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NATIONAL ARCHIVES AND RECORDS ADMINISTRATION
LITTERA SCRIPTA MANET
1985

FEDERAL REGISTER

Vol. 76 Thursday,
No. 42 March 3, 2011

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 113
Temperature-Indicating Devices; Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 113

[Docket No. FDA–2007–N–0265; Formerly Docket No. 2007P–0026]

Temperature-Indicating Devices; Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations for thermally processed low-acid foods packaged in hermetically sealed containers to allow for use of other temperature-indicating devices, in addition to mercury-in-glass thermometers, during processing. This final rule also establishes recordkeeping requirements relating to temperature-indicating devices and reference devices maintained by the processor and allows for the use of advanced technology for measuring and recording temperatures during processing. Finally, this final rule includes metric equivalents of avoirdupois (U.S.) measurements where appropriate. This final rule will allow low-acid canned food processors to transition from mercury-in-glass thermometers to alternative temperature-indicating devices. Use of temperature-indicating devices that do not contain mercury will eliminate concerns about potential contamination of the food or the processing environment from broken mercury-in-glass thermometers. Elsewhere in this issue of the **Federal Register**, FDA is publishing a 30-day notice announcing that it has submitted the information collection provisions of this final rule to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA). The notice also invites the public to submit comments on the information provisions to OMB. Prior to the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions of the final rule.

DATES: This final rule is effective March 5, 2012.

FOR FURTHER INFORMATION CONTACT: Mischelle B. Ledet, Center for Food Safety and Applied Nutrition (HFS–615), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2070.

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I. Background

In the **Federal Register** of March 14, 2007 (72 FR 11990), FDA published a proposed rule entitled "Temperature-Indicating Devices; Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers" (the proposed rule). We proposed to revise § 113.40 (21 CFR 113.40) to provide for use of temperature-indicating devices that accurately indicate the temperature during processing. We proposed that temperature-indicating devices shall be tested for accuracy against an accurate calibrated reference device upon installation and at least once a year thereafter, or more frequently if necessary, to ensure accuracy during processing. We also proposed that the design of the temperature-indicating device shall ensure that the accuracy of the device is not affected by electromagnetic interference and environmental conditions.

We proposed to require that each temperature-indicating device have a tag, seal, or other means of identity that will be used by the processor to identify the temperature-indicating device, and that each reference device have a tag, seal, or other means of identity that will be used by the processor to identify the reference device. We proposed the establishment and maintenance of written records to document the accuracy for each temperature-indicating device and each reference or standard device.

We also proposed to provide for the use of metric equivalents of avoirdupois (U.S.) measurements for temperature-indicating devices, to provide for use of temperature-recording devices that create analog, graphical, or digital recordings, and to clarify various operational and record requirements of the regulations.

In the preamble to the proposed rule, FDA stated that, pending issuance of a final rule, we intended to consider the exercise of our enforcement discretion on a case-by-case basis when processors of low-acid canned food elect to replace mercury-in-glass thermometers with alternative temperature-indicating devices in a manner that was consistent with the proposed rule (72 FR 11990 at 11999, March 14, 2007). The Federal Food, Drug, and Cosmetic Act's (the FD&C Act) enforcement provisions commit complete discretion to the Secretary of Health and Human Services (and by delegation to FDA) to decide how and when they should be exercised (*see Heckler* v. *Chaney,* 470 U.S. 821, 835 (1985); *see also Schering Corp.* v. *Heckler,* 779 F.2d 683, 685–86 (DC Cir. 1985) (stating that the provisions of the act "authorize, but do not compel FDA to undertake enforcement activity")). FDA will continue to consider the exercise of our enforcement discretion on a case-by-case basis when processors of low-acid canned food elect to replace mercury-in-glass thermometers with alternative temperature-indicating devices in a manner that is consistent with the proposed rule until the effective date of the final rule. In addition, we will consider the exercise of our enforcement discretion on a case-by-case basis for processors who comply with the provisions of this final rule prior to the effective date. All low-acid canned food processors must comply with the requirements of this final rule on and after the effective date.

II. Comments on the Proposed Rule

FDA received six letters, each containing one or more comments, to the proposed rule. The comments were from industry, a trade association, and individuals. Most of the letters generally supported the proposed rule, but provided some comments that suggested modifications to the proposed rule. Some of the comments addressed issues outside the scope of this rulemaking and will not be addressed in this document. A summary of the comments and FDA's responses follows.

(Comment 1) One comment requested that the effective date of this final rule be not less than 1 year from the date of publication. The comment indicated that companies that are continuing to use mercury-in-glass thermometers will need time to comply with the additional recordkeeping requirements for accuracy checks. Furthermore, companies with existing water retorts will need at least 1 year to comply with the additional equipment requirements of the regulation. The comment also indicated that firms that currently reprocess products or rework previously processed product into a new formulation need at least 1 year to review existing process schedules and conduct confirmatory testing if necessary, to comply with § 113.83 (21 CFR 113.83).

(Response) We agree with the comment's request to allow 1 year for processors to comply with recordkeeping requirements relating to use of mercury-in-glass thermometers and to other requirements relating to temperature-indicating devices established in this final rule. Thus, the effective date of this final rule is 1 year from the date of publication in the **Federal Register**. However, FDA does not agree with the comment's suggestion that processors need a year to comply with § 113.83 for reprocessed or reworked product. As discussed in our response to comment 38, although we clarified the requirements in final § 113.83, we did not propose new requirements for reprocessed or reworked products in the proposed rule or establish new requirements for reprocessed or reworked products in this final rule.

(Comment 2) One comment recommended defining the term "temperature-indicating device" as the entire system, including the sensor(s) and the temperature-indicating device display. The comment noted that separate references to the "temperature-indicating device" and the "sensor of the temperature-indicating device" could be interpreted to mean that the sensor is not part of the temperature-indicating device and thus does not have to be calibrated. The comment suggested using the term "temperature-indicating device display" to refer to the electronics/display portion only and to define "temperature-indicating device" to mean the entire system.

(Response) We agree that the term "temperature-indicating device" includes the temperature-indicating device sensor and the temperature-indicating device display. Accordingly, we revised the proposed requirements to clarify that each temperature-indicating device must have a sensor and a display (final § 113.40(a)(1), (b)(1), (c)(1), (d)(1), (e)(1), (f)(1), and (g)(1)(i)(A)). As appropriate, we replaced the terms "sensors of temperature-indicating devices" and "sensor of the temperature-indicating device" with "temperature-indicating device sensor" (final § 113.40(a)(1)(v), (b)(1)(v), (c)(1)(v), (d)(1)(v), and (e)(1)(v)). In final § 113.40(f)(1)(v), we clarified that the temperature-indicating device sensor, rather than the temperature-indicating device, must be located in the steam dome near the steam water interface or, when applicable, in each hydrostatic water leg.

Although the comment did not request similar clarification for temperature-recording devices, in this final rule we also clarified that each temperature-recording device must have a sensor and a mechanism for recording temperatures to a permanent record, such as a temperature-recording chart (final § 113.40(a)(2), (b)(2), (c)(2), (d)(2), (e)(2), (f)(2), and (g)(1)(i)(B)).

(Comment 3) One comment indicated that the mercury-in-glass thermometer originally was used for three important reasons, *i.e.,* permanent accuracy, no drift over time, and reliability. According to the comment, reliability means "it works or it doesn't work and you know when it doesn't work." The comment suggested that these factors should be characteristics of any alternative temperature-indicating device. Another comment suggested revising proposed § 113.40(a)(1) to require alternative temperature-indicating devices to meet or exceed the accuracy and reliability of mercury-in-glass thermometers.

(Response) The Agency recognizes that accuracy, drift, and reliability are important considerations for any temperature-indicating device. However, the comment does not specify any unique problems that may be associated with these factors that were not addressed by the proposed codified language. Thus, the Agency is not making any changes to the proposed codified in response to this comment.

The comment's reference to "permanent accuracy" is not clear. Perpetual and unfailing accuracy cannot be guaranteed for any temperature-indicating device, including mercury-in-glass thermometers. Each temperature-indicating device must be tested for accuracy, as required in final § 113.40(a)(1), (b)(1), (c)(1), (d)(1), (e)(1), (f)(1), and (g)(1)(i)(A) of this final rule. A temperature-indicating device that is defective or cannot be adjusted to the accurate calibrated reference device must be repaired before further use or replaced (final § 113.40(a)(1)(iii), (b)(1)(iii), (c)(1)(iii), (d)(1)(iii), (e)(1)(iii), (f)(1)(iii), and (g)(1)(i)(A)(*3*)).

We use the terms "accurate" and "accuracy" in this final rule to refer to "measurement accuracy." Measurement accuracy is defined in the International Vocabulary of Metrology as "closeness of agreement between a measured quantity value and a true quantity value of a measurand" (Ref. 1). For a temperature-indicating device, the temperature shown on the display is the "measured quantity value" and the actual or true temperature is the "true quantity value." As discussed in our response to Comment 9, this final rule provides that the measurement accuracy for a temperature-indicating device must be within 1 °F (0.5 °C) of the true quantity value, *i.e.,* the temperature-indicating device must be accurate to 1 °F (0.5 °C) (final § 113.40(a)(1)(iv), (b)(1)(iv), (c)(1)(iv), (d)(1)(iv), (e)(1)(iv), (f)(1)(iv), and (g)(1)(i)(A)(*4*)).

We agree that "drift over time" is a factor that must be considered to assure that the temperature-indicating device is accurate during processing. However, because an absolute requirement for no drift over time may prevent use of an otherwise appropriate temperature-indicating device, we do not agree that this characteristic should be specified in this final rule. We believe the requirement of this final rule for the temperature-indicating device to be accurate encompasses considerations relating to drift. If the accuracy of the temperature-indicating device may be affected by drift, it is our expectation that an appropriate calibration interval (*i.e.,* more frequently than once per year) or other appropriate mechanism will be established by the processor to ensure that the temperature-indicating device is accurate during processing.

The reliability of a temperature-indicating device is determined based on evaluation of past performance of the specific temperature-indicating device or similar temperature-indicating devices. Past performance may be used as an indicator, but not as an absolute guarantee or predictor, of future performance. Although we agree that warranties and predictions of reliability are important considerations for processors when choosing a temperature-indicating device, they do not ensure accuracy during processing or alleviate the processors' responsibility to ensure that the temperature-indicating device provides an accurate temperature reading during processing (final § 113.40(a)(1), (b)(1), (c)(1), (d)(1), (e)(1), (f)(1), and (g)(1)(i)(A)). A temperature-indicating device that does not accurately indicate the temperature during processing does not comply with the requirements of this final rule.

We believe that the requirement in this final rule for the temperature-indicating device to accurately indicate the temperature during processing (final § 113.40(a)(1), (b)(1), (c)(1), (d)(1), (e)(1), (f)(1), and (g)(1)(i)(A) is adequate to ensure the accuracy and reliability of the temperature-indicating device, and that it is not necessary to revise the regulation to require that alternate temperature-indicating devices meet or exceed the accuracy and reliability of mercury-in-glass thermometers, as suggested by the comment.

(Comment 4) One comment recommended revising proposed § 113.40(a)(1) to require temperature-indicating devices to be tested for

accuracy against a reference device for which the accuracy is traceable to a National Institute of Standards and Technology (NIST), or equivalent, standard reference device.

(Response) We agree with the comment. We revised the applicable proposed requirements to clarify that each temperature-indicating device and each reference device that is maintained by the processor must be tested for accuracy against a reference device for which the accuracy is traceable to a NIST, or other national metrology institute, standard reference device (final § 113.40(a)(1), (b)(1), (c)(1), (d)(1), (e)(1), (f)(1), and (g)(1)(i)(A)). The term "reference device maintained by the processor" refers to the reference device used by a processor who performs the accuracy tests at the processor's own facility or facility laboratory. For such reference device, the processor, rather than a third party laboratory, is responsible for ensuring accuracy of the reference device when it is used for the accuracy test and for ensuring that its accuracy is traceable to a NIST, or other national metrology institute, standard reference device. The term "traceable" refers to "metrological traceability," which is defined in the International Vocabulary of Metrology as the "property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty" (Ref. 2). "Measurement result" is defined as a "set of quantity values being attributed to a measurand together with any other available relevant information" (Ref. 3) and "measurement uncertainty" is defined as "the non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used" (Ref. 4).

This final rule also clarifies that the record of the accuracy test for a temperature-indicating device or a reference device maintained by the processor must include documentation of the traceability of the accuracy of the reference device to a NIST, or other national metrology institute, standard reference device (final § 113.100(c) and (d) (21 CFR 113.100(c) and (d))). For an accuracy test performed by the processor and, thus, for which the processor maintains the reference device, the documentation of traceability must be a guarantee, certificate of accuracy, certificate of calibration, or other document from the manufacturer or other source of the reference device. For an accuracy test performed by an outside facility, the documentation of traceability must be a guarantee, certificate of accuracy, certificate of calibration, or other document from the facility that includes a statement or other documentation regarding the traceability of the accuracy to a NIST, or other national metrology institute, standard reference device.

The information required to be included in the records of accuracy for temperature-indicating devices and reference devices was set forth in proposed § 113.40(a)(1)(ii), (b)(1)(ii), (c)(1)(ii), (d)(1)(ii), (e)(1)(ii), (f)(1)(ii), and (g)(1)(i)(A)(*2*). To eliminate redundancy, we moved the information requirements for the records of accuracy for temperature-indicating devices and reference devices maintained by the processor from each of these sections to final § 113.100(c) and (d) of Subpart F—Records and Reports. We redesignated proposed § 113.100(c), (d), and (e), as final § 113.100(e), (f), and (g), respectively. We also revised proposed § 113.87(c) (21 CFR 113.87(c)) to clarify that the records of accuracy tests for temperature-indicating devices used to determine the initial product temperature and reference devices maintained by the processor must be maintained in accordance with § 113.100(c) and (d).

(Comment 5) One comment expressed concern about the proposed requirement that the design of the temperature-indicating device ensure that the accuracy of the device is not affected by electromagnetic interference and environmental conditions (proposed § 113.40(a)(1)(i), (b)(1)(i), (c)(1)(i), (d)(1)(i), (e)(1)(i), (f)(1)(i), and (g)(1)(i)(A)(*1*)). According to the comment, the proposed language focuses on only a few of the considerations that a processor must take into account when selecting a temperature-indicating device and the considerations in the proposed language may not be applicable to future temperature-indicating technologies. The comment pointed out that a temperature-indicating device that is very robust in terms of the electromagnetic interference and environmental conditions could provide unreliable temperature readings because of other aspects of the design and installation. However, a temperature-indicating device that is less robust in terms of electromagnetic interference and environmental conditions could provide reliable and accurate readings due to good design and installation practices. The comment stated that the end goal of any temperature-indicating device is reliable and accurate readings. The comment suggested that it would be more effective to state that: "The design, installation, and operation of the temperature-indicating device shall be such that the accuracy and reliability of the device is ensured."

(Response) We do not agree that the language recommended by the comment provides clarity or value to the regulation. The requirements in the regulation for the temperature-indicating device to be accurate upon installation and during processing (final § 113.40(a)(1), (b)(1), (c)(1), (d)(1), (e)(1), (f)(1), and (g)(1)(i)(A)) encompass design, installation, operation, and reliability considerations traditionally associated with mercury-in-glass thermometers and that must be considered for other temperature-indicating devices. However, we believe it is necessary to emphasize in this final rule that the design of the temperature-indicating device must assure that accuracy is not affected by electromagnetic interference and environmental conditions because these factors are not traditionally associated with mercury-in-glass thermometers. As discussed in the preamble to the proposed final rule, although electromagnetic energy does not affect the accuracy of mercury-in-glass thermometers, temperature-indicating devices with electronic or electromagnetic components are vulnerable to electromagnetic interference. Electromagnetic energy may vary in the area where a temperature-indicating device is located as electronics are turned on and off, introduced into, and removed from the area. Electromagnetic energy exposure may also vary when a temperature-indicating device is moved from one location to another, *e.g.,* from one retort to another. Thus, unlike a mercury-in-glass thermometer, a temperature-indicating device that may be affected by electromagnetic energy must be designed based on consideration of that factor, *i.e.,* the temperature-indicating device must be designed to ensure that its accuracy during processing is not compromised by exposure to electronics that generate or cause fluctuations in electromagnetic energy. Similarly, some environmental conditions, such as humidity, vibrations, and air pressure, that do not affect the accuracy or performance of mercury-in-glass thermometers must be considered and addressed in the design of other temperature-indicating devices.

(Comment 6) One comment objected to the proposed requirement that the design of the temperature-indicating device ensure that accuracy is not affected by environmental conditions because it does not clearly state which

environmental conditions are important and which are not (proposed § 113.40(a)(1)(i), (b)(1)(i), (c)(1)(i), (d)(1)(i), (e)(1)(i), (f)(1)(i), and (g)(1)(i)(A)(*1*)). The comment expressed concern that some important environmental factors may not be adequately considered. The comment noted that there is a difference between environmental considerations for mechanical and electronic instruments. According to the comment, moisture is an important environmental concern with electronic instruments. The comment noted that condensation on a computer board or wiring terminals can be detrimental to making a measurement and can cause errors. The comment suggested requiring the use of temperature-indicating devices with an Ingress Protection code suitable for the environment. The comment also indicated concern about ambient temperature and vibration, either or both of which may affect some electronic and mechanical technologies. According to the comment, the ambient temperature coefficient, which is usually expressed as degrees of error per degree of change from a specified ambient temperature, may not be specified for some temperature-indicating devices. The comment expressed concern that most users will not have the ability to evaluate the impact of ambient temperature and may not be aware that the ambient temperature coefficient is important. The comment emphasized that design and installation are essential components in vibration resistance.

(Response) Processors are responsible for ensuring that environmental factors, including those expressed in the comment, are adequately considered. Processors must use temperature-indicating devices appropriate for the processing environment and take appropriate steps to evaluate environmental factors that may affect the accuracy of the temperature-indicating device. Processors who do not have specific expertise for evaluating the effect of environmental factors on temperature-indicating devices may need to obtain advice from a thermometry expert or obtain a manufacturer's guaranty or warranty regarding use of a specific temperature-indicating device in their specific food processing environment.

(Comment 7) One comment requested clarification of proposed § 113.40(a)(1)(i), which requires that the design of the temperature-indicating device ensure that the accuracy of the device is not affected by electromagnetic interference and environmental conditions. The comment questioned whether mechanical thermometers are exempt from this requirement. The comment stated that most processors will have no way to determine the effects of electromagnetic interference on an electronic thermometer design. The comment suggested that the regulation should state that temperature-indicating devices should comply with an electromagnetic interference standard that is current at the time they are designed. According to the comment, this would eliminate issues associated with changes to standards that make existing temperature-indicating devices noncompliant. The comment suggested that temperature-indicating devices should comply with the European standards EN 61326–1:2006 Electrical equipment for measurement, control and laboratory use; EN 61000–4–2 Personnel Electrostatic Discharge Immunity; EN 61000–4–3 Electromagnetic compatibility (EMC); and EN 61000–4–6 Conducted disturbances immunity.

(Response) This final rule does not exempt mechanical thermometers, *e.g.,* mercury-in-glass thermometers, from the requirement that the design ensure that accuracy is not affected by electromagnetic interference and environmental conditions. However, although the accuracy of mechanical thermometers may be affected by environmental conditions, they generally are not susceptible to the affects of electromagnetic interference as are electronic devices.

FDA is providing flexibility to processors with respect to this requirement and is not limiting processors to specific standards with which they must comply. Processors, in conjunction with temperature-indicating device manufacturers and appropriate thermometry experts, should ensure that the temperature-indicating devices that processors use are accurate during processing. A processor may elect to use an appropriate electronic standard, such as those established by the European Union, to ensure compliance with final § 113.40(a)(1)(i), (b)(1)(i), (c)(1)(i), (d)(1)(i), (e)(1)(i), (f)(1)(i), and (g)(1)(i)(A)(*1*).

