necessary. FSIS agrees with this comment and has changed the final rule to include this distinction; the safety factor is not required for digital clocks displaying seconds.

Another commenter suggested that the first sentence of the subsection be reworded to indicate that timing devices shall be accurate to the extent needed to measure process schedule times. FSIS has accepted the intent of this suggestion and has also clarified in the final rule that timing devices are used for other retort functions such as come-up time and venting.

The proposed rule requires that clock times on recording temperature charts correspond within 15 minutes to the time of day recorded on the written processing records to allow for correlation with these records. Two commenters noted that, although this procedure is desirable, a deviation from the time requirement would not affect the adequacy of thermal processing. Thus, they argued that the provision should be advisory rather than mandatory, particularly because FDA's provision in this area is advisory. FSIS agrees that deviations from this requirement do not affect the adequacy of thermal processing; however, FSIS believes that this provision must be mandatory so that plant employees and FSIS inspectors can correlate

handwritten retort records with temperature recording charts.

(e) Measurement of pH.

One commenter recommended that pH measurement be required only when pH is a critical factor, such as in acidified low acid foods. FSIS has accepted this comment and has changed the final rule accordingly.

*Sections 318.305 and 381.305
Equipment and Procedures for Heat Processing Systems*

Comments that apply to several subsections of §§ 318.305 and 381.305 are addressed in groups below; the remaining comments are then addressed by subsection.

Requests That Subsections Be Amended To Allow Alternate Approaches

Several commenters urged that certain subsections of the proposed rule be changed to provide for the use of retort installations, retorting equipment, or operating procedures that are not provided for in the proposal. They suggested that variations should be acceptable if plants have on file heat distribution data or other documentation to verify the accuracy of alternative systems or procedures.

The requirements set forth in these sections are intended to encompass the more common thermal processing equipment, installations, and operating procedures. FSIS acknowledges that the regulations cannot totally address all variations that may exist within these installations or variations in their operating procedures. Of critical importance is to have assurance that such variations do not adversely affect the delivery of the intended process schedule. Such assurance is most commonly obtained through heat distribution tests to document the uniformity of temperatures within a system during a process. Therefore, FSIS has accepted these comments and has incorporated their substance into the language of the following subsections of §§ 318.305 and 381.305 of the final rule: (b)(1)(v); (b)(1)(vi); (b)(1)(vii); (b)(1)(ix) (c) and (d); (b)(2)(v); (b)(4)(v); (c)(1)(iv); (c)(1)(ix); and (c)(1)(x). These subsections of the final rule also provide that documentation concerning heat distribution shall be made available to Program employees for review.

Data Required To Verify Reliability of Mufflers on Bleeders and Vents

One commenter argued that the proposed subsections on bleeder and vent mufflers are too specific about the type of evidence necessary to document the suitability of mufflers and suggested

substituting wording that would make the requirement advisory. FSIS has not made this requirement of the subsections advisory because it is essential that establishments have on file documentation to verify that mufflers on bleeders and vents do not impede the removal of air from the retort. FSIS also believes that the appropriate sources of such documentation were included in the subsections as they were proposed.

To make the subsections consistent with other subsections that require documentation concerning heat distribution, FSIS has added the requirement that the documentation be made available to Program employees for review. Affected subsections of the final rule are (b)(1)(viii), (b)(2)(vii), (b)(3)(vii), and (b)(4)(vii).

Suggestions for Changing Terminology Used for Retort Valves

In subsections that refer to "gate, plug cock, or other type valve," one commenter suggested that the phrase "other full-flow valve" be substituted for "other type valve." FSIS agrees that the phrase "other type valve" could be misinterpreted to include the use of valves which may restrict the free flow of steam. Therefore, FSIS has substituted the suggested terminology in the following subsections of the final rule: (b)(1)(ix)(a); (b)(1)(ix)(b); (b)(1)(ix)(e)(1); (b)(1)(ix)(e)(2).

Subsection-by-Subsection Analysis.

(a) Instruments and controls common to different thermal processing systems.

(1) *Indicating temperature device.*—(i) *Mercury-in-glass thermometers.* One commenter argued that mercury-in-glass thermometers are less accurate and less reliable than resistance temperature devices (RTDs) and remarked that it was unfortunate that mercury-in-glass thermometers are encouraged in the proposal. FSIS disagrees with this comment. Over the course of many years, the mercury-in-glass thermometer has proven both accurate and reliable and is still considered the "reference instrument" by the canning industry. The final rule does, however, recognize the advances in temperature measurement technology by providing for the use of other temperature-measuring devices approved by the Administrator.

In the second sentence of the proposed subsection, three commenters urged that the phrase "by the establishment" be deleted to permit firms to choose someone else to conduct thermometer calibrations. One of the three commenters also suggested the addition of the phrase "and the person or testing authority performing the test"

to the third sentence. FSIS concurs with these comments and has incorporated the proposed wording.

One commenter suggested that the requirement that establishments maintain records of thermometer testing on file be changed to a recommendation. FSIS disagrees with this comment because it is essential that firms have documentation that Program employees can review to ensure compliance with this subsection.

(ii) *Other devices.* Two commenters suggested the addition of wording that would allow a designated or testing authority other than the establishment to perform the required accuracy tests on temperature-measuring devices. FSIS concurs and has amended the final rule accordingly.

(2) *Temperature/time recording devices.* Seven commenters argued that the proposed requirement that the temperature recorder chart never read more than 1 Fahrenheit degree below the indicating temperature device is unnecessary. FSIS agrees because as long as the recorder temperature does not exceed the temperature on the reference indicating temperature device, the safety of the process will not be in question. Therefore, language has been added to the final rule making it a recommendation that the temperature recording device and the indicating temperature device are in agreement. This wording would allow the temperature recorder to read lower than the indicating temperature device. However, in no event shall the temperature recording device read higher than the indicating temperature device.

One commenter noted that the subsection does not provide a temperature reference for determining the accuracy of recorders and suggested adding the following phrase to the third sentence: "when compared to the accurate indicating temperature device." FSIS concurs and has accepted the proposed modification.

Another commenter suggested that the requirement concerning air filters on air-operated temperature controllers be changed to a recommendation. FSIS has rejected this suggestion. Air-operated temperature controllers must have adequate filters to stop debris from entering the control mechanism and causing malfunctions.

(i) *Chart-type devices* and (ii) *Other devices.* One commenter proposed that subsections (i) and (ii) be revised to read in part:

"The recorder shall print frequently enough to detect significant variations in temperature. The frequency of recording should not exceed 1-minute intervals.

Intervals longer than 1 minute will be acceptable upon a showing that they will accomplish the desired purpose of detecting thermal processing inadequacies."

FSIS has accepted the substance of this comment because it is the responsibility of the establishment to identify the proper printing frequency to ensure that any temperature deviations are identified. Therefore, language has been added to the final rule to indicate that temperatures shall be printed at sufficient frequencies to ensure that the parameters of the process time and temperature have been met. The subsection has also been revised to indicate that the printing frequency should not exceed 1-minute intervals.

One commenter argued that the proposal to print temperatures every 30 seconds is excessive and recommended the use of a sliding scale for printing temperatures. For example, temperatures would be printed every minute for processes lasting 90 minutes or less and every 5 minutes for processes lasting over 90 minutes. FSIS has rejected this comment because it knows of no sliding scales with frequencies that ensure that all possible process deviations will be identified.

Another commenter urged that subsection (i) be revised to indicate that graduations on charts shall not exceed 2F degrees within a range of 10F degrees of the sterilization temperature. FSIS has accepted this comment and has added the proposed language to the final rule because the wording is consistent with FDA requirements.

(4) *Air valves.* and (5) *Water valves.* Four commenters pointed out that the term "sealing valve" used in the requirements for air valves and water valves is unclear. One suggested substituting the phrase "a globe valve or other equivalent-type or piping arrangement suitable to prevent leakage." FSIS concurs with these comments and has incorporated the recommended language into subsections (4) and (5) because it more clearly indicates that equivalent-type valves or piping arrangements must be adequate to prevent leakage of water or air into the thermal processing vessel.

(b) *Pressure processing in steam.*

(1) *Batch still retorts.*—(iv) *Crate supports.* Two commenters urged that bottom crate supports should be required only if steam enters the bottom of the retort through a steam spreader. Presumably, the commenters consider crate supports necessary only to ensure that bottom-mounted steam spreaders are not damaged by retort crates. While FSIS agrees that this is an important

function of crate supports, the Agency also believes that supports are needed in vertical retorts using bottom steam entry without spreaders. In this case, the supports would prevent the crates from blocking steam entry and would allow for a full flow of steam into the retort. For these reasons, the wording in these subsections has been revised to clearly indicate that crate supports will be required only when vertical retorts are equipped with bottom entry steam.

(vi) *Bleeders and condensate removal.* One commenter recommended that the next-to-the-last sentence of the proposed subsection be changed to read: "In retorts having a steam inlet above the level of lowest container, a bleeder . . ." FSIS agrees with this recommendation because it more accurately describes the Agency's intent to require condensate bleeders in vertical retorts when the steam inlet is in any location other than in the bottom of the retort.

For clarity, FSIS has added language to the subsection to indicate that heat distribution data or other documentation from a processing authority shall be maintained on file by the establishment and made available to Program employees for review. The subsection has also been modified based on comments to subsection (b)(2)(iv) of the proposed rule dealing with condensate removal and the use of automatic alarm systems.

(vii) *Stacking equipment.* Regarding subparagraph (a) two commenters said that the requirement that retort crate bottoms have perforations 1-inch in diameter on 2-inch centers should be made a recommendation. One argued that the precise design of stacking equipment is not material if adequate heat distribution can be achieved and demonstrated by heat distribution testing.

After reviewing these comments, FSIS has decided to retain the proposed requirements for retort stacking equipment because, for the most part, they are industry standards. The subsection, however, has been revised to incorporate the intent of the comments relating to the use of other designs.

Regarding subparagraph (b), four commenters argued that when divider plates are used, heat distribution data, as supporting evidence, should be sufficient. FSIS agrees with the intent of these comments and has revised the subparagraph to require that whenever one or more divider plates are used between any two layers of containers or used on the bottom of the retort basket, the establishment shall have heat distribution data on file.

(ix) *Vents. (e) Typical installations and operating procedures.* One commenter argued that specific venting schedules should not be recommended in the final rule because by so doing USDA is assuming responsibility for issuing venting schedules for still retorts. The commenter also urged that if the venting schedules are retained, each diagram should have a clear warning that the schedules are not designed for systems with divider plates or sheets.

FSIS has rejected both comments and has retained the venting schedules in the final rule. The final rule makes it clear that the schedules are intended merely as examples. The venting schedules have been recognized for many years by both industry and processing authorities as adequate for the specific retort installations described. The schedules may be of considerable value to small canning establishments without ready access to processing authorities, provided their retort installations are identical to those given in this subsection. FSIS expects plants to have documentation on file that verifies the adequacy of their retort venting procedures if their installations differ from the examples. This requirement is specified in subsection (b)(1)(ix)(c), which also applies to installations with retort divider plates.

A second commenter urged that the entire subsection be deleted; in its place, the commenter suggested that establishments be required to have heat distribution test data or other documentation on file for all retort systems. FSIS has rejected this comment for the reasons given above.

Two commenters suggested that the phrase "typical installation" be changed to "examples of typical installations" and that the schematic retort drawings be labeled with figure numbers. These suggestions have been accepted and incorporated in the final rule.

(2) *Batch agitating retorts—(iv) Bleeders.* One commenter said that the subsection appeared to prohibit other modes of retort operation and suggested that it be made advisory rather than mandatory. FSIS wants to point out that the subsection states that other installations are acceptable, provided the establishment has data on file documenting the adequacy of the installation. Because the requirements of the subsection are essential to ensure that air is adequately removed from the retort during the venting procedure and the process cycle, FSIS has rejected the suggestion that the subsection be made advisory.

The same commenter noted that the subsection does not allow for the intermittent removal of condensate.

Another commenter provided a recommendation dealing with condensate bleeders. For clarity, FSIS has moved the reference to condensate removal from subsection (iv) to subsection (v). The two comments relating to condensate removal are addressed there.

(v) *Venting and condensate removal.* As noted in the preceding subsection, one commenter argued that the proposed rule did not allow for the intermittent removal of condensate. FSIS has added language to the final rule to allow for the use of intermittent condensate removal systems. In addition, an advisory statement has been included that bleeders for condensate removal should be visually checked at least every 15 minutes and the results recorded to ensure that such systems are functioning properly. Because intermittent condensate removal systems (equipped with automatic alarms) have been added to the final rule, the rule also requires that the alarms be tested at the beginning of each shift for proper functioning and the results recorded.

Under the preceding subsection one commenter argued that, in the context of retort design, the location of the vent has no relevance to the need for a condensate bleeder. The commenter suggested that this part of the proposed requirement be deleted and suggested alternative language. FSIS agrees with this argument; however, upon further consideration of this issue, the Agency believes that steam inlet location, likewise, is not relevant to the need for a condensate bleeder. Therefore, the final rule has been revised whereby a condensate bleeder is required in all batch agitating retorts using steam under pressure.

The same commenter also urged that the phrase "such as a letter or operating manual" be added to the second sentence of this subsection. FSIS has rejected adding the suggested phrase to the final rule. The Agency believes the words "other documentation" would cover many types of written documents such as letters and operating manuals from equipment manufacturers and processing authorities. In addition, to be consistent with other parts of the final rule, a requirement has been added whereby such data or other supporting documentation must be made available to Program employees for review.

(vi) *Retort or reel speed timing.* One commenter stated that other agitating-type systems covered in the proposal are not required to have a recording tachometer. A second commenter argued that allowing manual checks of

the reel speed would be more consistent with the FDA rules. While a third commenter supported the requirement for recording tachometers, it was suggested that tachometer accuracy need only to be verified every shift. FSIS agrees that manual checking of reel speed is acceptable, and has revised the final rule to reflect the comments received.

One of the commenters also argued that an establishment should have an option about what corrective action is taken if problems occur during the process cycle. Based on this comment, FSIS has deleted the language dealing with corrective actions. If a processing problem occurs, FSIS would expect the deviation to be handled in accordance with § 318.308 or § 381.308.

(3) *Continuous rotary retorts*—(iv) *Bleeders*. This subsection has been revised to be consistent with the language used in subsection (b)(2)(iv) dealing with batch agitating retorts. Comments received on the subsection regarding condensate removal are discussed in subsection (b)(3)(v) immediately below.

(v) *Venting and condensate removal*. One commenter stated that heat distribution data are not generally available from the manufacturers of processing vessels and asked what other documentation could be substituted. The commenter also questioned whether such documentation is necessary if the retort vessel has been used without incident for many years.

FSIS emphasizes that the equipment manufacturer and the plant are responsible for ensuring that the documentation is accurate. Even if retort systems have been used for many years, such documentation must still be on file and made available to Program employees so that they can verify the adequacy of the specific retort installation and operating procedures.

Other comments received on this subsection correspond to those received on subsection (b)(2)(v) dealing with batch agitating retorts. The final rule has been revised for consistency with that subsection.

(vi) *Retort speed timing*. One commenter believed that the proposed requirement that the reel speed be checked and recorded at least every 4 hours is excessive and suggested that it be changed to "at intervals of sufficient frequency to ensure that the speed is maintained as specified" and that checks should be made every 4 hours or less. FSIS has rejected this comment and has retained the proposed language in the final rule. FSIS believes that checking the reel speed at intervals not to exceed 4 hours is not excessive. This

frequency is a generally accepted industry practice.

Another commenter suggested that the language giving the frequency of the monitoring and recording be moved to §§ 318.306(a)(3) and 381.306(a)(3) under recordkeeping. FSIS has not accepted this suggestion because the recordkeeping requirement is a logical extension of the other requirements of this subsection and would be out of place elsewhere.

(vii) *Emergency stops* and

(viii) *Temperature drops*. Two commenters suggested that these subsections be moved to §§ 318.308 and 381.308, which deal with deviations in processing. FSIS agrees with this suggestion and has made the change in the final rule. Other specific comments to these subsections have been addressed under proposed §§ 318.308(a)(1)(iv) and 381.308(a)(1)(iv).

(4) *Hydrostatic retorts*—(vi) *Conveyor speed*. One commenter argued that a process schedule from the processing authority should list only the sterilization time, and that the plant should calculate the required conveyor speed to meet the specified time. Thus, the commenter objected to the proposed requirement that the conveyor speed be listed in the process schedule. A second commenter made a similar suggestion. FSIS has accepted the intent of these comments and has revised the first sentence of the subsection to indicate that the correct conveyor speed shall be calculated to obtain the required process time and recorded by the establishment when the retort is started. FSIS has also deleted the fourth sentence of the proposed subsection from the final rule because processing deviations are more appropriately addressed in §§ 318.308 and 381.308.

(c) *Pressure processing in water*.

(1) *Batch still retorts*. (i) One commenter suggested that the proposed specifications on where the recorder/controller bulb is located in both vertical and horizontal retorts be deleted. Another urged the deletion of the proposed minimum distance that the indicating temperature device must extend into the water in both vertical and horizontal retorts. FSIS sees no need to delete either of these two specifications because they are recognized industry standards. Further, the requirements are consistent with those of FDA.

(ii) *Pressure recording device*. One commenter suggested that such devices are unnecessary and should not be required. FSIS disagrees and has retained the requirement in the final rule

because it is essential that a record of retort pressure be maintained. Overriding pressure is critical in water processing to prevent damage to containers such as glass jars, retortable pouches, and semirigid containers. For retortable pouches and some semirigid containers, overriding pressure is also critical in maintaining the desired container dimensions during the thermal processing operation.

(iii) *Pressure relief valve*. A commenter urged that the subsection be eliminated from the final rule, noting that pressure relief valves are not required for other types of retort systems and that there is no basis requiring them on one system and not on another. FSIS agrees with this argument and has deleted the subsection from the final rule.

(vii) *Stacking equipment*. One commenter argued that the subsection is not necessary if adequate heat distribution is in fact achieved and documented. The commenter also argued that the proposed requirement concerning flexible containers belongs in another section, such as § 318.303. FSIS agrees with the first suggestion and has eliminated the first sentence regarding the construction of the stacking equipment. However, FSIS believes that the requirement concerning flexible containers is appropriate in this section of the regulations. Thus, FSIS has retained the language in the final rule and has clarified the fact that the subsection could also be applicable to semirigid containers.

(viii) *Drain valve*. One commenter suggested that the proposed requirement be changed to a recommendation, while another commenter argued that, because the drain valve does not materially affect the adequacy of the thermal process, its requirement should be eliminated from the final rule. FSIS disagrees with both commenters. Drain lines and valves are sometimes used as part of the recirculation system to maintain uniform heat distribution; it is essential that such systems be kept clear of debris. Thus, FSIS has retained the requirement in the final rule.

(ix) *Water level*. One commenter noted that the subsection does not take into account processing systems that use cascading water sterilization and proposed language for revising the subsection. FSIS has accepted the proposed language and has incorporated it into the final rule. FSIS believes that the revised subsection addresses the suggestions of other commenters. Those suggestions included allowing a device designed to sound an alarm when the water level falls as an acceptable

alternative to checking and recording the water level; deleting the second sentence because the third sentence of the proposed subsection contains the words "proper level"; deleting the proposed requirement that water completely cover containers during the cooling process; and deleting the example of using petcocks to determine water level because they are no longer recommended.

(x) *Air supply and controls.* Two commenters urged that steam be added as a source of overpressure and that the reference to the rate of introducing compressed air or steam be deleted. FSIS concurs with these suggestions and has changed the final rule accordingly. While steam is not widely used to produce overpressure, it is just as effective as air for this purpose. In addition, the rate at which air or steam is added to the retort is not critical in achieving the required overpressure.

A third commenter argued that the entire subsection should be deleted because it sets forth equipment specifications that are beyond the scope of the regulation. FSIS disagrees with this comment because ensuring adequate water or air circulation is critical to the thermal process and is an appropriate area of regulation.

(xi) *Water recirculation.* One commenter recommended that the entire subsection be deleted arguing that detailed equipment specifications are beyond the scope of the regulation. FSIS disagrees with this comment because ensuring the adequacy of heat distribution throughout the retort during the thermal process is essential.

Another commenter suggested that the use of a flow-meter alarm system be accepted as an adequate safeguard for proper water circulation. FSIS agrees and has revised the final rule to allow the use of flow-meter alarm systems.

A third commenter argued that the proposed requirement that suction outlets have nonclogging screens be changed to a recommended practice. FSIS has rejected this proposal because clogged suction outlets could affect the uniformity of heat distribution during the thermal process. However, the word nonclogging has been deleted in this subsection and elsewhere in the final rule. Screens can, in time, become clogged and it will be the responsibility of the establishment to keep all required screens free of debris.

(xii) *Cooling water entry.* One commenter argued that the subsection is not germane to the adequacy of the thermal process and should be deleted. FSIS agrees in part that this proposed requirement does not specifically affect the adequacy of the thermal process;

however, the improper entry of cooling water into the retort could damage glass containers. Therefore, FSIS has retained the current language but has made the subsection a recommendation as a good manufacturing practice.

(xiii) *Retort headspace.* Two commenters noted that this subsection discusses retort pressure rather than retort headspace. FSIS agrees and has established that retort pressure was adequately covered in proposed §§ 318.305(c)(2)(ix) and 381.305(c)(2)(ix). Therefore, in the final rule retort pressure control is addressed in §§ 318.305(c)(2)(viii) and 381.305(c)(2)(viii) titled, "Air supply and controls."

(2) *Batch agitating retorts.* Subsections (i) through (ix) and (xi) through (xiii): Comments received in response to these subsections were the same as those for identically titled subsections under (c)(1), batch still water retorts. The subsections for batch agitating retorts have been revised as indicated in the discussions under (c)(1).

(x) *Retort or reel speed timing.* One commenter argued that readjusting the reel speed may not be the best example of corrective action after a change in speed occurs because evaluation of product sterility is also necessary. Therefore, the commenter recommended that this example be deleted. FSIS concurs with this comment and has deleted the sentence from the final rule. The subsection has also been revised for consistency with (b)(2)(vi) covering batch agitating steam retorts.

(d) *Pressure processing with steam/air mixtures in batch retorts.*

(3) This subsection dealing with pressure relief valves has been deleted from the final rule. See subsection (c)(1)(iii) for discussion.

(e) *Atmospheric cookers.*

(2) *Stacking equipment.* and (3) *Temperature distribution.* Four commenters urged that the entire subsection be deleted on the grounds that the final rule should pertain only to shelf stable, low acid canned products. FSIS has not accepted the argument that the final rule should not cover acidified, low acid, shelf stable products (see the General Comments section of this preamble). Therefore, since atmospheric cookers can be used for the processing of acidified, low acid products, this subsection has been retained in the final rule.

Another commenter suggested that subsections (e) (2) and (3) be combined and suggested the wording for the combined subsection. FSIS agrees with this comment because subsection (e)(2) was proposed to assure that stacking equipment in atmospheric cookers

would allow for uniform heat distribution. Since the proposed subsection (e)(3) dealt in general with heat distribution, the Agency considers the effect of stacking equipment as part of the overall need to assure adequate heat distribution. Therefore, the suggested language has been incorporated into the final rule, with the additional requirement that the data or other documentation on heat distribution be made available to Program employees for review.

(g) *Equipment maintenance.*

Three commenters questioned the meaning of the term "extended shutdown," which is used in the proposed rule in subsections (1) and (2) to prescribe when retort systems should be examined for proper functioning. One of the three suggested that an extended period of time be defined as more than 45 days. FSIS agrees that the phrase "extended shutdown" is vague; however, the Agency believes that thoroughly examining thermal processing systems before the resumption of operations following a lengthy shutdown is a good manufacturing practice. Therefore, the final rule has been revised to incorporate the Agency's position as a recommendation.

Two commenters questioned the need to check and test each retort system when it is empty. One noted that some retort systems may not function properly without containers. FSIS accepts these comments and has deleted this phrase from the final rule.

One commenter also argued that it is unnecessary to check and test systems that are operated on a year-round basis because general maintenance is performed daily. FSIS intended that the subsection require that retort systems be audited by someone other than the day-to-day operators in the retort area. This trained individual should be knowledgeable about the effects any changes might have on the adequacy of the thermal process. The language of the proposed rule has been revised to reflect this intent.

For further simplicity, FSIS has removed the phrase "at least once a year" in subsection (1) because the same requirement is contained in subsection (2). The two sentences in subsection (2) have also been combined.

(6) One commenter argued that the requirement to keep records of all maintenance conducted on the processing equipment is burdensome and unnecessary. The commenter suggested that only major maintenance items that could affect the adequacy of the thermal process, such as radical

alterations of the venting system, should be subject to the recordkeeping requirements. FSIS agrees with this comment and has revised the language in the final rule accordingly.

(h) Container cooling and cooling water.

(3) Two commenters objected to the requirement that systems designed to recycle cooling water be approved by the Administrator, arguing that the requirement adds an unnecessary burden. The commenters believe that it is sufficient to require that recycled cooling water be treated with a bactericide so that there is a measurable residual in the water after use.

FSIS does not agree that a bactericide alone is sufficient to prevent a buildup of bacterial spores in reused container cooling waters. Additionally, FSIS believes that these systems must be properly designed and maintained to adequately control the levels of organic and objectionable inorganic matter in the water.

Another commenter urged that a processing authority should be allowed to approve such systems and make the documentation available to the Program employee.

A fourth commenter stated that plants currently using recycled cooling water systems and that have procedures to prevent the excessive buildup of organic material should not be required to obtain approval. The commenter said that approval should be required when a system is substantially modified or a new system is installed.

FSIS agrees in principle with the overall thrust of the comments; i.e., that such systems need not be approved by the Administrator before use. However, the Agency remains concerned with the growing use of recycled and reused container cooling water, particularly water in systems that are poorly designed, operated, or maintained. This concern is centered on the belief that reused water of poor quality will lead to increased incidents of post-processing contamination of canned product. Thus, subparagraph (3) has been revised in the final rule to require that systems for recycling or reusing container cooling water must be designed, constructed, operated, and maintained to ensure that the recycled/reused water will be of a quality acceptable for the intended purpose. No prior approval by the Administrator will be required since minimum requirements have been included in the final rule and can be evaluated by Program employees. However, establishments must maintain a file of current information regarding all aspects of a system including details on design and construction, operation

maintenance and water quality standards. Such information must be made available to Program employees for review.

Establishments recycling or reusing container cooling water as of the effective date of these regulations shall have the information required in §§ 318.305(h)(3) and 381.305(h)(3) on file and available for review by Program employees within 6 months of the date the regulations are effective. Establishments placing such systems into use after the effective date of these regulations shall have the required information on file and available for review within 6 months of the date a system is first used.

By dealing with cooling water reuse in new Subparts G and X, § 308.3(d)(2) has been revised. In the course of revising that subsection the Agency recognized that a strict interpretation of subsection 308.3(d)(3) would require that the reuse of water for the thermal processing of canned product be approved by the Administrator. While FSIS believes that reusing water in thermal processing equipment dictates that certain precautions be taken to protect the water, water quality has little consequence on the safety and stability of canned product. Therefore, § 308.3(d) has been revised to allow the circuit supervisor to approve the reuse of water that is used in the thermal processing of canned meat products. In a similar manner, a new paragraph (f) has been added to § 381.50 to allow for circuit supervisors to approve the reuse of water in the thermal processing of canned poultry products.

(i) Post-process handling of containers.

One commenter suggested that the proposal be revised to include a general requirement that containers be handled in a way to minimize the possible damage to containers or the exposure of hermetic seals to high levels of microorganisms. In addition, the commenter suggested that the specific proposed requirements be made recommendations. A second commenter questioned how frequently equipment had to be cleaned and what standards had to be met. These questions were directed at the proposed requirement that, "All post-process container handling equipment shall be kept clean and sanitized..."

FSIS agrees with the recommendation to include a general requirement for handling containers because the recommended wording would encompass all types of container handling equipment and operations. It has also modified the final rule to make most other requirements recommended

practices. FSIS, however, has retained the requirement that all worn and frayed belting, can retarders, cushions, and the like shall be replaced with nonporous materials because the Agency believes that it will minimize post-process contamination of containers. Furthermore, while the proposed requirement regarding the cleaning of post-process container handling equipment has been made a recommendation, FSIS believes that establishments should develop a plan for routinely cleaning and sanitizing all such equipment.

Sections 318.306 and 381.306 Processing and Production Records

Concerning the general requirements found at the beginning of §§ 318.306 and 381.306, a commenter suggested that it should not be necessary to record processing data found to be normal. FSIS disagrees with this suggestion. The recording of normal data is essential for three reasons. First, trends appearing in normal data may alert employees to developing problems and allow them to take corrective action before deviations occur. Second, records of normal data provide management with information necessary to ensure that all production is being monitored and controlled. And third, the recording of all data provides assurance to FSIS employees that an establishment is complying with USDA regulations. The recording of normal data has been a long-standing, generally-accepted practice in the U.S. canning industry.

Another commenter recommended that the production date be added to the list of information that is recorded. FSIS agrees with this suggestion and has modified the final rule accordingly.

(a) Processing in steam.

(1) *Batch still retorts.* Three commenters suggested that it is more appropriate to record the number of crates in the retort rather than the number of containers. However, because some retort systems do not make use of crates, FSIS has retained the proposed language but has included the recording of the number of crates as an alternative.

Two commenters suggested that recording the actual venting time be changed to recording the time the vent is closed. FSIS has accepted this suggestion because venting begins when steam is turned on, and that time must be recorded. Thus, by recording the vent closing time, the actual venting time is the elapsed time between steam on and vent closing.

Two commenters recommended substituting the phrase "start of process

timing" for "time sterilization temperature reached" in the list of data that must be recorded. FSIS agrees that the suggested terminology is more precise and has made the change in the final rule.

One commenter suggested modifying the phrase "time steam off" to "actual time steam off." FSIS has retained the proposed wording in the final rule because the final rule also requires the recording of actual (elapsed) processing time.

(2) *Batch agitating retorts.* One commenter suggested that this subsection include a cross-reference to subsection (a)(1) above. This addition has been made in the final rule, and the two sentences of the proposed subsection (a)(2) have been combined.

(3) *Continuous rotary retorts.* One commenter urged that the frequency at which readings of the indicating temperature device and temperature recorder are taken and recorded not be mandatory. In addition, the commenter believed that the recommended frequency should be changed from every 30 minutes to every hour. The commenter argued that the proposed requirement is excessive because most retorts are equipped with low-temperature alarms, and the temperature recording charts provide a record of the process temperature. Another commenter, however, suggested that the requirement should be retained, but that the frequency of comparing the indicating temperature device with the temperature recording device should be at least every hour of continuous retort operation rather than at least every 30 minutes.

In consideration of the comments received and to be consistent with wording found elsewhere in the final rule, this subsection has been revised to require comparative readings to be made and recorded at a frequency that will ensure that the actual retort temperature complies with the temperature specified in the process schedule.

Another commenter suggested that the final rule specify the frequency (at least every 4 hours) at which the retort or reel speed shall be observed and recorded. FSIS has accepted this recommendation because it reiterates a requirement found in §§ 318.305(b)(3)(vi) and 381.305(b)(3)(vi).

Two commenters stated that recording the times that the first container enters and the last container exits should be required. FSIS agrees that recording this information is necessary and the final rule has been modified accordingly. This information, in conjunction with other required

records, will provide assurance that the proper retort temperature was attained before the first container entered and was maintained until the last container exited the retort.

For clarity, FSIS has retained the requirement that the functioning of the condensate bleeder be recorded but has added a cross-reference to the requirements of §§ 318.305 (b)(3)(v) and 381.305 (b)(3)(v).

FSIS has also changed "sterilization temperature" to "time process temperature reached" for consistency with §§ 318.300(n) and 381.300(n) and "actual venting time and temperature" to "the time and temperature vent closed" for consistency with §§ 318.306(a)(1) and 381.306(a)(1).

(4) *Hydrostatic retorts.* Two commenters argued that the requirement that the indicating temperature device in the steam dome must be read and recorded every 30 minutes is excessive. One suggested that hourly observations are sufficient for systems in which the temperature of the steam dome is monitored by a continuous temperature recording device. Another commenter argued that FSIS should only recommend and not prescribe the frequency of observing and recording the temperature.

After reviewing these comments, FSIS has retained the proposed language in the final rule requiring that a reading of the indicating temperature device in the steam dome shall be taken and recorded at the time the first container enters the steam dome. For consistency with §§ 318.306(a)(3) and 381.306(a)(3), FSIS has also added wording to require that after the initial reading, these instruments shall be read and the results recorded in order to ensure compliance with the temperature specified in the process schedule and that such readings should be made at least every hour of continuous retort operation.

Another commenter urged that the first sentence of the proposed subsection be revised to read: "Record the retort system number, the approximate total number of containers retorted, product initial temperature, time steam on, actual time and temperature vent closed, time at end of come-up, time first container enters retort, time last container exits retort, and if specified . . ." FSIS agrees with the comment; however, for consistency with §§ 318.300(n) and 381.300(n), FSIS has used the phrase "time process temperature reached" in the first sentence. The commenter also suggested that the last sentence be revised to require that for agitating hydrostatic retorts, the rotative chain speed be determined and recorded at intervals

not to exceed 4 hours. FSIS concurs because maintaining a specified rotative chain speed is critical in assuring process schedule adequacy. Also, for consistency with §§ 318.306(a)(3) and 381.306(a)(3), FSIS has indicated that such readings shall be taken at intervals of sufficient frequency to ensure compliance with the process schedule and has recommended that readings be made at least every 4 hours.

(b) Processing in water.

(1) *Batch still retorts.* See subsection (a)(1) for a discussion of whether the number of containers or crates must be recorded.

A commenter suggested the following additions to the first sentence: *actual time steam off*; and *actual sterilization time*. FSIS has rejected the first suggestion because the Agency intends the term "time steam off" to mean the actual time the steam is turned off and not the predicted time. The second suggestion was obviated by a revision made in §§ 318.300 and 381.300 whereby the definition for "sterilization time" was replaced by "process time" as discussed previously in this preamble.

(2) *Batch agitating retorts.* One commenter suggested that this subsection include a cross-reference to subsection (b)(1). FSIS has accepted this comment and has revised the final rule accordingly.

(c) Processing in steam/air mixtures.

Two commenters noted that venting this type of retort system may not be necessary and suggested the addition of the qualifying phrase "if applicable." FSIS concurs with this comment and has added the phrase to the final rule. The phrase "venting time and temperature" has also been changed to "venting procedure" to allow the use of alternate venting methods that may be established by processing authorities.

One commenter suggested that the phrase "air flow rate" should either be omitted or changed to "air flow rate (if applicable)." The commenter also suggested changing the word "pressure" to "overriding pressure maintained." FSIS has revised the final rule to indicate that air flow rate shall be recorded only when it is identified as a critical factor in the process schedule. The suggestion to use the term "overriding pressure maintained" was accepted because it clearly identifies the pressure condition that must be recorded.

Three commenters urged that the last sentence of the subsection concerning critical factors be deleted, arguing that the requirement is out of place and redundant. FSIS concurs with this comment and has deleted the sentence

from the final rule because the controlling and recording of critical factors are required in §§ 318.303 and 381.303.

(d) Atmospheric cookers.

One commenter argued that subsections (1) and (2) should be deleted because the final rule should apply only to low acid canned meat and poultry products, which cannot be processed in atmospheric cookers. As noted in the General Comments section of this preamble, FSIS has retained the requirements for the processing of acidified, low acid foods. Because atmospheric cookers can be used for the processing of these foods, the recordkeeping requirements for atmospheric cookers have also been retained in the final rule.

One commenter suggested that the word "cooker" be inserted between the words "each" and "batch" in the first sentence of subsection (1). FSIS agrees and has revised the final rule accordingly.

Sections 318.307 and 381.307 Record Review and Maintenance

(a) Process records.

Three commenters argued that establishments should be required to provide Program employees only those processing and production records related to the process schedules. In light of these comments, FSIS has modified the proposed language to indicate that those processing and production records required by Subparts G and X must be made available to Program employees.

A commenter requested that the final rule include a clarification that the term "processing system number" could refer to the retort number, the hydrostatic cooker number, or other systems of identification. FSIS has accepted this suggestion and has substituted the wording proposed by the commenter.

Another commenter suggested that records relating to critical factors be added to the examples of records that must be signed or initialed and dated by the person who reviews process records for the plant. FSIS agrees that these records should be included in the examples and has modified the subsection accordingly.

(c) Container closure records.

Two commenters noted that the subsection does not specify how often representatives of plant management must review records on container closures. One commenter suggested that the subsection state that these reviews shall be conducted within 1 working day after the actual production. FSIS agrees that the frequency of reviews should be specified in the final rule. For consistency with §§ 318.307(a) and

381.307(a), FSIS has accepted the proposed language.

Sections 318.308 and 381.308 Deviations in Processing

(a) Shelf stable canned product.

(1) *Deviations identified in-process.* (i) Five commenters argued that decisions of designated processing authorities regarding the handling of products involved in deviations do not need to be reviewed and approved by FSIS before they are implemented. They contended that FSIS is responsible only for ensuring that the recommendations of processing authorities are properly implemented. The commenters recommended requiring only that the establishment provide copies of a processing authority's evaluation and recommendations for disposition of product to the inspector for review.

FSIS has provisions under the total and partial quality control regulations (9 CFR 318.4 and 9 CFR 381.145), that allow owners and operators of official establishments to handle process deviations in the manner suggested by the commenters. However, under traditional (non-TQC) inspection, FSIS has no statutory basis to extend authority to owners and operators to handle such inspection problems and responsibilities.

To date, FSIS has reviewed and approved more than 30 quality control programs for handling process deviations and welcomes the opportunity to consider more from other official establishments. Those that have been approved were submitted either as partial quality control programs or as part of total quality control systems. The programs state how each establishment will handle process deviations, and for the most part, eliminate the need for officially retaining products and submitting evaluations of process deviations to FSIS for review and approval each time a deviation occurs. Through the quality control program, the establishment and FSIS have agreed on procedures for handling deviations. FSIS has thus retained the intent of the proposal, but the final rule has been reorganized for clarity.

(ii) Three commenters argued that this subsection should be deleted from the final rule. FSIS has rejected this suggestion; see subsection (a)(1)(i) above for a discussion of the comments.

A fourth commenter observed that the subsection could be interpreted as requiring approval from FSIS before an establishment ships products that have been either fully reprocessed or processed under an approved alternate process schedule. FSIS believes that the commenter misinterpreted this

subsection because there was a codification error in the published proposal. Because the Agency intended that it pertain only to subsection (a)(1)(i)(c) of the proposed rule, the final rule has been recodified to reflect this intent.

(iii) One commenter noted that the subsection applies only when alternate process schedules that are on file with the inspector are used.

The commenter suggested clarifying the subsection by adding the following clause to the beginning: "If an alternate schedule used is not on file with the inspector, the product involved . . ." FSIS concurs with this comment and has incorporated the intent of the suggestion into the final rule.

(iv) One commenter recommended that proposed §§ 318.305(b)(3) (vii) and (viii) and 381.305(b)(3) (vii) and (viii), which pertain to handling process deviations in continuous rotary retorts, be moved to this subsection. The commenter also argued that the subsection should apply to both hydrostatic retorts and continuous rotary retorts.

FSIS has accepted the first recommendation. The Agency agrees with the commenter that all requirements for handling process deviations should be located in §§ 318.308 and 381.308. Therefore, the handling of process deviations for continuous rotary retorts has been recodified as §§ 318.308(d)(1)(vi) and 381.308(d)(1)(vi). FSIS, however, has rejected the suggestion that the subsections be modified to include hydrostatic retorts because the commenter did not provide supporting data to demonstrate that all the procedures and requirements for handling deviations in continuous rotary retorts are also applicable to hydrostatic retorts. FSIS will consider amending the rule if supporting data are provided and found acceptable.

Three commenters argued that it is unnecessary and unworkable to require that the inspector supervise the reprocessing, repacking and reprocessing, or the destruction of products involved in process deviations, provided adequate records are maintained.

FSIS concurs, in part, with these comments. The intent of the proposal was to require that condemned product be destroyed under the direct supervision of the inspector. The final rule has been modified to clarify the Agency's intent. And while the phrase "discarded under the supervision of an inspector" has been deleted, FSIS has the statutory obligation to ensure that

condemned product is destroyed. Therefore, language has been added to the final rule that will require that condemned product be destroyed in accordance with applicable regulations. However, the reprocessing or repacking and reprocessing of product would be subject to inspection comparable to that provided to other operations performed by the establishment. FSIS has also added to §§ 318.308(d)(1)(vi)(a)(1) and 381.308(d)(1)(vi)(a)(2) a requirement that the handling of the containers shall be fully documented by the establishment on the production records.

One commenter also urged that a provision be made for holding product involved in temperature drops of 10F degrees or more for a process deviation evaluation by the designated processing authority. FSIS agrees with the suggestion because it provides an acceptable alternate method for handling process deviations in continuous rotary retorts. Therefore, §§ 318.308(d)(1)(vi) and 381.308(d)(1)(vi) of the final rule have been revised to provide the option of handling product in accordance with §§ 318.308(d)(1)(iii) and (iv) and 381.308(d)(1)(iii) and (iv).

(3) Three commenters argued that the subsection should be changed to provide that the processing authority, rather than the inspector, determine whether products are safe and stable before they are shipped. FSIS rejects these comments; see subsection (a)(1)(i) for its rationale and a discussion of responsibilities for the handling of process deviations and the disposition of the affected production.

(c) Process deviation file.

One commenter argued that requiring a separate process deviation file is a needless duplication. The commenter suggested that a log indicating where the files on deviations are located would be an adequate record and offered the following revision to the subsection: "All process deviations . . . shall be recorded and made the subject of a separate file (or a log identifying the appropriate data) detailing those deviations and the actions taken." FSIS agrees with this comment and has provided an option in the final rule that allows plants to maintain a log identifying the location of the appropriate data.

Another commenter pointed out that the subsection does not give a time period for which the deviation file or log must be maintained. FSIS agrees and has added language to the final rule requiring that the file or log be retained in accordance with §§ 318.307(e) and 381.307(e).

Sections 318.309 and 381.309 Finished Product Inspection

(a) Incubation of shelf stable canned product.

One commenter argued that the adoption of the canning regulations should eliminate the need for incubation of finished products, except in cases of process deviations. In those cases, the commenter argued that sampling levels should be high; otherwise, no incubation should be required because, if the requirements of the regulations are met, the products can be presumed to be safe and stable. The commenter also noted that FDA regulations do not require the incubation of finished products.

FSIS disagrees with this argument. In the past USDA has identified numerous problems with finished products through incubation testing. Thus, FSIS believes that incubation testing is a valuable tool in providing increased assurance of the safety and stability of product entering the marketplace. Many companies have voluntarily adopted incubation testing procedures that are more rigorous than those contained in the final rule. This is additional testimony to the value of incubation testing.

Moreover, as stated in the proposal, an establishment can, as provided in §§ 318.4 or 381.145, develop a total or partial quality control program in which it assumes greater responsibility for handling product incubation. These responsibilities can include all aspects of incubation testing, the investigation of incubation failures, and the disposition of affected production. To further clarify this option, the opening paragraph in the proposal has been expanded in the final rule in a manner similar to the modifications made to §§ 318.308 and 381.308.

(2) Incubation temperature. Four commenters argued that brief temperature deviations above 103 °F should not be a reason for resampling and starting a new incubation test. One suggested qualifying the requirement to state that if the temperature reaches or exceeds 103 °F for more than 2 hours, the test must be restarted. FSIS agrees with the comments and has revised the final rule accordingly. It is the Agency's position that unless the temperature reaches or exceeds 103 °F for more than 2 hours, the validity of the incubation results will not be affected.

(4) Incubation samples. Two commenters noted that the proposed requirement that one container be sampled for each 1,000 containers processed in batch-type retort systems exceeds current USDA sampling requirements. The commenters suggested retaining the current

requirement of one container for each retort load.

FSIS agrees that current sampling requirements for batch-type retort systems are adequate and has adopted those requirements in the final rule. Many plants, however, voluntarily sample more than one container per retort load; FSIS encourages this practice.

Another commenter suggested inserting the word "retort" between the words "each" and "batch" to distinguish retort batches from product batches. FSIS appreciates the comment; however, the Agency considers the term "thermal processing system" to be more inclusive and has revised the final rule to incorporate both the term and the commenter's concern.

(6) Incubation checks and record maintenance. One commenter argued that plant employees should not be required to visually check containers in incubation each working day if a plant does not have access to the incubator. The commenter suggested that this requirement be made discretionary.

FSIS believes it is essential that plant employees check the incubator every working day and notify the inspector when an abnormal container is detected. Sections 318.309(a)(1) and 381.309(a)(1) provide that the Program is responsible for the security of the incubator and for determining appropriate policies for access by plant employees. Plants should work with inspectors to determine when plant employees may have access to incubators.

A second commenter requested that a sentence be added to indicate that all containers that appear to be abnormal should be cooled to room temperature before a final decision about their condition is made. FSIS has accepted this suggestion because it is in line with current FSIS procedures.

This subsection of the proposed rule includes examples of abnormal containers. These examples have been removed from the final rule because a definition of abnormal containers has been added as §§ 318.300(a) and 381.300(a).

(8) Shipping. Three commenters requested that plants be allowed to notify the FSIS inspector rather than the area supervisor of their intention to ship product before samples have completed incubation. FSIS believes that this subsection has been misunderstood. It was intended that all future lots could be shipped without specific approval once the area supervisor approves a firm's proposal for shipping before the end of incubation. A clarifying sentence

to this effect has been added to the final rule.

(b) Container condition.

(1) *Normal containers.* One commenter pointed out that the proposed language could imply that 100 percent inspection is required at the time of shipping. Because this implication was not intended, the final rule has been revised to indicate that the condition of a lot shall be determined by the use of an appropriate sampling plan or other means acceptable to Program employees.

A second commenter suggested making this subsection a recommended practice rather than a requirement, arguing that compliance with this subsection is not possible without 100 percent inspection. Although FSIS recognizes that it is not possible to guarantee that all containers are normal, it rejects the idea of weakening this subsection by making it a recommended practice that only sound, normal-appearing containers be shipped. Such a change would allow the subsection to be interpreted as allowing plants to make decisions arbitrarily about the shipment of lots that include abnormal containers.

(2) *Abnormal containers.* Four commenters argued that, when abnormal containers are found by any means other than incubation, establishments, rather than the USDA, should determine whether the product is safe and stable and may be shipped.

As with the case of handling process deviations discussed above, FSIS has provisions under the total and partial quality control regulations, 9 CFR 318.4 and 9 CFR 381.145, that allow owners and operators of official establishments to handle abnormal containers under approved procedures.

To date, FSIS has reviewed and approved more than 10 quality control programs for handling abnormal containers and welcomes the opportunity to consider more from other official establishments. Those that have been approved were submitted either as partial quality control programs or as part of total quality control systems. Each program states how the establishment will handle abnormal container incidents and, for the most part, eliminates the need for officially retaining product and submitting samples to an FSIS laboratory for analysis. Through the quality control program, the establishment and FSIS have agreed on procedures for handling such incidents. FSIS has thus retained the proposed language in the final rule but has reorganized the subsection for clarity.

Sections 318.310 and 381.310 Personnel and Training

One commenter argued that prior approval of the courses offered through the Better Process Control Schools is premature and should be withheld until the courses are changed to offer instruction in the differences between FDA and USDA canning regulations. FSIS agrees with this comment and has revised the final rule by deleting the reference to Better Process Control Schools. Moreover, in further considering this matter, FSIS has concluded that it will forgo official approval of any school because specific criteria are lacking. This does not mean, however, that FSIS is not concerned with the effectiveness of such schools. FSIS would expect the curricula to include such things as fundamentals of thermally processing products for shelf stability, function and proper operation of equipment involved, critical control points, and the regulatory requirements. The curricula of the Better Process Control Schools, approved by the FDA, cover those areas. They are generally recognized by experts in the canning industry and academia as being adequate to properly train canning plant personnel who supervise canning operations because of the curriculum; because ample time is spent on the subject matter; because of the manner in which they are conducted; and because they are conducted by highly trained experts. It should be noted that with appropriate modifications to reflect the unique requirements of this final rule, the Better Process Control Schools will satisfy the requirements of §§ 318.310 and 381.310 of the rule. Any organization interested in developing a school may wish to pattern the curriculum after that of the Better Process Control School, as modified.

FSIS personnel are available to consult with interested individuals or organizations concerning modifications to the curricula of the Better Process Schools, or developing a curriculum for other schools of instruction.