(Comment 8) One comment stated that electronic thermometers are not capable of communicating that there is an accuracy problem. The comment stated that it is risky to rely on the history of calibration to prove an instrument's accuracy because the temperature-indicating device may perform properly for years and then fail without warning. The comment pointed out that a failure that occurs between calibration cycles may not be detected for a significant period of time. The comment suggested that additional features are needed to ensure that a temperature-indicating device retains its accuracy, will not drift, and will report any potential errors. The comment indicated that a system with internal diagnostics and error reporting to the operator would be one way of providing this evidence. The comment suggested that FDA require that an electronic temperature-indicating device incorporate technology to alert the operator of measurement errors.

(Response) Processors must ensure that temperature-indicating devices are accurate during processing (final § 113.40(a)(1), (b)(1), (c)(1), (d)(1), (e)(1), (f)(1), and (g)(1)(i)(A)). Processors must test the temperature-indicating device for accuracy upon installation and at least once per year thereafter, or more frequently if necessary, to ensure accuracy (emphasis added) (*see, e.g.,* final § 113.40(a)(1)). These requirements for accuracy for all temperature-indicating devices make it unnecessary for this final rule to require specific mechanisms to alert the operator of measurement errors. Processors should adopt whatever features or systems are appropriate to ensure the accuracy of a given temperature-indicating device, and to detect defects or failures that may cause a temperature-indicating device to be inaccurate. For mercury-in-glass thermometers, the process for detecting failure may include periodic visual examinations and appropriate followup based on findings of defects or potential for failure. Electronic devices may have hardware and software components with built-in diagnostic and alarm features. Processors also may use backup or duplicate devices to detect defects or failures. In addition, when adjustments are made to the temperature-recording device so that it agrees as nearly as possible with, but to be in no event higher than, the temperature-indicating device during the process time, as required by this regulation (final § 113.40(a)(2)(iii), (b)(2)(iii), (c)(2)(iii), (d)(2)(iii), (e)(2)(iii), (f)(2)(iii), and (g)(1)(i)(B)(*3*)), the need for such adjustment may be used as a signal for determining whether a temperature-indicating device failure occurred. Thus, features or systems for ensuring accuracy or for detecting inaccuracies may be different for different types of temperature-indicating devices, as well as subject to technological advancements that we may not anticipate at this time. To ensure processors have flexibility to adopt future technologies to detect

defects or failures of temperature-indicating devices, we have not required in this final rule specific features or systems to detect such defects or failures.

(Comment 9) One comment expressed concern that the proposed rule did not mention measurement uncertainties or test accuracy ratio, which are essential parameters for assuring an accurate calibration that are specified in standards issued by the American National Standards Institute (ANSI) and the International Organization for Standardization (ISO) for certification of calibration laboratories. The comment stated that the ANSI and ISO standards provide a limit for measurement uncertainty and establish a minimum test accuracy ratio that is commonly used by calibration facilities. According to the comment, although the proposed rule requires use of a calibrated accurate reference device, the lack of specific calibration parameters may lead to inaccurate calibrations for temperature-indicating devices.

(Response) Measurement uncertainty is inherent in the proposed requirement that the temperature-indicating device be easily readable to 1 °F (0.5 °C), (*i.e.,* the dispersion of the quantity values for the temperature must be within 1 °F (0.5 °C) of the actual temperature) (proposed § 113.40(a)(1)(iv), (b)(1)(iv), (c)(1)(iv), (d)(1)(iv), (e)(1)(iv), (f)(1)(iv), and (g)(1)(i)(A)(*4*)). However, we acknowledge that the term "easily readable" is readily understood for a mercury-in-glass thermometer, which has a visible scale of temperature gradations, but it may not be clear for other temperature-indicating devices, such as those that display a digital reading of the temperature. Therefore, we removed the term "easily readable" and clarified in this final rule that a temperature-indicating device must be accurate to 1 °F (0.5 °C) (final § 113.40(a)(1)(iv), (b)(1)(iv), (c)(1)(iv), (d)(1)(iv), (e)(1)(iv), (f)(1)(iv), and (g)(1)(i)(A)(*4*)).

We do not agree that the regulations should specify calibration parameters, such as those relating to measurement uncertainties or test accuracy ratio, or require use of specific calibration standards, such as the ANSI and ISO standards suggested by the comment. Metrology authorities, in addition to ANSI and ISO, issue calibration standards, which may be revised or replaced. It would be impractical for FDA to maintain in the regulations a current list of acceptable calibration standards. Processors are responsible for ensuring that the temperature-indicating device is accurate during processing and for testing each temperature-indicating device for accuracy against a reference device for which the accuracy is traceable to a NIST, or other national metrology institute, standard reference device by appropriate standard procedures, upon installation and at least once a year thereafter, or more frequently if necessary (final § 113.40(a)(1), (b)(1), (c)(1), (d)(1), (e)(1), (f)(1), and (g)(1)(i)(A)). Thus, processors are responsible for ensuring that accuracy tests are performed by appropriate standard procedures or by calibration facilities that use appropriate standard procedures.

(Comment 10) One comment recommended revising proposed § 113.40(a)(1) to clarify that the identity of each temperature-indicating device and reference device must be "unique."

(Response) We do not agree that the term "unique" is necessary because each temperature-indicating device and each reference device that is maintained by the processor must have a tag, seal, or other means of identity (final § 113.40(a)(1), (b)(1), (c)(1), (d)(1), (e)(1), (f)(1), and (g)(1)(i)(A)). The purpose of a tag, seal, or other means of identity is, in part, to uniquely identify each temperature-indicating device and each reference device that is maintained by the processor so that one temperature-indicating or reference device can be distinguished from another and so that appropriate records can be associated with each temperature-indicating device or reference device.

(Comment 11) One comment expressed concern about the information required in proposed § 113.40(a)(1)(ii)(A) and (a)(1)(ii)(B) for documentation of accuracy of temperature-indicating devices and reference devices. The comment suggested that the final rule should instead require documentation that conforms to the standards established by the American National Standards Institute, National Conference of Standards Laboratories (ANSI/NCSL) or the International Organization for Standardization, International Electrotechnical Commission (ISO/IEC) for accrediting calibration laboratories. The comment stated that the laboratory accreditation standards indicate acceptable reporting practices. The comment acknowledged that the standards may be too prescriptive for food processors who perform their own calibrations.

(Response) We do not agree that the regulation should require the documentation of accuracy of temperature-indicating devices and reference devices to conform to the standards specified in the comment for accrediting calibration laboratories. Although FDA supports use of accredited calibration laboratories and recognizes that the laboratories must maintain certain documentation for the accreditation, the records required by this final rule are appropriately limited to those necessary to document that the temperature-indicating device was tested for accuracy at sufficient frequency to ensure accuracy during processing. As acknowledged by the comment, a requirement for processors to adhere to accreditation standards would impose an unnecessary burden on those who successfully perform their own calibrations but are not accredited by ANSI/NCSL or ISO/IEC.

(Comment 12) One comment recommended revising proposed § 113.40(a)(1)(ii)(A) and (a)(1)(ii)(B) to require that documentation of the results of the accuracy test include before and after data, *i.e.,* the temperature reading of the temperature-indicating device compared to the accurate calibrated reference device, before and after the calibration. The comment indicated that the before data is needed because it is the basis for determining whether the device was accurate at the time of calibration and for documenting any adjustment that was made.

(Response) Proposed § 113.40(a)(1)(ii)(A) and (a)(1)(ii)(B) require that the results of each accuracy test be documented. Although not explicitly stated in the proposed rule, we would expect documentation of the results of the accuracy test to include information about the amount of calibration adjustment that was necessary. The "before and after data" suggested by the comment would be reflected in the amount of calibration adjustment. The amount of calibration adjustment is an indication of whether the temperature-indicating device was accurate at the time of the calibration. If an adjustment is required, the processor should evaluate the need for more frequent accuracy tests and also determine whether food processed prior to the adjustment is under processed. To provide clarity in the regulation regarding the requirement to record the amount of calibration adjustment that was necessary for a temperature-indicating device, we are revising final § 113.100 "Processing and production records" to indicate that the record of each accuracy test for each temperature-indicating device and for each reference device that is maintained by the processor must include the results of each accuracy test, including the amount of calibration adjustment (final § 113.100(c)(5) and (d)(5)).

Other information relating to the results of the accuracy test that should be recorded when it is relevant includes information about the condition of the temperature-indicating device (*i.e.,* intact or broken mercury column, worn or broken components) and disposition of the temperature-indicating device if it cannot be calibrated (*i.e.,* destroyed, repaired, or replaced).

(Comment 13) One comment addressed the proposed requirement that records of the accuracy test for the temperature-indicating device include the date of the next scheduled accuracy test (proposed § 113.40(a)(1)(ii)(A), (b)(1)(ii)(A), (c)(1)(ii)(A), (d)(1)(ii)(A), (e)(1)(ii)(A), (f)(1)(ii)(A), and (g)(1)(i)(A)(*2*)(*i*)). One comment interpreted this requirement to imply that the test must be conducted on that specific date. The comment suggested removing the requirement or changing the language to "the date of the calibration expiration."

(Response) We acknowledge that the proposed requirement concerning the date of the next scheduled accuracy test may be misinterpreted to mean that the next accuracy test must be conducted on that specific date. However, we do not agree that the revised language recommended by the comment, *i.e.,* the date of the calibration expiration, adequately clarifies that the next accuracy test must be conducted on or before the specified date. In this final rule, we require that the record of accuracy for a temperature-indicating device and a reference device maintained by the processor include the date on or before which the next accuracy test must be performed (final § 113.100(c)(6) and (d)(6)).

(Comment 14) One comment recommended placing on each temperature-indicating device a calibration sticker that indicates the date of the last calibration and the date the next calibration is due. According to the comment, the calibration standard ISO/IEC 17025 does not require the calibration due date to be recorded on the certificate issued by the calibration facility, which may have no knowledge of the calibration interval for the specific device.

(Response) We recognize that outside calibration facilities are not responsible for determining the frequency of the accuracy tests for temperature-indicating devices and, thus, are not required to record the frequency on a calibration certificate. We do not agree with the comment's recommendation to require a sticker on each temperature-indicating device with the date of the last calibration and date the next calibration is due. Although we do not object to processors using stickers or similar mechanisms on temperature-indicating devices to emphasize when the next accuracy test for a temperature-indicating device must be performed, we consider it sufficient to require that information relating to the accuracy test, such as the date on or before which the next accuracy test must be performed, be included in the processor's records of the accuracy test (final § 113.100(c)).

(Comment 15) One comment questioned why the documentation requirements for accuracy tests in proposed § 113.40(a)(1)(ii)(B) apply to reference devices. The comment pointed out that the reference device may be located in a third party calibration laboratory.

(Response) Accuracy tests for temperature-indicating devices may be performed by the processor or by a third party calibration laboratory. Processors who perform their own accuracy test must ensure that the reference device they use is accurate and must maintain records to document that accuracy. In this final rule, we clarify that the required records of the accuracy tests for reference devices are for reference devices maintained by the processor (final §§ 113.40(a)(1), (b)(1), (c)(1), (d)(1), (e)(1), (f)(1), and (g)(1)(i)(A), 113.87(c), and 113.100(d)).

(Comment 16) One comment recommended that processors be required to implement a method or process for identifying when a temperature-indicating device needs to be calibrated. The comment pointed out that inexpensive software packages are readily available for this purpose.

(Response) We recognize that processors may desire to establish a system to prompt them when scheduled activities, such as calibrations, need to be performed. Although available software may be appropriate for that purpose, we do not agree that the regulations should require processors to develop or use existing software or any other specific method or system to identify when a temperature-indicating device needs to be calibrated. Processors must test temperature-indicating devices for accuracy upon installation and at least once a year thereafter, or more frequently if necessary (final § 113.40(a)(1), (b)(1), (c)(1), (d)(1), (e)(1), (f)(1), and (g)(1)(i)(A)). The appropriate frequency for the accuracy test should be determined based on previous accuracy test results, evidence of damage, and other factors or situations that cause the accuracy of the temperature-indicating device to be questionable.

(Comment 17) One comment objected to the preamble statement, "FDA recommends, but is not proposing to require, a dual probe design." (72 FR 11989 at 11993). According to the comment, FDA's recommendation for a dual probe design will lead companies to purchase a dual probe unit to reduce any potential conflict with FDA. The comment stated that the dual probe design is a patented technology and other designs or mechanisms may be used for detecting malfunctions.

(Response) In the preamble to the proposed rule, FDA stated, "The design of the mercury-in-glass thermometer makes it relatively easy to detect a malfunction, including those caused by environmental conditions, because most are associated with a broken thermometer, separated column, or scale slippage. However, malfunction of other temperature-indicating devices may need to be detected by means other than observation. For example, a temperature-indicating device could be designed with a dual probe sensor that would enable detection of loss of accuracy of one of the probes when the probe readings do not agree. FDA recommends, but is not proposing to require, a dual probe design. FDA recognizes that specific design specifications for temperature-indicating devices may limit the flexibility of the regulation for current and future technologies" (72 FR 11990 at 11993). Thus, in the preamble to the proposed rule, we discussed a dual probe sensor as one means to detect a malfunction of a temperature-indicating device. We agree that a dual probe sensor is not the only design, mechanism, or process that may help detect temperature-indicating device failures. Therefore, this final rule does not require a dual probe design to detect malfunctions or failures of a temperature-indicating device.

(Comment 18) One comment objected to the requirement for "written documentation," found in proposed §§ 113.40(a)(1)(ii), (b)(1)(ii), (c)(1)(ii), (d)(1)(ii), (e)(1)(ii), (f)(1)(ii), and (g)(1)(i)(A)(*2*). The comment indicated that the term "written" implies hand-written documentation and will limit new documentation technologies. The comment stated that the term "written" should be removed to allow for means of documentation other than just written records, especially since the Agency proposed in § 113.100(f) to allow electronic records. The comment also stated that the term "written" should be removed from other sections of the regulations that apply to records.

(Response) We do not agree that the term "written" implies that the documents are hand-written. Written documentation may be generated

mechanically, such as when a stylus generates a tracing onto a paper chart, or electronically, including computer generated documents. However, we do agree that the term is not necessary for describing the requirements for establishing and maintaining records. Therefore, in this final rule, we used the term "record" or "records" without the qualifying term "written" (final §§ 113.87(e) and 113.100(b) and (e)). For consistency, we also removed the qualifying term "written" from § 113.87(b). In addition, where the term "written documentation" is intended to mean "records" that must be established and maintained, we changed the term "written documentation" to "records" (final § 113.40(a)(1)(ii), (b)(1)(ii), (c)(1)(ii), (d)(1)(ii), (e)(1)(ii), (f)(1)(ii), and (g)(1)(i)(A)(*2*)).

(Comment 19) One comment recommended that proposed § 113.40(b)(6)(ii) on water circulation be redesignated as new § 113.40(b)(9). The comment suggested that it was inappropriate to place the requirements for water circulation and for air supply in the same section, specifically proposed § 113.40(b)(6)(i) and (b)(6)(ii), which, according to the comment, respectively addressed air supply and water control. The comment stated that, for discontinuous water retort, air supply and water circulation are not related functions as they are for vertical water retorts covered in § 113.40(b).

(Response) The proposed rule does not have a § 113.40(b)(6)(ii). Because the comment was related to water circulation for discontinuous agitating retorts, we assume the comment was requesting redesignation of proposed § 113.40(e)(6)(ii). We also assume the comment was comparing proposed § 113.40(e)(6)(ii), related to water circulation in discontinuous agitating retorts, to proposed § 113.40(b)(10)(ii), related to water circulation in still retorts, including vertical still retorts. We reviewed the structure of proposed § 113.40(b)(10) and (e)(6) and agree that separating the requirements for the air supply and controls and the water circulation functions into distinct paragraphs for both discontinuous agitating and still retorts enhances the clarity of the regulation. We also determined that, based on changes to proposed § 113.40(e)(8), as explained in response to Comment 20, proposed § 113.40(b)(9) and (e)(8), relating to the water level indicator, should be redesignated to immediately precede proposed § 113.40(b)(10)(ii) and (e)(6)(ii), respectively, relating to water circulation. Thus, in this final rule, we redesignated proposed § 113.40(b)(9), (b)(10)(i), and (b)(10)(ii) as final § 113.40(b)(10), (b)(9), and (b)(11), respectively. We redesignated proposed § 113.40(e)(6)(ii) and (e)(8) as final § 113.40(e)(7) and (e)(6)(ii), respectively. We made conforming changes to the numbering of proposed § 113.40(b)(11), (b)(12), (b)(13), and (b)(14), which is now final § 113.40(b)(12), (b)(13), (b)(14), and (b)(15), respectively. Similarly, we redesignated proposed § 113.40(e)(6)(ii) and (e)(7), as final § 113.40(e)(7) and (e)(8), respectively.

(Comment 20) One comment suggested revising proposed § 113.40(b)(6), relating to air supply and controls, to clarify that the requirements apply only if air is used for providing overpressure. The comment also suggested revising proposed § 113.40(e)(8), which requires a water level indicator and operator checks of the water level to ensure that water covers the top layer of containers during the entire come-up time and processing periods. The comment requested revisions to clarify that the requirements of proposed § 113.40(e)(8) apply only if water level is determined to be a critical factor in the scheduled process or retort operating procedures. According to the comment, these revisions would accommodate current systems for pressure processing in discontinuous agitating retorts that utilize steam as the source of overpressure. The comment stated that for such systems, the processing authority may have determined that water level is not critical to the scheduled process because of the influences of steam in the retort headspace area and the continuous rotation of the retort baskets.

(Response) Because proposed § 113.40(b)(6) does not relate to air supply and controls, but is instead about crate supports, we assume here as we did in our response to Comment 19 that the comment is referring to proposed § 113.40(e)(6)(i), relating to air supply and controls for pressure processing in water in discontinuous agitating retorts. Proposed § 113.40(e)(6)(i) requires that a means be provided for introducing compressed air at the proper pressure and rate. We agree with the comment that the requirement of proposed § 113.40(e)(6)(i) applies only if air is used for providing overpressure. We also agree that the requirement of proposed § 113.40(e)(6)(ii) for a water level indicator and recorded checks of the water level during processing should be revised to accommodate discontinuous agitating retorts that utilize steam as the source of overpressure. Accordingly, in final § 113.40(e)(6)(i) and (e)(6)(ii), we clarified that the requirements relating to air supply and controls and to the water level indicator apply only if air is used for providing overpressure.

(Comment 21) One comment suggested revising proposed § 113.40(b)(10)(ii), which requires the water circulation pump to be equipped with a bleeder to remove air when starting operations. The comment suggested revising this requirement to allow for use of other suitable devices for air removal.

(Response) We agree that proposed § 113.40(b)(10)(ii), redesignated as § 113.40(b)(11) in this final rule, should be revised to allow for use of water circulation pumps, other than a water circulation pump with a bleeder, designed to ensure proper heat distribution. To ensure proper heat distribution, the water circulation pump must be designed to properly start the flow of water and to maintain the flow of water at the appropriate flow rate. To obtain the appropriate flow rate, the water circulation pump must be designed or equipped with a suitable means, such as a bleeder, to remove air from the pump chamber or the pump must be self priming. In addition, the pumping system must ensure that it avoids cavitation, *i.e.,* changes in water pressure caused by the formation of cavities or voids within the circulating water. Water circulation pumps that use mechanisms other than bleeders to remove air must be designed to ensure appropriate water circulation and to prevent cavitation.