Many individuals associated with meat and poultry canning establishments, particularly those establishments that also pack FDA-regulated products, have satisfactorily completed courses of instruction required by that agency. Since these individuals have been taught the essential principles of thermal processing, and since FSIS has not previously required such individuals to complete such courses, and in order not to impose an unnecessary burden on the industry, further training of such persons will not be necessary in order to be in

compliance with §§ 318.310 and 381.310. In addition, FSIS recognizes that ample time will be needed for Better Process Control Schools to make appropriate modifications to their curricula, for other interested parties to develop appropriate courses of instruction, and for establishment personnel to complete the required training. Therefore, within 2 years of publication of these regulations, establishments must provide proof to the Administrator that they have operators of thermal processing systems and container closure technicians under the direct operating supervision of a person who has successfully completed a school of instruction. This individual may only supervise those activities for which a school has identified the person as having successfully completed the prescribed courses of instruction.

Sections 318.311 and 381.311 Recall Procedure

Two commenters argued that, because USDA does not have the authority to require product recalls, it also does not have the authority to require that companies provide their recall procedures to USDA inspectors. The commenters noted, however, that it is important that plants have written recall procedures and that they maintain the procedures on file.

It is true that the enabling legislation does not explicitly authorize recalls. Even though FSIS is responsible for protecting consumers from potential hazards from products in commerce, which can be exercised in various ways, such as the use of the media, and even though any good establishment will have recall procedures on file, FSIS has eliminated the requirement that such procedures be filed with the inspector. Instead, the final rule provides that a current recall procedure must be maintained on file by the official establishment. To assure compliance with this section, the final rule also provides that, upon request, the recall procedure shall be made readily available to Program employees for review.

With regard to the required notification of the inspector and the Administrator, two commenters argued that the proposal should be revised to require that companies notify the inspector and the Administrator of a recall only when a company believes that the recall involves a potential public health threat. One also argued that notification before the actual recall may be impossible and that the time element should be deleted from the final rule.

FSIS recognizes the concerns. In many instances effective recalls are difficult to implement and coordinate, requiring the establishment's diligence and commitment to communicate with many parties to effect a recall. Moreover, the industry has a commendable record in this area. However, FSIS is responsible under the Acts to assure the consumer a safe product. Upon considering the industry's concerns, and recognizing that FSIS policies relating to recalls are included in FSIS Directive 8080.1, Recall of Inspected Meat and Poultry Products, dated August 4, 1983, FSIS has deleted the proposed sentence concerning notification from the final rule. This directive covers all FSIS-inspected products, including canned products. Two commenters, in fact, suggested that the substance of this directive be incorporated into §§ 318.311 and 381.311. FSIS has not accepted this suggestion because at a later date the Agency may desire to issue proposed rules incorporating the substance of the directive in the meat and poultry inspection regulations to cover all meat and poultry products.

Finally, a commenter suggested that, in the first sentence, the description of establishments should be changed from those engaged "in the thermal processing of canned product" to "in the packaging of thermally processed product." FSIS has not made this change but has deleted the original phrase from the final rule. To compensate, the sentence has been modified to indicate that establishments shall prepare and maintain on file a current procedure for recall of all products covered by this rule. Canned products are defined in §§ 318.300(d) and 381.300(d) of the final rule.

Final Rule

After careful consideration of the comments received on the proposed rule, FSIS is adopting the proposal as a final rule, with the modifications previously discussed in the preamble.

List of Subjects

9 CFR Parts 308, 320 and 327

Meat inspection.

9 CFR Part 318

Canning, Containers, Meat inspection.

9 CFR Part 381

Canning, Containers, Poultry inspection.

Accordingly, the Federal meat and poultry products inspection regulations are amended as set forth below:

1. The authority citation for Part 308 is revised to read as follows:

Authority: 34 Stat. 1260, 79 Stat. 903, as amended, 81 Stat. 584, 84 Stat. 91, 438; 21 U.S.C. 71 *et seq.*, 601 *et seq.*, unless otherwise noted.

PART 308—[AMENDED]

2. Section 308.3, paragraphs (d) (2) and (3), are revised to read as follows:

§ 308.3 Establishments; sanitary condition; requirements.

(d)(1) * * *

(2) The circuit supervisor may permit the reuse of water in vapor lines leading from deodorizers used in the preparation of lard and similar edible product and in equipment where such water is used to thermally process canned product packed in hermetically sealed containers, provided:

(i) The reuse is for the identical original purpose.

(ii) All pipelines, reservoirs, tanks, cooling towers, and like equipment employed in handling the reused water are so constructed and installed so they can be cleaned and drained, and are kept clean.

(3) Approval for the reuse of water other than as specified in paragraph (d)(2) of this section or in § 318.305(h) shall be obtained from the Administrator in specific cases.

3. The authority citation for Part 318 continues to read as follows:

Authority: 34 Stat. 1260, 81 Stat. 584, as amended (21 U.S.C. 601 *et seq.*), 72 Stat. 862, 92 Stat. 1069, as amended (7 U.S.C. 1901 *et seq.*), 76 Stat. 663 (7 U.S.C. 450 *et seq.*).

PART 318—[AMENDED]

4. Part 318 is amended by designating existing §§ 318.1 through 318.10 and 318.12 through 318.20 as new Subpart A—General.

§ 318.11 [Removed and Reserved]

5. Section 318.11 is removed and reserved for future use. All references to "§ 318.11" are changed to read "§§ 318.300 through 318.311", wherever they occur in 7 CFR Chapter III.

6. Subparts B through F of Part 318 are reserved for future use. The Table of Contents is revised accordingly.

7. A new Subpart G—Canning and Canned Products, consisting of sections 318.300 through 318.311 is added to Part 318 to read as follows:

Subpart G—Canning and Canned Products

Sec.

318.300 Definitions.

318.301 Containers and closures.

318.302 Thermal processing.

Sec.

318.303 Critical factors and the application of the process schedule.

318.304 Operations in the thermal processing area.

318.305 Equipment and procedures for heat processing systems.

318.306 Processing and production records.

318.307 Record review and maintenance.

318.308 Deviations in processing.

318.309 Finished product inspection.

318.310 Personnel and training.

318.311 Recall procedure.

Subpart G—Canning and Canned Products

§ 318.300 Definitions.

(a) *Abnormal container*. A container with any sign of swelling or product leakage or any evidence that the contents of the unopened container may be spoiled.

(b) *Acidified low acid product*. A canned product which has been formulated or treated so that every component of the finished product has a pH of 4.6 or lower within 24 hours after the completion of the thermal process unless data are available from the establishment's processing authority demonstrating that a longer time period is safe.

(c) *Bleeders*. Small orifices on a retort through which steam, other gasses, and condensate are emitted from the retort throughout the entire thermal process.

(d) *Canned product*. A meat food product with a water activity above 0.85 which receives a thermal process either before or after being packed in a hermetically sealed container. Unless otherwise specified, the term "product" as used in this Subpart G shall mean "canned product."

(e) *Closure technician*. The individual(s) identified by the establishment as being trained to perform specific container integrity examinations as required by this subpart and designated by the establishment to perform such examinations.

(f) *Code lot*. All production of a particular product in a specific size container marked with a specific container code.

(g) *Come-up time*. The elapsed time, including venting time (if applicable), between the introduction of the heating medium into a closed retort and the start of process timing.

(h) *Critical factor*. Any characteristic, condition or aspect of a product, container, or procedure that affects the adequacy of the process schedule. Critical factors are established by processing authorities.

(i) *Headspace*. That portion of a container not occupied by the product.

(1) *Gross headspace.* The vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the top edge of the container (i.e., the flange of an unsealed can, the top of the double seam on a sealed can, or the top edge of an unsealed jar).

(2) *Net headspace.* The vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the inside surface of the lid.

(j) *Hermetically sealed containers.* Air-tight containers which are designed and intended to protect the contents against the entry of microorganisms during and after thermal processing.

(1) *Rigid container.* A container, the shape or contour of which, when filled and sealed, is neither affected by the enclosed product nor deformed by external mechanical pressure of up to 10 pounds per square inch gauge (0.7 kg/cm²) (i.e., normal firm finger pressure).

(2) *Semirigid container.* A container, the shape or contour of which, when filled and sealed, is not significantly affected by the enclosed product under normal atmospheric temperature and pressure, but can be deformed by external mechanical pressure of less than 10 pounds per square inch gauge (0.7 kg/cm²) (i.e., normal firm finger pressure).

(3) *Flexible container.* A container, the shape or contour of which, when filled and sealed, is significantly affected by the enclosed product.

(k) *Incubation tests.* Tests in which the thermally processed product is kept at a specific temperature for a specified period of time in order to determine if outgrowth of microorganisms occurs.

(l) *Initial temperature.* The temperature, determined at the initiation of a thermal process cycle, of the contents of the coldest container to be processed.

(m) *Low acid product.* A canned product in which any component has a pH value above 4.6.

(n) *Process schedule.* The thermal process and any specified critical factors for a given canned product required to achieve shelf stability.

(o) *Process temperature.* The minimum temperature(s) of the heating medium to be maintained as specified in the process schedule.

(p) *Process time.* The intended time(s) a container is to be exposed to the heating medium while the heating medium is at or above the process temperature(s).

(q) *Processing authority.* The person(s) or organization(s) having expert knowledge of thermal processing requirements for foods in hermetically

sealed containers, having access to facilities for making such determinations, and designated by the establishment to perform certain functions as indicated in this subpart.

(r) *Program employee.* Any inspector or other individual employed by the Department or any cooperating agency who is authorized by the Secretary to do any work or perform any duty in connection with the Program (see § 301.2(f)).

(s) *Retort.* A pressure vessel designed for thermal processing of product packed in hermetically sealed containers.

(t) *Seals.* Those parts of a semirigid container and lid or of a flexible container that are fused together in order to hermetically close the container.

(u) *Shelf stability.* The condition achieved by application of heat, sufficient, alone or in combination with other ingredients and/or treatments, to render the product free of microorganisms capable of growing in the product at nonrefrigerated conditions (over 50 °F or 10 °C) at which the product is intended to be held during distribution and storage. Shelf stability and shelf stable are synonymous with commercial sterility and commercially sterile, respectively.

(v) *Thermal process.* The heat treatment necessary to achieve shelf stability as determined by the establishment's processing authority. It is quantified in terms of:

- (1) Time(s) and temperature(s); or
- (2) Minimum product temperature.

(w) *Venting.* The removal of air from a retort before the start of process timing.

(x) *Water activity.* The ratio of the water vapor pressure of the product to the vapor pressure of pure water at the same temperature.

§ 318.301 Containers and closures.

(a) *Examination and cleaning of empty containers.* (1) Empty containers, closures, and flexible pouch roll stock shall be evaluated by the establishment to ensure that they are clean and free of structural defects and damage that may affect product or container integrity. Such an examination should be based upon a statistical sampling plan.

(2) All empty containers, closures, and flexible pouch roll stock shall be stored, handled, and conveyed in such a manner that will prevent soiling and damage that could affect the hermetic condition of the sealed container.

(3) Just before filling, rigid containers shall be cleaned to prevent incorporation of foreign matter into the finished product. Closures, semirigid containers, preformed flexible pouches,

and flexible pouch roll stock contained in original wrappings do not need to be cleaned before use.

(b) *Closure examinations for rigid containers (cans)—(1) Visual examinations.* A closure technician shall visually examine the double seams formed by each closing machine head. When seam defects (e.g., cutovers, sharpness, knocked down flanges, false seams, droops) are observed, necessary corrective actions, such as adjusting or repairing the closing machine, shall be taken. In addition to the double seams, the entire container shall be examined for product leakage or obvious defects. A visual examination shall be performed on at least one container from each closing machine head, and the observations, along with any corrective actions, shall be recorded. Visual examinations shall be conducted with sufficient frequency to ensure proper closure and should be conducted at least every 30 minutes of continuous closing machine operation. Additional visual examinations shall be made by the closure technician at the beginning of production, immediately following every jam in the closing machine and after closing machine adjustment (including adjustment for changes in container size).

(2) *Teardown examinations.* Teardown examinations of double seams formed by each closing machine head shall be performed by a closure technician at a frequency sufficient to ensure proper closure. These examinations should be made at intervals of not more than 4 hours of continuous closing machine operation. At least one container from each closing head shall be examined on the packer's end during each regular examination period. Examination results along with any necessary corrective actions, such as adjusting or repairing the closing machine, shall be promptly recorded by the closure technician. The establishment shall have container specification guidelines for double seam integrity on file and available for review by Program employees. A teardown examination of the can maker's end shall be performed on at least one container selected from each closing machine during each examination period except when teardown examinations are made on incoming empty containers or when, in the case of self-manufactured containers, the containers are made in the vicinity of the establishment and the container plant records are made available to Program employees. Additional teardown examinations on the packer's end should be made at the beginning of

production, immediately following every jam in a closing machine and after closing machine adjustment (including adjustment for a change in container size). The following procedures shall be used in teardown examinations of double seams:

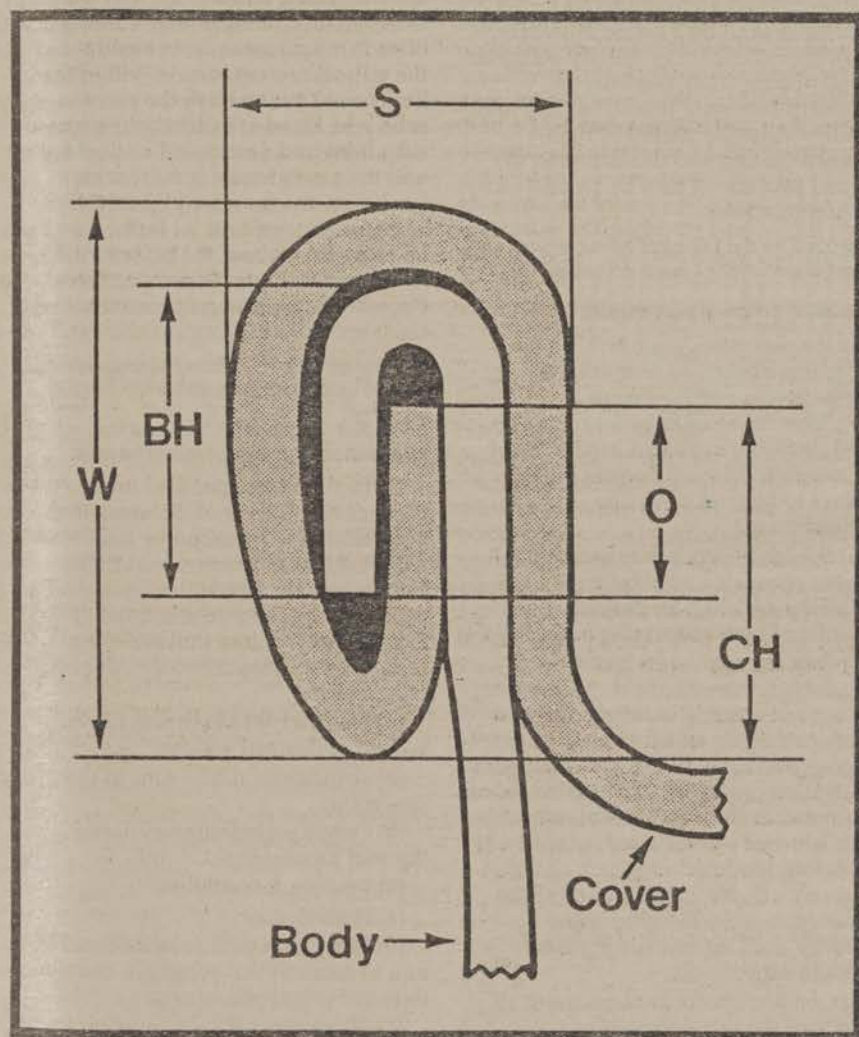
(i) One of the following two methods shall be employed for dimensional measurements of the double seam.

(a) *Micrometer measurement.* For cylindrical containers, measure the

following dimensions (Figure 1) at three points approximately 120 degrees apart on the double seam excluding and at least one-half inch from the side seam juncture:

- (1) Double seam length—W;
- (2) Double seam thickness—S;
- (3) Body hook length—BH; and
- (4) Cover hook length—CH.

Maximum and minimum values for each dimensional measurement shall be recorded by the closure technician.



(b) *Seamscope or seam projector.*

Required measurements of the seam include thickness, body hook, and overlap. Seam thickness shall be obtained by micrometer. For cylindrical

containers, at least two locations, excluding the side seam juncture, shall be used to obtain the required measurements.

(ii) *Seam tightness.* Regardless of the dimensional measurement method used to measure seam dimensions, at a minimum, the seam(s) examined shall be stripped to assess the degree of wrinkling.

(iii) *Side seam juncture rating.* Regardless of the dimensional measurement method used to measure seam dimensions, the cover hook shall be stripped to examine the cover hook droop at the juncture for containers having side seams.

(iv) *Examination of noncylindrical containers.* Examination of noncylindrical containers (e.g., square, rectangular, "D"-shaped, and irregularly-shaped) shall be conducted as described in paragraphs (b)(2) (i), (ii), and (iii) of this section except that the required dimensional measurements shall be made on the double seam at the points listed in the establishment's container specification guidelines.

(c) *Closure examinations for glass containers.* (1) *Visual examinations.* A closure technician shall visually assess the adequacy of the closures formed by each closing machine. When closure defects, such as loose or cocked caps, fractured or cracked containers and low vacuum jars, are observed, necessary corrective actions, such as adjusting or repairing the closing machine shall be taken and recorded. In addition to the closures, the entire container shall be examined for defects. Visual examinations shall be made with sufficient frequency to ensure proper closure and should be conducted at least every 30 minutes of continuous closing machine operation. Additional visual examinations shall be made by the closure technician and the observations recorded at the beginning of production, immediately following every jam in the closing machine, and after closing machine adjustment (including adjustment for a change in container size).

(2) *Closure examinations and tests.* Depending upon the container and closure, tests shall be performed by a closure technician at a frequency sufficient to ensure proper closure. These examinations should be made either before or after thermal processing and at intervals of not more than 4 hours of continuous closing machine

operation. At least one container from each closing machine shall be examined during each regular examination period. Examination results along with any necessary corrective actions, such as adjusting or repairing the closing machine, shall be promptly recorded by the closure technician. The establishment shall have specification guidelines for closure integrity on file and available for review by Program employees. Additional closure examinations should be made at the beginning of production, immediately following every jam in the closing machine, and after closing machine adjustment (including adjustment for a change in container size).

(d) *Closure examinations for semirigid and flexible containers—(1) Heat seals—(i) Visual examinations.* A closure technician shall visually examine the seals formed by each sealing machine. When sealing defects are observed, necessary corrective actions, such as adjusting or repairing the sealing machine, shall be taken and recorded. In addition to examining the heat seals, the entire container shall be examined for product leakage or obvious defects. Visual examinations shall be performed before and after the thermal processing operation and with sufficient frequency to ensure proper closure. These examinations should be conducted at least in accordance with a statistical sampling plan. All defects noted and corrective actions taken shall be promptly recorded.

(ii) *Physical tests.* Tests determined by the establishment as necessary to assess container integrity shall be conducted by the closure technician at a frequency sufficient to ensure proper closure. These tests shall be performed after the thermal processing operation and should be made at least every 2 hours of continuous production. The establishment's acceptance guidelines for each test procedure shall be on file and available for review by Program employees. Test results along with any necessary corrective actions, such as adjusting or repairing the sealing machine, shall be recorded.

(2) Double seams on semirigid or flexible containers shall be examined and the results recorded as provided in paragraph (b) of this section. Any additional measurements specified by the container manufacturer shall also be made and recorded.

(e) *Container coding.* Each container shall be marked with a permanent, legible, identifying code mark. The mark shall, at a minimum, identify in code the product (unless the product name lithographed or printed elsewhere on the

container) and the day and year the product was packed.

(f) *Handling of containers after closure.* (1) Containers and closures shall be protected from damage which may cause defects that are likely to affect the hermetic condition of the containers. The accumulation of stationary containers on moving conveyors should be minimized to avoid damage to the containers.

(2) The maximum time lapse between closing and initiation of thermal processing shall be 2 hours. However, the Administrator may specify a shorter period of time when considered necessary to ensure product safety and stability. A longer period of time between closing and the initiation of thermal processing may be permitted by the Administrator.

[Approved by the Office of Management and Budget under control number 0583-0015]

§ 318.302 Thermal processing.

(a) *Process schedules.* Prior to the processing of canned product for distribution in commerce, an establishment shall have a process schedule (as defined in § 318.300(n) of this subpart) for each canned meat product to be packed by the establishment.

(b) *Source of process schedules.* (1) Process schedules used by an establishment shall be developed or determined by a processing authority.

(2) 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.

(3) Complete records concerning all aspects of the development or determination of a process schedule, including any associated incubation tests, shall be made available by the establishment to the Program employee upon request.

(c) *Submittal of process information.*

(1) Prior to the processing of canned product for distribution in commerce, the establishment shall provide the inspector at the establishment with a list of the process schedules (including alternate schedules) along with any additional applicable information, such as the retort come-up operating procedures and critical factors.

(2) Letters or other written communications from a processing authority recommending all process schedules shall be maintained on file by the establishment. Upon request by Program employees, the establishment shall make available such letters or written communications (or copies thereof). If critical factors are identified in the process schedule, the establishment shall provide the inspector with a copy of the procedures for measuring, controlling, and recording these factors, along with the frequency of such measurements, to ensure that the critical factors remain within the limits used to establish the process schedule. Once submitted, the process schedules and associated critical factors and the procedures for measuring (including the frequency), controlling, and recording of critical factors shall not be changed without the prior written submittal of the revised procedures (including supporting documentation) to the inspector at the establishment.

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§ 318.303 Critical factors and the application of the process schedule.

Critical factors specified in the process schedule shall be measured, controlled and recorded by the establishment to ensure that these factors remain within the limits used to establish the process schedule. Examples of factors that are often critical to process schedule adequacy may include:

- (a) *General.* (1) Maximum fill-in weight or drained weight;
- (2) Arrangement of pieces in the container;
- (3) Container orientation during thermal processing;
- (4) Product formulation;
- (5) Particle size;
- (6) Maximum thickness for flexible, and to some extent semirigid containers during thermal processing;
- (7) Maximum pH;
- (8) Percent salt;
- (9) Ingoing (or formulated) nitrite level (ppm);
- (10) Maximum water activity; and
- (11) Product consistency or viscosity.
- (b) *Continuous rotary and batch agitating retorts.* (1) Minimum headspace; and
- (2) Retort reel speed.
- (c) *Hydrostatic retorts.* (1) Chain or conveyor speed.
- (d) *Steam/air retorts.* (1) Steam/air ratio; and
- (2) Heating medium flow rate.

§ 318.304 Operations in the thermal processing area.

(a) *Posting of processes.* Process schedules (or operating process schedules) for daily production, including minimum initial temperatures and operating procedures for thermal processing equipment, shall be posted in a conspicuous place near the thermal processing equipment. Alternatively, such information shall be available to the thermal processing system operator and the inspector.

(b) *Process indicators and retort traffic control.* A system for product traffic control shall be established to prevent product from bypassing the thermal processing operation. Each basket, crate or similar vehicle containing unprocessed product, or at least one visible container in each vehicle, shall be plainly and conspicuously marked with a heat sensitive indicator that will visually indicate whether such unit has been thermally processed. Exposed heat sensitive indicators attached to container vehicles shall be removed before such vehicles are refilled with unprocessed product. Container loading systems for crateless retorts shall be designed to prevent unprocessed product from bypassing the thermal processing operation.

(c) *Initial temperature.* The initial temperature of the contents of the coldest container to be processed shall be determined and recorded by the establishment at the time the processing cycle begins to assure 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. Thermal processing systems which subject the filled and sealed containers to water at any time before process timing begins shall be operated to assure that such water will not lower the temperature of the product below the minimum initial temperature specified in the process schedule.

(d) *Timing devices.* Devices used to time applicable thermal processing operation functions or events, such as process schedule time, come-up time and retort venting, shall be accurate to assure that all such functions or events are achieved. Pocket watches and wrist watches are not considered acceptable timing devices. Analog and digital clocks are considered acceptable. If such clocks do not display seconds, all required timed functions or events shall have at least a 1-minute safety factor over the specified thermal processing operation times. Temperature/time recording devices shall correspond within 15 minutes to the time of the day

recorded on written records required by § 318.306.