To clarify this requirement, in § 113.40(b)(11) of this final rule we specify that the water circulation pump must be designed to provide proper flow on startup and during operation, such as with a bleeder or other suitable means to remove air during startup and with an appropriate device or design to prevent pump cavitation during operation. In addition, the pump must be equipped with a signaling device to warn the operator when it is not running. For consistency, we made similar changes to proposed § 113.40(e)(6)(ii) (redesignated as § 113.40(e)(7) in this final rule). In final § 113.40(b)(11) and (e)(7), we removed the reference to "pilot light" as the example of a signaling device to avoid the appearance of preference for a pilot light signaling device and to provide flexibility for processors to determine an appropriate signaling device.

(Comment 22) One comment agreed with the provision of proposed § 113.40(b)(1)(v) that allows a temperature-indicating device to be installed in a separate well or sleeve, *i.e.,* "If a separate well or sleeve is used, there must be adequate circulation to

ensure accurate temperature measurement." However, the comment indicated that the provision appears to conflict with another requirement in proposed § 113.40(b)(1)(v) for the temperature-indicating device sensor to extend directly into the water a minimum of at least 2 inches (5.1 centimeters) without a separable well or sleeve.

(Response) We agree that additional clarification is needed. In this final rule, we revised proposed § 113.40(b)(1)(v) and a similar requirement in proposed § 113.40(e)(1)(v) to clarify that the temperature-indicating device sensor must be installed directly into the retort shell or in a separate well or sleeve attached to the retort. In addition, for all retorts covered by these sections, the temperature-indicating device sensor must be located so that it is beneath the surface of the water throughout the process and where there is adequate circulation to ensure accurate temperature measurement. We also removed the requirement for the temperature-indicating device sensor to extend at least 2 inches (5.1 centimeters) directly into the water when the temperature-indicating device sensor is not located in a separate well or sleeve. We believe the requirement for adequate water circulation to ensure accurate temperature measurement obviates the need to specify how far the temperature-indicating device sensor must extend into the water and allows for use of alternative technologies.

(Comment 23) One comment noted that proposed § 113.40(f)(1)(v) should be revised to clarify that placement requirements in the steam dome and the hydrostatic water leg are for the temperature-indicating device sensor.

(Response) We agree. In this final rule, we revised proposed § 113.40(f)(1)(v) to clarify that the placement requirements in the steam dome and the hydrostatic water leg apply to the temperature-indicating device sensor, rather than the entire temperature-indicating device.

(Comment 24) One comment stated that the requirement for the temperature-recording device sensor to be installed either within the retort shell or in a well attached to the shell is misplaced in the paragraph heading, *Temperature controller* (proposed § 113.40(a)(2)(iv), (c)(2)(iv), (d)(2)(iv), (e)(2)(iv), and (f)(2)(iv)). The comment indicated that the statement applies to all temperature-recording device sensors, but its placement in the regulations implies that it applies only to combination recording-controlling devices. The comment suggested moving the statement relating to installation of the sensor, along with the requirement for the temperature-recording device sensor well to have a 1/16-inch (1.5 millimeters) or larger bleeder, to a separate paragraph.

(Response) We agree. In this final rule, we moved the statements relating to installation of the sensor and, where relevant, the requirement for the temperature-recording device sensor well to have a 1/16-inch (1.5 millimeters) or larger bleeder to the paragraph heading, *Temperature-recording device* (final § 113.40(a)(2), (c)(2), (d)(2), (e)(2), and (f)(2)).

(Comment 25) One comment objected to the requirement in proposed § 113.40(e)(1)(v) for the temperature-indicating device sensor to be installed either within the retort shell or in an external well attached to the retort. The comment indicated that placement of the temperature-indicating device in the suction manifold shows good agreement with temperatures inside the retort once the Cook Hold step begins. According to the comment, this placement is an improvement over using a thermometer well, since the water line for a partial immersion process is normally below the feed leg of the thermometer well and the temperature at that location may not be representative of the retort temperature. The comment suggested revising § 113.40(e)(1)(v) by adding the following language to permit alternative sensor placement, if appropriately documented: "Other installations deviating from these sensor locations may be used if the processor has evidence, on file, in the form of heat distribution data that its installation accomplishes adequate heat distribution. Such documentation is likely to include heat distribution studies conducted and documented by the processor to show that the process temperature will be reached once the Cook Hold time begins."

(Response) We do not agree with the comment's recommendation that § 113.40(e)(1)(v) should state that process deviations relating to placement of temperature-indicating device sensors may be acceptable if supported by heat distribution data. Section 108.35 states the requirements for submitting information to demonstrate process adequacy for a system design that deviates from the requirements of the regulations. A change in the design of a system for processing in water in discontinuous agitating retorts, such as placement of a temperature-indicating device sensor in a suction manifold rather than within the retort shell or in an external well attached to the retort, would require substantiation by qualified scientific authority as to its adequacy, including, for example, heat distribution studies as suggested by the comment. Such information must be submitted to FDA (§ 108.35(c)(2)(ii) (21 CFR 108.35(c)(2)(ii))).

(Comment 26) One comment expressed concern that proposed § 113.40(a)(2), which requires each retort to have an accurate temperature-recording device, does not define the term "accurate" or state how to determine that a temperature-recording device is accurate. The comment suggested using the same calibration method for temperature-recording devices as used for temperature-indicating devices and reference devices by requiring annual calibrations of temperature-recording devices with NIST traceability. The comment stated that this would effectively allow the temperature-recording device to be used as a secondary component of a "redundant system" to verify the accuracy of the temperature-indicating device. Accordingly, the temperature-indicating device would still be "the standard" device and should still be required to have the characteristics of high accuracy and reliability. The comment indicated that if the temperature-recording device is adjusted to the temperature-indicating device and the temperature-indicating device slowly drifts, this may not be known until the next calibration cycle, which could be up to a year later. However, according to the comment, if the devices are allowed to vary within their individual established calibration tolerances, it will be known if one device drifts out of its tolerance. The comment stated that adjusting the temperature-recording to the temperature-indicating device does not ensure the accuracy of the temperature-recording device or the recorded data.

(Response) This final rule requires the temperature-recording device to be adjusted to agree as nearly as possible with, but to be in no event higher than, the temperature-indicating device during the process time (final § 113.40(a)(2)(iii), (b)(2)(iii), (c)(2)(iii), (d)(2)(iii), (e)(2)(iii), (f)(2)(iii), and (g)(1)(i)(B)(*3*)). Processors must ensure that the temperature-indicating device is accurate during processing and that the recording mechanism of the temperature-recording device is adjusted to and reflects the temperature indicated by the temperature-indicating device. For some temperature-recording devices, such as those that record to a chart, adjustments to the mechanism that draws onto the chart are made by hand based on visually determining where the mechanism should be placed in contact with the chart. Unavoidable

imprecision relating to, for example, manual placement of the recording mechanism onto a chart, must result in recording a temperature that is not greater than the actual processing temperature. A recorded temperature that is higher than the actual processing temperature may mean that the product was not processed at or above the required processing temperature (*i.e.,* the product was under processed) and may pose a health hazard. However, if the temperature-recording device records a temperature that is lower than the actual processing temperature, although the quality of the product may be affected, processing at a higher temperature than recorded (*i.e.,* over processing) does not create a health hazard. Thus, although the recorded temperature should reflect the actual processing temperature as precisely as possible, we believe the requirement to not record a temperature that is higher than the temperature-indicating device, which must be accurate, provides an appropriate parameter for ensuring that the product is not under processed.

We believe processors should adjust the temperature-recording device mechanism for each batch at least at the beginning of the process and, as necessary, check the adjustment during the process time to ensure compliance with the regulation and to ensure that the batch is processed at or above the scheduled process temperature. To emphasize that the adjustment must occur with sufficient frequency to ensure that the temperature-recording device record reflects the temperature indicated by the temperature-indicating device, we revised the final rule to require the temperature-recording device to be adjusted with sufficient frequency to ensure agreement as nearly as possible with, but to be in no event higher than, the temperature-indicating device during processing (final § 113.40(a)(2)(iii), (b)(2)(iii), (c)(2)(iii), (d)(2)(iii), (e)(2)(iii), (f)(2)(iii), and (g)(1)(i)(B)(*3*)).

(Comment 27) One comment suggested replacing the term "recording chart" with "temperature-recording device record" in proposed § 113.40(c)(8)(ii).

(Response) We agree. In § 113.40(c)(8)(ii) of this final rule, we replaced the term "recording chart" with "temperature-recording device record." Also, because the term "marked" may be interpreted to mean a manual action, for clarity and to allow for use of alternative technologies, we replaced the term "marked" with "indicated" in § 113.40(c)(8)(ii) and (c)(9).

(Comment 28) One comment suggested that the statement that air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air is misplaced in the regulations (proposed § 113.40(a)(2)(iv), (b)(2)(iv), (c)(2)(iv), (d)(2)(iv), (e)(2)(iv), and (f)(2)(iv)). The comment stated that, because this statement applies to all air-operated temperature or steam control systems, regardless of whether or not it is a combination recorder-controller, it should be moved to proposed § 113.40(a)(4), (b)(4), (c)(4), (d)(4), (e)(4), and (f)(5), respectively, which set out the requirements for the steam controller.

(Response) We agree. In this final rule, we moved the statement that air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air from proposed § 113.40(a)(2)(iv), (b)(2)(iv), (c)(2)(iv), (d)(2)(iv), (e)(2)(iv), and (f)(2)(iv) to final § 113.40(a)(4), (b)(4), (c)(4), (d)(4), (e)(4), and (f)(5). In addition, for consistency in terminology, we replaced the term "recording-controlling instrument" with "recorder-controller" in final § 113.40(a)(2)(iv), (a)(4), (b)(2)(iv), (b)(4), (c)(2)(iv), (c)(4), (d)(2)(iv), (d)(4), (e)(2)(iv), (e)(4), (f)(2)(iv), and (f)(5).

(Comment 29) One comment stated that the requirement in proposed § 113.40(g)(1)(i)(E) for the differential pressure recorder-controller to be installed on the product-to-product regenerator is confusing because it implies that the recorder-controller needs to be physically attached to the product-to-product regenerator. Thus, according to the comment, the requirement does not accommodate operational practices where recording and control are done in remote systems. The comment stated that the pressure sensing device, rather than the recorder-controller, is installed on the regenerator.

(Response) We agree with the comment's suggestion to allow for use of alternative differential pressure recorder-controllers by eliminating the requirement for the differential pressure recorder-controller to be installed on the product-to-product regenerator. In this final rule, we clarify that when a product-to-product regenerator is used, it must be equipped with an accurate differential pressure recorder-controller (final § 113.40(g)(1)(i)(E)).

(Comment 30) One comment stated that the scale division requirements for differential pressure recorder-controllers in proposed § 113.40(g)(1)(i)(E) do not allow for use of differential pressure recorder-controllers that incorporate alternative technologies, such as digital recordings, for recording and controlling differential pressure.

(Response) We agree with the comment. In this final rule, we clarify that the requirements for scale divisions apply to graphical recordings and allowed for use of digital recordings, as well as analog or graphical recordings (final § 113.40(g)(1)(i)(E)(*i*) and (g)(1)(i)(E)(*ii*)). We also clarified that the differential pressure recorder-controller must be accurate to within 2 pounds per square inch (13.8 kilopascals) and that the sensor and the recorder of the differential pressure recorder-controller must be tested for accuracy against an accurate reference device (final § 113.40(g)(1)(i)(E)).

Although the comment did not request a similar change for pressure gages, in this final rule, for consistency, we changed the recommendation for each retort to be equipped with a pressure gage that is "graduated in divisions of 2 pounds per square inch (13.8 kilopascals) or less" to a recommendation that each retort be "equipped with a pressure gage that is accurate to 2 pounds per square inch (13.8 kilopascals) or less" (§ 113.40(a)(3), (b)(3), (c)(3), (d)(3), (e)(3) and (f)(3)).

(Comment 31) One comment stated that the requirement for the differential pressure recorder-controller to be tested for accuracy against a known accurate standard pressure indicator upon installation and at least once every 3 months of operation, is confusing and not reflective of actual operating conditions (proposed § 113.40(g)(1)(i)(E)). The comment indicated that the pressure sensors, rather than the controller, are tested for accuracy and that the controller should be tested for proper functioning. In addition, the comment stated that the required minimum frequency for testing the differential pressure recorder-controller after installation should be once per year, consistent with the requirement for testing temperature-indicating devices, instead of once every 3 months.

(Response) We do not agree with the comment's suggestion to reduce the requirement to test for accuracy from at least once every 3 months to once every year. The requirement to test the differential pressure recorder-controller for accuracy at least once every 3 months of operation is well established (current § 113.40(g)(1)(i)(E). The comment did not provide, and we do not have, data to support the adequacy of testing only once every year. Accordingly, we are making no changes in response to this comment.

(Comment 32) One comment suggested revising proposed § 113.40(g)(1)(ii)(C) and (g)(2)(ii)(B) to be consistent with § 113.40(g)(1)(ii)(B),

which states that a processing deviation must be handled in accordance with § 113.89 (21 CFR 113.89).

(Response) We agree that the suggested revision clarifies and provides consistency in the regulation. In this final rule, we clarify that the processing deviation must be handled in accordance with final § 113.89 (§ 113.40(g)(1)(ii)(C) and (g)(2)(ii)(B)).

(Comment 33) One comment objected to the way we expressed temperatures in Fahrenheit, followed by a parenthetical reference to the temperature expressed in Celsius. According to the comment, food chemists use only metric equivalents and their equipment is only calibrated in metric units. The comment suggested that we list the temperature in Celsius followed by a parenthetical reference in Fahrenheit, *i.e.,* instead of 220 °F (104.4 °C), use 105 °C (221 °F). The comment stated that the proposed temperature conversions do not follow the Omnibus Trade and Competitiveness Act of 1988. The comment also objected to expressing Celsius temperatures to four digits.

(Response) We do not agree with the comments suggestion to first list the Celsius temperature, followed by a parenthetical reference to the Fahrenheit temperature. Thermal processing temperatures are expressed in Fahrenheit in the current low-acid canned food regulations (part 113 (21 CFR part 113)) and many processors use temperature-indicating devices that express temperature in Fahrenheit. In the proposed rule, we added appropriate conversions to Celsius to ensure consistency in such conversions. Each conversion provided in the proposed rule was carefully evaluated to ensure that it appropriately expressed the required Fahrenheit temperature, or increments of temperature changes, and that any rounding did not significantly alter the intended temperature measurement established in the regulations in Fahrenheit. As demonstrated by the one degree Fahrenheit change in the comment's example, the conversion and rounding of the Fahrenheit temperature, based on the converted and rounded Celsius temperature, may result in a change that could significantly impact scheduled processes established based on Fahrenheit temperatures in the regulation. The comment did not provide a basis for changing the required scheduled process temperatures or cite specific provisions of the Omnibus Trade and Competitiveness Act of 1988 that would be applicable to Fahrenheit conversions in this regulation.

The comment also did not explain the basis for objecting to expressing Celsius temperatures to four digits. We interpret the comment to mean that, above 100 °C, the temperature should be rounded to the nearest whole number, rather than to the nearest tenth, which adds a fourth digit to the temperature measurement. We agree that it is not necessary to convert the Fahrenheit temperatures to the nearest tenth degree Celsius. Rather, we believe rounding should be to the nearest 0.5 degree Celsius, consistent with the requirement for temperature-indicating devices to be accurate to 1 °F (0.5 °C) ((final § 113.40(a)(1)(iv), (b)(1)(iv), (c)(1)(iv), (d)(1)(iv), (e)(1)(iv), (f)(1)(iv), and (g)(1)(i)(A)(*4*)). Accordingly, in this final rule we rounded the Celsius temperatures up to the nearest 0.5 degree Celsius, *i.e.,* we rounded 101.7 °C to 102 °C, 103.3 °C to 103.5 °C, 104.4 °C to 104.5 °C, and 107.2 °C to 107.5 °C (final § 113.40(a)(12)(i)(A), (a)(12)(i)(B), (a)(12)(i)(C), (a)(12)(i)(D), (a)(12)(ii)(A), and (a)(12)(ii)(B)).

(Comment 34) One comment indicated that using kilopascals as the metric equivalent for pounds per square inch may cause confusion. According to the comment, many systems use other units for pressure, such as bar. The comment suggested that the parenthetical addition of "kilopascals" at various locations in the proposed rule be qualified with "or equivalent unit" to support the use of the different, but equivalent, ways of referring to pressure.

(Response) We disagree with the comment. Each measurement in the regulations, including pounds per square inch, may be converted to the units appropriate for the equipment or system used by the processor, provided that the converted measurement does not differ significantly from the U.S. measurement in the regulation. Processors are responsible for ensuring that converted measurements are consistent with the requirements of the regulations, regardless of the unit of measure used.

(Comment 35) One comment noted that, in proposed § 113.40(d)(7) and (d)(8), the word "schedules" should be "scheduled."

(Response) We agree. We revised proposed § 113.40(d)(7) and (d)(8) accordingly.

(Comment 36) One comment suggested revising proposed § 113.40(g)(1)(ii)(E) to change the term "metering pump" to "flow controlling device" to be consistent with changes in proposed § 113.40(g)(1)(i)(F).

(Response) We agree that the term "metering pump" should be replaced with a more current term. As noted by the comment, in proposed § 113.40(g)(1)(i)(F), we used the term "flow controlling device." However, we believe the term "flow control device" is more consistent with current terminology. Thus, we replaced the terms "flow controlling device" and "metering pump" with "flow control device" in § 113.40(g)(1)(i)(F) and (g)(1)(ii)(E) of this final rule.

(Comment 37) One comment objected to the requirements in proposed § 113.60(d) for container handling equipment to be designed, constructed, and operated to preserve the can seam or other container closure integrity and for container handling equipment to be checked with sufficient frequency and repaired or replaced to prevent damage to containers. The comment stated that these proposed changes will not provide greater public health protection than the current regulations. According to the comment, the proposed changes will not provide FDA with any additional enforcement tools because they do not specify what processors must do to comply with the requirements and, thus, are subject to interpretation. The comment requested that no change be made to § 113.60(d) in the current regulations.

(Response) We do not agree with the comment's request to make no change to previous § 113.60(d), relating to container handling equipment. Previous § 113.60(d) recommends specific preventive measures that may be taken to prevent damage to containers and container closures, but does not clearly express that the measures are a few examples, rather than an exhaustive expression of the processor's responsibility to ensure that the can seam and container closure are not compromised during post-process handling. The proposed revision to § 113.60(d) was intended to clarify that processors are responsible for ensuring that container handling equipment used in handling filled containers, including automated and non-automated equipment, is designed and operated to preserve the can seam and container closure integrity. This proposal allows flexibility regarding appropriate design, construction, and operation of container handling equipment. We believe processors currently ensure can seam and container closure integrity without prescriptive instructions from the Agency. Also, we recognize that the proposed revision does not establish a new enforcement tool for FDA. The revised language is intended to clarify processors' responsibilities relating to post-process handling. We believe consumer protection will be enhanced

by processors who, as a result of the clarification to § 113.60(d), evaluate their post-process handling equipment and procedures and either confirm that they are adequate or correct deficiencies.

(Comment 38) One comment encouraged FDA to develop guidance for processors and inspection personnel on how to verify compliance with the proposed revision to § 113.83, which indicates that when a product is reprocessed or a previously processed product is blended into a new formulation, this condition must be covered in the scheduled process. According to the comment, amending existing process filings for thousands of products that currently meet this new requirement will be burdensome to both the industry and FDA. The comment suggested that a note in the processor's file from the processing authority should satisfy this requirement.