(e) *Measurement of pH.* Unless other methods are approved by the Administrator, potentiometric methods using electronic instruments (pH meters) shall be used for making pH determinations when a maximum pH value is specified as a critical factor in a process schedule.

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§ 318.305 Equipment and procedures for heat processing systems.

(a) *Instruments and controls common to different thermal processing systems—(1) Indicating temperature devices.* Each retort shall be equipped with at least one indicating temperature device that measures the actual temperature within the retort. The indicating temperature device, not the temperature/time recording device, shall be used as the reference instrument for indicating the process temperature.

(i) *Mercury-in-glass thermometers.* A mercury-in-glass thermometer shall have divisions that are readable to 1°F (or 0.5°C) and whose scale contains not more than 17°F/inch (or 4.0°C/cm) of graduated scale. Each mercury-in-glass thermometer shall be tested for accuracy against a known accurate standard upon installation and at least once a year to ensure its accuracy. Records that specify the date, standard used, test method, and the person or testing authority performing the test shall be maintained on file by the establishment and made available to Program employees. A mercury-in-glass thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired and tested for accuracy before further use, or replaced.

(ii) *Other devices.* In lieu of mercury-in-glass thermometers, the Administrator, upon request, will consider other indicating temperature devices, such as resistance temperature detectors. Any such device that is approved shall, upon installation and at least once a year thereafter, be tested for accuracy against a known accurate standard. Records that specify the date, standard used, test method, and the person or testing authority performing the test shall be maintained on file by the establishment and made available to Program employees. Any such device which cannot be adjusted to the standard shall be replaced, or repaired and tested for accuracy before further use.

(2) *Temperature/time recording devices.* Each thermal processing system shall be equipped with at least one

temperature/time recording device to provide a permanent record of temperatures within the thermal processing system. This recording device may be combined with the steam controller and may be a recording/controlling instrument. When compared to the known accurate indicating temperature device, the recording accuracy shall be equal to or better than 1°F (or 0.5°C) at the process temperature. The temperature recording chart should be adjusted to agree with, but shall never be higher than, the known accurate indicating temperature device. A means of preventing unauthorized changes in the adjustment shall be provided. For example, a lock or a notice from management posted at or near the recording device warning that only authorized persons are permitted to make adjustments, are satisfactory means for preventing unauthorized changes. Air-operated temperature controllers shall have adequate filter systems to ensure a supply of clean, dry air. The recorder timing mechanism shall be accurate.

(i) *Chart-type devices.* Devices using charts shall be used only with the correct chart. Each chart shall have a working scale of not more than 55°F/inch (or 12°C/cm) within a range of 20°F (or 11°C) of the process temperature. Chart graduations shall not exceed 2°F degrees (or 1°C degree) within a range of 10°F degrees (or 5°C degrees) of the process temperature. Multipoint plotting chart-type devices shall print temperature readings at intervals that will assure that the parameters of the process time and process temperature have been met. The frequency of recording should not exceed 1-minute intervals.

(ii) *Other devices.* In lieu of chart-type devices, the Administrator will consider for approval other recording devices upon request.

(3) *Steam controllers.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording/controlling instrument when combined with a temperature/time recording device.

(4) *Air valves.* All air lines connected to retorts designed for pressure processing in steam shall be 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.

(5) *Water valves.* All retort water lines that are intended to be closed during a process cycle shall be equipped with a globe valve or other equivalent-type valve or piping arrangement that

will prevent leakage of water into the retort during the process cycle.

(b) *Pressure processing in steam*—(1) *Batch still retorts.* (i) The basic requirements and recommendations for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, bulb sheaths or probes of indicating temperature devices and probes of temperature/time recording devices shall be installed either within the retort shell or in external wells attached to the retort. External wells shall be connected to the retort through at least a $\frac{1}{4}$ inch (1.9 cm) diameter opening and equipped with a $\frac{1}{16}$ inch (1.6 mm) or larger bleeder opening so located as to provide a constant flow of steam past the length of the bulb or probe. The bleeder for external wells shall emit steam continuously during the entire thermal processing period.

(ii) Steam controllers are required as described under paragraph (a)(3) of this section.

(iii) *Steam inlet.* The steam inlet to each retort shall be large enough to provide steam for proper operation of the retort, and shall enter at a point to facilitate air removal during venting.

(iv) *Crate supports.* Vertical still retorts with bottom steam entry shall employ bottom retort crate supports. Baffle plates shall not be used in the bottom of retorts.

(v) *Steam spreader.* Perforated steam spreaders, if used, shall be maintained to ensure they are not blocked or otherwise inoperative. Horizontal still retorts shall be equipped with perforated steam spreaders that extend the full length of the retort unless the adequacy of another arrangement is documented by heat distribution data or other documentation from a processing authority. Such information shall be maintained on file by the establishment and made available to Program employees for review.

(vi) *Bleeders and condensate removal.* Bleeders, except those for external wells of temperature devices, shall have $\frac{1}{8}$ inch (or 3 mm) or larger openings and shall be wide open during the entire process, including the come-up time. For horizontal still retorts, bleeders shall be located within approximately 1 foot (or 30 cm) of the outermost locations of containers at each end along the top of the retort. Additional bleeders shall be located not more than 8 feet (2.4 m) apart along the top. Bleeders may be installed at positions other than those specified above, as long as the establishment has heat distribution data or other documentation from the manufacturer or from a processing

authority demonstrating that the bleeders accomplish removal of air and circulate the steam within the retort. This information shall be maintained on file by the establishment and made available to Program employees for review. All bleeders shall be arranged in a way that enables the retort operator to observe that they are functioning properly. Vertical retorts shall have at least one bleeder opening located in the portion of the retort opposite the steam inlet. All bleeders shall be arranged so that the retort operator can observe that they are functioning properly. In retorts having a steam inlet above the level of the lowest container, a bleeder shall be installed in the bottom of the retort to remove condensate. The condensate bleeder shall be so arranged that the retort operator can observe that it is functioning properly. The condensate bleeder shall be checked with sufficient frequency to ensure adequate removal of condensate. Visual checks should be performed at intervals of not more than 15 minutes and the results recorded. Intermittent condensate removal systems shall be equipped with an automatic alarm system that will serve as a continuous monitor of condensate bleeder functioning. The automatic alarm system shall be tested at the beginning of each shift for proper functioning and the results recorded. If the alarm system is not functioning properly, it must be repaired before the retort is used.

(vii) *Stacking equipment.*

(a) *Equipment for holding or stacking containers in retorts.* Crates, trays, gondolas, carts, and other vehicles for holding or stacking product containers in the retort shall be so constructed to ensure steam circulation during the venting, come-up, and process times. The bottom of each vehicle shall have perforations at least 1 inch (2.5 cm) in diameter on 2 inch (or 5 cm) centers or the equivalent unless the adequacy of another arrangement is documented by heat distribution data or other documentation from a processing authority and such information is maintained on file by the establishment and made available to Program employees for review.

(b) *Divider plates.* Whenever one or more divider plates are used between any two layers of containers or placed on the bottom of a retort vehicle, the establishment shall have on file documentation that the venting procedure allows the air to be removed from the retort before timing of the thermal process is started. Such documentation shall be in the form of heat distribution data or documentation from a processing authority. This

information shall be made available to Program employees for review.

(viii) *Bleeder and vent mufflers.* If mufflers are used on bleeders or vent systems, the establishment shall have on file documentation that the mufflers do not impede the removal of air from the retort. Such documentation shall consist of either heat distribution data or documentation from the muffler manufacturer or from a processing authority. This information shall be made available to Program employees for review.

(ix) *Vents.*

(a) Vents shall be located in that portion of the retort opposite the steam inlet and shall be designed, installed, and operated in such a way that air is removed from the retort before timing of the thermal process is started. Vents shall be controlled by a gate, plug cock, or other full-flow valve which shall be fully opened to permit rapid removal of air from retorts during the venting period.

(b) Vents shall not be connected to a closed drain system without an atmospheric break in the line. Where a retort manifold connects several pipes from a single retort, the manifold shall be controlled by a gate, plug cock, or other full-flow valve and the manifold shall be of a size such that the cross-sectional area of the manifold is larger than the total cross-sectional area of all connecting vents. The discharge shall not be connected to a closed drain without an atmospheric break in the line. A manifold header connecting vents or manifolds from several still retorts shall lead to the atmosphere. The manifold header shall not be controlled by a valve and shall be of a size such that the cross-sectional area is at least equal to the total cross-sectional area of all connecting retort manifold pipes from the maximum number of retorts to be vented simultaneously.

(c) Some typical installations and operating procedures are described below. Other retort installations, vent piping arrangements, operating procedures or auxiliary equipment such as divider plates may be used provided there is documentation that the air is removed from the retort before the process is started. Such documentation shall be in the form of heat distribution data or other documentation from the equipment manufacturer or processing authority. This information shall be maintained on file by the establishment and made available to Program employees for review.

(d) For crateless retort installations, the establishment shall have heat distribution data or other documentation

from the equipment manufacturer or from a processing authority that demonstrates that the venting procedure used accomplishes the removal of air and condensate. This information shall be maintained on file by the establishment and made available to Program employees for review.

(e) Examples of typical installations and operating procedures that comply with the requirements of this section are as follows:

- (1) Venting horizontal retorts.
- (i) Venting through multiple 1 inch (2.5 cm) vents discharging directly to the atmosphere.

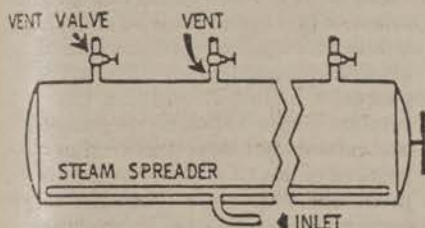


Figure 1.

Specifications (Figure 1): One, 1-inch (2.5 cm) vent for every 5 feet (1.5 m) of retort length, equipped with a gate, plug cock, or other full-flow valve and discharging to atmosphere. The end vents shall not be more than 2½ feet (or 75 cm) from ends of retort.

Venting method (Figure 1): Vent valves shall be wide open for at least 5 minutes and to at least 225 °F (or 107 °C), or at least 7 minutes and to at least 220 °F (or 104.5 °C).

- (ii) Venting through multiple 1 inch (2.5 cm) vents discharging through a manifold to the atmosphere.

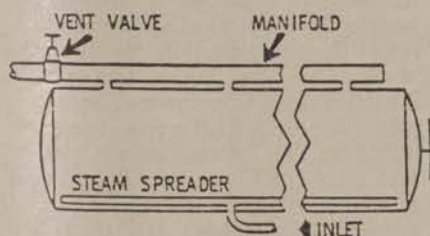


Figure 2.

Specifications (Figure 2): One, 1-inch (2.5 cm) vent for every 5 feet (1.5 m) of retort length; vents not over 2½ feet (or 75 cm) from ends of retort; size of manifold for retorts less than 15 feet (4.6 m) in length, 2½ inches (6.4 cm), and for retorts 15 feet (4.6 m) and over in length, 3 inches (7.6 cm).

Venting method (Figure 2): The manifold vent gate, plug cock, or other full-flow valve shall be wide open for at least 6 minutes and to at least 225 °F (or 107 °C) or for at least 8 minutes and to at least 220 °F (or 104.5 °C).

- (iii) Venting through water spreaders.

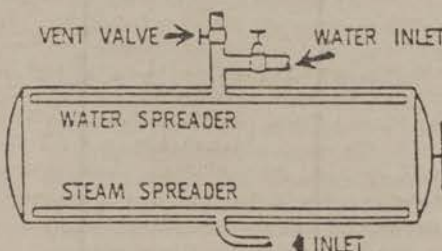


Figure 3.

Specifications (Figure 3): Size of vent and vent valve. For retorts less than 15 feet (4.6 m) in length, 2 inches (or 5 cm); for retorts 15 feet (4.6 m) and over in length, 2½ inches (6.4 cm).

Size of water spreader (Figure 3): For retorts less than 15 feet (4.6 m) in length, 1½ inches (3.8 cm); for retorts 15 feet (4.6 m) and over in length, 2 inches (or 5 cm). The number of holes shall be such that their total cross-sectional area is equal to the cross-sectional area of the vent pipe inlet.

Venting method (Figure 3): The gate, plug cock, or other full-flow valve on the water spreader vent shall be wide open for at least 5 minutes and to at least 225 °F (or 107 °C), or for at least 7 minutes and to at least 220 °F (or 104.5 °C).

- (iv) Venting through a single 2½ inch (6.4 cm) top vent for retorts not exceeding 15 feet (4.6 m) in length.

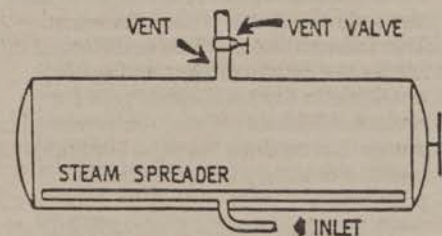


Figure 4.

Specifications (Figure 4): A 2½ inch (6.4 cm) vent equipped with a 2½ inch (6.4 cm) gate, plug cock, or other full-flow valve and located within 2 feet (61 cm) of the center of the retort.

Venting method (Figure 4): The vent valve shall be wide open for at least 4 minutes and to at least 220 °F (or 104.5 °C).

- (2) Venting vertical retorts.
- (i) Venting through a 1½ inch (3.8 cm) overflow.

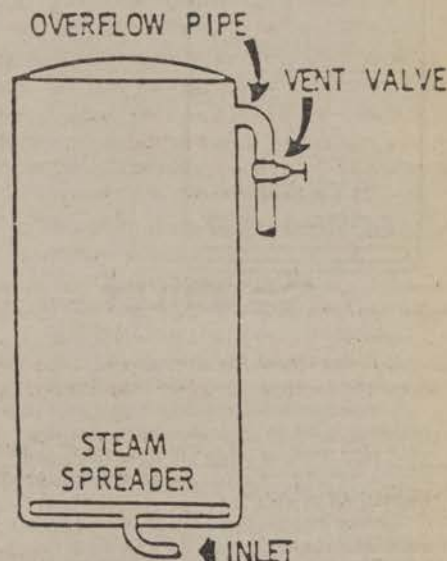
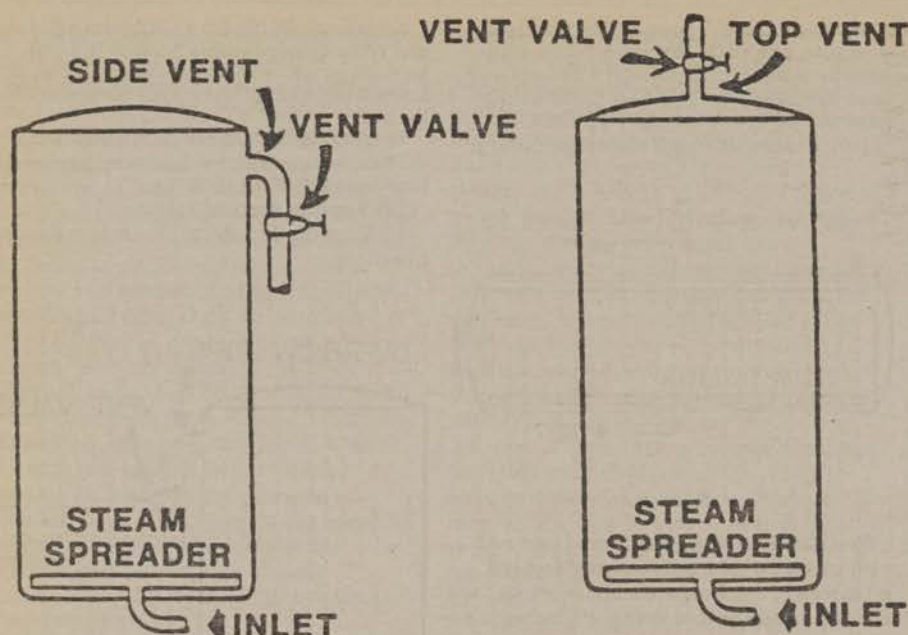


Figure 5.

Specifications (Figure 5): A 1½ inch (3.8 cm) overflow pipe equipped with a 1½ inch (3.8 cm) gate, plug cock, or other full-flow valve and with not more than 6 feet (1.8 m) of 1½ inch (3.8 cm) pipe beyond the valve before a break to the atmosphere or to a manifold header.

Venting method (Figure 5): The vent valve shall be wide open for at least 4 minutes and to at least 218 °F (or 103.5 °C), or for at least 5 minutes and to at least 215 °F (or 101.5 °C).

- (ii) Venting through a single 1 inch (2.5 cm) side or top vent.



Specifications (Figure 6 or 7): A 1 inch (2.5 cm) vent in lid or top side, equipped with a gate, plug cock, or other full-flow valve and discharging directly into the atmosphere or to a manifold header.

Venting method (Figure 6 or 7): The vent valve shall be wide open for at least 5 minutes and to at least 230 °F (110 °C), or for at least 7 minutes and to at least 220 °F (or 104.5 °C).

(2) *Batch agitating retorts.* (i) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, bulb sheaths or probes of indicating temperature devices and probes of temperature/time recording devices shall be installed either within the retort shell or in external wells attached to the retort. External wells shall be connected to the retort through at least a 3/4 inch (1.9 cm) diameter opening and equipped with a 1/16 (1.6 mm) or larger bleeder opening so located as to provide a constant flow of steam past the length of the bulbs or probes. The bleeder for external wells shall emit steam continuously during the entire thermal processing period.

(ii) Steam controllers are required as described in paragraph (a)(3) of this section.

(iii) *Steam inlet.* The steam inlet to each retort shall be large enough to provide steam for proper operation of the retort and shall enter at a point(s) to facilitate air removal during venting.

(iv) *Bleeders.* Bleeders, except those for external wells of temperature devices, shall be 1/8 inch (or 3 mm) or

larger and shall be wide open during the entire process including the come-up time. Bleeders shall be located within approximately 1 foot (or 30 cm) of the outermost location of containers, at each end along the top of the retort.

Additional bleeders shall be located not more than 8 feet (2.4 m) apart along the top. Bleeders may be installed at positions other than those specified above, as long as the establishment has heat distribution data or other documentation from the manufacturer or from a processing authority that the bleeders accomplish removal of air and circulate the steam within the retort. This information shall be maintained on file by the establishment and made available to Program employees for review. All bleeders shall be arranged in a way that enables the retort operator to observe that they are functioning properly.

(v) *Venting and condensate removal.* The air in the retort shall be removed before processing is started. Heat distribution data or other documentation from the manufacturer or from the processing authority who developed the venting procedure shall be kept on file by the establishment and made available to Program employees for review. At the time the steam is turned on, the drain shall be opened to remove steam condensate from the retort. A bleeder shall be installed in the bottom of the retort to remove condensate during retort operation. The condensate bleeder shall be so arranged that the retort operator can observe that it is

functioning properly. The condensate bleeder shall be checked with sufficient frequency to ensure adequate removal of condensate. Visual checks should be performed at intervals of not more than 15 minutes and the results recorded. Intermittent condensate removal systems shall be equipped with an automatic alarm system that will serve as a continuous monitor of condensate bleeder functioning. The automatic alarm system shall be tested at the beginning of each shift for proper functioning and the results recorded. If the alarm system is not functioning properly, it must be repaired before the retort is used.

(vi) *Retort or reel speed timing.* The retort or reel speed shall be checked before process timing begins and, if needed, adjusted as specified in the process schedule. In addition, the rotational speed shall be determined and recorded at least once during process timing of each retort load processed. Alternatively, a recording tachometer can be used to provide a continuous record of the speed. The accuracy of the recording tachometer shall be determined and recorded at least once per shift by checking the retort or reel speed using an accurate stopwatch. A means of preventing unauthorized speed changes on retorts shall be provided. For example, a lock or a notice from management posted at or near the speed adjustment device warning that only authorized persons are permitted to make adjustments are satisfactory means of preventing unauthorized changes.

(vii) *Bleeder and vent mufflers.* If mufflers are used on bleeders or vent systems, the establishment shall have documentation that the mufflers do not impede the removal of air from the retort. Such documentation shall consist of either heat distribution data or documentation from the muffler manufacturer or from a processing authority. This information shall be maintained on file by the establishment and made available to Program employees for review.

(3) *Continuous rotary retorts.* (i) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, bulb sheaths or probes of indicating temperature devices and probes of temperature/time recording devices shall be installed either within the retort shell or in external wells attached to the retort. External wells shall be connected to the retort through at least a 3/4 inch (1.9 cm) diameter opening and equipped with a 1/16 inch

(1.6 mm) or larger bleeder opening so located as to provide a constant flow of steam past the length of the bulbs or probes. The bleeder for external wells shall emit steam continuously during the entire thermal processing period.

(ii) Steam controllers are required as described in paragraph (a)(3) of this section.

(iii) *Steam inlet.* The steam inlet to each retort shall be large enough to provide steam for proper operation of the retort, and shall enter at a point(s) to facilitate air removal during venting.

(iv) *Bleeders.* Bleeders, except those for external wells of temperature devices, shall be $\frac{1}{8}$ inch (3.2 mm) or larger and shall be wide open during the entire process, including the come-up time. Bleeders shall be located within approximately 1 foot (or 30 cm) of the outermost location of containers at each end along the top of the retort. Additional bleeders shall be located not more than 8 feet (2.4 m) apart along the top of the retort. Bleeders may be installed at positions other than those specified above, as long as the establishment has heat distribution data or other documentation from the manufacturer or a processing authority that the bleeders accomplish removal of air and circulate the steam within the retort. This information shall be maintained on file by the establishment and made available to Program employees for review. All bleeders shall be arranged so that the retort operator can observe that they are functioning properly.

(v) *Venting and condensate removal.* The air in the retort shall be removed before processing is started. Heat distribution data or other documentation from the manufacturer or from the processing authority who developed the venting procedure shall be kept on file by the establishment and made available to Program employees for review. At the time the steam is turned on, the drain shall be opened to remove steam condensate from the retort. A bleeder shall be installed in the bottom of the shell to remove condensate during the retort operation. The condensate bleeder shall be so arranged that the retort operator can observe that it is functioning properly. The condensate bleeder shall be checked with sufficient frequency to ensure adequate removal of condensate. Visual checks should be performed at intervals of not more than 15 minutes and the results recorded. Intermittent condensate removal systems shall be equipped with an automatic alarm system that will serve as a continuous monitor of condensate bleeder functioning. The automatic alarm system shall be tested at the

beginning of each shift for proper functioning and the results recorded. If the alarm system is not functioning properly, it must be repaired before the retort is used.

(vi) *Retort speed timing.* The rotational speed of the retort shall be specified in the process schedule. The speed shall be adjusted as specified, and recorded by the establishment when the retort is started, and checked and recorded at intervals not to exceed 4 hours to ensure that the correct retort speed is maintained. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. If a recording tachometer is used, the speed shall be manually checked against an accurate stopwatch at least once per shift and the results recorded. A means of preventing unauthorized speed changes on retorts shall be provided. For example, a lock or a notice from management posted at or near the speed adjustment device warning that only authorized persons are permitted to make adjustments are satisfactory means of preventing unauthorized changes.

(vii) *Bleeders and vent mufflers.* If mufflers are used on bleeders or vent systems, the establishment shall have documentation that the mufflers do not impede the removal of air from the retort. Such documentation shall consist of either heat distribution data or other documentation from the muffler manufacturer or from a processing authority. This information shall be maintained on file by the establishment and made available to Program employees for review.

(4) *Hydrostatic retorts.* (i) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, indicating temperature devices shall be located in the steam dome near the steam/water interface. Where the process schedule specifies maintenance of particular water temperatures in the hydrostatic water legs, at least one indicating temperature device shall be located in each hydrostatic water leg so that it can accurately measure water temperature and be easily read. The temperature/time recorder probe shall be installed either within the steam dome or in a well attached to the dome. Each probe shall have a $\frac{1}{8}$ inch (1.6 mm) or larger bleeder opening which emits steam continuously during the processing period. Additional temperature/time recorder probes shall be installed in the hydrostatic water legs if the process schedule specifies maintenance of particular temperatures in these water legs.

(ii) Steam controllers are required as described in paragraph (a)(3) of this section.

(iii) *Steam inlet.* The steam inlets shall be large enough to provide steam for proper operation of the retort.

(iv) *Bleeders.* Bleeder openings $\frac{1}{4}$ inch (or 6 mm) or larger shall be located in the steam chamber(s) opposite the point of steam entry. Bleeders shall be wide open and shall emit steam continuously during the entire process, including the come-up time. All bleeders shall be arranged in such a way that the operator can observe that they are functioning properly.