(Response) Previous § 113.83 requires the type, range, and combination of variations encountered in commercial production to be adequately provided for in establishing the scheduled process. Variations may occur due to seasonal or growing fluctuations, variety differences, or supplier processes. Variations also may occur when a food is reprocessed or when a previously processed product is mixed with a batch of the same unprocessed product before it is processed. In proposed § 113.83 we clarified that variations that occur due to reprocessing or mixing processed and unprocessed batches must be provided for in the scheduled process. In this final rule, we clarify in § 113.83 that variations include those that occur due to seasonal or growing fluctuations, variety differences, supplier processes, reprocessing, and mixing a batch of processed product with the same unprocessed product before it is processed. Therefore, this clarification does not represent a change from what has already been required of processors. Consistent with current § 108.35(c)(2)(ii), a processor who intentionally makes a change in a previously filed scheduled process by changing a condition that is basic to the adequacy of the scheduled process must obtain substantiation by a qualified scientific authority as to its adequacy, promptly record the substantiation, and obtain and file written verification from the authority for review by FDA. In addition, within 30 days after the first use, the processor must submit to FDA a copy of the file record showing the substantiation by a qualified scientific authority.

(Comment 39) One comment stated that proposed § 113.100(g) duplicates, in part, the requirements of § 108.35(h). The comment recommended removing the requirement from § 113.100(g) or, if retained, making the language identical to the language in § 108.35(h).

(Response) We agree with the comment and deleted § 113.100(g) from this final rule.

III. Minor Revisions in Regulations

We made minor revisions in this final rule, including the following:

In final § 113.40(a)(12)(i)(C), we corrected the metric conversion for 2.5 inches to 6.4 centimeters.

In final § 113.40(d)(6), we changed the word "containing" to "continuing."

In final § 113.40(e)(7), we changed the word "cross-section" to "cross-sectional," for consistency with use of the term in final § 113.40(a)(7) and (a)(12).

IV. Analysis of Economic Impacts

A. Final Regulatory Impact Analysis

FDA has examined the impacts of this final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule is not a significant regulatory action under the Executive Order.

1. Need for Regulation

This final rule is needed to address inflexibility in the current regulations with regard to the requirement to use mercury-in-glass thermometry in low-acid canned food manufacturing, as well as to update and clarify current regulations. Previous regulations for thermally processed low-acid foods in hermetically sealed containers, except for aseptic packaging and processing, required the exclusive use of mercury-in-glass thermometers for indicating temperatures during food processing. The requirement for exclusive use of mercury-in-glass thermometers reflects the absence of alternatives on the market at the time current regulations became effective in 1973. Because of technological advances in thermometry since that time, alternatives to mercury-in-glass thermometers may now be available for the low-acid canned food industry.

Moreover, the number and variety of low-acid canned food products, the technologies, and the countries where they are processed have changed substantially since 1973 when the low-acid canned food regulations became effective. Data on imported foods obtained from FDA's "Consumption of Imported Foods" model indicates that approximately 15 billion pounds of low-acid canned food were imported from more than 100 countries in 2006 (Ref. 5). Provisions in the regulations issued in 1973 that were targeted toward technologies at that time may be less clear when applied to technologies being used today.

2. Costs and Benefits of Revisions Suggested by Comments

There were no comments that directly addressed the economic sections in the proposed regulatory impact analysis. We evaluated the revisions to the proposed rule to determine whether they may have implications for costs and benefits of this final rule. We identify each revision to the proposed rule that may have implications for the costs and benefits of this final rule as belonging to one of three categories of provisions, each category distinguished by the way it contributes to the costs and benefits. The categories of provisions are: Revisions to proposed recordkeeping requirements reported in table 1 of this document, revisions to the proposed non-recordkeeping requirements that may facilitate adoption of alternative technologies reported in table 2 of this document, and other minor revisions. Even though many of the revisions lie outside the framework of the economic analysis in the proposed rule, their categorization may help identify any potential costs and benefits. The costs and benefits of this final rule are reported in table 3 of this document.

TABLE 1—REVISIONS TO PROPOSED RECORDKEEPING REQUIREMENTS

Proposed 21 CFR Section	Final 21 CFR Section	Revision
113.40(a)(1)(ii)(A) and (a)(1)(ii)(B), 113.40(b)(1)(ii)(A) and (b)(1)(ii)(B), 113.40(c)(1)(ii)(A) and (c)(1)(ii)(B), 113.40(d)(1)(ii)(A) and (d)(1)(ii)(B), 113.40(e)(1)(ii)(A) and (e)(1)(ii)(B), 113.40(f)(1)(ii)(A) and (f)(1)(ii)(B), 113.40(g)(1)(i)(A)(*2*)(*i*) and (g)(1)(i)(A)(2)(*ii*).	113.100(c)(3) and (d)(3)	Make explicit the records requirements that apply when an accuracy test for a temperature-indicating device and for a reference device that is maintained by the processor is conducted by an outside facility.
113.40(a)(1)(ii)(A) and (a)(1)(ii)(B), 113.40(b)(1)(ii)(A) and (b)(1)(ii)(B), 113.40(c)(1)(ii)(A) and (c)(1)(ii)(B), 113.40(d)(1)(ii)(A) and (d)(1)(ii)(B), 113.40(e)(1)(ii)(A) and (e)(1)(ii)(B), 113.40(f)(1)(ii)(A) and (f)(1)(ii)(B), 113.40(g)(1)(i)(A)(*2*)(*i*) and (g)(1)(i)(A)(*2*)(*ii*).	113.100(c)(5) and (d)(5)	Clarify that records of the accuracy of a temperature-indicating device and a reference device maintained by the processor must include the date and results of each accuracy test, including the amount of calibration adjustment.
113.40(a)(1)(ii)(A) and (a)(1)(ii)(B), 113.40(b)(1)(ii)(A) and (b)(1)(ii)(B), 113.40(c)(1)(ii)(A) and (c)(1)(ii)(B), 113.40(d)(1)(ii)(A) and (d)(1)(ii)(B), 113.40(e)(1)(ii)(A) and (e)(1)(ii)(B), 113.40(f)(1)(ii)(A) and (f)(1)(ii)(B), 113.40(g)(1)(i)(A)(*2*)(*i*) and (g)(1)(i)(A)(*2*)(*ii*).	113.100(c)(6) and (d)(6)	Indicate "[t]he date on or before which the next accuracy test must be performed" instead of the proposed "the date of the next scheduled accuracy test."

FDA believes that the information required by this final rule to be established and maintained for accuracy tests is currently generated even though it may not currently be permanently recorded. We estimate that the revisions to the proposed records requirements reported in table 1 of this document will add very little or no additional costs to the recordkeeping costs estimated in the analysis of the proposed rule. Thus, the estimated costs of the records of the accuracy tests for this final rule are not different than those estimated for the analysis of the proposed rule (72 FR 11990 at 11999, March 14, 2007).

TABLE 2—REVISIONS TO PROPOSED NON-RECORDKEEPING REQUIREMENTS THAT MAY FACILITATE ADOPTION OF ALTERNATIVE TECHNOLOGIES

Revised 21 CFR Section	Revision
113.40(a)(1), 113.40(b)(1), 113.40(c)(1), 113.40(d)(1), 113.40(e)(1), 113.40(f)(1) and (g)(1)(i)(A), 113.87(c).	Replace "an accurate calibrated reference device" with "a reference device for which the accuracy is traceable to a National Institute of Standards and Technology (NIST), or other national metrology institute, standard reference device."
113.40(a)(1)(iv), 113.40(b)(1)(iv), 113.40(c)(1)(iv), 113.40(e)(1)(iv) and (f)(1)(iv), 113.40(g)(1)(i)(A)(*4*).	Replace "easily readable to" with "accurate to" to describe the measurement uncertainty allowed for temperature-indicating devices.
Proposed 113.40(b)(10)(ii): Final 113.40(b)(11) Proposed 113.40(e)(6)(ii): Final 113.40(e)(7)	Change the term "pilot light or other signaling device" to "signaling device" on the pump that controls water circulation to allow for the use of alternative signaling devices.
113.40(g)(1)(i)(E)	Clarify that recordings for differential pressure recorder-controllers may be analog or graphical or digital.
130.40(g)(1)(i)(F) and (g)(1)(ii)(E)	Replace "metering pump" with "flow control device".

The costs for the revisions to the proposed rule of non-recordkeeping requirements that may facilitate adoption of alternative technologies are estimated to be zero since the adoption of alternative technologies is voluntary and there would be no additional health risks from their adoption. The benefits of these revisions are estimated to be positive since they would allow additional flexibility for adopting alternative thermometry and other technologies that, consistent with the framework in the analysis of the proposed rule, could slightly improve labor productivity in the manufacture of low-acid canned food.

Other revisions in this final rule include those that are editorial in nature and clarifications of existing regulations that have neither additional costs nor additional benefits to those considered in the analysis of the proposed rule (72 FR 11990 at 11999, March 14, 2007).

3. Regulatory Options

This section reports estimates of the costs and benefits of several regulatory options. The regulatory options include: (a) No new regulation; (b) allow flexibility to use temperature-indicating devices, including mercury-in-glass thermometers, without explicit recordkeeping requirements; and (c) final rule—Option (b), with explicit recordkeeping requirements for accuracy tests for temperature-indicating devices and reference devices maintained by the processor.

- Option (a)—No new regulation.

There would be neither costs nor benefits from this option.

- Option (b)—Allow flexibility to use temperature-indicating devices, including mercury-in-glass thermometers, without explicit recordkeeping requirements.

There would be neither costs nor benefits from this option.

- Option (c)—Final rule—Option (b), with explicit recordkeeping requirements for accuracy tests for temperature-indicating devices and reference devices maintained by the processor.

Tables 3 and 4 of this document report the costs and benefits of this final rule based on estimates derived in the analysis of the proposed rule and modified in accordance with changes to the final rule, as indicated in the tables. In the analysis of the proposed rule, we estimated the costs to be from the recordkeeping provisions that involved one-time and recurring costs. The benefits from the proposed rule were from the reduced presence of mercury in food processing facilities, the reduced mercury cleanup and remediation costs, and improved labor productivity due to the voluntary adoption of alternative temperature device technologies. In addition, benefits from the recordkeeping provisions were from the

enhanced ability to track critical accuracy test data, particularly during the transition from mercury-in-glass thermometers to alternative temperature-indicating devices (72 FR 11990 at 11999, March 14, 2007).

TABLE 3—COSTS OF THE FINAL RULE

One-time recordkeeping costs	
Design of new recordkeeping forms	Minimal.
Recordkeeping training	Minimal.
Recurring Costs (annual)	
Recordkeeping [1]	$5,000–$23,000 plus a minimal amount in accordance to the changes to the recordkeeping language.
Purchase and additional testing of alternative devices	Voluntarily incurred.

[1] Estimates based on those reported in the analysis for the proposed rule.

TABLE 4—BENEFITS OF THE FINAL RULE

Benefits (annual)	
Change in risk from low-acid canned foods	No change.
Clarification of existing processor's responsibilities	Not quantified.
Avoided mercury cleanup costs [1]	$31,000–$152,000.
Enhanced labor productivity from adopting alternative temperature-indicating devices and other processing technologies.	Not quantified.
Enhanced ability to track critical accuracy performance data—especially during the transition period following the adoption of alternative temperature indicating devices.	Not quantified.

[1] Estimates based on those reported in the analysis for the proposed rule.

B. Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA) requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. An estimate of the cost of the proposed rule on small entities was made in the proposed rule. For firms of all sizes, the per-firm costs were estimated to be between $1 and $4 per year for each of the estimated 6,700 firms. The per-firm costs for small firms were estimated to be on the lower end of that range. Based on these estimates, FDA certified that the proposed rule would not have a significant impact on a substantial number of small entities. Under the RFA, no further analysis is required. For the complete discussion, *see* the Regulatory Flexibility Analysis of the proposed rule (72 FR 11990 at 11999 and 12003 to 12004, March 14, 2007). No comments objected to or suggested significant modifications to the estimates of the per-firm costs in the regulatory flexibility analysis in the proposed rule.

C. Unfunded Mandate Analysis

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, for "any rule that includes any Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year." The current threshold after adjustment for inflation is $135 million, using the most current (2009) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

V. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by OMB under the PRA (44 U.S.C. 3501–3520). The final rule revises information collection requirements in part 113 that are currently approved under OMB control number 0910–0037 (expires August 31, 2011). Comments on the information collection requirements currently approved under OMB control number 0910–0037, as amended by the information collection provisions of this final rule, are being solicited in a separate notice published elsewhere in this issue of the **Federal Register**. That notice also announces that FDA has submitted the information collection provisions of the final rule to OMB for approval, along with a request for extension of the related information collection provisions already approved under OMB control number 0910–0037, as revised by the final rule. Prior to the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

In compliance with the PRA (44 U.S.C. 3506(c)(2)(B)), the Agency requested public comment on the information collection provisions of the proposed rule (72 FR 11990 at 12004). The proposed rule also stated that FDA had submitted the information collection provisions to OMB for review (72 FR 11990 at 12005). However, due to an administrative error, the Agency did not actually do so, and therefore is submitting them to OMB now. No public comments to the analysis of the information collection provisions in the proposed rule suggested that we modify our burden estimates. Thus, we have not changed our estimates of the annual frequency per recordkeeping or the hours per record. We have, however, increased the estimated number of recordkeepers to reflect growth in the low-acid canned food processing industry since the 2007 proposed rule.

Title: Recordkeeping Requirements for Temperature-Indicating Devices.

Description: The information to be collected is related to accuracy tests of temperature-indicating devices and reference devices maintained by processors of low-acid canned foods. These tests must be performed to ensure the accuracy of the devices during the processing of these foods. If these devices are not accurate, the processor cannot ensure that the low-acid canned foods it produces are safe to eat, and consumers may be harmed. The recordkeeping requirements of the rule are necessary to document that

appropriate accuracy tests have been performed with the appropriate frequencies for each temperature-indicating device and each reference device maintained by the processor. Records of accuracy tests for these devices also help processors determine how frequently the devices should be tested for accuracy. Much of the information is currently generated for accuracy tests performed under current regulations. However, the information may not be recorded as required under the final rule.

Current low-acid canned food regulations recommend, but do not require, that processors keep records of accuracy tests for mercury-in-glass thermometers, including test date, standard used, method used, and person performing the test. This final rule requires processors to keep records documenting the accuracy of temperature-indicating devices (including but not limited to mercury-in-glass thermometers) and of reference devices that are maintained by the processor. These records include: The identifier of the device being tested, such as its tag or seal; the name of the manufacturer of the device; the identity of the reference device, equipment, and procedures used for the accuracy test and to adjust the device or, if an outside facility conducts the accuracy test, documentation tracing the accuracy to a NIST or other national metrology institute standard; the identity of the person or facility that performed the accuracy test and adjusted or calibrated the device; the date and results of each accuracy test, including the amount of adjustment; and the date on or before which the next accuracy test must be performed.

Description of Respondents: The respondents to this information collection are commercial low-acid canned food processors. Based on FDA's low-acid canned food manufacturers' registration database as of September 2009, we estimate that there are approximately 8,450 foreign and domestic low-acid canned food processing establishments.

Burden: The burden of the recordkeeping requirement consists of the setup time required to design and establish a form for recording the required information, and the additional hours of labor needed to record the information. The setup time required for designing a new recordkeeping form is assumed to be minimal since we estimate that only a few data elements required in the final rule are currently unreported by some processors and that only small modifications to a processor's recordkeeping form would be required to accommodate the additional data elements.

We estimate that the time needed to comply with the recordkeeping requirements of the final rule will be small because current industry practice is to keep track of most, if not all, of this information. Because current incentives to track accuracy of mercury-in-glass thermometers may vary across the industry, however, some information that is currently generated during accuracy tests may not be recorded as required under the final rule. Thus, we assume there will be a burden incurred from the final rule to record information that is currently generated, but not recorded.

We assume that half of the industry currently does not record all of the device accuracy testing information that the final rule requires. We further assume that current practice by these firms is to leave unrecorded 1 to 4 separate pieces of information required under the final rule, and that each piece of information takes between 10 and 15 seconds to record. Consequently, we estimate that half of all low-acid canned food manufacturers will spend between 10 seconds and 1 minute (*i.e.,* 1×10 seconds and 4×15 seconds) per device to record information required in the final rule.

Based on a survey conducted by FDA between 1992 and 1993 of mercury-in-glass thermometer calibration in the low-acid canned food industry, we estimate that low-acid food firms use an average of 10 temperature-indicating devices, including reference devices. We estimate that 4,225 low-acid canned food manufacturers (half of the industry) currently do not fully record the accuracy test results required by the final rule. Because the regulations specify that each device must be tested upon installation and at least once a year thereafter, or more frequently if necessary to ensure accuracy, we estimate that each device requires 1 to 2 tests per year (midpoint of 1.5 tests per year). We therefore estimate the annual frequency per recordkeeping to be 15 (*i.e.,* 10 devices $\times$ 1.5 tests per year). We estimate the burden for recording the additional information to be between 10 and 60 seconds per device (midpoint of 35 seconds or 0.0097 hours per device). Therefore, the estimated total annual burden in hours for the recordkeeping requirements of the final rule is approximately 615 hours ($63{,}375 \times 0.0097 = 614.7$ hours, rounded to 615 hours). Table 5 of this document reports the average annual recordkeeping burden described previously in this section of the document.

TABLE 5—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
113.100(c) and (d)	4,225	15	63,375	0.0097	615

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VII. References

We have placed the following references on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. You may see them between 9 a.m. and 4 p.m., Monday through Friday. FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.

1. International Vocabulary of Metrology—Basic and General Concepts and Associated Terms (VIM), BIPM, IEC, IFCC, ILAC, ISO, IUPAC, IUPAP, OIML, 3d ed., p. 21, definition 2.13, 2008; accessed online October 20, 2010, at *http://www.bipm.org/utils/common/documents/jcgm/JCGM_200_2008.pdf.*

2. International Vocabulary of Metrology—Basic and General Concepts and Associated Terms (VIM), BIPM, IEC, IFCC, ILAC, ISO, IUPAC, IUPAP, OIML, 3d ed., p. 29, definition 2.41, 2008; accessed online October 20, 2010, at *http://www.bipm.org/utils/common/documents/jcgm/JCGM_200_2008.pdf.*

3. International Vocabulary of Metrology—Basic and General Concepts and Associated Terms (VIM), BIPM, IEC, IFCC, ILAC, ISO, IUPAC, IUPAP, OIML, 3d ed., p. 19, definition 2.9, 2008; accessed online October 20, 2010, at *http://www.bipm.org/utils/common/documents/jcgm/JCGM_200_2008.pdf.*

4. International Vocabulary of Metrology—Basic and General Concepts and Associated Terms (VIM), BIPM, IEC, IFCC, ILAC, ISO, IUPAC, IUPAP, OIML, 3d ed., p. 25, definition 2.26, 2008; accessed online October 20, 2010, at *http://www.bipm.org/utils/common/documents/jcgm/JCGM_200_2008.pdf.*

5. U.S. FDA, Consumption of Imported Foods, Final Report. RTI International, Contract 223–01–2466, Task Order 11, RTI Project Number 0208184.011, August 2008.

List of Subjects in 21 CFR Part 113

Food packaging, Foods, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 113 is amended as follows:

PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS

■ 1. The authority citation for 21 CFR part 113 continues to read as follows:

Authority: 21 U.S.C. 342, 371, 374; 42 U.S.C. 264.

■ 2. Revise § 113.40 to read as follows:

§ 113.40 Equipment and procedures.