(v) *Venting.* Before the start of processing operations, the retort steam chamber(s) shall be vented to ensure removal of air. Heat distribution data or other documentation from the manufacturer or from a processing authority demonstrating that the air is removed from the retort prior to processing shall be kept on file at the establishment and made available to Program employees for review.

(vi) *Conveyor speed.* The conveyor speed shall be calculated to obtain the required process time and recorded by the establishment when the retort is started. The speed shall be checked and recorded at intervals not to exceed 4 hours to ensure that the correct conveyor speed is maintained. A recording device may be used to provide a continuous record of the conveyor speed. When a recording device is used, the speed shall be manually checked against an accurate stopwatch at least once per shift by the establishment. A means of preventing unauthorized speed changes of the conveyor shall be provided. For example, a lock or a notice from management posted at or near the speed adjustment device warning that only authorized persons are permitted to make adjustments are satisfactory means of preventing unauthorized changes.

(vii) *Bleeders and vent mufflers.* If mufflers are used on bleeders or vent systems, the establishment shall have documentation that the muffler do not impede the removal of air from the retort. Such documentation shall consist of either heat distribution data or other documentation from the muffler manufacturer or from a processing authority. This information shall be maintained on file by the establishment and made available to Program employees for review.

(c) *Pressure processing in water—(1) Batch still retorts.* (i) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs

(a)(1) and (2) of this section.

Additionally, bulbs or probes of indicating temperature devices shall be located in such a position that they are beneath the surface of the water throughout the process. On horizontal retorts, the indicating temperature device bulb or probe shall be inserted directly into the retort shell. In both vertical and horizontal retorts, the indicating temperature device bulb or probe shall extend directly into the water a minimum of 2 inches (or 5 cm) without a separable well or sleeve. In vertical retorts equipped with a recorder/controller, the controller probe shall be located at the bottom of the retort below the lowest crate rest in such a position that the steam does not strike it directly. In horizontal retorts so equipped, the controller probe shall be located between the water surface and the horizontal plane passing through the center of the retort so that there is no opportunity for direct steam impingement on the controller probe. Air-operated temperature controllers shall have filter systems to ensure a supply of clean, dry air.

(ii) *Pressure recording device.* Each retort shall be equipped with a pressure recording device which may be combined with a pressure controller.

(iii) *Steam controllers* are required as described in paragraph (a)(3) of this section.

(iv) *Heat distribution.* Heat distribution data or other documentation from the equipment manufacturer or a processing authority demonstrating uniform heat distribution within the retort shall be kept on file at the establishment and made available to Program employees for review.

(v) *Crate supports.* A bottom crate support shall be used in vertical retorts. Baffle plates shall not be used in the bottom of the retort.

(vi) *Stacking equipment.* For filled flexible containers and, where applicable, semirigid containers, stacking equipment shall be designed to ensure that the thickness of the filled containers does not exceed that specified in the process schedule and that the containers do not become displaced and overlap or rest on one another during the thermal process.

(vii) *Drain valve.* A nonclogging, water-tight drain valve shall be used. Screens shall be installed over all drain openings.

(viii) *Water level.* There shall be a means of determining the water level in the retort during operation (i.e., by using a gauge, electronic sensor, or sight glass indicator). For retorts requiring complete immersion of containers, water shall cover the top layer of containers during

the entire come-up time and thermal processing periods and should cover the top layer of containers during cooling. For retorts using cascading water or water sprays, the water level shall be maintained within the range specified by the retort manufacturer or processing authority during the entire come-up, thermal processing, and cooling periods. A means to ensure that water circulation continues as specified throughout the come-up, thermal processing, and cooling periods shall be provided. The retort operator shall check and record the water level at intervals to ensure it meets the specified processing parameters.

(ix) *Air supply and controls.* In both horizontal and vertical still retorts, a means shall be provided for introducing compressed air or steam at the pressure required to maintain container integrity. Compressed air and steam entry shall be controlled by an automatic pressure control unit. A nonreturn valve shall be provided in the air supply line to prevent water from entering the system. Overriding air or steam pressure shall be maintained continuously during the come-up, thermal processing, and cooling periods. If air is used to promote circulation, it shall be introduced into the steam line at a point between the retort and the steam control valve at the bottom of the retort. The adequacy of the air circulation for maintaining uniform heat distribution within the retort shall be documented by heat distribution data or other documentation from a processing authority, and such data shall be maintained on file by the establishment and made available to Program employees for review.

(x) *Water recirculation.* When a water recirculation system is used for heat distribution, the water shall be drawn from the bottom of the retort through a suction manifold and discharged through a spreader that extends the length or circumference of the top of the retort. The holes in the water spreader shall be uniformly distributed. The suction outlets shall be protected with screens to keep debris from entering the recirculation system. The pump shall be equipped with a pilot light or a similar device to warn the operator when it is not running, and with a bleeder to remove air when starting operations. Alternatively, a flow-meter alarm system can be used to ensure proper water circulation. The adequacy of water circulation for maintaining uniform heat distribution within the retort shall be documented by heat distribution or other documentation from a processing authority and such data shall be maintained on file by the establishment and made available to

Program employees for review. Alternative methods for recirculation of water in the retort may be used, provided there is documentation in the form of heat distribution data or other documentation from a processing authority maintained on file by the establishment and made available to Program employees for review.

(xi) *Cooling water entry.* In retorts for processing product packed in glass jars, the incoming cooling water should not directly strike the jars, in order to minimize glass breakage by thermal shock.

(2) *Batch agitating retorts.* (i) The basic requirements and recommendations for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, the indicating temperature device bulb or probe shall extend directly into the water without a separable well or sleeve. The recorder/controller probe shall be located between the water surface and the horizontal plane passing through the center of the retort so that there is no opportunity for steam to directly strike the controller bulb or probe.

(ii) *Pressure recording device.* Each retort shall be equipped with a pressure recording device which may be combined with a pressure controller.

(iii) *Steam controllers* are required as described in paragraph (a)(3) of this section.

(iv) *Heat distribution.* Heat distribution data or other documentation from the equipment manufacturer or a processing authority shall be kept on file by the establishment and made available to Program employees for review.

(v) *Stacking equipment.* All devices used for holding product containers (e.g., crates, trays, divider plates) shall be so constructed to allow the water to circulate around the containers during the come-up and thermal process periods.

(vi) *Drain valve.* A nonclogging, water-tight drain valve shall be used. Screens shall be installed over all drain openings.

(vii) *Water level.* There shall be a means of determining the water level in the retort during operation (i.e., by using a gauge, electronic sensor, or sight glass indicator). Water shall completely cover all containers during the entire come-up, thermal processing, and cooling periods. A means to ensure that water circulation continues as specified throughout the come-up, thermal processing, and cooling periods shall be provided. The retort operator shall

check and record the adequacy of the water level with sufficient frequency to ensure it meets the specified processing parameters.

(viii) *Air supply and controls.* Retorts shall be provided with a means for introducing compressed air or steam at the pressure required to maintain container integrity. Compressed air and steam entry shall be controlled by an automatic pressure control unit. A nonreturn valve shall be provided in the air supply line to prevent water from entering the system. Overriding air or steam pressure shall be maintained continuously during the come-up, thermal processing, and cooling periods. If air is used to promote circulation, it shall be introduced into the steam line at a point between the retort and the steam control valve at the bottom of the retort. The adequacy of the air circulation for maintaining uniform heat distribution within the retort shall be documented by heat distribution data or other documentation from a processing authority, and such data shall be maintained on file by the establishment and made available to Program employees for review.

(ix) *Retort or reel speed timing.* The retort or reel speed timing shall be checked before process timing begins and, if needed, adjusted as specified in the process schedule. In addition, the rotational speed shall be determined and recorded at least once during process timing of each retort load processed. Alternatively, a recording tachometer can be used to provide a continuous record of the speed. The accuracy of the recording tachometer shall be determined and recorded at least once per shift by the establishment by checking the retort or reel speed using an accurate stopwatch. A means of preventing unauthorized speed changes on retorts shall be provided. For example, a lock or a notice from management posted at or near the speed adjustment device warning that only authorized persons are permitted to make adjustments are satisfactory means of preventing unauthorized changes.

(x) *Water recirculation.* If a water recirculation system is used for heat distribution, it shall be installed in such a manner that water will be drawn from the bottom of the retort through a suction manifold and discharged through a spreader which extends the length of the top of the retort. The holes in the water spreader shall be uniformly distributed. The suction outlets shall be protected with screens to keep debris from entering the recirculation system. The pump shall be equipped with a pilot

light or a similar device to warn the operator when it is not running and with a bleeder to remove air when starting operations. Alternatively, a flow-meter alarm system can be used to ensure proper water circulation. The adequacy of water circulation for maintaining uniform heat distribution within the retort shall be documented by heat distribution data or other documentation from a processing authority, and such data shall be maintained on file by the establishment and made available to Program employees for review.

Alternative methods for recirculation of water in the retort may be used provided there is documentation in the form of heat distribution data or other documentation from a processing authority maintained on file by the establishment and made available to Program employees for review.

(xi) *Cooling water entry.* In retorts for processing product packed in glass jars, the incoming cooling water should not directly strike the jars, in order to minimize glass breakage by thermal shock.

(d) *Pressure processing with steam/air mixtures in batch retorts.* (1) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, bulb sheaths or probes for indicating temperature devices and temperature/time recording devices or controller probes shall be inserted directly into the retort shell in such a position that steam does not strike them directly.

(2) Steam controllers are required as described in paragraph (a)(3) of this section.

(3) *Recording pressure controller.* A recording pressure controller shall be used to control the air inlet and the steam/air mixture outlet.

(4) *Circulation of steam/air mixtures.* A means shall be provided for the circulation of the steam/air mixture to prevent formation of low-temperature pockets. The efficiency of the circulation system shall be documented by heat distribution data or other documentation from a processing authority, and such data shall be maintained on file by the establishment and made available to Program employees for review. The circulation system shall be checked to ensure its proper functioning and shall be equipped with a pilot light or a similar device to warn the operator when it is not functioning. Because of the variety of existing designs, reference shall be made to the equipment manufacturer for details of installation, operation, and control.

(5) The Administrator shall be notified immediately by the official establishment of any such system in use or placed into use on or after the effective date of this rule.

(e) *Atmospheric cookers—(1) Temperature/time recording device.* Each atmospheric cooker (e.g., hot water bath) shall be equipped with at least one temperature/time recording device in accordance with the basic requirements described in paragraph (a)(2) of this section.

(2) *Heat distribution.* Each atmospheric cooker shall be equipped and operated to ensure uniform heat distribution throughout the processing system during the thermal process. Heat distribution data or other documentation from the manufacturer or a processing authority demonstrating uniform heat distribution within the cooker shall be kept on file by the establishment and made available to Program employees for review.

(f) *Other systems.* All other systems not specifically delineated in this section and used for the thermal processing of canned product will be evaluated on a case-by-case basis by the Administrator. Systems will be approved if they are found to conform to the applicable requirements of this section and to produce shelf stable products consistently and uniformly.

(g) *Equipment maintenance.* (1) Upon installation, all instrumentation and controls shall be checked by the establishment for proper functioning and accuracy and, thereafter, at any time their functioning or accuracy is suspect.

(2) At least once a year each thermal processing system shall be examined by an individual not directly involved in daily operations to ensure the proper functioning of the system as well as all auxiliary equipment and instrumentation. In addition, each thermal processing system should be examined before the resumption of operation following an extended shutdown.

(3) Air and water valves that are intended to be closed during thermal processing shall be checked by the establishment for leaks. Defective valves shall be repaired or replaced as needed.

(4) Vent and bleeder mufflers shall be checked and maintained or replaced by the establishment to prevent any reduction in vent or bleeder efficiency.

(5) When water spreaders are used for venting, a maintenance schedule shall be developed and implemented to assure that the holes are maintained at their original size.

(6) Records shall be kept on all maintenance items that could affect the adequacy of the thermal process. Records shall include the date and type of maintenance performed and the person conducting the maintenance.

(h) *Container cooling and cooling water* (1) Potable water shall be used for cooling except as provided for in paragraphs (h) (2) and (3) of this section.

(2) Cooling canal water shall be chlorinated or treated with a chemical approved by the Administrator as having a bactericidal effect equivalent to chlorination. There shall be a measurable residual of the sanitizer in the water at the discharge point of the canal. Cooling canals shall be cleaned and replenished with potable water to prevent the buildup of organic matter and other materials.

(3) Container cooling waters that are recycled or reused shall be handled in systems that are so designed, operated, and maintained so there is no buildup of microorganisms, organic matter, and other materials in the systems and in the waters. System equipment, such as pipelines, holding tanks and cooling towers, shall be constructed and installed so that they can be cleaned and inspected. In addition, the establishment shall maintain, and make available to Program employees for review, information on at least the following:

- (i) System design and construction;
- (ii) System operation including the rates of renewal with fresh, potable water and the means for treating the water so that there is a measurable residual of an acceptable sanitizer, per paragraph (h)(2) of this section, in the water at the point where the water exits the container cooling vessel;
- (iii) System maintenance including procedures for the periodic cleaning and sanitizing of the entire system; and
- (iv) Water quality standards, such as microbiological, chemical and physical, monitoring procedures including the frequency and site(s) of sampling, and the corrective actions taken when water quality standards are not met.

(i) *Post-process handling of containers* Containers shall be handled in a manner that will prevent damage to the hermetic seal area. All worn and frayed belting, can retarders, cushions, and the like shall be replaced with nonporous materials. To minimize container abrasions, particularly in the seal area, containers should not remain stationary on moving conveyors. All post-process container handling equipment should be kept clean so there is no buildup of microorganisms on surfaces in contact with the containers.

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§ 318.306 Processing and production records.

At least the following processing and production information shall be recorded by the establishment: date of production; product name and style; container code; container size and type; and the process schedule, including the minimum initial temperature. Measurements made to satisfy the requirements of § 318.303 regarding the control of critical factors shall be recorded. In addition, where applicable, the following information and data shall also be recorded:

(a) *Processing in steam* (1) *Batch still retorts.* For each retort batch, record the retort number or other designation, the approximate number of containers or the number of retort crates per retort load, product initial temperature, time steam on, the time and temperature vent closed, the start of process timing, time steam off, and the actual processing time. The indicating temperature device and the temperature recorder shall be read at the same time at least once during process timing and the observed temperatures recorded.

(2) *Batch agitating retorts.* In addition to recording the information required for batch, still steam retorts in paragraph (a)(1) of this section, record the functioning of the condensate bleeder(s) and the retort or reel speed.

(3) *Continuous rotary retorts.* Record the retort system number, the approximate total number of containers retorted, product initial temperature, time steam on, the time and temperature vent closed, time process temperature reached, the time the first can enters and the time the last can exits the retort. The retort or reel speed shall be determined and recorded at intervals not to exceed 4 hours. Readings of the indicating temperature device(s) and temperature recorder(s) shall be made and recorded at the time the first container enters the retort and thereafter with sufficient frequency to ensure compliance with the process schedule. These observations should be made and recorded at intervals not exceeding 30 minutes of continuous retort operation. Functioning of the condensate bleeder(s) shall be observed and recorded at the time the first container enters the retort and thereafter as specified in § 318.305(b)(3)(v).

(4) *Hydrostatic retorts.* Record the retort system number, the approximate total number of containers retorted, product initial temperature, time steam on, the time and temperature vent(s)

closed, time process temperature reached, time first containers enter the retort, time last containers exit the retort, and, if specified in the process schedule, measurements of temperatures in the hydrostatic water legs. Readings of the temperature indicating device, which is located in the steam/water interface, and the temperature recording device shall be observed and the temperatures recorded at the time the first containers enter the steam dome. Thereafter, these instruments shall be read and the temperatures recorded with sufficient frequency to ensure compliance with the temperature specified in the process schedule and should be made at least every hour of continuous retort operation. Container conveyor speed, and for agitating hydrostatic retorts, the rotative chain speed, shall be determined and recorded at intervals of sufficient frequency to ensure compliance with the process schedule and should be performed at least every 4 hours.

(b) *Processing in water*—(1) *Batch still retorts.* For each retort batch, record the retort number or other designation, the approximate number of containers or number of retort crates per retort load, product initial temperature, time steam on, the start of process timing, water level, water recirculation rate (if critical), overriding pressure maintained, time steam off, and actual processing time. The indicating temperature device and the temperature recorder shall be read at the same time at least once during process timing and the observed temperatures recorded.

(2) *Batch agitating retorts.* In addition to recording the information required in paragraph (b)(1) of this section, record the retort or reel speed.

(c) *Processing in steam/air mixtures.* For each retort batch, record the retort number or other designation, the approximate number of containers or number of retort crates per retort load, product initial temperature, time steam on, venting procedure, if applicable, the start of process timing, maintenance of circulation of the steam/air mixture, air flow rate or forced recirculation flow rate (if critical), overriding pressure maintained, time steam off, and actual processing time. The indicating temperature device and the temperature recorder shall be read at the same time at least once during process timing and the observed temperatures recorded.

(d) *Atmospheric cookers*—(1) *Batch-type systems.* For each cooker batch, record the cooker number or other designation and the approximate number of containers. In addition, record all critical factors of the process

schedule such as cooker temperature, initial temperature, the time the thermal process cycle begins and ends, hold time, and the final internal product temperature.

(2) *Continuous-type systems.* Record the cooker number or other designation, the time the first containers enter and the last containers exit a cooker, and the approximate total number of containers processed. In addition, record all critical factors of the process schedule such as the initial temperature, cooker speed, and final internal product temperature.

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§ 318.307 Record review and maintenance.

(a) *Process records.* Charts from temperature/time recording devices shall be identified by production date, container code, processing vessel number or other designation, and other data as necessary to enable correlation with the records required in § 318.306. Each entry on a record shall be made at the time the specific event occurs, and the recording individual shall sign or initial each record form. No later than 1 working day after the actual process, the establishment shall review all processing and production records to ensure completeness and to determine if all product received the process schedule. All records, including the temperature/time recorder charts and critical factor control records, shall be signed or initialed and dated by the person conducting the review. All processing and production records required in this subpart shall be made available to Program employees for review.

(b) *Automated process monitoring and recordkeeping.* When requested by an establishment, the Administrator will consider the approval of automated process monitoring and recordkeeping systems. An approved system, alone or in combination with written records, shall be designed and operated in a manner which will ensure compliance with the applicable requirements of § 318.306.

(c) *Container closure records.* Written records of all container closure examinations shall specify the container code, the date and time of container closure examination, the measurement(s) obtained, and any corrective actions taken. Records shall be signed or initialed by the container closure technician and shall be reviewed and signed by the establishment within 1 working day after the actual production to ensure that the records are complete and that the closing operations have been

properly controlled. All container closure examination records required in this subpart shall be made available to Program employees for review.

(d) *Distribution of product.* Records shall be maintained by the establishment identifying initial distribution of the finished product to facilitate, if necessary, the segregation of specific production lots that may have been contaminated or are otherwise unsound for their intended use.

(e) *Retention of records.* Copies of all processing and production records required in § 318.306 shall be retained for no less than 1 year at the establishment, and for an additional 2 years at the establishment or other location from which the records can be made available to Program employees within 3 working days.

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§ 318.308 Deviations in processing.

(a) Whenever the actual process is less than the process schedule or when any critical factor does not comply with the requirements for that factor as specified in the process schedule, it shall be considered a deviation in processing.

(b) Deviations in processing (or process deviations) shall be handled under an approved quality control program as provided in paragraph (c) of this section or shall be handled in accordance with paragraph (d) of this section.

(c) Any partial quality control program or any portion of a total quality control system for handling process deviations shall be prepared and submitted to the Administrator for approval in accordance with § 318.4.

(d) Handling process deviations without an approved quality control program. (1) *Deviations identified in-process.* If a deviation is noted at any time before the completion of the intended process schedule, the establishment shall:

(i) Immediately reprocess the product using the full process schedule; or

(ii) Use an appropriate alternate process schedule provided such a process schedule has been established in accordance with § 318.302 (a) and (b) and is filed with the inspector in accordance with § 318.302(c); or

(iii) Hold the product involved and have the deviation evaluated by a processing authority to assess the safety and stability of the product. Upon completion of the evaluation, the establishment shall provide the inspector the following:

(a) A complete description of the deviation along with all necessary supporting documentation;

(b) A copy of the evaluation report; and

(c) A description of any product disposition actions, either taken or proposed.

(iv) Product handled in accordance with paragraph (d)(1)(iii) of this section shall not be shipped from the establishment until the Program has reviewed all of the information submitted and approved the product disposition actions.

(v) If an alternate process schedule is used that is not on file with the inspector or if an alternate process schedule is immediately calculated and used, the product shall be set aside for further evaluation in accordance with paragraphs (d)(1) (iii) and (iv) of this section.

(vi) When a deviation occurs in a continuous rotary retort, the product shall be handled in accordance with paragraphs (d)(1) (iii) and (iv) of this section or in accordance with the following procedures:

(a) *Emergency stops.*

(1) When retort jams or breakdowns occur during the processing operations, all containers shall be given an emergency still process (developed per § 318.302(b)) before the retort is cooled or the retort shall be cooled promptly and all containers removed and either reprocessed, repacked and reprocessed, or destroyed. Regardless of the procedure used, containers in the retort intake valve and in transfer valves between retort shells at the time of a jam or breakdown shall be removed and either reprocessed, repacked and reprocessed and or destroyed. Product to be destroyed shall be handled as "U.S. Inspected and Condemned", as defined in § 301.2(ee) of this subchapter, and disposed of in accordance with Part 314 of this subchapter.

(2) The time the retort reel stopped and the time the retort is used for an emergency still retort process shall be noted on the temperature/time recording device and entered on the other production records required in § 318.306.

(b) *Temperature drops.* When the retort temperature drops below the temperature specified in the process schedule, the reel shall be stopped and the following actions shall be taken:

(1) For temperature drops of less than 10 °F (or 5.5 °C) either, (i) all containers in the retort shall be given an emergency still process (developed per § 318.302(b)) before the reel is restarted; (ii) container entry to the retort shall be prevented and an emergency agitating process (developed per § 318.302(b)) shall be used before container entry to the retort is restarted; or (iii) container entry to

the retort shall be prevented and the reel restarted to empty the retort. The discharged containers shall be reprocessed, repacked and reprocessed, or destroyed. Product to be destroyed shall be handled as "U.S. Inspected and Condemned", as defined in § 318.2(ee) of this subchapter, and disposed of in accordance with Part 314 of this subchapter.

(2) For temperature drops of 10 °F (or 5.5 °C) or more, all containers in the retort shall be given an emergency still process (developed per § 318.302(b)). The time the reel was stopped and the time the retort was used for a still retort process shall be marked on the temperature/time recording device by the establishment and entered on the other production records required in § 318.306. Alternatively, container entry to the retort shall be prevented and the reel restarted to empty the retort. The discharged containers shall be either reprocessed, repacked and reprocessed, or destroyed. Product to be destroyed shall be handled as "U.S. Inspected and Condemned", as defined in § 301.2(ee) of this subchapter, and disposed of in accordance with Part 314 of this subchapter.

(2) *Deviations identified through record review.* Whenever a deviation is noted during review of the processing and production records required by § 318.307 (a) and (b), the establishment shall hold the product involved and the deviation shall be handled in accordance with paragraphs (d)(1) (iii) and (iv) of this section.

(e) *Process deviation file.* The establishment shall maintain full records regarding the handling of each deviation. Such records shall include, 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. Such records shall be maintained in a separate file or in a log that contains the appropriate information. The file or log shall be retained in accordance with § 318.307(e) and shall be made available to Program employees upon request.

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§ 318.309 Finished product inspection.

(a) Finished product inspections shall be handled under an approved quality control program as provided in paragraph (b) or paragraph (c) of this section or shall be handled in accordance with paragraph (d) of this section.

(b) Any partial quality control program designed to ensure compliance

with the requirements of this section (or any part thereof) shall be prepared and submitted to the Administrator for approval in accordance with § 318.4 of this subchapter.

(c) A total quality control system prepared and submitted to the Administrator for approval in accordance with § 318.4 of this subchapter shall be designed to ensure compliance with the requirements of this section.

(d) Handling finished product inspections without an approved quality control program.

(1) *Incubation of shelf stable canned product—(i) Incubator.*

The establishment shall provide incubation facilities which include an accurate temperature/time recording device, an indicating temperature device, a means for the circulation of the air inside the incubator to prevent temperature variations, and a means to prevent unauthorized entry into the facility. The Program is responsible for the security of the incubator.

(ii) *Incubation temperature.* The incubation temperature shall be maintained at 95 ± 5 °F (35 ± 2.8 °C). If the incubation temperature falls below 90 °F (or 32 °C) or exceeds 100 °F (or 38 °C) but does not reach 103 °F (or 39.5 °C), the incubation temperature shall be adjusted within the required range and the incubation time extended for the time the sample containers were held at the deviant temperature. If the incubation temperature is at or above 103 °F (or 39.5 °C) for more than 2 hours, the incubation test(s) shall be terminated, the temperature lowered to within the required range, and new sample containers incubated for the required time.

(iii) *Product requiring incubation.* Shelf stable product requiring incubation includes:

(a) Low acid products as defined in § 318.300(m); and

(b) Acidified low acid products as defined in § 318.300(b).

(iv) *Incubation samples.* (a) From each load of product processed in a batch-type thermal processing system (still or agitation), the establishment shall select at least one container for incubation.

(b) For continuous rotary retorts, hydrostatic retorts, or other continuous-type thermal processing systems, the establishment shall select at least one container per 1,000 for incubation.

(c) Only normal-appearing containers shall be selected for incubation.

(v) *Incubation time.* Canned product requiring incubation shall be incubated for not less than 10 days (240 hours) under the conditions specified in paragraph (d)(1)(ii) of this section.

(vi) *Incubation checks and record maintenance.* Designated establishment employees shall visually check all containers under incubation each working day and the inspector shall be notified when abnormal containers are detected. All abnormal containers should be allowed to cool before a final decision on their condition is made. For each incubation test the establishment shall record at least the product name, container size, container code, number of containers incubated, in and out dates, and incubation results. The establishment shall retain such records, along with copies of the temperature/time recording charts, in accordance with § 318.307(e).

(vii) *Abnormal containers.* The finding of abnormal containers (as defined in § 318.300(a)) among incubation samples is cause to officially retain at least the code lot involved.

(viii) *Shipping.* No product shall be shipped from the establishment before the end of the required incubation period except as provided in this paragraph. An establishment wishing to ship product prior to the completion of the required incubation period shall submit a written proposal to the area supervisor. Such a proposal shall include provisions that will assure that shipped product will not reach the retail level of distribution before sample incubation is completed and that product can be returned promptly to the establishment should such action be deemed necessary by the incubation test results. Upon receipt of written approval from the area supervisor, product may be routinely shipped provided the establishment continues to comply with all requirements of this subpart.

(2) *Container condition—(i) Normal containers.* Only normal-appearing containers shall be shipped from an establishment as determined by an appropriate sampling plan or other means acceptable to Program employees.

(ii) *Abnormal containers.* When abnormal containers are detected by any means other than incubation, the establishment shall inform the inspector, and the affected code lot(s) shall not be shipped until the Program has determined that the product is safe and stable. Such a determination will take into account the cause and level of abnormalities in the affected lot(s) as well as any product disposition actions either taken or proposed by the establishment.

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examination, that the product does not meet the requirements of the Act and regulations thereunder, the consignment shall be refused entry. However, a consignment rejected for container defects but otherwise acceptable may be reoffered for inspection under the following conditions:

(i) If the defective containers are not indicative of an unsafe or unstable product as determined by the Administrator;

(ii) If the number and kinds of container defects found in the original sample do not exceed the limits specified for this purpose in FSIS guidelines; and

(iii) If the defective containers in the consignment have been sorted out and exported or destroyed under the supervision of an inspector.

(2) Representative samples of canned product designated by the Administrator in instructions to inspectors shall be incubated under the supervision of such inspectors in accordance with § 381.309 (d)(1)(ii), (d)(1)(iii), (d)(1)(iv)(c), (d)(1)(v), (d)(1)(vii), and (d)(1)(viii) of this subchapter. The importer or his/her agent shall provide the necessary incubation facilities in accordance with § 381.309(d)(1)(i) of this subchapter.

(3) Sampling plans and acceptance levels as prescribed in paragraphs (d)(1) and (d)(2) of this section may be obtained, upon request, from International Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

19. A new Subpart X—Canning and Canned Products, consisting of §§ 381.300 through 381.311 is added to Part 381 to read as follows:

Subpart X—Canning and Canned Products

Secs.

381.300	Definitions.
381.301	Containers and closures.
381.302	Thermal processing.
381.303	Critical factors and the application of the process schedule.
381.304	Operations in the thermal processing area.
381.305	Equipment and procedures for heat processing systems.
381.306	Processing and production records.
381.307	Record review and maintenance.
381.308	Deviations in processing.
381.309	Finished product inspection.
381.310	Personnel and training.
381.311	Recall procedure.

Subpart X—Canning and Canned Products

§ 381.300 Definitions.

(a) *Abnormal container.* A container with any sign of swelling or product leakage or any evidence that the contents of the unopened container may be spoiled.

(b) *Acidified low acid product.* A canned product which has been formulated or treated so that every component of the finished product has a pH of 4.6 or lower within 24 hours after the completion of the thermal process unless data are available from the establishment's processing authority demonstrating that a longer time period is safe.

(c) *Bleeders.* Small orifices on a retort through which steam, other gasses, and condensate are emitted from the retort throughout the entire thermal process.

(d) *Canned product.* A poultry food product with a water activity above 0.85 which receives a thermal process either before or after being packed in a hermetically sealed container. Unless otherwise specified, the term "product" as used in this Subpart G shall mean "canned product."

(e) *Closure technician.* The individual(s) identified by the establishment as being trained to perform specific container integrity examinations as required by this subpart and designated by the establishment to perform such examinations.

(f) *Code lot.* All production of a particular product in a specific size container marked with a specific container code.

(g) *Come-up time.* The elapsed time, including venting time (if applicable), between the introduction of the heating medium into a closed retort and the start of process timing.

(h) *Critical factor.* Any characteristic, condition or aspect of a product, container, or procedure that affects the adequacy of the process schedule. Critical factors are established by processing authorities.

(i) *Headspace.* That portion of a container not occupied by the product.

(1) *Gross headspace.* The vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the top edge of the container (i.e., the flange of an unsealed can, the top of the double seam on a sealed can, or the top edge of an unsealed jar).

(2) *Net headspace.* The vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the inside surface of the lid.

(j) *Hermetically sealed containers.* Air-tight containers which are designed and intended to protect the contents against the entry of microorganisms during and after thermal processing.

(1) *Rigid container.* A container, the shape or contour of which, when filled and sealed, is neither affected by the enclosed product nor deformed by

external mechanical pressure of up to 10 pounds per square inch gauge (0.7 kg/cm²) (i.e., normal firm finger pressure).

(2) *Semirigid container.* A container, the shape or contour of which, when filled and sealed, is not significantly affected by the enclosed product under normal atmospheric temperature and pressure, but can be deformed by external mechanical pressure of less than 10 pounds per square inch gauge (0.7 kg/cm²) (i.e., normal firm finger pressure).

(3) *Flexible container.* A container, the shape or contour of which, when filled and sealed, is significantly affected by the enclosed product.

(k) *Incubation tests.* Tests in which the thermally processed product is kept at a specific temperature for a specified period of time in order to determine if outgrowth of microorganisms occurs.

(l) *Initial temperature.* The temperature, determined at the initiation of a thermal process cycle, of the contents of the coldest container to be processed.

(m) *Low acid product.* A canned product in which any component has a pH value above 4.6.

(n) *Process schedule.* The thermal process and any specified critical factors for a given canned product required to achieve shelf stability.

(o) *Process temperature.* The minimum temperature(s) of the heating medium to be maintained as specified in the process schedule.

(p) *Process time.* The intended time(s) a container is to be exposed to the heating medium while the heating medium is at or above the process temperature(s).

(q) *Processing authority.* The person(s) or organization(s) having expert knowledge of thermal processing requirements for foods in hermetically sealed containers, having access to facilities for making such determinations, and designated by the establishment to perform certain functions as indicated in this subpart.

(r) *Program employee.* Any inspector or other individual employed by the Department or any cooperating agency who is authorized by the Secretary to do any work or perform any duty in connection with the Program (see § 301.2(f)).

(s) *Retort.* A pressure vessel designed for thermal processing of product packed in hermetically sealed containers.

(t) *Seals.* Those parts of a semirigid container and lid or of a flexible container that are fused together in order to hermetically close the container.

(u) *Shelf stability.* The condition achieved by application of heat, sufficient, alone or in combination with other ingredients and/or treatments, to render the product free of microorganisms capable of growing in the product at nonrefrigerated conditions (over 50 °F or 10 °C) at which the product is intended to be held during distribution and storage. Shelf stability and shelf stable are synonymous with commercial sterility and commercially sterile, respectively.

(v) *Thermal process.* The heat treatment necessary to achieve shelf stability as determined by the establishment's processing authority. It is quantified in terms of:

- (1) Time(s) and temperature(s); or
- (2) Minimum product temperature.

(w) *Venting.* The removal of air from a retort before the start of process timing.

(x) *Water activity.* The ratio of the water vapor pressure of the product to the vapor pressure of pure water at the same temperature.

§ 381.301 Containers and closures.

(a) *Examination and cleaning of empty containers.* (1) Empty containers, closures, and flexible pouch roll stock shall be evaluated by the establishment to ensure that they are clean and free of structural defects and damage that may affect product or container integrity. Such an examination should be based upon a statistical sampling plan.

(2) All empty containers, closures, and flexible pouch roll stock shall be stored, handled, and conveyed in such a manner that will prevent soiling and damage that could affect the hermetic condition of the sealed container.

(3) Just before filling, rigid containers shall be cleaned to prevent incorporation of foreign matter into the finished product. Closures, semirigid containers, preformed flexible pouches, and flexible pouch roll stock contained in original wrappings do not need to be cleaned before use.

(b) *Closure examinations for rigid containers (cans).* (1) Visual examinations. A closure technician shall visually examine the double seams formed by each closing machine head. When seam defects (e.g., cutovers, sharpness, knocked down flanges, false seams, droops) are observed, necessary corrective actions, such as adjusting or repairing the closing machine, shall be taken. In addition to the double seams, the entire container shall be examined for product leakage or obvious defects. A visual examination shall be performed on at least one container from each closing machine head, and the observations, along with any corrective actions, shall be recorded. Visual

examinations shall be recorded. Visual examinations shall be conducted with sufficient frequency to ensure proper closure and should be conducted at least every 30 minutes of continuous closing machine operation. Additional visual examinations shall be made by the closure technician at the beginning of production, immediately following every jam in the closing machine and after closing machine adjustment (including adjustment for changes in container size).

(2) *Teardown examinations.*

Teardown examinations of double seams formed by each closing machine head shall be performed by a closure technician at a frequency sufficient to ensure proper closure. These examinations should be made at intervals of not more than 4 hours of continuous closing machine operation. At least one container from each closing head shall be examined on the packer's end during each regular examination period. Examination results along with any necessary corrective actions, such as adjusting or repairing the closing machine, shall be promptly recorded by the closure technician. The establishment shall have container specification guidelines for double seam integrity on file and available for review by Program employees. A teardown examination of the can maker's end shall be performed on at least one container selected from each closing machine during each examination period except when teardown examinations are made on incoming empty containers or when, in the case of self-manufactured containers, the containers are made in the vicinity of the establishment and the container plant records are made available to Program employees. Additional teardown examinations on the packer's end should be made at the beginning of production, immediately following every jam in a closing machine and after closing machine adjustment (including adjustment for a change in container size). The following procedures shall be used in teardown examinations of double seams:

(i) One of the following two methods shall be employed for dimensional measurements of the double seam.

(a) *Micrometer measurement.* For cylindrical containers, measure the following dimensions (Figure 1) at three points approximately 120 degrees apart on the double seam excluding and at least one-half inch from the side seam juncture:

- (1) Double seam length—W;
- (2) Double seam thickness—S;
- (3) Body hook length—BH; and
- (4) Cover hook length—CH.

Maximum and minimum values for each dimensional measurement shall be recorded by the closure technician.

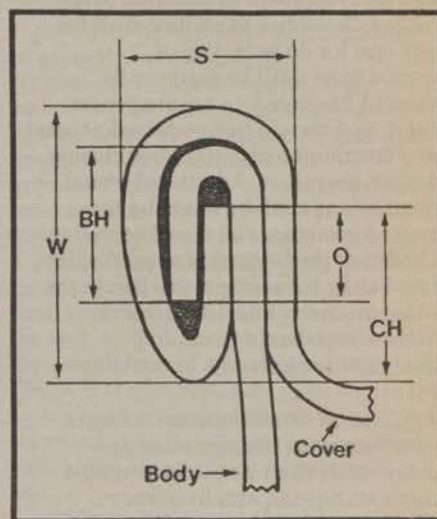


Figure 1

(b) *Seamscope or seam projector.* Required measurements of the seam include thickness, body hook, and overlap. Seam thickness shall be obtained by micrometer. For cylindrical containers, at least two locations, excluding the side seam juncture, shall be used to obtain the required measurements.

(ii) *Seam tightness.* Regardless of the dimensional measurement method used to measure seam dimensions, at a minimum, the seam(s) examined shall be stripped to assess the degree of wrinkling.

(iii) *Side seam juncture rating.* Regardless of the dimensional measurement method used to measure seam dimensions, the cover hook shall be stripped to examine the cover hook droop at the juncture for containers having side seams.

(iv) *Examination of noncylindrical containers.* Examination of noncylindrical containers (e.g., square, rectangular, "D"-shaped, and irregularly-shaped) shall be conducted as described in paragraphs (b)(2) (i), (ii), and (iii) of this section except that the required dimensional measurements shall be made on the double seam at the points listed in the establishment's container specification guidelines.

(c) *Closure examinations for glass containers.* (1) *Visual examinations.* A closure technician shall visually assess the adequacy of the closures formed by each closing machine. When closure defects, such as loose or cocked caps, fractured or cracked containers and low

vacuum jars, are observed, necessary corrective actions, such as adjusting or repairing the closing machine, shall be taken and recorded. In addition to the closures, the entire container shall be examined for defects. Visual examinations shall be made with sufficient frequency to ensure proper closure and should be conducted at least every 30 minutes of continuous closing machine operation. Additional visual examinations shall be made by the closure technician and the observations recorded at the beginning of production, immediately following every jam in the closing machine, and after closing machine adjustment (including adjustment for a change in container size).

(2) *Closure examinations and tests.* Depending upon the container and closure, tests shall be performed by a closure technician at a frequency sufficient to ensure proper closure. These examinations should be made either before or after thermal processing and at intervals of not more than 4 hours of continuous closing machine operation. At least one container from each closing machine shall be examined during each regular examination period. Examination results along with any necessary corrective actions, such as adjusting or repairing the closing machine, shall be promptly recorded by the closure technician. The establishment shall have specification guidelines for closure integrity on file and available for review by Program employees. Additional closure examinations should be made at the beginning of production, immediately following every jam in the closing machine and after closing machine adjustment (including adjustment for a change in container size).

(d) *Closure examinations for semirigid and flexible containers*—(1) *Heat seals*—(i) *Visual examinations.* A closure technician shall visually examine the seals formed by each sealing machine. When sealing defects are observed, necessary corrective actions, such as adjusting or repairing the sealing machine, shall be taken and recorded. In addition to examining the heat seals, the entire container shall be examined for product leakage or obvious defects. Visual examinations shall be performed before and after the thermal processing operation with sufficient frequency to ensure proper closure. These examinations should be conducted at least in accordance with a statistical sampling plan. All defects noted and corrective actions taken shall be promptly recorded.

(ii) *Physical tests.* Tests determined by the establishment as necessary to assess container integrity shall be conducted by the closure technician at a frequency sufficient to ensure proper closure. These tests shall be performed after the thermal processing operation and should be made at least every 2 hours of continuous production. The establishment's acceptance guidelines for each test procedure shall be on file and available for review by Program employees. Test results along with any necessary corrective actions, such as adjusting or repairing the sealing machine, shall be recorded.

(2) Double seams on semirigid or flexible containers shall be examined and the results recorded as provided in paragraph (b) of this section. Any additional measurements specified by the container manufacturer shall also be made and recorded.

(e) *Container coding.* Each container shall be marked with a permanent, legible, identifying code mark. The mark shall, at a minimum, identify in code the product (unless the product name is lithographed or printed elsewhere on the container) and the day and year the product was packed.

(f) *Handling of containers after closure.* (1) Containers and closures shall be protected from damage which may cause defects that are likely to affect the hermetic condition of the containers. The accumulation of stationary containers on moving conveyors should be minimized to avoid damage to the containers.

(2) The maximum time lapse between closing and initiation of thermal processing shall be 2 hours. However, the Administrator may specify a shorter period of time when considered necessary to ensure product safety and stability. A longer period of time between closing and the initiation of thermal processing may be permitted by the Administrator.

(Approved by the Office of Management and Budget under control number 0583-0015)

§ 381.302 Thermal processing.

(a) *Process schedules.* Prior to the processing of canned product for distribution in commerce, an establishment shall have a process schedule (as defined in § 381.300(n) of this subpart) for each canned poultry product to be packed by the establishment.

(b) *Source of process schedules.* (1) Process schedules used by an establishment shall be developed or determined by a processing authority.

(2) 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.

(3) Complete records concerning all aspects of the development or determination of a process schedule, including any associated incubation tests, shall be made available by the establishment to the Program employee upon request.

(c) *Submittal of process information.*

(1) Prior to the processing of canned product for distribution in commerce, the establishment shall provide the inspector at the establishment with a list of the process schedules (including alternate schedules) along with any additional applicable information, such as the retort come-up operating procedures and critical factors.

(2) Letters or other written communications from a processing authority recommending all process schedules shall be maintained on file by the establishment. Upon request by Program employees, the establishment shall make available such letters or written communications (or copies thereof). If critical factors are identified in the process schedule, the establishment shall provide the inspector with a copy of the procedures for measuring, controlling, and recording these factors, along with the frequency of such measurements, to ensure that the critical factors remain within the limits used to establish the process schedule. Once submitted, the process schedules and associated critical factors and the procedures for measuring (including the frequency), controlling, and recording of critical factors shall not be changed without the prior written submittal of the revised procedures (including supporting documentation) to the inspector at the establishment.

(Approved by the Office of Management and Budget under control number 0583-0015)

§ 381.303 Critical factors and the application of the process schedule.

Critical factors specified in the process schedule shall be measured, controlled and recorded by the establishment to ensure that these factors remain within the limits used to establish the process schedule. Examples of factors that are often critical to process schedule adequacy may include:

- (a) *General.* (1) Maximum fill-in weight or drained weight;
 (2) Arrangement of pieces in the container;
 (3) Container orientation during thermal processing;
 (4) Product formulation;
 (5) Particle size;
 (6) Maximum thickness for flexible, and to some extent semirigid containers during thermal processing;
 (7) Maximum pH;
 (8) Percent salt;
 (9) Ingoing (or formulated) nitrite level (ppm);
 (10) Maximum water activity; and
 (11) Product consistency or viscosity.
 (b) *Continuous rotary and batch agitating retorts.* (1) Minimum headspace; and
 (2) Retort reel speed.
 (c) *Hydrostatic retorts.* (1) Chain or conveyor speed.
 (d) *Steam/air retorts.* (1) Steam/air ratio; and
 (2) Heating medium flow rate.

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§ 381.304 Operations in the thermal processing area.

(a) *Posting of processes.* Process schedules (or operating process schedules) for daily production, including minimum initial temperatures and operating procedures for thermal processing equipment, shall be posted in a conspicuous place near the thermal processing equipment. Alternatively, such information shall be available to the thermal processing system operator and the inspector.

(b) *Process indicators and retort traffic control.* A system for product traffic control shall be established to prevent product from bypassing the thermal processing operation. Each basket, crate or similar vehicle containing unprocessed product, or at least one visible container in each vehicle, shall be plainly and conspicuously marked with a heat sensitive indicator that will visually indicate whether such unit has been thermally processed. Exposed heat sensitive indicators attached to container vehicles shall be removed before such vehicles are refilled with unprocessed product. Container loading systems for crateless retorts shall be designed to prevent unprocessed product from bypassing the thermal processing operation.

(c) *Initial temperature.* The initial temperature of the contents of the coldest container to be processed shall be determined and recorded by the establishment at the time the processing cycle begins to assure 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. Thermal processing systems which subject the filled and sealed containers to water at any time before process timing begins shall be operated to assure that such water will not lower the temperature of the product below the minimum initial temperature specified in the process schedule.

(d) *Timing devices.* Devices used to time applicable thermal processing operation functions or events, such as process schedule time, come-up time and retort venting, shall be accurate to assure that all such functions or events are achieved. Pocket watches and wrist watches are not considered acceptable timing devices. Analog and digital clocks are considered acceptable. If such clocks do not display seconds, all required timed functions or events shall have at least a 1-minute safety factor over the specified thermal processing operation times. Temperature/time recording devices shall correspond within 15 minutes to the time of the day recorded on written records required by § 381.306.

(e) *Measurement of pH.* Unless other methods are approved by the Administrator, potentiometric methods using electronic instruments (pH meters) shall be used for making pH determinations when a maximum pH value is specified as a critical factor in a process schedule.

§ 381.305 Equipment and procedures for heat processing systems.

(a) *Instruments and controls common to different thermal processing systems.*

(1) *Indicating temperature devices.* Each retort shall be equipped with at least one indicating temperature device that measures the actual temperature within the retort. The indicating temperature device, not the temperature/time recording device, shall be used as the reference instrument for indicating the process temperature.

(i) *Mercury-in-glass thermometers.* A mercury-in-glass thermometer shall have divisions that are readable to 1 °F (or 0.5 °C) and whose scale contains not more than 17 °F/inch (or 4.0 °C/cm) of graduated scale. Each mercury-in-glass thermometer shall be tested for accuracy against a known accurate standard upon installation and at least once a year to ensure its accuracy. Records that specify the date, standard used, test method, and the person or testing authority performing the test shall be maintained on file by the establishment and made available to Program employees. A mercury-in-glass

thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired and tested for accuracy before further use, or replaced.

(ii) *Other devices.* In lieu of mercury-in-glass thermometers, the Administrator, upon request, will consider other indicating temperature devices, such as resistance temperature detectors. Any such device that is approved shall, upon installation and at least once a year thereafter, be tested for accuracy against a known accurate standard. Records that specify the date, standard used, test method, and the person or testing authority performing the test shall be maintained on file by the establishment and made available to Program employees. Any such device which cannot be adjusted to the standard shall be replaced, or repaired and tested for accuracy before further use.

(2) *Temperature/time recording devices.* Each thermal processing system shall be equipped with at least one temperature/time recording device to provide a permanent record of temperatures within the thermal processing system. This recording device may be combined with the steam controller and may be a recording/controlling instrument. When compared to the known accurate indicating temperature device, the recording accuracy shall be equal to or better than 1 °F (or 0.5 °C) at the process temperature. The temperature recording chart should be adjusted to agree with, but shall never be higher than, the known accurate indicating temperature device. A means of preventing unauthorized changes in the adjustment shall be provided. For example, a lock or a notice from management posted at or near the recording device warning that only authorized persons are permitted to make adjustments, are satisfactory means for preventing unauthorized changes. Air-operated temperature controllers shall have adequate filter systems to ensure a supply of clean, dry air. The recorder timing mechanism shall be accurate.

(i) *Chart-type devices.* Devices using charts shall be used only with the correct chart. Each chart shall have a working scale of not more than 55 °F/inch (or 12 °C/cm) within a range of 20 °F (or 11 °C) of the process temperature. Chart graduations shall not exceed 2 °F (or 1 °C) within a range of 10 °F (or 5 °C) of the process temperature. Multipoint plotting chart-type devices shall print temperature readings at intervals that will assure that the parameters of the process time and process temperature

have been met. The frequency of recording should not exceed 1-minute intervals.

(ii) *Other devices.* In lieu of chart-type devices, the Administrator will consider for approval other recording devices upon request.

(3) *Steam controllers.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording/controlling instrument when combined with a temperature/time recording device.

(4) *Air valves.* All air lines connected to the retorts designed for pressure processing in steam shall be 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.

(5) *Water valves.* All retort water lines that are intended to be closed during a process cycle shall be equipped with a globe valve or other equivalent-type valve or piping arrangement that will prevent leakage of water into the retort during the process cycle.