(a) *Equipment and procedures for pressure processing in steam in still retorts*—(1) *Temperature-indicating device.* Each retort shall be equipped with at least one temperature-indicating device that accurately indicates the temperature during processing. Each temperature-indicating device shall have a sensor and a display. Each temperature-indicating device and each reference device that is maintained by the processor shall be tested for accuracy against a reference device for which the accuracy is traceable to a National Institute of Standards and Technology (NIST), or other national metrology institute, standard reference device by appropriate standard procedures, upon installation and at least once a year thereafter, or more frequently if necessary, to ensure accuracy during processing. Each temperature-indicating device and each reference device that is maintained by the processor shall have a tag, seal, or other means of identity.

(i) The design of the temperature-indicating device shall ensure that the accuracy of the device is not affected by electromagnetic interference and environmental conditions.

(ii) Records of the accuracy of the temperature-indicating device and of a reference device that is maintained by the processor shall be established and maintained in accordance with § 113.100(c) and (d).

(iii) A temperature-indicating device that is defective or cannot be adjusted to the accurate calibrated reference device shall be repaired before further use or replaced.

(iv) A temperature-indicating device shall be accurate to 1 °F (0.5 °C). The temperature range of a mercury-in-glass thermometer shall not exceed 17 °F per inch (4 °C per centimeter) of graduated scale. A mercury-in-glass thermometer that has a divided mercury column shall be considered defective.

(v) Each temperature-indicating device shall be installed where it can be accurately and easily read. The temperature-indicating device sensor shall be installed either within the retort shell or in external wells attached to the retort. External wells or pipes shall be connected to the retort through at least a ¾-inch (2 centimeters) diameter opening and equipped with a 1/16-inch (1.5 millimeters) or larger bleeder opening so located as to provide a full flow of steam past the length of the temperature-indicating device sensor. The bleeders for external wells shall emit steam continuously during the entire processing period. The temperature-indicating device—not the temperature recording device—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature-recording device.* Each retort shall have an accurate temperature-recording device. Each temperature-recording device shall have a sensor and a mechanism for recording temperatures to a permanent record, such as a temperature-recording chart. The temperature-recording device sensor shall be installed either within the retort shell or in a well attached to the shell. Each temperature-recording device sensor well shall have a 1/16-inch (1.5 millimeters) or larger bleeder that emits steam continuously during the processing period.

(i) *Analog or graphical recordings.* Temperature-recording devices that create analog or graphical recordings may be used. Temperature-recording devices that record to charts shall be used only with the appropriate chart. Each chart shall have a working scale of not more than 55 °F per inch (12 °C per centimeter) within a range of 20 °F (10 °C) of the process temperature. Chart graduations shall not exceed 2 °F (1 °C) within a range of 10 °F (5 °C) of the process temperature. Temperature-recording devices that create multipoint plottings of temperature readings shall record the temperature at intervals that will assure that the parameters of the process time and process temperature have been met.

(ii) *Digital recordings.* Temperature-recording devices, such as data loggers, that record numbers or create other digital records may be used. Such a device shall record the temperature at intervals that will assure that the parameters of the process time and process temperature have been met.

(iii) *Adjustments.* The temperature-recording device shall be adjusted with sufficient frequency to ensure agreement as nearly as possible with, but to be in no event higher than, the temperature-indicating device during processing. A means of preventing unauthorized changes in adjustment shall be provided. A lock or a notice from management posted at or near the temperature-recording device that provides a warning that only authorized persons are permitted to make adjustments is a satisfactory means of preventing unauthorized changes.

(iv) *Temperature controller.* The temperature-recording device may be combined with the steam controller and may be a recorder-controller.

(3) *Pressure gages.* Each retort should be equipped with a pressure gage that is accurate to 2 pounds per square inch (13.8 kilopascals) or less.

(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recorder-controller when combined with a temperature-recording device. The steam controller may be air-operated and actuated by a temperature sensor positioned near the temperature-indicating device in the retort. Air-operated temperature controllers should have adequate filter systems to ensure a

supply of clean, dry air. A steam controller activated by the steam pressure of the retort is acceptable if it is carefully maintained mechanically so that it operates satisfactorily.

(5) *Steam inlet.* The steam inlet to each still retort shall be large enough to provide sufficient steam for proper operation of the retort. Steam may enter either the top portion or the bottom portion of the retort but, in any case, shall enter the portion of the retort opposite the vent; for example, steam inlet in bottom portion and vent in top portion.

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

(7) *Steam spreaders.* Steam spreaders are continuations of the steam inlet line inside the retort. Horizontal still retorts shall be equipped with steam spreaders that extend the length of the retort. For steam spreaders along the bottom of the retort, the perforations should be along the top 90° of the pipe, that is, within 45° on either side of the top center. Horizontal still retorts over 30 feet (9.1 meters) long should have two steam inlets connected to the spreader. In vertical still retorts, the steam spreaders, if used, should be perforated along the center line of the pipe facing the interior of the retort or along the sides of the pipe. The number of perforations should be such that the total cross-sectional area of the perforations is equal to 1.5 to 2 times the cross-sectional area of the smallest restriction in the steam inlet line.

(8) *Bleeders.* Bleeders, except those for temperature-indicating device wells, shall be 1/8-inch (3 millimeters) or larger 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 (30.5 centimeters) 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 meters) apart along the top. Bleeders may be installed at positions other than those specified in this paragraph, as long as there is evidence in the form of heat distribution data that they accomplish adequate removal of air and circulation of steam within the retort. Vertical retorts shall have at least one bleeder opening located in that portion of the retort opposite the steam inlet. In retorts having top steam inlet and bottom venting, a bleeder shall be installed in the bottom of the retort to remove condensate. All bleeders shall be arranged so that the operator can observe that they are functioning properly.

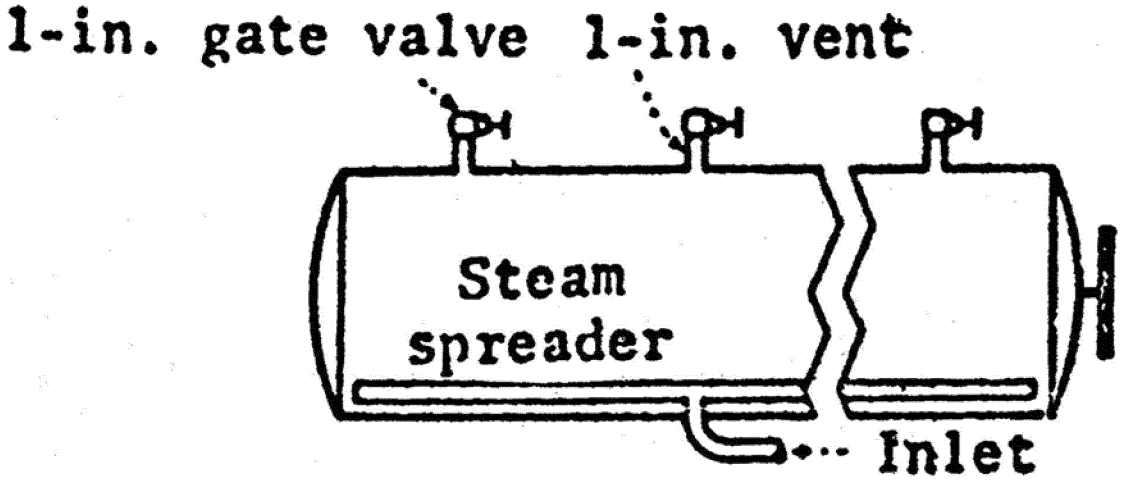
(9) *Stacking equipment and position of containers.* Crates, trays, gondolas, *etc.,* for holding containers shall be made of strap iron, adequately perforated sheet metal, or other suitable material. When perforated sheet metal is used for the bottoms, the perforations should be approximately the equivalent of 1-inch (2.5 centimeters) holes on 2-inch (5.1 centimeters) centers. If dividers are used between the layers of containers, they should be perforated as stated in this paragraph. The positioning of containers in the retort, when specified in the scheduled process, shall be in accordance with that process.

(10) *Air valves.* Retorts using air for pressure cooling shall be equipped with a suitable valve to prevent air leakage into the retort during processing.

(11) *Water valves.* Retorts using water for cooling shall be equipped with a suitable valve to prevent leakage of water into the retort during processing.

(12) *Vents.* Vents shall be installed in such a way that air is removed from the retort before timing of the process is started. Vents shall be controlled by gate, plug cock, or other adequate type valves which shall be fully open to permit rapid discharge of air from the retort during the venting period. Vents shall not be connected directly to a closed drain system. If the overflow is used as a vent, there shall be an atmospheric break in the line before it connects to a closed drain. The vent shall be located in that portion of the retort opposite the steam inlet; for example, steam inlet in bottom portion and vent in top portion. Where a retort manifold connects several vent pipes from a single still retort, it shall be controlled by a gate, plug cock, or other adequate type of valve. The retort manifold shall be of a size that the cross-sectional area of the pipe is larger than the total cross-sectional area of all connecting vents. The discharge shall not be directly 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 that the cross-sectional area is at least equal to the total cross-sectional area of all connecting retort manifold pipes from all retorts venting simultaneously. Timing of the process shall not begin until the retort has been properly vented and the processing temperature has been reached. Some typical installations and operating procedures reflecting the requirements of this section for venting still retorts without divider plates are given in paragraphs (a)(12)(i)(A) through (a)(12)(i)(D) and (a)(12)(ii)(A) and (a)(12)(ii)(B) of this section.

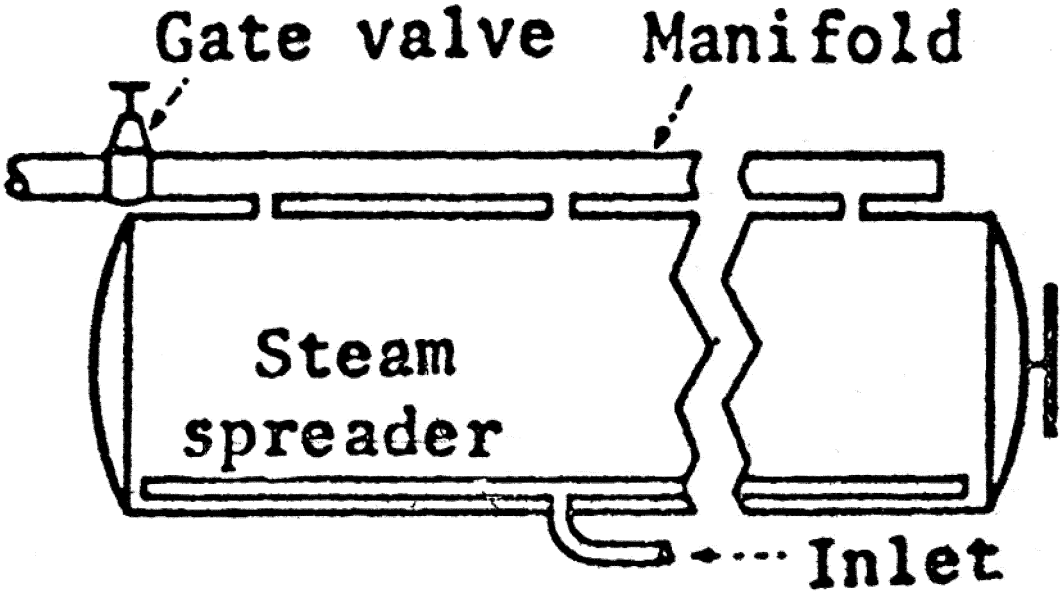
(i) *Venting horizontal retorts.* (A) Venting through multiple 1-inch (2.5 centimeters) vents discharging directly to atmosphere.



(*1*) *Specifications.* One 1-inch (2.5 centimeters) vent for every 5 feet (1.5 meters) of retort length equipped with a gate or plug cock valve and discharging to atmosphere; end vents not more than 2.5 feet (76 centimeters) from ends of retort.

(*2*) *Venting method.* Vent valves should be wide open for at least 5 minutes and to at least 225 °F (107 °C), or at least 7 minutes and to at least 220 °F (104.5 °C).

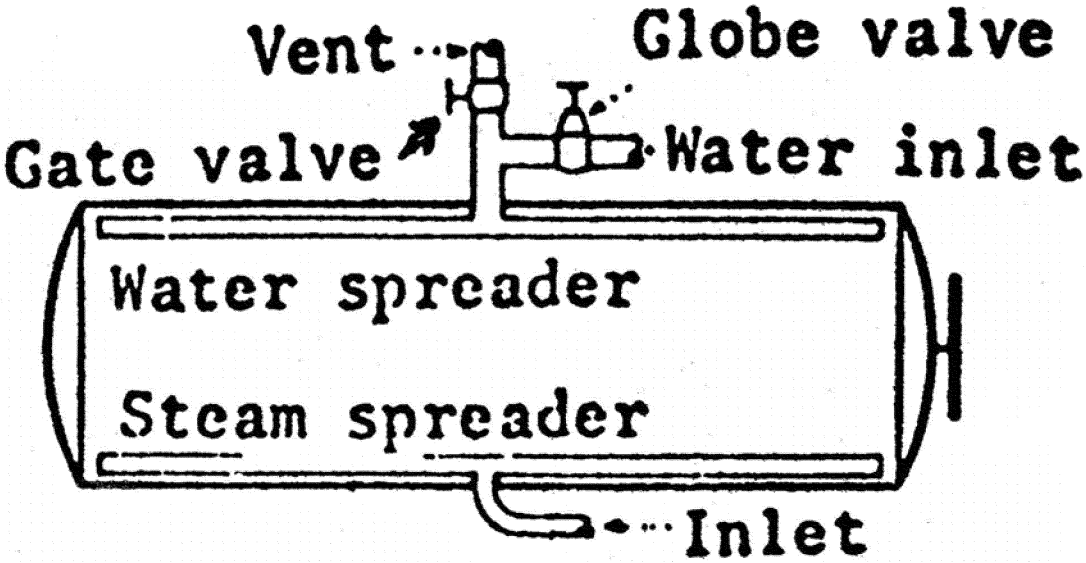
(B) Venting through multiple 1-inch (2.5 centimeters) vents discharging through a manifold to atmosphere.



(*1*) *Specifications.* One 1-inch (2.5 centimeters) vent for every 5 feet (1.5 meters) of retort length; and vents not over 2.5 feet (76 centimeters) from ends of retort. Size of manifold—for retorts less than 15 feet (4.6 meters) in length, 2.5 inches (6.4 centimeters); for retorts 15 feet (4.6 meters) and over in length, 3 inches (7.6 centimeters).

(*2*) *Venting method.* Manifold vent gate or plug cock valve should be wide open for at least 6 minutes and to at least 225 °F (107 °C), or for at least 8 minutes and to at least 220 °F (104.5 °C).

(C) Venting through water spreaders.

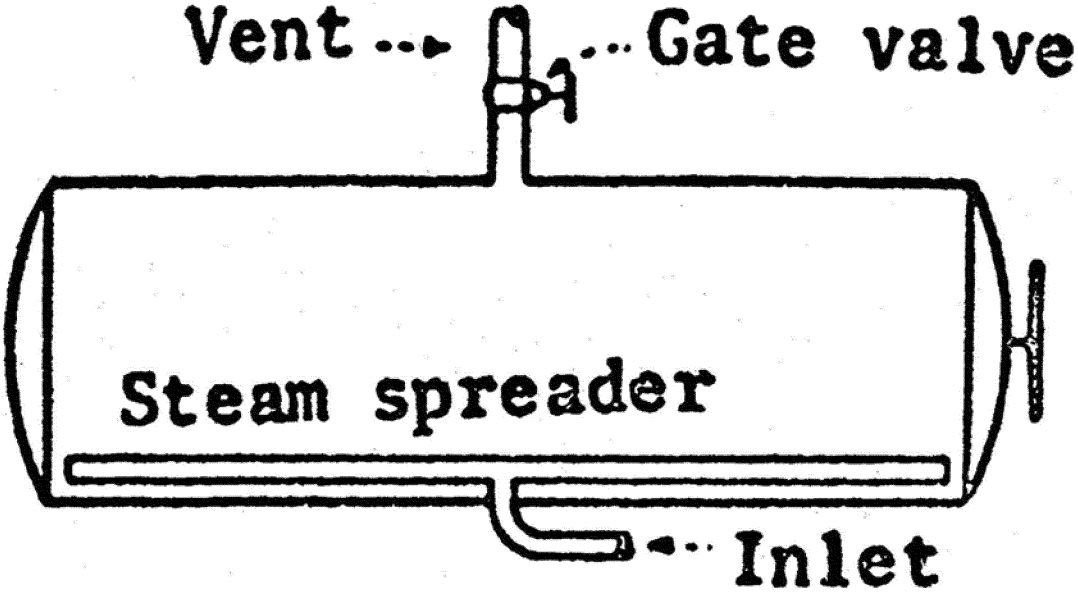


(*1*) *Size of vent and vent valve.* For retorts less than 15 feet (4.6 meters) in length, 2 inches (5.1 centimeters); for retorts 15 feet (4.6 meters) and over in length, 2.5 inches (6.4 centimeters).

(*2*) *Size of water spreader.* For retorts less than 15 feet (4.6 meters) in length, 1.5 inches (3.8 centimeters); for retorts 15 feet (4.6 meters) and over in length, 2 inches (5.1 centimeters). The number of holes should be such that their total cross-sectional area is approximately equal to the cross-sectional area of the vent pipe inlet.

(*3*) *Venting method.* Water spreader vent gate or plug cock valve should be wide open for at least 5 minutes and to at least 225 °F (107 °C), or for at least 7 minutes and to at least 220 °F (104.5 °C).

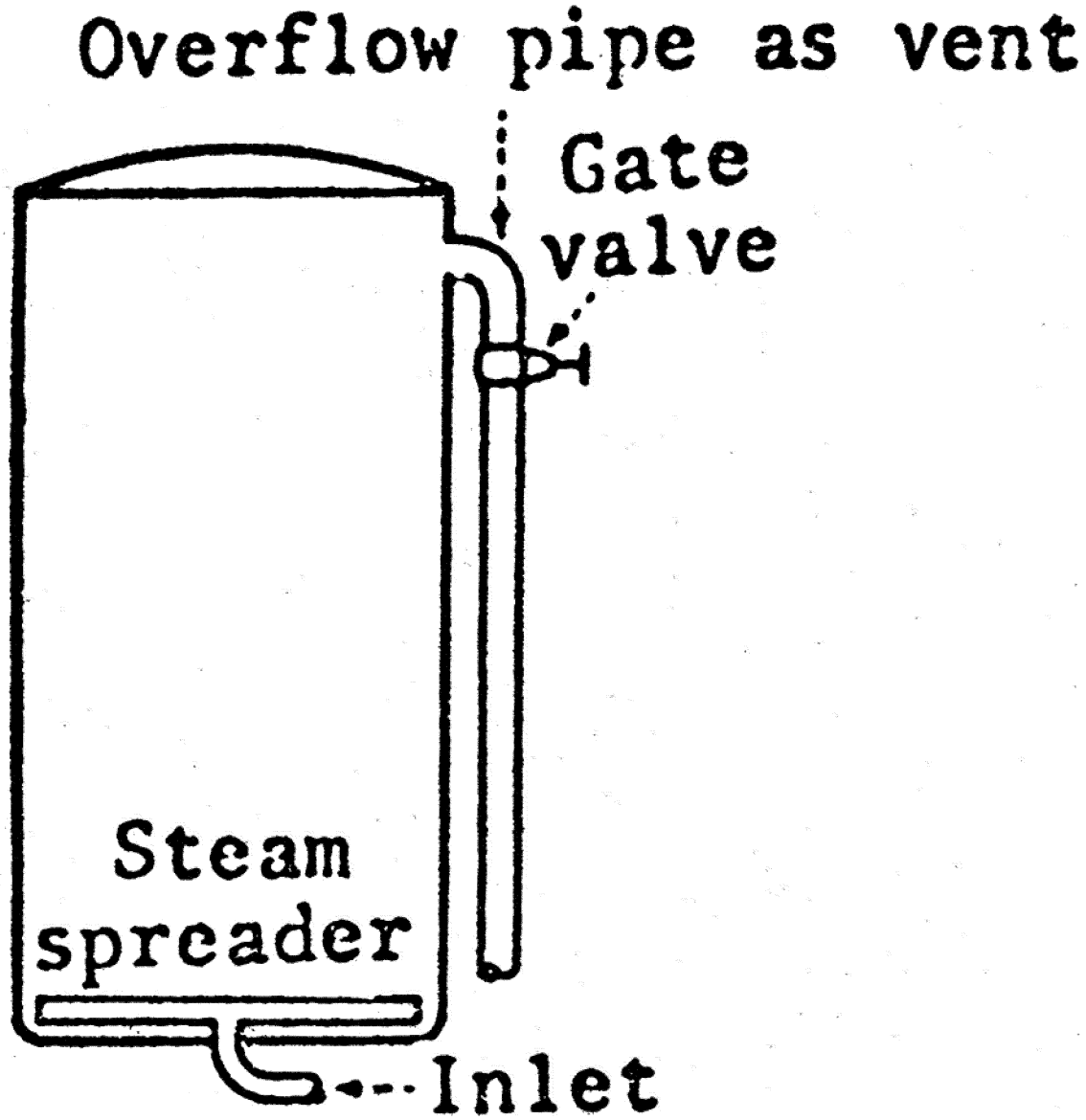
(D) Venting through a single 2.5-inch (6.4 centimeters) top vent (for retorts not exceeding 15 feet (4.6 meters) in length).