(b) *Pressure processing in steam—(1) Batch still retorts.* (i) The basic requirements and recommendations for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, bulb sheaths or probes of indicating temperature devices and probes of temperature/time recording devices shall be installed either within the retort shell or in external wells attached to the retort. External wells shall be connected to the retort through at least a $\frac{3}{4}$ inch (1.9 cm) diameter opening and equipped with a $\frac{1}{4}$ inch (1.6 mm) or larger bleeder opening so located as to provide a constant flow of steam past the length of the bulb or probe. The bleeder for external wells shall emit steam continuously during the entire thermal processing period.

(ii) Steam controllers are required as described in paragraph (a)(3) of this section.

(iii) *Steam inlet.* The steam inlet to each retort shall be large enough to provide steam for proper operation of the retort, and shall enter at a point to facilitate air removal during venting.

(iv) *Crate supports.* Vertical still retorts with bottom steam entry shall employ bottom retort crate supports. Baffle plates shall not be used in the bottom of retorts.

(v) *Steam spreader.* Perforated steam spreaders, if used, shall be maintained to ensure they are not blocked or otherwise inoperative. Horizontal still retorts shall be equipped with perforated steam spreaders that extend

the full length of the retort unless the adequacy of another arrangement is documented by heat distribution data or other documentation from a processing authority. Such information shall be maintained on file by the establishment and made available to Program employees for review.

(vi) *Bleeders and condensate removal.* Bleeders, except those for external wells of temperature devices, shall have $\frac{1}{4}$ inch (or 3 mm) or larger openings and shall be wide open during the entire process including the come-up time. For horizontal still retorts, bleeders shall be located within approximately 1 foot (or 30 cm) of the outermost locations of containers at each end along the top of the retort. Additional bleeders shall be located not more than 8 feet (2.4 m) apart along the top. Bleeders may be installed at positions other than those specified above, as long as the establishment has heat distribution data or other documentation from the manufacturer or from a processing authority demonstrating that the bleeders accomplish removal of air and circulate the steam within the retort. This information shall be maintained on file by the establishment and made available to Program employees for review. All bleeders shall be arranged in a way that enables the retort operator to observe that they are functioning properly. Vertical retorts shall have at least one bleeder opening located in the portion of the retort opposite the steam inlet. All bleeders shall be arranged so that the retort operator can observe that they are functioning properly. In retorts having a steam inlet above the level of the lowest container, a bleeder shall be installed in the bottom of the retort to remove condensate. The condensate bleeder shall be so arranged that the retort operator can observe that it is functioning properly. The condensate bleeder shall be checked with sufficient frequency to ensure adequate removal of condensate. Visual checks should be performed at intervals of not more than 15 minutes and the results recorded.

Intermittent condensate removal systems shall be equipped with an automatic alarm system that will serve as a continuous monitor of condensate bleeder functioning. The automatic alarm system shall be tested at the beginning of each shift for proper functioning and the results recorded. If the alarm system is not functioning properly, it must be repaired before the retort is used.

(vii) *Stacking equipment.* (a) Equipment for holding or stacking containers in retorts. Crates, trays, gondolas, carts, and other vehicles for holding or stacking product containers

in the retort shall be so constructed to ensure steam circulation during the venting, come-up, and process times. The bottom of each vehicle shall have perforations at least 1 inch (2.5 cm) in diameter on 2 inch (or 5 cm) centers or the equivalent unless the adequacy of another arrangement is documented by heat distribution data or other documentation from a processing authority and such information is maintained on file by the establishment and made available to Program employees for review.

(b) *Divider plates.* Whenever one or more divider plates are used between any two layers of containers or placed on the bottom of a retort vehicle, the establishment shall have on file documentation that the venting procedure allows the air to be removed from the retort before timing of the thermal process is started. Such documentation shall be in the form of heat distribution data or documentation from a processing authority. This information shall be made available to Program employees for review.

(viii) *Bleeder and vent mufflers.* If mufflers are used on bleeders or vent systems, the establishment shall have on file documentation that the mufflers do not impede the removal of air from the retort. Such documentation shall consist of either heat distribution data or documentation from the muffler manufacturer or from a processing authority. This information shall be made available to Program employees for review.

(ix) *Vents.* (a) Vents shall be located in that portion of the retort opposite the steam inlet and shall be designed, installed, and operated in such a way that air is removed from the retort before timing of the thermal process is started. Vents shall be controlled by a gate, plug cock, or other full-flow valve which shall be fully opened to permit rapid removal of air from retorts during the venting period.

(b) Vents shall not be connected to a closed drain system without an atmospheric break in the line. Where a retort manifold connects several pipes from a single retort, the manifold shall be controlled by a gate, plug cock, or other full-flow valve and the manifold shall be of a size such that the cross-sectional area of the manifold is larger than the total cross-sectional area of all connecting vents. The discharge shall not be connected to a closed drain without an atmospheric break in the line. A manifold header connecting vents or manifolds from several still retorts shall lead to the atmosphere. The manifold header shall not be controlled

by a valve and shall be of a size such that the cross-sectional area is at least equal to the total cross-sectional area of all connecting retort manifold pipes from the maximum number of retorts to be vented simultaneously.

(c) Some typical installations and operating procedures are described below. Other retort installations, vent piping arrangements, operating procedures or auxiliary equipment such as divider plates may be used provided there is documentation that the air is removed from the retort before the process is started. Such documentation shall be in the form of heat distribution data or other documentation from the equipment manufacturer or processing authority. This information shall be maintained on file by the establishment and made available to Program employees for review.

(d) For crateless retort installations, the establishment shall have heat distribution data or other documentation from the equipment manufacturer or from a processing authority that demonstrates that the venting procedure used accomplishes the removal of air and condensate. This information shall be maintained on file by the establishment and made available to Program employees for review.

(e) Examples of typical installations and operating procedures that comply with the requirements of this section are as follows:

(1) Venting horizontal retorts.

(i) Venting through multiple 1 inch (2.5 cm) vents discharging directly to the atmosphere.

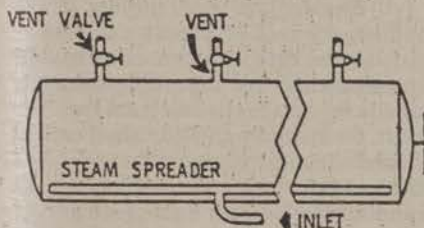


Figure 1.

Specifications (Figure 1): One, 1-inch (2.5 cm) vent for every 5 feet (1.5 m) of retort length, equipped with a gate, plug cock, or other full-flow valve and discharging to atmosphere. The end vents shall not be more than 2½ feet (or 75 cm) from ends of retort.

Venting method (Figure 1): Vent valves shall be wide open for at least 5 minutes and to at least 225 °F (or 107 °C), or at least 7 minutes and to at least 220 °F (or 104.5 °C).

(ii) Venting through multiple 1 inch (2.5 cm) vents discharging through a manifold to the atmosphere.

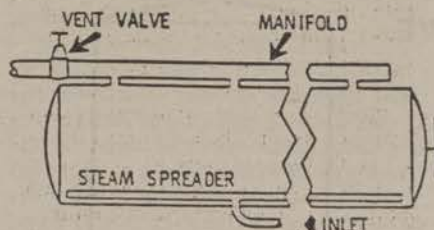


Figure 2.

Specifications (Figure 2): One, 1-inch (2.5 cm) vent for every 5 feet (1.5 m) of retort length; vents not over 2½ feet (or 75 cm) from ends of retort; size of manifold for retorts less than 15 feet (4.6 m) in length, 2½ inches (6.4 cm), and for retorts 15 feet (4.6 m) and over in length, 3 inches (7.6 cm).

Venting method (Figure 2): The manifold vent gate, plug cock, or other full-flow valve shall be wide open for at least 6 minutes and to at least 225 °F (or 107 °C) or for at least 8 minutes and to at least 220 °F (or 104.5 °C).

(iii) Venting through water spreaders.

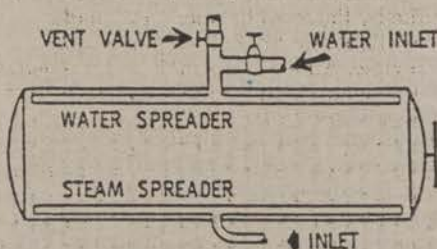


Figure 3.

Specifications (Figure 3): Size of vent and vent valve. For retorts less than 15 feet (4.6 m) in length, 2 inches (or 5 cm); for retorts 15 feet (4.6 m) and over in length, 2½ inches (6.4 cm).

Size of water spreader (Figure 3): For retorts less than 15 feet (4.6 m) in length, 1½ inches (3.8 cm); for retorts 15 feet (4.6 m) and over in length 2 inches (or 5 cm). The number of holes shall be such that their total cross-sectional area is equal to the cross-sectional area of the vent pipe inlet.

Venting method (Figure 3): The gate, plug cock, or other full-flow valve on the water spreader vent shall be wide open for at least 5 minutes and to at least 225 °F (or 107 °C), or for at least 7 minutes and to at least 220 °F (or 104.5 °C).

(iv) Venting through a single 2½ inch (6.4 cm) top vent for retorts not exceeding 15 feet (4.6 m) in length.

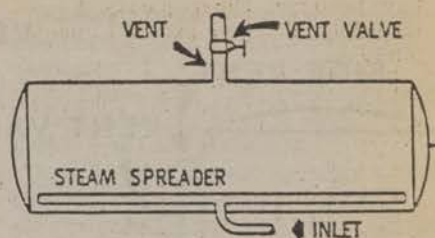


Figure 4.

Specifications (Figure 4): A 2½ inch (6.4 cm) vent equipped with a 2½ inch (6.4 cm) gate, plug cock, or other full-flow valve and located within 2 feet (61 cm) of the center of the retort.

Venting method (Figure 4): The vent valve shall be wide open for at least 4 minutes and to at least 220 °F (or 104.5 °C).

(2) Venting vertical retorts.

(i) Venting through a 1½ inch (3.8 cm) overflow.

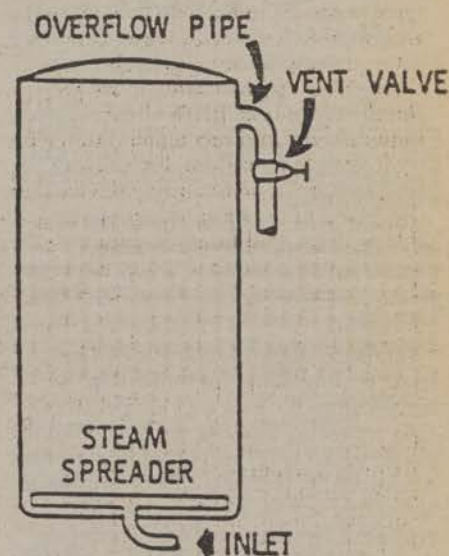


Figure 5.

Specifications (Figure 5): A 1½ inch (3.8 cm) overflow pipe equipped with a 1½ inch (3.8 cm) gate, plug cock, or other full-flow valve and with not more than 6 feet (1.8 m) of 1½ inch (3.8 cm) pipe beyond the valve before a break to the atmosphere or to a manifold header.

Venting method (Figure 5): The vent valve shall be wide open for at least 4 minutes and to at least 218 °F (or 103.5 °C), or for at least 5 minutes and to at least 215 °F (or 101.5 °C).

(ii) Venting through a single 1 inch (2.5 cm) side or top vent.

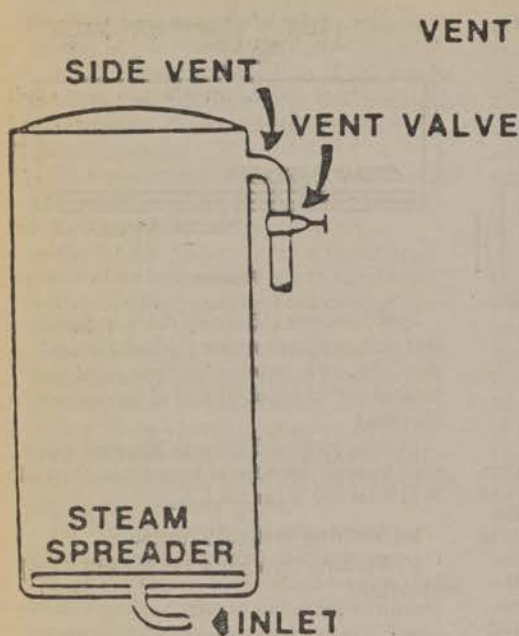


Figure 6.

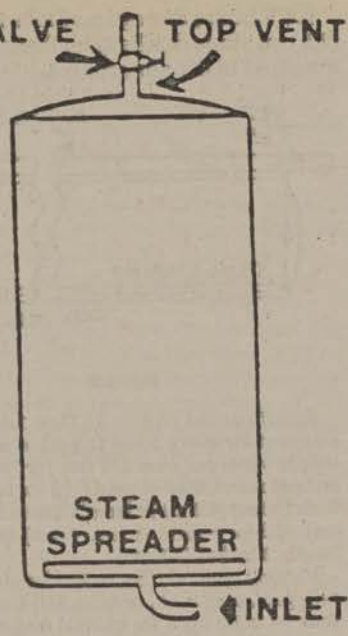


Figure 7.

Specifications (Figure 6 or 7): A 1 inch (2.5 cm) vent in lid or top side, equipped with a gate, plug cock, or other full-flow valve and discharging directly into the atmosphere or to a manifold header.

Venting method (Figure 6 or 7): The vent valve shall be wide open for at least 5 minutes and to at least 230 °F (110 °C), or for at least 7 minutes and to at least 220 °F (or 104.5 °C).

(2) *Batch agitating retorts.* (i) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, bulb sheaths or probes of indicating temperature devices and probes of temperature/time recording devices shall be installed either within the retort shell or in external wells attached to the retort. External wells shall be connected to the retort through at least a ¼ inch (1.9 cm) diameter opening and equipped with a ½ inch (1.6 mm) or larger bleeder opening so located as to provide a constant flow of steam past the length of the bulbs or probes. The bleeder for external wells shall emit steam continuously during the entire thermal processing period.

(ii) Steam controllers are required as described in paragraph (a)(3) of this section.

(iii) *Steam inlet.* The steam inlet to each retort shall be large enough to provide steam for proper operation of the retort and shall enter at a point(s) to facilitate air removal during venting.

(iv) *Bleeders.* Bleeders, except those for external wells of temperature devices, shall be ½ inch (or 3 mm) or

larger and shall be wide open during the entire process including the come-up time. Bleeders shall be located within approximately 1 foot (or 30 cm) of the outermost location of containers, at each end along the top of the retort. Additional bleeders shall be located not more than 8 feet (2.4 m) apart along the top. Bleeders may be installed at positions other than those specified above, as long as the establishment has heat distribution data or other documentation from the manufacturer or from a processing authority that the bleeders accomplish removal of air and circulate the steam within the retort. This information shall be maintained on file by the establishment and made available to Program employees for review. All bleeders shall be arranged in a way that enables the retort operator to observe that they are functioning properly.

(v) *Venting and condensate removal.* The air in the retort shall be removed before processing is started. Heat distribution data or other documentation from the manufacturer or from the processing authority who developed the venting procedure shall be kept on file by the establishment and made available to Program employees for review. At the time the steam is turned on, the drain shall be opened to remove steam condensate from the retort. A bleeder shall be installed in the bottom of the retort to remove condensate during retort operation. The condensate bleeder shall be so arranged that the retort operator can observe that it is

functioning properly. The condensate bleeder shall be checked with sufficient frequency to ensure adequate removal of condensate. Visual checks should be performed at intervals of not more than 15 minutes and the results recorded. Intermittent condensate removal systems shall be equipped with an automatic alarm system that will serve as a continuous monitor of condensate bleeder functioning. The automatic alarm system shall be tested at the beginning of each shift for proper functioning and the results recorded. If the alarm system is not functioning properly, it must be repaired before the retort is used.

(vi) *Retort or reel speed timing.* The retort or reel speed shall be checked before process timing begins and, if needed, adjusted as specified in the process schedule. In addition, the rotational speed shall be determined and recorded at least once during process timing of each retort load processed. Alternatively, a recording tachometer can be used to provide a continuous record of the speed. The accuracy of the recording tachometer shall be determined and recorded at least once per shift by checking the retort or reel speed using an accurate stopwatch. A means of preventing unauthorized speed changes on retorts shall be provided. For example, a lock or a notice from management posted at or near the speed adjustment device warning that only authorized persons are permitted to make adjustments are satisfactory means of preventing unauthorized changes.

(vii) *Bleeder and vent mufflers.* If mufflers are used on bleeders or vent systems, the establishment shall have documentation that the mufflers do not impede the removal of air from the retort. Such documentation shall consist of either heat distribution data or documentation from the muffler manufacturer or from a processing authority. This information shall be maintained on file by the establishment and made available to Program employees for review.

(3) *Continuous rotary retorts.* (i) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, bulb sheaths or probes of indicating temperature devices and probes of temperature/time recording devices shall be installed either within the retort shell or in external wells attached to the retort. External wells shall be connected to the retort through at least a ¼ inch (1.9 cm) diameter opening and equipped with a ½ inch

(1.6 mm) or larger bleeder opening so located as to provide a constant flow of steam past the length of the bulbs or probes. The bleeder for external wells shall emit steam continuously during the entire thermal processing period.

(ii) Steam controllers are required as described in paragraph (a)(3) of this section.

(iii) *Steam inlet.* The steam inlet to each retort shall be large enough to provide steam for proper operation of the retort, and shall enter at a point(s) to facilitate air removal during venting.

(iv) *Bleeders.* Bleeders, except those for external wells of temperature devices, shall be 1/4 inch (3.2 mm) or larger and shall be wide open during the entire process, including the come-up time. Bleeders shall be located within approximately 1 foot (or 30 cm) of the outermost location of containers at each end along the top of the retort. Additional bleeders shall be located not more than 8 feet (2.4 m) apart along the top of the retort. Bleeders may be installed at positions other than those specified above, as long as the establishment has heat distribution data or other documentation from the manufacturer or a processing authority that the bleeders accomplish removal of air and circulate the steam within the retort. This information shall be maintained on file by the establishment and made available to Program employees for review. All bleeders shall be arranged so that the retort operator can observe that they are functioning properly.

(v) *Venting and condensate removal.* The air in the retort shall be removed before processing is started. Heat distribution data or other documentation from the manufacturer or from the processing authority who developed the venting procedure shall be kept on file by the establishment and made available to Program employees for review. At the time the steam is turned on, the drain shall be opened to remove steam condensate from the retort. A bleeder shall be installed in the bottom of the shell to remove condensate during the retort operation. The condensate bleeder shall be so arranged that the retort operator can observe that it is functioning properly. The condensate bleeder shall be checked with sufficient frequency to ensure adequate removal of condensate. Visual checks should be performed at intervals of not more than 15 minutes and the results recorded. Intermittent condensate removal systems shall be equipped with an automatic alarm system that will serve as a continuous monitor of condensate bleeder functioning. The automatic alarm system shall be tested at the

beginning of each shift for proper functioning and the results recorded. If the alarm system is not functioning properly, it must be repaired before the retort is used.

(vi) *Retort speed timing.* The rotational speed of the retort shall be specified in the process schedule. The speed shall be adjusted as specified, and recorded by the establishment when the retort is started, and checked and recorded at intervals not to exceed 4 hours to ensure that the correct retort speed is maintained. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. If a recording tachometer is used, the speed shall be manually checked against an accurate stopwatch at least once per shift and the results recorded. A means of preventing unauthorized speed changes on retorts shall be provided. For example, a lock or a notice from management posted at or near the speed adjustment device warning that only authorized persons are permitted to make adjustments are satisfactory means of preventing unauthorized changes.

(vii) *Bleeders and vent mufflers.* If mufflers are used on bleeders or vent systems, the establishment shall have documentation that the mufflers do not impede the removal of air from the retort. Such documentation shall consist of either heat distribution data or other documentation from the muffler manufacturer or from a processing authority. This information shall be maintained on file by the establishment and made available to Program employees for review.

(4) *Hydrostatic retorts.* (i) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, indicating temperature devices shall be located in the steam dome near the steam/water interface. Where the process schedule specifies maintenance of particular water temperatures in the hydrostatic water legs, at least one indicating temperature device shall be located in each hydrostatic water leg so that it can accurately measure water temperature and be easily read. The temperature/time recorder probe shall be installed either within the steam dome or in a well attached to the dome. Each probe shall have a 1/16 inch (1.6 mm) or larger bleeder opening which emits steam continuously during the processing period. Additional temperature/time recorder probes shall be installed in the hydrostatic water legs if the process schedule specifies maintenance of particular temperatures in these water legs.

(ii) Steam controllers are required as described in paragraph (a)(3) of this section.

(iii) *Steam inlet.* The steam inlets shall be large enough to provide steam for proper operation of the retort.

(iv) *Bleeders.* Bleeder openings 1/4 inch (or 6 mm) or larger shall be located in the steam chamber(s) opposite the point of steam entry. Bleeders shall be wide open and shall emit steam continuously during the entire process, including the come-up time. All bleeders shall be arranged in such a way that the operator can observe that they are functioning properly.

(v) *Venting.* Before the start of processing operations, the retort steam chamber(s) shall be vented to ensure removal of air. Heat distribution data or other documentation from the manufacturer or from a processing authority demonstrating that the air is removed from the retort prior to processing shall be kept on file at the establishment and made available to Program employees for review.

(vi) *Conveyor speed.* The conveyor speed shall be calculated to obtain the required process time and recorded by the establishment when the retort is started. The speed shall be checked and recorded at intervals not to exceed 4 hours to ensure that the correct conveyor speed is maintained. A recording device may be used to provide a continuous record of the conveyor speed. When a recording device is used, the speed shall be manually checked against an accurate stopwatch at least once per shift by the establishment. A means of preventing unauthorized speed changes of the conveyor shall be provided. For example, a lock or a notice from management posted at or near the speed adjustment device warning that only authorized persons are permitted to make adjustments are satisfactory means of preventing unauthorized changes.

(vii) *Bleeders and vent mufflers.* If mufflers are used on bleeders or vent systems, the establishment shall have documentation that the mufflers do not impede the removal of air from the retort. Such documentation shall consist of either heat distribution data or other documentation from the muffler manufacturer or from a processing authority. This information shall be maintained on file by the establishment and made available to Program employees for review.

(c) *Pressure processing in water—(1) Batch still retorts.* (i) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs

(a)(1) and (2) of this section. Additionally, bulbs or probes of indicating temperature devices shall be located in such a position that they are beneath the surface of the water throughout the process. On horizontal retorts, the indicating temperature device bulb or probe shall be inserted directly into the retort shell. In both vertical and horizontal retorts, the indicating temperature device bulb or probe shall extend directly into the water a minimum of 2 inches (or 5 cm) without a separable well or sleeve. In vertical retorts equipped with a recorder/controller, the controller probe shall be located at the bottom of the retort below the lowest crate rest in such a position that the steam does not strike it directly. In horizontal retorts so equipped, the controller probe shall be located between the water surface and the horizontal plane passing through the center of the retort so that there is no opportunity for direct steam impingement on the controller probe. Air-operated temperature controllers shall have filter systems to ensure a supply of clean, dry air.

(ii) *Pressure recording device.* Each retort shall be equipped with a pressure recording device which may be combined with a pressure controller.

(iii) *Steam controllers* are required as described in paragraph (a)(3) of this section.

(iv) *Heat distribution.* Heat distribution data or other documentation from the equipment manufacturer or a processing authority demonstrating uniform heat distribution within the retort shall be kept on file at the establishment and made available to Program employees for review.

(v) *Crate supports.* A bottom crate support shall be used in vertical retorts. Baffle plates shall not be used in the bottom of the retort.

(vi) *Stacking equipment.* For filled flexible containers and, where applicable, semirigid containers, stacking equipment shall be designed to ensure that the thickness of the filled containers does not exceed that specified in the process schedule and that the containers do not become displaced and overlap or rest on one another during the thermal process.

(vii) *Drain valve.* A nonclogging, water-tight drain valve shall be used. Screens shall be installed over all drain openings.

(viii) *Water level.* There shall be a means of determining the water level in the retort during operation (i.e., by using a gauge, electronic sensor, or sight glass indicator). For retorts requiring complete immersion of containers, water shall cover the top layer of containers during

the entire come-up time and thermal processing periods and should cover the top layer of containers during cooling. For retorts using cascading water or water sprays, the water level shall be maintained within the range specified by the retort manufacturer or processing authority during the entire come-up, thermal processing, and cooling periods. A means to ensure that water circulation continues as specified throughout the come-up, thermal processing, and cooling periods shall be provided. The retort operator shall check and record the water level at intervals to ensure it meets the specified processing parameters.