(*1*) *Specifications.* A 2.5-inch (6.4 centimeters) vent equipped with a 2.5-inch (6.4 centimeters) gate or plug cock valve and located within 2 feet (61 centimeters) of the center of the retort.

(*2*) *Venting method.* Vent gate or plug cock valve should be wide open for at least 4 minutes and to at least 220 °F (104.5 °C).

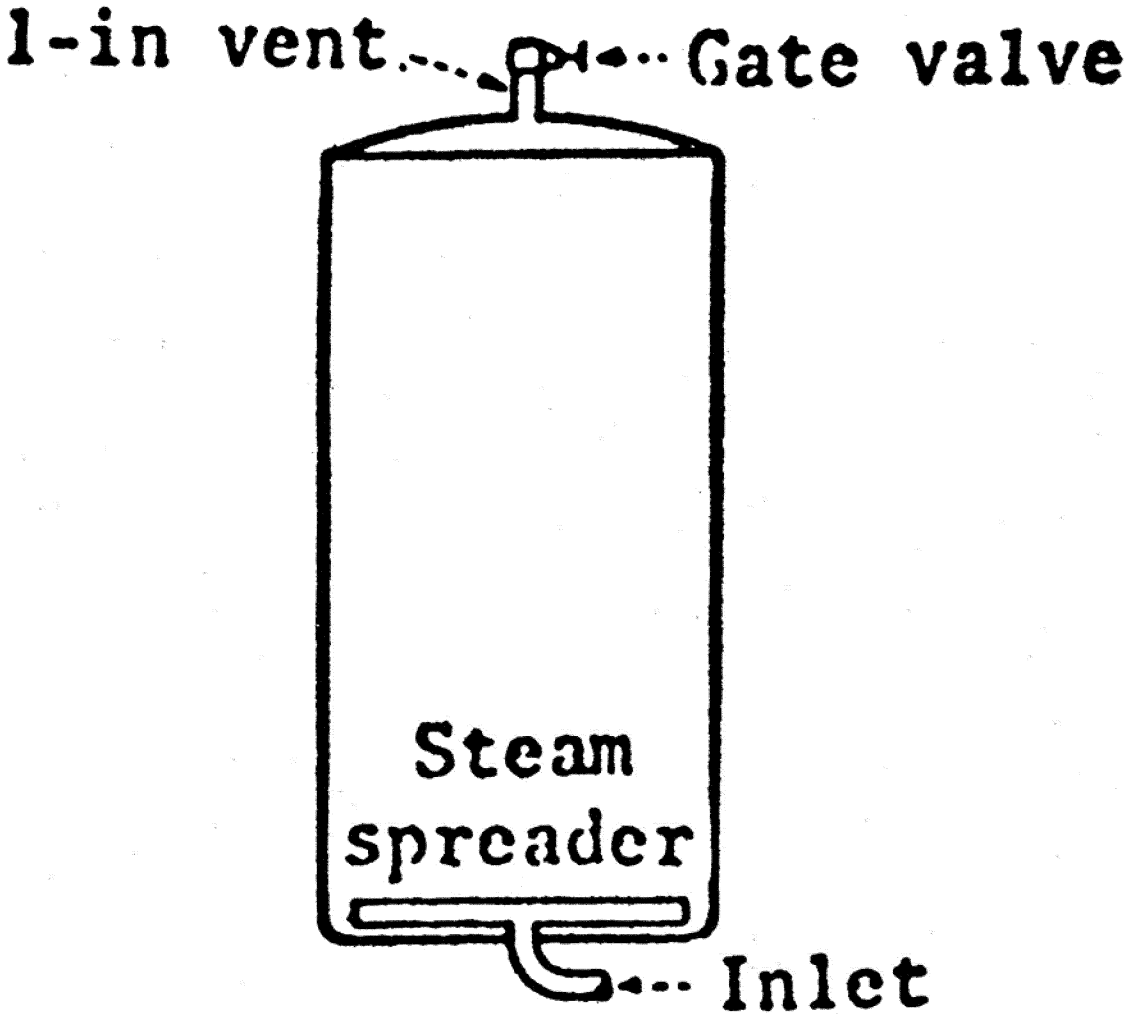
(ii) *Venting vertical retorts.* (A) Venting through a 1.5-inch (3.8 centimeters) overflow.



(*1*) *Specifications.* A 1.5-inch (3.8 centimeters) overflow pipe equipped with a 1.5-inch (3.8 centimeters) gate or plug cock valve and with not more than 6 feet (1.8 meters) of 1.5-inch (3.8 centimeters) pipe beyond the valve before break to the atmosphere or to a manifold header.

(*2*) *Venting method.* Vent gate or plug cock valve should be wide open for at least 4 minutes and to at least 218 °F (103.5 °C), or for at least 5 minutes and to at least 215 °F (102 °C).

(B) Venting through a single 1-inch (2.5 centimeters) side or top vent.



(*1*) *Specifications.* A 1-inch (2.5 centimeters) vent in lid or top side, equipped with a 1-inch (2.5 centimeters) gate or plug cock valve and discharging directly into the atmosphere or to a manifold header.

(*2*) *Venting method.* Vent gate or plug cock valve should 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 (104.5 °C).

(iii) *Other procedures.* Other installations and operating procedures that deviate from the requirements in paragraph (a)(12) of this section may be used if there is evidence in the form of heat distribution data, which shall be kept on file, that they accomplish adequate venting of air.

(13) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process.

(i) When maximum fill-in or drained weight is specified in the scheduled process, it shall be measured and recorded at intervals of sufficient frequency to ensure that the weight of the product does not exceed the maximum for the given container size specified in the scheduled process.

(ii) Closing machine vacuum in vacuum-packed products shall be observed and recorded at intervals of sufficient frequency to ensure that the vacuum is as specified in the scheduled process.

(iii) Such measurements and recordings should be made at intervals not to exceed 15 minutes.

(iv) When the product style results in stratification or layering of the primary product in the containers, the positioning of containers in the retort shall be according to the scheduled process.

(b) *Equipment and procedures for pressure processing in water in still retorts*—(1) *Temperature-indicating device.* Each retort shall be equipped with at least one temperature-indicating device that accurately indicates the temperature during processing. Each temperature-indicating device shall have a sensor and a display. Each temperature-indicating device and each reference device that is maintained by the processor shall be tested for accuracy against a reference device for which the accuracy is traceable to a National Institute of Standards and Technology (NIST), or other national metrology institute, standard reference device by appropriate standard procedures, upon installation and at least once a year thereafter, or more frequently if necessary, to ensure accuracy during processing. Each temperature-indicating device and each reference device that is maintained by the processor shall have a tag, seal, or other means of identity.

(i) The design of the temperature-indicating device shall ensure that the accuracy of the device is not affected by electromagnetic interference and environmental conditions.

(ii) Records of the accuracy of the temperature-indicating device and of a reference device that is maintained by the processor shall be established and

maintained in accordance with § 113.100(c) and (d).

(iii) A temperature-indicating device that is defective or cannot be adjusted to the accurate calibrated reference device shall be repaired before further use or replaced.

(iv) A temperature-indicating device shall be accurate to 1 °F (0.5 °C). The temperature range of a mercury-in-glass thermometer shall not exceed 17 °F per inch (4 °C per centimeter) of graduated scale. A mercury-in-glass thermometer that has a divided mercury column shall be considered defective.

(v) Each temperature-indicating device shall be installed where it can be accurately and easily read. In both horizontal and vertical retorts, the temperature-indicating device sensor shall be inserted directly into the retort shell or in a separate well or sleeve attached to the retort. The temperature-indicating device sensor shall be located so that it is beneath the surface of the water throughout the process and where there is adequate circulation to ensure accurate temperature measurement. On horizontal retorts, the temperature-indicating device sensor should be located in the side at the center of the retort. The temperature-indicating device—not the temperature-recording device—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature-recording device.* Each retort shall have an accurate temperature-recording device. Each temperature-recording device shall have a sensor and a mechanism for recording temperatures to a permanent record, such as a temperature-recording chart.

(i) *Analog or graphical recordings.* Temperature-recording devices that create analog or graphical recordings may be used. Temperature-recording devices that record to charts shall be used only with the appropriate chart. Each chart shall have a working scale of not more than 55 °F per inch (12 °C per centimeter) within a range of 20 °F (10 °C) of the process temperature. Chart graduations shall not exceed 2 °F (1 °C) within a range of 10 °F (5 °C) of the process temperature. Temperature-recording devices that create multipoint plottings of temperature readings shall record the temperature at intervals that will assure that the parameters of the process time and process temperature have been met.

(ii) *Digital recordings.* Temperature-recording devices, such as data loggers, that record numbers or create other digital records may be used. Such a device shall record the temperature at intervals that will assure that the parameters of the process time and process temperature have been met.

(iii) *Adjustments.* The temperature-recording device shall be adjusted with sufficient frequency to ensure agreement as nearly as possible with, but to be in no event higher than, the temperature-indicating device during processing. A means of preventing unauthorized changes in adjustment shall be provided. A lock or a notice from management posted at or near the temperature-recording device that provides a warning that only authorized persons are permitted to make adjustments is a satisfactory means of preventing unauthorized changes.

(iv) *Temperature controller.* The temperature-recording device may be combined with the steam controller and may be a combination recorder-controller. For a vertical retort equipped with a combination recorder-controller, the temperature recorder-controller sensor 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. For a horizontal retort equipped with a combination recorder-controller, the temperature recorder-controller sensor 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 sensor. For all still retort systems that pressure process in water and are equipped with combination recorder-controllers, the temperature recorder-controller sensors shall be located where the recorded temperature is an accurate measurement of the scheduled process temperature and is not affected by the heating media.

(3) *Pressure gages.* (i) Each retort should be equipped with a pressure gage that is accurate to 2 pounds per square inch (13.8 kilopascals) or less.

(ii) Each retort should have an adjustable pressure relief or control valve of a capacity sufficient to prevent an undesired increase in retort pressure when the water valve is wide open and should be installed in the overflow line.

(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. The steam controller may be combined with a temperature-recording device and, thus, may be a combination recorder-controller. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air.

(5) *Steam introduction.* Steam shall be distributed in the bottom of the retort in a manner adequate to provide uniform heat distribution throughout the retort. In vertical retorts, uniform steam distribution can be achieved by any of several methods. In horizontal retorts, the steam distributor shall run the length of the bottom of the retort with perforations distributed uniformly along the upper part of the pipe.

(6) *Crate supports.* A bottom crate support shall be used in vertical still retorts. Baffle plates shall not be used in the bottom of the retort. Centering guides should be installed so as to ensure that there is about a 1.5-inch (3.8 centimeters) clearance between the side wall of the crate and the retort wall.

(7) *Stacking equipment and position of containers.* Crates, trays, gondolas, *etc.,* for holding containers shall be made of strap iron, adequately perforated sheet metal, or other suitable material. When perforated sheet metal is used for the bottoms, the perforations should be approximately the equivalent of 1-inch (2.5 centimeters) holes on 2-inch (5.1 centimeters) centers. If divider plates are used between the layers of containers, they should be perforated as stated in this paragraph. The positioning of containers in the retort, when specified in the scheduled process, shall be in accordance with that process. Dividers, racks, trays, or other means of positioning of flexible containers shall be designed and employed to ensure even circulation of heating medium around all containers in the retort.

(8) *Drain valve.* A nonclogging, water-tight valve shall be used. A screen shall be installed or other suitable means shall be used on all drain openings to prevent clogging.

(9) *Air supply and controls.* In both horizontal and vertical still retorts for pressure processing in water, a means shall be provided for introducing compressed air at the proper pressure and rate. The proper pressure shall be controlled by an automatic pressure control unit. A check valve shall be provided in the air supply line to prevent water from entering the system. Air or water circulation shall be maintained continuously during the come-up time and during processing and cooling periods. The adequacy of the air or water circulation for uniform heat distribution within the retort shall be established in accordance with procedures recognized by a competent processing authority and records shall be kept on file. 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.

(10) *Water level indicator.* There shall be a means of determining the water level in the retort during operation, *e.g.,* by using a sensor, gage, water glass, or petcock(s). Water shall cover the top

layer of containers during the entire come-up time and processing periods and should cover the top layer of containers during the cooling periods. The operator shall check and record the water level at intervals sufficient to ensure its adequacy.

(11) *Water circulation.* When a water circulating 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 and should have an aggregate area not greater than the cross-sectional area of the outlet line from the pump. The suction outlets shall be protected with nonclogging screens or other suitable means shall be used to keep debris from entering the circulating system. The pump shall be designed to provide proper flow on startup and during operation, such as with a bleeder or other suitable means to remove air during startup and with an appropriate device or design to prevent pump cavitation during operation. The pump shall be equipped with a signaling device to warn the operator when it is not running. Alternative methods for circulation of water in the retort may be used when established by a competent authority as adequate for even heat distribution.

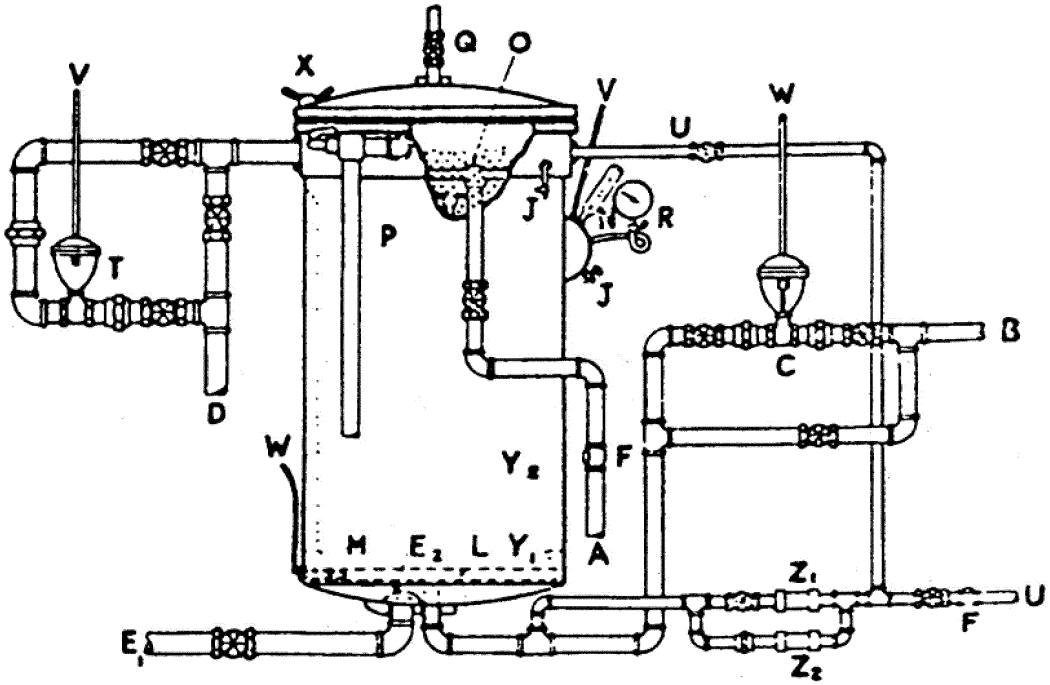
(12) *Cooling water supply.* In vertical retorts, the cooling water should be introduced at the top of the retort between the water and container levels. In horizontal retorts the cooling water should be introduced into the suction side of the pump. A check valve should be included in the cooling water line.

(13) *Retort headspace.* The headspace necessary to control the air pressure should be maintained between the water level and the top of the retort shell.

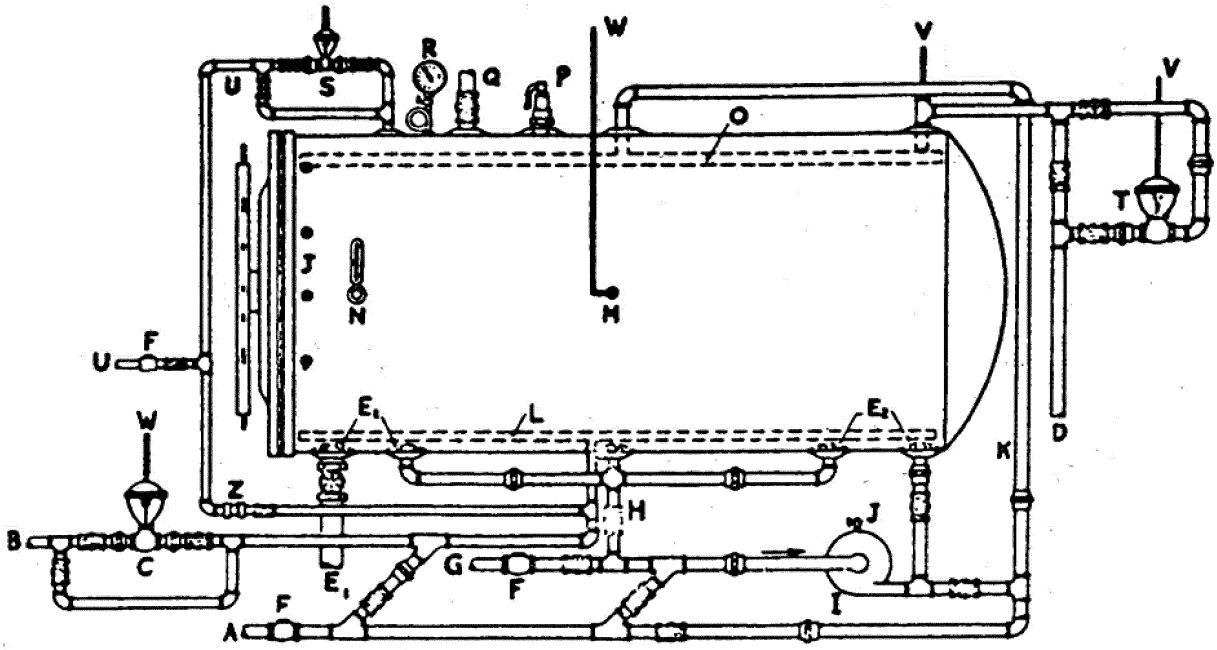
(14) *Vertical and horizontal still retorts.* Vertical and horizontal still retorts should follow the arrangements in the diagrams in this paragraph. Other installation and operating procedures that deviate from these arrangements may be used, as long as there is evidence in the form of heat distribution data or other suitable information, which shall be kept on file, which demonstrates that the heat distribution is adequate.

BILLING CODE 4160–01–P

Vertical Retorts



Horizontal Retorts



BILLING CODE 4160–01–C

Legend for Vertical and Horizontal Still Retorts

A—Water line.
B—Steam line.
C—Temperature control.
D—Overflow line.
E_1—Drain line.
E_2—Screens.
F—Check valves.
G—Line from hot water storage.
H—Suction line and manifold.
I—Circulating pump.
J—Petcocks.

K—Recirculating line.
L—Steam distributor.
M—Temperature-controller sensor.
N—Temperature-indicating device sensor.
O—Water spreader.
P—Safety valve.
Q—Vent valve for steam processing.
R—Pressure gage.
S—Inlet air control.
T—Pressure control.
U—Air line.
V—To pressure control instrument.
W—To temperature control instrument.
X—Wing nuts.
Y_1—Crate support.
Y_2—Crate guides.
Z—Constant flow orifice valve.
Z_1—Constant flow orifice valve used during come-up.
Z_2—Constant flow orifice valve used during cook.

(15) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process.

(i) When maximum fill-in or drained weight is specified in the scheduled process, it shall be measured and recorded at intervals of sufficient frequency to ensure that the weight of the product does not exceed the maximum for the given container size specified in the scheduled process.

(ii) Closing machine vacuum in vacuum-packed products shall be observed and recorded at intervals of sufficient frequency to ensure that the vacuum is as specified in the scheduled process.

(iii) Such measurements and recordings should be made at intervals not to exceed 15 minutes.

(iv) When the product style results in stratification or layering of the primary product in the containers, the positioning of containers in the retort shall be according to the scheduled process.

(c) *Equipment and procedures for pressure processing in steam in continuous agitating retorts*—(1) *Temperature-indicating device.* Each retort shall be equipped with at least one temperature-indicating device that accurately indicates the temperature during processing. Each temperature-indicating device shall have a sensor and a display. Each temperature-indicating device and each reference device that is maintained by the processor shall be tested for accuracy against a reference device for which the accuracy is traceable to a National Institute of Standards and Technology (NIST), or other national metrology institute, standard reference device by appropriate standard procedures, upon installation and at least once a year thereafter, or more frequently if necessary, to ensure accuracy during processing. Each temperature-indicating device and each reference device that is maintained by the processor shall have a tag, seal, or other means of identity.

(i) The design of the temperature-indicating device shall ensure that the accuracy of the device is not affected by electromagnetic interference and environmental conditions.

(ii) Records of the accuracy of the temperature-indicating device and of a reference device that is maintained by the processor shall be established and maintained in accordance with § 113.100(c) and (d).

(iii) A temperature-indicating device that is defective or cannot be adjusted to the accurate calibrated reference device shall be repaired before further use or replaced.

(iv) A temperature-indicating device shall be accurate to 1 °F (0.5 °C). The temperature range of a mercury-in-glass thermometer shall not exceed 17 °F per inch (4 °C per centimeter) of graduated scale. A mercury-in-glass thermometer that has a divided mercury column shall be considered defective.

(v) Each temperature-indicating device shall be installed where it can be accurately and easily read. The temperature-indicating device sensor shall be installed either within the retort shell or in external wells attached to the retort. External wells or pipes shall be connected to the retort through at least a ¾-inch (2 centimeters) diameter opening and equipped with a 1/16-inch (1.5 millimeters) or larger bleeder opening so located as to provide a full flow of steam past the length of the temperature-indicating device sensor. The bleeders for external wells shall emit steam continuously during the entire processing period. The temperature-indicating device—not the temperature-recording device—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature-recording device.* Each retort shall have an accurate temperature-recording device. Each temperature-recording device shall have a sensor and a mechanism for recording temperatures to a permanent record, such as a temperature-recording chart. The temperature-recording device sensor shall be installed either within the retort shell or in a well attached to the shell. Each temperature-recording device sensor well shall have a 1/16-inch (1.5 millimeters) or larger bleeder that emits steam continuously during the processing period.

(i) *Analog or graphical recordings.* Temperature-recording devices that create analog or graphical recordings may be used. Temperature-recording devices that record to charts shall be used only with the appropriate chart. Each chart shall have a working scale of not more than 55 °F per inch (12 °C per centimeter) within a range of 20 °F (10 °C) of the process temperature. Chart graduations shall not exceed 2 °F (1 °C) within a range of 10 °F (5 °C) of the process temperature. Temperature-recording devices that create multipoint plottings of temperature readings shall record the temperature at intervals that will assure that the parameters of the process time and process temperature have been met.

(ii) *Digital recordings.* Temperature-recording devices, such as data loggers, that record numbers or create other digital records may be used. Such a device shall record the temperature at intervals that will assure that the parameters of the process time and process temperature have been met.

(iii) *Adjustments.* The temperature-recording device shall be adjusted with sufficient frequency to ensure agreement as nearly as possible with, but to be in no event higher than, the temperature-indicating device during processing. A means of preventing unauthorized changes in adjustment shall be provided. A lock or a notice from management posted at or near the temperature-recording device that provides a warning that only authorized persons are permitted to make adjustments is a satisfactory means of preventing unauthorized changes.

(iv) *Temperature controller.* The temperature-recording device may be combined with the steam controller and may be a recorder-controller.

(3) *Pressure gages.* Each retort should be equipped with a pressure gage that is accurate to 2 pounds per square inch (13.8 kilopascals) or less.

(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recorder-controller when combined with a temperature-recording device. A steam controller activated by the steam pressure of the retort is acceptable if it is carefully maintained mechanically so that it operates satisfactorily. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air.

(5) *Bleeders.* Bleeders, except those for temperature-indicating device wells, shall be ⅛-inch (3 millimeters) or larger and shall be wide open during the entire process, including the come-up time. Bleeders shall be located within approximately 1 foot (30.5 centimeters) 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 meters) apart along the top of the retort. All bleeders shall be arranged so that the operator can observe that they are functioning properly. The condensate bleeder shall be checked with sufficient frequency to ensure adequate removal of condensate or shall be equipped with an automatic alarm system(s) that would serve as a continuous monitor of condensate-bleeder functioning. Visual checks should be done at intervals of not more than 15 minutes. A record of such checks should be kept to show that the bleeder is functioning properly.

(6) *Venting and condensate removal.* Vents shall be located in that portion of the retort opposite the steam inlet. Air shall be removed before processing is started. Heat distribution data or documentary proof from the manufacturer or from a competent processing authority, demonstrating that adequate venting is achieved, shall be kept on file. At the time steam is turned on, the drain should be opened for a time sufficient to remove steam condensate from the retort, and provision shall be made for continuing drainage of condensate during the retort operation. The condensate bleeder in the bottom of the shell serves as an indicator of continuous condensate removal.

(7) *Retort speed timing.* The rotational speed of the retort shall be specified in the scheduled process. The speed shall be adjusted and recorded when the retort is started, at any time a speed change is made, and at intervals of sufficient frequency to ensure that the retort speed is maintained as specified in the scheduled process. These adjustments and recordings should be made every 4 hours or less. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. A means of preventing unauthorized speed changes on retorts shall be provided. A lock or a notice from management posted at or near the speed adjustment device that provides a warning that only authorized persons are permitted to make adjustments is a satisfactory means of preventing unauthorized changes.

(8) *Emergency stops.* If a retort jams or breaks down during processing operations, necessitating cooling the retort for repairs, the retort shall be operated in such a way that ensures that the product is commercially sterile, or the retort is to be cooled promptly and all containers either reprocessed, repacked and reprocessed, or discarded. When operated as a still retort, all containers shall be given a full still retort process before the retort is cooled. If, in such an emergency, a scheduled still process or another process established to ensure commercial sterility is to be used, it shall be made readily available to the retort operator.

(i) Any containers in the retort intake valve or in transfer valves between cooker shells of a continuous retort at the time of breakdown shall either be reprocessed, repacked and reprocessed, or discarded.

(ii) Both the time at which the reel stopped and the time the retort was used for a still retort process, if so used, shall be indicated on the temperature-recording device record and entered on the other production records required in this chapter. If the alternative procedure of prompt cooling is followed, the subsequent handling methods used for the containers in the retort at the time of stopping and cooling shall be entered on the production records.

(9) *Temperature drop.* If the temperature of the continuous retort drops below the temperature specified in the scheduled process while containers are in the retort, the retort reel shall be stopped promptly. An automatic device should be used to stop the reel when the temperature drops below the specified process temperature. Before the reel is restarted, all containers in the retort shall be given a complete scheduled still retort process if the temperature drop was 10 °F (5 °C) or more below the specified temperature, or alternatively, container entry to the retort shall be stopped and the reel restarted to empty the retort. The discharged containers shall be either reprocessed, repacked and reprocessed, or discarded. Both the time at which the reel stopped and the time the retort was used for a still retort process, if so used, shall be indicated on the temperature-recording device record and entered on the other production records required in this chapter. If the alternative procedure of emptying the retort is followed, the subsequent handling methods used for the containers in the retort at the time of the temperature drop shall be entered on the production records. If the temperature drop was less than 10 °F (5 °C), a scheduled authorized emergency still process approved by a qualified person(s) having expert knowledge of thermal processing requirements may be used before restarting the retort reel. Alternatively, container entry to the retort shall be stopped and an authorized emergency agitating process may be used before container entry to the retort is restarted. When emergency procedures are used, no containers may enter the retort and the process and procedures used shall be noted on the production records.

(10) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process. The minimum headspace of containers, if specified in the scheduled process, shall be measured and recorded at intervals of sufficient frequency to ensure that the headspace is as specified in the scheduled process. The headspace of solder-tipped, lapseam (vent hole) cans may be measured by net weight determinations. The headspace of double seamed cans may also be measured by net weight determinations for homogenous liquids, taking into account the specific can end profile and other factors which affect the headspace, if proof of the accuracy of such measurements is maintained and the procedure and resultant headspace is in accordance with the scheduled process. When the product consistency is specified in the scheduled process, the consistency of the product shall be determined by objective measurements on the product taken from the filler before processing and recorded at intervals of sufficient frequency to ensure that the consistency is as specified in the scheduled process. Minimum closing machine vacuum in vacuum-packed products, maximum fill-in or drained weight, minimum net weight, and percent solids shall be as specified in the scheduled process for all products when deviations from such specifications may affect the scheduled process. All measurements and recordings of critical factors should be made at intervals not to exceed 15 minutes.

(d) *Equipment and procedures for pressure processing in steam in discontinuous agitating retorts*—(1) *Temperature-indicating device.* Each retort shall be equipped with at least one temperature-indicating device that accurately indicates the temperature during processing. Each temperature-indicating device shall have a sensor and a display. Each temperature-indicating device and each reference device that is maintained by the processor shall be tested for accuracy against a reference device for which the accuracy is traceable to a National Institute of Standards and Technology (NIST), or other national metrology institute, standard reference device by appropriate standard procedures, upon installation and at least once a year thereafter, or more frequently if necessary, to ensure accuracy during

processing. Each temperature-indicating device and each reference device that is maintained by the processor shall have a tag, seal, or other means of identity.

(i) The design of the temperature-indicating device shall ensure that the accuracy of the device is not affected by electromagnetic interference and environmental conditions.

(ii) Records of the accuracy of the temperature-indicating device and of a reference device that is maintained by the processor shall be established and maintained in accordance with § 113.100(c) and (d).

(iii) A temperature-indicating device that is defective or cannot be adjusted to the accurate calibrated reference device shall be repaired before further use or replaced.

(iv) A temperature-indicating device shall be accurate to 1 °F (0.5 °C). The temperature range of a mercury-in-glass thermometer shall not exceed 17 °F per inch (4 °C per centimeter) of graduated scale. A mercury-in-glass thermometer that has a divided mercury column shall be considered defective.

(v) Each temperature-indicating device shall be installed where it can be accurately and easily read. The temperature-indicating device sensor shall be installed either within the retort shell or in external wells attached to the retort. External wells or pipes shall be connected to the retort through at least a ¾-inch (2 centimeters) diameter opening and equipped with a 1/16-inch (1.5 millimeters) or larger bleeder opening so located as to provide a full flow of steam past the length of the temperature-indicating device sensor. The bleeders for external wells shall emit steam continuously during the entire processing period. The temperature-indicating device—not the temperature-recording device—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature-recording device.* Each retort shall have an accurate temperature-recording device. Each temperature-recording device shall have a sensor and a mechanism for recording temperatures to a permanent record, such as a temperature-recording chart. The temperature-recording device sensor shall be installed either within the retort shell or in a well attached to the shell. Each temperature-recording device sensor well shall have a 1/16-inch (1.5 millimeters) or larger bleeder that emits steam continuously during the processing period.

(i) *Analog or graphical recordings.* Temperature-recording devices that create analog or graphical recordings may be used. Temperature-recording devices that record to charts shall be used only with the appropriate chart. Each chart shall have a working scale of not more than 55 °F per inch (12 °C per centimeter) within a range of 20 °F (10 °C) of the process temperature. Chart graduations shall not exceed 2 °F (1 °C) within a range of 10 °F (5 °C) of the process temperature. Temperature-recording devices that create multipoint plottings of temperature readings shall record the temperature at intervals that will assure that the parameters of the process time and process temperature have been met.

(ii) *Digital recordings.* Temperature-recording devices, such as data loggers, that record numbers or create other digital records may be used. Such a device shall record the temperature at intervals that will assure that the parameters of the process time and process temperature have been met.

(iii) *Adjustments.* The temperature-recording device shall be adjusted with sufficient frequency to ensure agreement as nearly as possible with, but to be in no event higher than, the temperature-indicating device during processing. A means of preventing unauthorized changes in adjustment shall be provided. A lock or a notice from management posted at or near the temperature-recording device that provides a warning that only authorized persons are permitted to make adjustments is a satisfactory means of preventing unauthorized changes.

(iv) *Temperature controller.* The temperature-recording device may be combined with the steam controller and may be a recorder-controller.

(3) *Pressure gages.* Each retort should be equipped with a pressure gage that is accurate to 2 pounds per square inch (13.8 kilopascals) or less.

(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recorder-controller when combined with a temperature-recording device. A steam controller activated by the steam pressure of the retort is acceptable if it is mechanically maintained so that it operates satisfactorily. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air.

(5) *Bleeders.* Bleeders, except those for temperature-indicating device wells, shall be ⅛-inch (3 millimeters) or larger and shall be wide open during the entire process, including the come-up time. Bleeders shall be located within approximately 1 foot (30.5 centimeters) 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 meters) apart along the top. Bleeders may be installed at positions other than those specified in this paragraph, as long as there is evidence in the form of heat distribution data that they accomplish adequate removal of air and circulation of heat within the retort. In retorts having top steam inlet and bottom venting, a bleeder shall be installed in the bottom of the retort to remove condensate. All bleeders shall be arranged in a way that enables the operator to observe that they are functioning properly.

(6) *Venting and condensate removal.* The air in each retort shall be removed before processing is started. Heat distribution data or documentary proof from the manufacturer or from a competent processing authority, demonstrating that adequate venting is achieved, shall be kept on file. At the time steam is turned on, the drain should be opened for a time sufficient to remove steam condensate from the retort and provision should be made for continuing drainage of condensate during the retort operation.

(7) *Retort speed timing.* The rotational speed of the retort shall be specified in the scheduled process. The speed shall be adjusted, as necessary, to ensure that the speed is as specified in the scheduled process. The rotational speed as well as the process time shall be recorded for each retort load processed. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. A means of preventing unauthorized speed changes on retorts shall be provided. A lock or a notice from management posted at or near the speed-adjustment device that provides a warning that only authorized persons are permitted to make adjustments is a satisfactory means of preventing unauthorized changes.

(8) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process. The minimum headspace of containers in each retort load to be processed, if specified in the scheduled process, shall be measured and recorded at intervals of sufficient frequency to ensure that the headspace is as specified in the scheduled process. The headspace of solder-tipped, lap seam (vent hole) cans may be measured by net weight determinations. When the product consistency is specified in the scheduled process, the consistency of the product shall be determined by objective measurements on the product taken from the filler before processing and recorded at intervals of sufficient frequency to ensure that the consistency

is as specified in the scheduled process. Minimum closing machine vacuum in vacuum-packed products, maximum fill-in or drained weight, minimum net weight, and percent solids shall be as specified in the scheduled process for all products for which deviations from such specifications may affect the scheduled process. All measurements and recordings of critical factors should be made at intervals not to exceed 15 minutes.

(e) *Equipment and procedures for pressure processing in water in discontinuous agitating retorts*—(1) *Temperature-indicating device.* Each retort shall be equipped with at least one temperature-indicating device that accurately indicates the temperature during processing. Each temperature-indicating device shall have a sensor and a display. Each temperature-indicating device and each reference device that is maintained by the processor shall be tested for accuracy against a reference device for which the accuracy is traceable to a National Institute of Standards and Technology (NIST), or other national metrology institute, standard reference device by appropriate standard procedures, upon installation and at least once a year thereafter, or more frequently if necessary, to ensure accuracy during processing. Each temperature-indicating device and each reference device that is maintained by the processor shall have a tag, seal, or other means of identity.

(i) The design of the temperature-indicating device shall ensure that the accuracy of the device is not affected by electromagnetic interference and environmental conditions.

(ii) Records of the accuracy of the temperature-indicating device and of a reference device that is maintained by the processor shall be established and maintained in accordance with § 113.100(c) and (d).

(iii) A temperature-indicating device that is defective or cannot be adjusted to the accurate calibrated reference device shall be repaired before further use or replaced.

(iv) A temperature-indicating device shall be accurate to 1 °F (0.5 °C). The temperature range of a mercury-in-glass thermometer shall not exceed 17 °F per inch (4 °C per centimeter) of graduated scale. A mercury-in-glass thermometer that has a divided mercury column shall be considered defective.

(v) Each temperature-indicating device shall be installed where it can be accurately and easily read. In both horizontal and vertical retorts, the temperature-indicating device sensor shall be inserted directly into the retort shell or in a separate well or sleeve attached to the retort. The temperature-indicating device sensor shall be located so that it is beneath the surface of the water throughout the process and where there is adequate circulation to ensure accurate temperature measurement. On horizontal retorts, the temperature-indicating device sensor should be located in the side at the center of the retort. The temperature-indicating device—not the temperature-recording device—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature-recording device.* Each retort shall have an accurate temperature-recording device. Each temperature-recording device shall have a sensor and a mechanism for recording temperatures to a permanent record, such as a temperature-recording chart. The temperature-recording device sensor shall be installed either within the retort shell or in a well attached to the shell.

(i) *Analog or graphical recordings.* Temperature-recording devices that create analog or graphical recordings may be used. Temperature-recording devices that record to charts shall be used only with the appropriate chart. Each chart shall have a working scale of not more than 55 °F per inch (12 °C per centimeter) within a range of 20 °F (10 °C) of the process temperature. Chart graduations shall not exceed 2 °F (1 °C) within a range of 10 °F (5 °C) of the process temperature. Temperature-recording devices that create multipoint plottings of temperature readings shall record the temperature at intervals that will assure that the parameters of the process time and process temperature have been met.

(ii) *Digital recordings.* Temperature-recording devices, such as data loggers, that record numbers or create other digital records may be used. Such a device shall record the temperature at intervals that will assure that the parameters of the process time and process temperature have been met.

(iii) *Adjustments.* The temperature-recording device shall be adjusted with sufficient frequency to ensure agreement as nearly as possible with, but to be in no event higher than, the temperature-indicating device during processing. A means of preventing unauthorized changes in adjustment shall be provided. A lock or a notice from management posted at or near the temperature-recording device that provides a warning that only authorized persons are permitted to make adjustments is a satisfactory means of preventing unauthorized changes.