(ix) *Air supply and controls.* In both horizontal and vertical still retorts, a means shall be provided for introducing compressed air or steam at the pressure required to maintain container integrity. Compressed air and steam entry shall be controlled by an automatic pressure control unit. A nonreturn valve shall be provided in the air supply line to prevent water from entering the system. Overriding air or steam pressure shall be maintained continuously during the come-up, thermal processing, and cooling periods. If air is used to promote circulation, it shall be introduced into the steam line at a point between the retort and the steam control valve at the bottom of the retort. The adequacy of the air circulation for maintaining uniform heat distribution within the retort shall be documented by heat distribution data or other documentation from a processing authority, and such data shall be maintained on file by the establishment and made available to Program employees for review.

(x) *Water recirculation.* When a water recirculation system is used for heat distribution, the water shall be drawn from the bottom of the retort through a suction manifold and discharged through a spreader that extends the length or circumference of the top of the retort. The holes in the water spreader shall be uniformly distributed. The suction outlets shall be protected with screens to keep debris from entering the recirculation system. The pump shall be equipped with a pilot light or a similar device to warn the operator when it is not running, and with a bleeder to remove air when starting operations. Alternatively, a flow-meter alarm system can be used to ensure proper water circulation. The adequacy of water circulation for maintaining uniform heat distribution within the retort shall be documented by heat distribution data or other documentation from a processing authority and such data shall be maintained on file by the establishment

and made available to Program employees for review. Alternative methods for recirculation of water in the retort may be used, provided there is documentation in the form of heat distribution data or other documentation from a processing authority maintained on file by the establishment and made available to Program employees for review.

(xi) *Cooling water entry.* In retorts for processing product packed in glass jars, the incoming cooling water should not directly strike the jars, in order to minimize glass breakage by thermal shock.

(2) *Batch agitating retorts.* (i) The basic requirements and recommendations for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, the indicating temperature device bulb or probe shall extend directly into the water without a separable well or sleeve. The recorder/controller probe shall be located between the water surface and the horizontal plane passing through the center of the retort so that there is no opportunity for steam to directly strike the controller bulb or probe.

(ii) *Pressure recording device.* Each retort shall be equipped with a pressure recording device which may be combined with a pressure controller.

(iii) *Steam controllers* are required as described in paragraph (a)(3) of this section.

(iv) *Heat distribution.* Heat distribution data or other documentation from the equipment manufacturer or a processing authority shall be kept on file by the establishment and made available to Program employees for review.

(v) *Stacking equipment.* All devices used for holding product containers (e.g., crates, trays, divider plates) shall be so constructed to allow the water to circulate around the containers during the come-up and thermal process periods.

(vi) *Drain valve.* A nonclogging, water-tight drain valve shall be used. Screens shall be installed over all drain openings.

(vii) *Water level.* There shall be a means of determining the water level in the retort during operation (i.e., by using a gauge, electronic sensor, or sight glass indicator). Water shall completely cover all containers during the entire come-up, thermal processing, and cooling periods. A means to ensure that water circulation continues as specified throughout the come-up, thermal processing, and cooling periods shall be

provided. The retort operator shall check and record the adequacy of the water level with sufficient frequency to ensure it meets the specified processing parameters.

(viii) *Air supply and controls.* Retorts shall be provided with a means for introducing compressed air or steam at the pressure required to maintain container integrity. Compressed air and steam entry shall be controlled by an automatic pressure control unit. A nonreturn valve shall be provided in the air supply line to prevent water from entering the system. Overriding air or steam pressure shall be maintained continuously during the come-up, thermal processing, and cooling periods. If air is used to promote circulation, it shall be introduced into the steam line at a point between the retort and the steam control valve at the bottom of the retort. The adequacy of the air circulation for maintaining uniform heat distribution within the retort shall be documented by heat distribution data or other documentation from a processing authority, and such data shall be maintained on file by the establishment and made available to Program employees for review.

(ix) *Retort or reel speed timing.* The retort or reel speed timing shall be checked before process timing begins and, if needed, adjusted as specified in the process schedule. In addition, the rotational speed shall be determined and recorded at least once during process timing of each retort load processed. Alternatively, a recording tachometer can be used to provide a continuous record of the speed. The accuracy of the recording tachometer shall be determined and recorded at least once per shift by the establishment by checking the retort or reel speed using an accurate stopwatch. A means of preventing unauthorized speed changes on retorts shall be provided. For example, a lock or a notice from management posted at or near the speed adjustment device warning that only authorized persons are permitted to make adjustments are satisfactory means of preventing unauthorized changes.

(x) *Water recirculation.* If a water recirculation system is used for heat distribution, it shall be installed in such a manner that water will be drawn from the bottom of the retort through a suction manifold and discharged through a spreader which extends the length of the top of the retort. The holes in the water spreader shall be uniformly distributed. The suction outlets shall be protected with screens to keep debris from entering the recirculation system.

The pump shall be equipped with a pilot light or a similar device to warn the operator when it is not running and with a bleeder to remove air when starting operations. Alternatively, a flow-meter alarm system can be used to ensure proper water circulation. The adequacy of water circulation for maintaining uniform heat distribution within the retort shall be documented by heat distribution data or other documentation from a processing authority and such data shall be maintained on file by the establishment and made available to Program employees for review. Alternative methods for recirculation of water in the retort may be used provided there is documentation in the form of heat distribution data or other documentation from a processing authority maintained on file by the establishment and made available to Program employees for review.

(xi) *Cooling water entry.* In retorts for processing product packed in glass jars, the incoming cooling water should not directly strike the jars, in order to minimize glass breakage by thermal shock.

(d) *Pressure processing with steam/air mixtures in batch retorts.* (1) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, bulb sheaths or probes for indicating temperature devices and temperature/time recording devices or controller probes shall be inserted directly into the retort shell in such a position that steam does not strike them directly.

(2) Steam controllers are required as described in paragraph (a)(3) of this section.

(3) *Recording pressure controller.* A recording pressure controller shall be used to control the air inlet and the steam/air mixture outlet.

(4) *Circulation of steam/air mixture.* A means shall be provided for the circulation of the steam/air mixture to prevent formation of low-temperature pockets. The efficiency of the circulation system shall be documented by heat distribution data or other documentation from a processing authority, and such data shall be maintained on file by the establishment and made available to Program employees for review. The circulation system shall be checked to ensure its proper functioning and shall be equipped with a pilot light or a similar device to warn the operator when it is not functioning. Because of the variety of existing designs, reference shall be made to the equipment

manufacturer for details of installation, operation and control.

(5) The Administrator shall be notified immediately by the official establishment of any such system in use or placed into use on or after the effective date of this rule.

(e) *Atmospheric cookers—(1) Temperature/time recording device.* Each atmospheric cooker (e.g., hot water bath) shall be equipped with at least one temperature/time recording device in accordance with the basic requirements described in paragraph (a)(2) of this section.

(2) *Heat distribution.* Each atmospheric cooker shall be equipped and operated to ensure uniform heat distribution throughout the processing system during the thermal process. Heat distribution data or other documentation from the manufacturer or a processing authority demonstrating uniform heat distribution within the cooker shall be kept on file by the establishment and made available to Program employees for review.

(f) *Other systems.* All other systems not specifically delineated in this section and used for the thermal processing of canned product will be evaluated on a case-by-case basis by the Administrator. Systems will be approved if they are found to conform to the applicable requirements of this section and to produce shelf stable products consistently and uniformly.

(g) *Equipment maintenance.* (1) Upon installation, all instrumentation and controls shall be checked by the establishment for proper functioning and accuracy and, thereafter, at any time their functioning or accuracy is suspect.

(2) At least once a year each thermal processing system shall be examined by an individual not directly involved in daily operations to ensure the proper functioning of the system as well as all auxiliary equipment and instrumentation. In addition, each thermal processing system should be examined before the resumption of operation following an extended shutdown.

(3) Air and water valves that are intended to be closed during thermal processing shall be checked by the establishment for leaks. Defective valves shall be repaired or replaced as needed.

(4) Vent and bleeder mufflers shall be checked and maintained or replaced by the establishment to prevent any reduction in vent or bleeder efficiency.

(5) When water spreaders are used for venting, a maintenance schedule shall be developed and implemented to

assure that the holes are maintained at their original size.

(6) Records shall be kept on all maintenance items that could affect the adequacy of the thermal process. Records shall include the date and type of maintenance performed and the person conducting the maintenance.

(h) *Container cooling and cooling water.* (1) Potable water shall be used for cooling except as provided for in paragraphs (h) (2) and (3), of this section.

(2) Cooling canal water shall be chlorinated or treated with a chemical approved by the Administrator as having a bactericidal effect equivalent to chlorination. There shall be a measurable residual of the sanitizer in the water at the discharge point of the canal. Cooling canals shall be cleaned and replenished with potable water to prevent the buildup of organic matter and other materials.

(3) Container cooling waters that are recycled or reused shall be handled in systems that are so designed, operated, and maintained so there is no buildup of microorganisms, organic matter, and other materials in the systems and in the waters. System equipment, such as pipelines, holding tanks and cooling towers, shall be constructed and installed so that they can be cleaned and inspected. In addition, the establishment shall maintain, and make available to Program employees for review, information on at least the following:

- (i) System design and construction;
- (ii) System operation including the rates of renewal with fresh, potable water and the means for treating the water so that there is a measurable residual of an acceptable sanitizer, per paragraph (h)(2) of this section, in the water at the point where the water exits the container cooling vessel;
- (iii) System maintenance including procedures for the periodic cleaning and sanitizing of the entire system; and
- (iv) Water quality standards, such as microbiological, chemical and physical, monitoring procedures including the frequency and site(s) of sampling, and the corrective actions taken when water quality standards are not met.

(i) *Post-process handling of containers.* Containers shall be handled in a manner that will prevent damage to the hermetic seal area. All worn and frayed belting, can retarders, cushions, and the like shall be replaced with nonporous materials. To minimize container abrasions, particularly in the seal area, containers should not remain stationary on moving conveyors. All post-process container handling equipment should be kept clean so there

is no buildup of microorganisms on surfaces in contact with the containers.

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§ 381.306 Processing and production records.

At least the following processing and production information shall be recorded by the establishment: date of production; product name and style; container code; container size and type; and the process schedule, including the minimum initial temperature. Measurements made to satisfy the requirements of § 381.303 regarding the control of critical factors shall be recorded. In addition, where applicable, the following information and data shall also be recorded:

(a) *Processing in steam—(1) Batch still retorts.* For each retort batch, record the retort number or other designation, the approximate number of containers or the number of retort crates per retort load, product initial temperature, time steam on, the time and temperature vent closed, the start of process timing, time steam off, and the actual processing time. The indicating temperature device and the temperature recorder shall be read at the same time at least once during process timing and the observed temperatures recorded.

(2) *Batch agitating retorts.* In addition to recording the information required for batch, still steam retorts in paragraph (a)(1) of this section, record the functioning of the condensate bleeder(s) and the retort or reel speed.

(3) *Continuous rotary retorts.* Record the retort system number, the approximate total number of containers retorted, product initial temperature, time steam on, the time and temperature vent closed, time process temperature reached, the time the first can enters and the time the last can exits the retort. The retort or reel speed shall be determined and recorded at intervals not to exceed 4 hours. Readings of the indicating temperature device(s) and temperature recorder(s) shall be made and recorded at the time the first container enters the retort and thereafter with sufficient frequency to ensure compliance with the process schedule. These observations should be made and recorded at intervals not exceeding 30 minutes of continuous retort operation. Functioning of the condensate bleeder(s) shall be observed and recorded at the time the first container enters the retort and thereafter as specified in § 381.305(b)(3)(v).

(4) *Hydrostatic retorts.* Record the retort system number, the approximate total number of containers retorted,

product initial temperature, time steam on, the time and temperature vent(s) closed, time process temperature reached, time first containers enter the retort, time last containers exit the retort, and, if specified in the process schedule, measurements of temperatures in the hydrostatic water legs. Readings of the temperature indicating device, which is located in the steam/water interface, and the temperature recording device shall be observed and the temperatures recorded at the time the first containers enter the steam dome. Thereafter, these instruments shall be read and the temperatures recorded with sufficient frequency to ensure compliance with the temperature specified in the process schedule and should be made at least every hour of continuous retort operation. Container conveyor speed, and for agitating hydrostatic retorts, the rotative chain speed, shall be determined and recorded at intervals of sufficient frequency to ensure compliance with the process schedule and should be performed at least every 4 hours.

(b) *Processing in water—(1) Batch still retorts.* For each retort batch, record the retort number or other designation, the approximate number of containers or number of retort crates per retort load, product initial temperature, time steam on, the start of process timing, water level, water recirculation rate (if critical), overriding pressure maintained, time steam off, and actual processing time. The indicating temperature device and the temperature recorder shall be read at the same time at least once during process timing and the observed temperatures recorded.

(2) *Batch agitating retorts.* In addition to recording the information required in paragraph (b)(1) of this section, record the retort or reel speed.

(c) *Processing in steam/air mixtures.* For each retort batch, record the retort number or other designation, the approximate number of containers or number of retort crates per retort load, product initial temperature, time steam on, venting procedure, if applicable, the start of process timing, maintenance of circulation of the steam/air mixture, air flow rate or forced recirculation flow rate (if critical), overriding pressure maintained, time steam off, and actual processing time. The indicating temperature device and the temperature recorder shall be read at the same time at least once during process timing and the observed temperatures recorded.

(d) *Atmospheric cookers—(1) Batch-type systems.* For each cooker batch, record the cooker number or other designation and the approximate

number of containers. In addition, record all critical factors of the process schedule such as cooker temperature, initial temperature, the time the thermal process cycle begins and ends, hold time, and the final internal product temperature.

(2) *Continuous-type systems.* Record the cooker number or other designation, the time the first containers enter and the last containers exit a cooker, and the approximate total number of containers processed. In addition, record all critical factors of the process schedule such as the initial temperature, cooker speed, and final internal product temperature.

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§ 318.307 Record review and maintenance.

(a) *Process records.* Charts from temperature/time recording devices shall be identified by production date, container code, processing vessel number or other designation and other data as necessary to enable correlation with the records required in § 381.306. Each entry on a record shall be made at the time the specific event occurs, and the recording individual shall sign or initial each record form. No later than 1 working day after the actual process, the establishment shall review all processing and production records to ensure completeness and to determine if all product received the process schedule. All records, including the temperature/time recorder charts and critical factor control records, shall be signed or initialed and dated by the person conducting the review. All processing and production records required in this subpart shall be made available to Program employees for review.

(b) *Automated process monitoring and recordkeeping.* When requested by an establishment, the Administrator will consider the approval of automated process monitoring and recordkeeping systems. An approved system, alone or in combination with written records, shall be designed and operated in a manner which will ensure compliance with the applicable requirements of § 381.306.

(c) *Container closure records.* Written records of all container closure examinations shall specify the container code, the date and time of container closure examination, the measurement(s) obtained, and any corrective actions taken. Records shall be signed or initialed by the container closure technician and shall be reviewed and signed by the establishment within 1 working day after the actual production to ensure

that the records are complete and that the closing operations have been properly controlled. All container closure examination records required in this subpart shall be made available to Program employees for review.

(d) *Distribution of product.* Records shall be maintained by the establishment identifying initial distribution of the finished product to facilitate, if necessary, the segregation of specific production lots that may have been contaminated or are otherwise unsound for their intended use.

(e) *Retention of records.* Copies of all processing and production records required in § 381.306 shall be retained for no less than 1 year at the establishment, and for an additional 2 years at the establishment or other location from which the records can be made available to Program employees within 3 working days.

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§ 381.308 Deviations in processing.

(a) Whenever the actual process is less than the process schedule or when any critical factor does not comply with the requirements for that factor as specified in the process schedule, it shall be considered a deviation in processing.

(b) Deviations in processing (or process deviations) shall be handled under an approved quality control program as provided in paragraph (c) of this section or shall be handled in accordance with paragraph (d) of this section.

(c) Any partial quality control program or any portion of a total quality control system for handling process deviations shall be prepared and submitted to the Administrator for approval in accordance with § 381.145.

(d) Handling process deviations without an approved quality control program.

(1) *Deviations identified in-process.* If a deviation is noted at any time before the completion of the intended process schedule, the establishment shall:

(i) Immediately reprocess the product using the full process schedule; or,

(ii) Use an appropriate alternate process schedule provided such a process schedule has been established in accordance with § 381.302 (a) and (b) and is filed with the inspector in accordance with § 381.302(c); or,

(iii) Hold the product involved and have the deviation evaluated by a processing authority to assess the safety and stability of the product. Upon completion of the evaluation, the establishment shall provide the inspector the following:

(a) A complete description of the deviation along with all necessary supporting documentation;

(b) A copy of the evaluation report; and,

(c) A description of any product disposition actions, either taken or proposed.

(iv) Product handled in accordance with paragraph (d)(1)(iii) of this section shall not be shipped from the establishment until the Program has reviewed all of the information submitted and approved the product disposition actions.

(v) If an alternate process schedule is used that is not on file with the inspector or if an alternate process schedule is immediately calculated and used, the product shall be set aside for further evaluation in accordance with paragraphs (d)(1) (iii) and (iv) of this section.

(vi) When a deviation occurs in a continuous rotary retort, the product shall be handled in accordance with paragraphs (d)(1) (iii) and (iv) of this section or in accordance with the following procedures:

(a) *Emergency stops.*

(1) When retort jams or breakdowns occur during the processing operations, all containers shall be given an emergency still process (developed per § 381.302(b)) before the retort is cooled or the retort shall be cooled promptly and all containers removed and either reprocessed, repacked and reprocessed, or destroyed. Regardless of the procedure used, containers in the retort intake valve and in transfer valves between retort shells at the time of a jam or breakdown shall be removed and either reprocessed, repacked and reprocessed, or destroyed. Product to be destroyed shall be handled as "U.S. Inspected and Condemned", as defined in § 301.2(ee) of this chapter, and disposed of in accordance with Part 314 of this chapter.

(2) The time the retort reel stopped and the time the retort is used for an emergency still retort process shall be noted on the temperature/time recording device and entered on the other production records required in § 381.306.

(b) *Temperature drops.* When the retort temperature drops below the temperature specified in the process schedule, the reel shall be stopped and the following actions shall be taken:

(1) For temperature drops of less than 10 °F (or 5.5 °C) either (i) all containers in the retort shall be given an emergency still process (developed per § 381.302(b)) before the reel is restarted; (ii) container entry to the retort shall be prevented and an emergency agitating process

(developed per § 381.302(b)) shall be used before container entry to the retort is restarted; or (iii) container entry to the retort shall be prevented and the reel restarted to empty the retort. The discharged containers shall be reprocessed, repacked and reprocessed, or destroyed. Product to be destroyed shall be handled as "U.S. Inspected and Condemned", as defined in § 301.2(ee) of this chapter, and disposed of in accordance with Part 314 of this chapter.

(2) For temperature drops of 10 °F (or 5.5 °C) or more, all containers in the retort shall be given an emergency still process (developed per § 381.302(b)). The time the reel was stopped and the time the retort was used for a still retort process shall be marked on the temperature/time recording device by the establishment and entered on the other production records required in § 381.306. Alternatively, container entry to the retort shall be prevented and the reel restarted to empty the retort. The discharged containers shall be either reprocessed, repacked and reprocessed, or destroyed. Product to be destroyed shall be handled as "U.S. Inspected and Condemned" as defined in § 301.2(ee) of this chapter, and disposed of in accordance with Part 314 of this chapter.

(2) *Deviations identified through record review.* Whenever a deviation is noted during review of the processing and production records required by § 381.307 (a) and (b), the establishment shall hold the product involved and the deviation shall be handled in accordance with paragraphs (d)(1) (iii) and (iv) of this section.

(e) *Process deviation file.* The establishment shall maintain full records regarding the handling of each deviation. Such records shall include, 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. Such records shall be maintained in a separate file or in a log that contains the appropriate information. The file or log shall be retained in accordance with § 381.307(e) and shall be made available to Program employees upon request.

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§ 381.309 Finished product inspection.

(a) Finished product inspections shall be handled under an approved quality control program as provided in paragraph (b) or paragraph (c) of this section or shall be handled in accordance with paragraph (d) of this section.

(b) Any partial quality control program designed to ensure compliance with the requirements of this section (or any part thereof) shall be prepared and submitted to the Administrator for approval in accordance with § 381.145 of this subchapter.

(c) A total quality control system prepared and submitted to the Administrator for approval in accordance with § 381.145 of this subchapter shall be designed to ensure compliance with the requirements of this section.

(d) Handling finished product inspections without an approved quality control program.

(1) *Incubation of shelf stable canned product.*—(i) *Incubator.* The establishment shall provide incubation facilities which include an accurate temperature/time recording device, an indicating temperature device, a means for the circulation of the air inside the incubator to prevent temperature variations, and a means to prevent unauthorized entry into the facility. The Program is responsible for the security of the incubator.

(ii) *Incubation temperature.* The incubation temperature shall be maintained at 95 ± 5 °F 35 ± 2.8 °C. If the incubation temperature falls below 90 °F (or 32 °C) or exceeds 100 °F (or 38 °C) but does not reach 103 °F (or 39.5 °C), the incubation temperature shall be adjusted within the required range and the incubation time extended for the time the sample containers were held at the deviant temperature. If the incubation temperature is at or above 103 °F (or 39.5 °C) for more than 2 hours, the incubation test(s) shall be terminated, the temperature lowered to within the required range, and new sample containers incubated for the required time.

(iii) *Product requiring incubation.* Shelf stable product requiring incubation includes:

(a) Low acid products as defined in § 381.300(m); and

(b) Acidified low acid products as defined in § 381.300(b).

(iv) *Incubation samples.* (a) From each load of product processed in a batch-type thermal processing system (still or agitation), the establishment shall select at least one container for incubation.

(b) For continuous rotary retorts, hydrostatic retorts, or other continuous-type thermal processing systems, the establishment shall select at least one container per 1,000 for incubation.

(c) Only normal-appearing containers shall be selected for incubation.

(v) *Incubation time.* Canned product requiring incubation shall be incubated for not less than 10 days (240 hours)

under the conditions specified in paragraph (d)(1)(ii) of this section.

(vi) *Incubation checks and record maintenance.* Designated establishment employees shall visually check all containers under incubation each working day and the inspector shall be notified when abnormal containers are detected. All abnormal containers should be allowed to cool before a final decision on their condition is made. For each incubation test the establishment shall record at least the product name, container size, container code, number of containers incubated, in and out dates, and incubation results. The establishment shall retain such records, along with copies of the temperature/time recording charts, in accordance with § 381.307(e).

(vii) *Abnormal containers.* The finding of abnormal containers (as defined in § 381.300(a)) among incubation samples is cause to officially retain at least the code lot involved.

(viii) *Shipping.* No product shall be shipped from the establishment before the end of the required incubation period except as provided in this paragraph. An establishment wishing to ship product prior to the completion of the required incubation period shall submit a written proposal to the area supervisor. Such a proposal shall include provisions that will assure that shipped product will not reach the retail level of distribution before sample incubation is completed and that product can be returned promptly to the establishment should such action be deemed necessary by the incubation test results. Upon receipt of written approval from the area supervisor, product may be routinely shipped provided the establishment continues to comply with all requirements of this subpart.

(2) *Container condition.* (i) *Normal containers.* Only normal-appearing containers shall be shipped from an establishment as determined by an appropriate sampling plan or other means acceptable to Program employees.

(ii) *Abnormal containers.* When abnormal containers are detected by any means other than incubation, the establishment shall inform the inspector and the affected code lot(s) shall not be shipped until the Program has determined that the product is safe and stable. Such a determination will take into account the cause and level of abnormalities in the affected lot(s) as well as any product disposition actions either taken or proposed by the establishment.

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§ 381.310 Personnel and training.

All operators of thermal processing systems specified in § 381.305 and container closure technicians shall be 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.

§ 381.311 Recall procedure.

Establishments shall prepare and maintain a current procedure for the recall of all canned product covered by this subpart. Upon request, the recall procedure shall be made available to Program employees for review.

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Done at Washington, DC, on: September 19, 1986.

Donald L. Houston,

Administrator, Food Safety and Inspection Service.

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