(iv) *Temperature controller.* The temperature-recording device may be combined with the steam controller and may be a recorder-controller. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air.

(3) *Pressure gages.* Each retort should be equipped with a pressure gage that is accurate to 2 pounds per square inch (13.8 kilopascals) or less.

(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recorder-controller when combined with a temperature-recording device. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air.

(5) *Retort speed timing.* The rotational speed of the retort shall be specified in the scheduled process. The speed shall be adjusted, as necessary, to ensure that the speed is as specified in the scheduled process. The rotational speed as well as the process time shall be recorded for each retort load processed. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. A means of preventing unauthorized speed changes shall be provided. A lock or a notice from management posted at or near the speed adjustment device that provides a warning that only authorized persons are permitted to make adjustment is a satisfactory means of preventing unauthorized changes.

(6) *Air supply and controls.* When air is used to provide overpressure:

(i) A means shall be provided for introducing compressed air at the proper pressure and rate. The proper pressure shall be controlled by an automatic pressure control unit. A check valve shall be provided in the air supply line to prevent water from entering the system.

(ii) A water level indicator, *e.g.,* sensor, gage, water glass, or petcock(s), shall be used for determining the water level in the retort during operation. Water shall cover the top layer of containers during the entire come-up time and processing periods and should also cover the top layer of containers during the cooling periods. The operator shall check and record the water level at intervals sufficient to ensure its adequacy.

(7) *Water circulation.* When a water circulating 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 and should have an

aggregate area not greater than the cross-sectional area of the outlet line from the pump. The suction outlets shall be protected with nonclogging screens or other suitable means shall be used to keep debris from entering the circulating system. The pump shall be designed to provide proper flow on startup and during operation, such as with a bleeder or other suitable means to remove air during startup and with an appropriate device or design to prevent pump cavitation during operation. The pump shall be equipped with a signaling device to warn the operator when it is not running. Alternative methods for circulation of water in the retort may be used when established by a competent authority as adequate for even heat distribution.

(8) *Drain valve.* A nonclogging, water-tight valve shall be used. A screen shall be installed or other suitable means shall be used on all drain openings to prevent clogging.

(9) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process. The minimum headspace of containers, if specified in the scheduled process, shall be measured and recorded at intervals of sufficient frequency to ensure that the headspace is as specified in the scheduled process. The headspace of solder-tipped, lap seam (vent hole) cans may be measured by net weight determinations. When the product consistency is specified in the scheduled process, the consistency of the product shall be determined by objective measurements on the product taken from the filler before processing and recorded at intervals of sufficient frequency to ensure that the consistency is as specified in the scheduled process. Minimum closing machine vacuum in vacuum-packed products, maximum fill-in or drained weight, minimum net weight, and percent solids shall be as specified in the scheduled process for all products when deviations from such specifications may affect the scheduled process. All measurements and recordings of critical factors should be made at intervals not to exceed 15 minutes.

(f) *Equipment and procedures for pressure processing in steam in hydrostatic retorts*—(1) *Temperature-indicating device.* Each retort shall be equipped with at least one temperature-indicating device that accurately indicates the temperature during processing. Each temperature-indicating device shall have a sensor and a display. Each temperature-indicating device and each reference device that is maintained by the processor shall be tested for accuracy against a reference device for which the accuracy is traceable to a National Institute of Standards and Technology (NIST), or other national metrology institute, standard reference device by appropriate standard procedures, upon installation and at least once a year thereafter, or more frequently if necessary, to ensure accuracy during processing. Each temperature-indicating device and each reference device that is maintained by the processor shall have a tag, seal, or other means of identity.

(i) The design of the temperature-indicating device shall ensure that the accuracy of the device is not affected by electromagnetic interference and environmental conditions.

(ii) Records of the accuracy of the temperature-indicating device and of a reference device that is maintained by the processor shall be established and maintained in accordance with § 113.100(c) and (d).

(iii) A temperature-indicating device that is defective or cannot be adjusted to the accurate calibrated reference device shall be repaired before further use or replaced.

(iv) A temperature-indicating device shall be accurate to 1 °F (0.5 °C). The temperature range of a mercury-in-glass thermometer shall not exceed 17 °F per inch (4 °C per centimeter) of graduated scale. A mercury-in-glass thermometer that has a divided mercury column shall be considered defective.

(v) Each temperature-indicating device shall be installed where it can be accurately and easily read. The temperature-indicating device sensor shall be located in the steam dome near the steam-water interface. When the scheduled process specifies maintenance of particular temperatures in the hydrostatic water legs, a temperature-indicating device sensor shall be located in each hydrostatic water leg in a position near the bottom temperature-recording device sensor. The temperature-indicating device—not the temperature-recording device—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature-recording device.* Each retort shall have an accurate temperature-recording device. Each temperature-recording device shall have a sensor and a mechanism for recording temperatures to a permanent record, such as a temperature-recording chart. The temperature-recording device sensor shall be installed either within the steam dome or in a well attached to the dome. Each temperature-recording device sensor well shall have a 1/16-inch (1.5 millimeters) or larger bleeder that emits steam continuously during the processing period. Additional temperature-recording device sensors shall be installed in the hydrostatic water legs in situations where the scheduled process specifies maintenance of particular temperatures in the hydrostatic water legs.

(i) *Analog or graphical recordings.* Temperature-recording devices that create analog or graphical recordings may be used. Temperature-recording devices that record to charts shall be used only with the appropriate chart. Each chart shall have a working scale of not more than 55 °F per inch (12 °C per centimeter) within a range of 20 °F (10 °C) of the process temperature. Chart graduations shall not exceed 2 °F (1 °C) within a range of 10 °F (5 °C) of the process temperature. Temperature-recording devices that create multipoint plottings of temperature readings shall record the temperature at intervals that will assure that the parameters of the process time and process temperature have been met.

(ii) *Digital recordings.* Temperature-recording devices, such as data loggers, that record numbers or create other digital recordings may be used. Such a device shall record the temperature at intervals that will assure that the parameters of the process time and process temperature have been met.

(iii) *Adjustments.* The temperature-recording device shall be adjusted with sufficient frequency to ensure agreement as nearly as possible with, but to be in no event higher than, the temperature-indicating device during processing. A means of preventing unauthorized changes in adjustment shall be provided. A lock or a notice from management posted at or near the temperature-recording device that provides a warning that only authorized persons are permitted to make adjustments is a satisfactory means of preventing unauthorized changes.

(iv) *Temperature controller.* The temperature-recording device may be combined with the steam controller and may be a recorder-controller.

(3) *Pressure gages.* Each retort should be equipped with a pressure gage that is accurate to 2 pounds per square inch (13.8 kilopascals) or less.

(4) *Recording of temperatures.* Temperatures indicated by the temperature-indicating device or devices shall be entered on a suitable form during processing operations. Temperatures shall be recorded by an accurate temperature-recording device or devices at the following points:

(i) In the steam chamber between the steam-water interface and the lowest container position.

(ii) Near the top and the bottom of each hydrostatic water leg if the scheduled process specifies maintenance of particular temperatures in the legs.

(5) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recorder-controller when combined with a temperature-recording device. A steam controller activated by the steam pressure of the retort is acceptable if it is carefully mechanically maintained so that it operates satisfactorily. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air.

(6) *Venting.* Before the start of processing operations, the retort steam chamber or chambers shall be vented to ensure removal of air.

(7) *Bleeders.* Bleeder openings ¼-inch (6 millimeters) or larger shall be located at the top of the steam chamber or chambers 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.

(8) *Retort speed.* The speed of the container-conveyor chain shall be specified in the scheduled process and shall be determined and recorded at the start of processing and at intervals of sufficient frequency to ensure that the retort speed is maintained as specified. The speed should be determined and recorded every 4 hours. An automatic device should be used to stop the chain when the temperature drops below that specified in the scheduled process. A means of preventing unauthorized speed changes shall be provided. A lock or a notice from management posted at or near the speed-adjusting device that provides a warning that only authorized persons are permitted to make adjustments is a satisfactory means of preventing unauthorized changes.

(9) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process.

(i) When maximum fill-in or drained weight is specified in the scheduled process, it shall be measured and recorded at intervals of sufficient frequency to ensure that the weight of the product does not exceed the maximum for the given container size specified in the scheduled process.

(ii) Closing machine vacuum in vacuum-packed products shall be observed and recorded at intervals of sufficient frequency to ensure that the vacuum is as specified in the scheduled process.

(iii) Such measurements and recordings should be made at intervals not to exceed 15 minutes.

(g) *Aseptic processing and packaging systems*—(1) *Product sterilizer*—(i) *Equipment*—(A) *Temperature-indicating device.* Each product sterilizer shall be equipped with at least one temperature-indicating device that accurately indicates the temperature during processing. Each temperature-indicating device shall have a sensor and a display. Each temperature-indicating device and each reference device that is maintained by the processor shall be tested for accuracy against a reference device for which the accuracy is traceable to a National Institute of Standards and Technology (NIST), or other national metrology institute, standard reference device by appropriate standard procedures, upon installation and at least once a year thereafter, or more frequently if necessary, to ensure accuracy during processing. Each temperature-indicating device and each reference device that is maintained by the processor shall have a tag, seal, or other means of identity.

(*1*) The design of the temperature-indicating device shall ensure that the accuracy of the device is not affected by electromagnetic interference and environmental conditions.

(*2*) Records of the accuracy of the temperature-indicating device and of a reference device that is maintained by the processor shall be established and maintained in accordance with § 113.100(c) and (d).

(*3*) A temperature-indicating device that is defective or cannot be adjusted to the accurate calibrated reference device shall be repaired before further use or replaced.

(*4*) A temperature-indicating device shall be accurate to 1 °F (0.5 °C). The temperature range of a mercury-in-glass thermometer shall not exceed 17 °F per inch (4 °C per centimeter) of graduated scale. A mercury-in-glass thermometer that has a divided mercury column shall be considered defective.

(*5*) Each temperature-indicating device shall be installed where it can be accurately and easily read. The temperature-indicating device—not the temperature-recording device—shall be the reference instrument for indicating the processing temperature.

(B) *Temperature-recording device.* Each product sterilizer shall have an accurate temperature-recording device. Each temperature-recording device shall have a sensor and a mechanism for recording temperatures to a permanent record, such as a temperature-recording chart. A temperature-recording device sensor shall be installed in the product at the holding-tube outlet between the holding tube and the inlet to the cooler. Additional temperature-recording device sensors shall be located at each point where temperature is specified as a critical factor in the scheduled process.

(*1*) *Analog or graphical recordings.* Temperature-recording devices that create analog or graphical recordings may be used. Temperature-recording devices that record to charts shall be used only with the appropriate chart. Each chart shall have a working scale of not more than 55 °F per inch (12 °C per centimeter) within a range of 20 °F (10 °C) of the desired product sterilization temperature. Chart graduations shall not exceed 2 °F (1 °C) within a range of 10 °F (5 °C) of the process temperature. Temperature-recording devices that create multipoint plottings of temperature readings shall record the temperature at intervals that will assure that the parameters of the process time and process temperature have been met.

(*2*) *Digital recordings.* Temperature-recording devices, such as data loggers, that record numbers or create other digital recordings may be used. Such a device shall record the temperature at intervals that will assure that the parameters of the process time and process temperature have been met.

(*3*) *Adjustments.* The temperature-recording device shall be adjusted with sufficient frequency to ensure agreement as nearly as possible with, but to be in no event higher than, the temperature-indicating device during processing. A means of preventing unauthorized changes in adjustment shall be provided. A lock or a notice from management posted at or near the temperature-recording device that provides a warning that only authorized persons are permitted to make adjustments is a satisfactory means of preventing unauthorized changes.

(C) *Temperature controller.* An accurate temperature controller shall be installed and capable of ensuring that the desired product sterilization temperature is maintained. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air.

(D) *Product-to-product regenerators.* When a product-to-product regenerator

is used to heat the cold unsterilized product entering the sterilizer by means of a heat exchange system, it shall be designed, operated, and controlled so that the pressure of the sterilized product in the regenerator is greater than the pressure of any unsterilized product in the regenerator to ensure that any leakage in the regenerator is from the sterilized product into the unsterilized product.

(E) *Differential pressure recorder-controller.* When a product-to-product regenerator is used, it shall be equipped with an accurate differential pressure recorder-controller. The differential pressure recorder-controller shall be accurate to within 2 pounds per square inch (13.8 kilopascals). One pressure sensor shall be installed at the sterilized product regenerator outlet and the other pressure sensor shall be installed at the unsterilized product regenerator inlet. The sensor and recorder of the differential pressure recorder-controller shall be tested for accuracy against an accurate reference device upon installation and at least once every 3 months of operation thereafter, or more frequently if necessary, to ensure its accuracy.

(*1*) *Analog or graphical recordings.* Differential pressure recorder-controllers that create analog or graphical recordings may be used. Differential pressure recorder-controllers that record to charts shall be used only with the appropriate chart. The scale divisions of the chart shall not exceed 2 pounds per square inch (13.8 kilopascals) on a working scale of not more than 20 pounds per square inch per inch of scale (55 kilopascals per centimeter).

(*2*) *Digital recordings.* Differential pressure recorder-controllers, such as data loggers, that record numbers or create other digital recordings may be used. Such differential pressure recorder-controllers shall record the differential pressure at intervals that will assure that the minimum differential pressure is maintained.

(F) *Flow control.* A flow control device shall be located upstream from the holding tube and shall be operated to maintain the required rate of product flow. A means of preventing unauthorized flow adjustments shall be provided. A lock or a notice from management posted at or near the flow controlling device that provides a warning that only authorized persons are permitted to make adjustments is a satisfactory means of preventing unauthorized changes.

(G) *Product holding tube.* The product-sterilizing holding tube shall be designed to give continuous holding of every particle of food for at least the minimum holding time specified in the scheduled process. The holding tube shall be designed so that no portion of the tube between the product inlet and the product outlet can be heated, and it must be sloped upward at least ¼-inch per foot (2.1 centimeters per meter).

(H) *Flow-diversion systems.* If a processor elects to install a flow-diversion system, it should be installed in the product piping located between the product cooler and the product filler or aseptic surge tank and should be designed to divert flow away from the filler or aseptic surge tank automatically. Controls and/or warning systems should be designed and installed with necessary sensors and actuators to operate whenever the sterilizing temperature in the holding tube or pressure differential in the product regenerator drops below specified limits. Flow-diversion systems should be designed and operated in accordance with recommendations of an aseptic processing and packaging authority.

(I) *Equipment downstream from the holding tube.* Product coolers, aseptic surge tanks, or any other equipment downstream from the holding tube, with rotating or reciprocating shafts, valve stems, instrument connections, or other such points, are subject to potential entry of microorganisms into the product. Such locations in the system should be equipped with steam seals or other effective barriers at the potential access points. Appropriate means should be provided to permit the operator to monitor the performance of the seals or barriers during operations.

(ii) *Operation*—(A) *Startup.* Before the start of aseptic processing operations the product sterilizer and all product-contact surfaces downstream shall be brought to a condition of commercial sterility.

(B) *Temperature drop in product-sterilizing holding tube.* When product temperature in the holding tube drops below the temperature specified in the scheduled process, product flow should be diverted away from the filler or aseptic surge tank by means of a flow-diversion system. If for any reason product subjected to a temperature drop below the scheduled process is filled into containers, the product shall be segregated from product that received the scheduled process. The processing deviation shall be handled in accordance with § 113.89. The product holding tube and any further system portions affected shall be returned to a condition of commercial sterility before product flow is resumed to the filler or to the aseptic surge tank.

(C) *Loss of proper pressures in the regenerator.* When a regenerator is used, the product may lose sterility whenever the pressure of sterilized product in the regenerator is less than 1 pound per square inch (6.9 kilopascals) greater than the pressure of unsterilized product in the regenerator. In this case, product flow should be diverted away from the filler or aseptic surge tank by means of the flow-diversion system. If for any reason the product is filled into containers, the product shall be segregated from product that received the scheduled process. The processing deviation shall be handled in accordance with § 113.89. Product flow to the filler or to the aseptic surge tank shall not be resumed until the cause of the improper pressure relationships in the regenerator has been corrected and the affected system(s) has been returned to a condition of commercial sterility.

(D) *Loss of sterile air pressure or other protection level in the aseptic surge tank.* When an aseptic surge tank is used, conditions of commercial sterility may be lost when the sterile air overpressure or other means of protection drops below the scheduled process value. Product flow to and/or from the aseptic surge tank shall not be resumed until the potentially contaminated product in the tank is removed, and the aseptic surge tank has been returned to a condition of commercial sterility.

(E) *Records.* Readings at the following points shall be observed and recorded at the start of aseptic packaging operations and at intervals of sufficient frequency to ensure that these values are as specified in the scheduled process: Temperature-indicating device in holding tube outlet; temperature-recording device in holding tube outlet; differential pressure recorder-controller, if a product-to-product regenerator is used; product flow rate as established by the flow control device or as determined by filling and closing rates and, if an aseptic surge tank is used, sterile air pressure or other protection means; and proper performance of steam seals or other similar devices. The measurements and recordings should be made at intervals not to exceed 1 hour.

(2) *Container sterilizing, filling, and closing operation*—(i) *Equipment*—(A) *Recording device.* The container and closure sterilization system and product filling and closing system shall be implemented to demonstrate that the required sterilization is being accomplished continuously. Recording devices shall be used to record, when applicable, the sterilization media flow rates, temperature, concentration, or other factors. When a batch system is

used for container sterilization, the sterilization conditions shall be recorded.

(B) *Timing method(s).* A method(s) shall be used either to give the retention time of containers, and closures if applicable, in the sterilizing environment specified in the scheduled process, or to control the sterilization cycle at the rate specified in the scheduled process. A means of preventing unauthorized speed changes must be provided. A lock or a notice from management posted at or near the speed adjusting device that provides a warning that only authorized persons are permitted to make adjustments is a satisfactory means of preventing unauthorized changes.

(ii) *Operation*—(A) *Startup.* Before the start of packaging operations, both the container and closure sterilizing system and the product filling and closing system shall be brought to a condition of commercial sterility.

(B) *Loss of sterility.* A system shall be provided to stop packaging operations, or alternatively to ensure segregation of any product packaged when the packaging conditions fall below scheduled processes. Compliance with this requirement may be accomplished by diverting product away from the filler, by preventing containers from entering the filler, or by other suitable means. In the event product is packaged under conditions below those specified in the scheduled process, all such product shall be segregated from product that received the scheduled process. The processing deviation shall be handled in accordance with § 113.89. In the event of loss of sterility, the system(s) shall be returned to a condition of commercial sterility before resuming packaging operations.

(C) *Records.* Observations and measurements of operating conditions shall be made and recorded at intervals of sufficient frequency to ensure that commercial sterility of the food product is being achieved; such measurements shall include the sterilization media flow rates, temperatures, the container and closure rates (if applicable) through the sterilizing system, and the sterilization conditions if a batch system is used for container sterilization. The measurements and recordings should be made at intervals not to exceed 1 hour.

(3) *Incubation.* Incubation tests should be conducted on a representative sample of containers of product from each code; records of the test results should be maintained.

(4) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process. Such measurements and recordings should be done at intervals not to exceed 15 minutes.

(h) *Equipment and procedures for flame sterilizers.* The container conveyor speed shall be specified in the scheduled process. The container conveyor speed shall be measured and recorded at the start of operations and at intervals of sufficient frequency to ensure that the conveyor speed is as specified in the scheduled process. Such measurements and recordings should be done at 1-hour intervals. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. A means of preventing changes in flame intensity and unauthorized speed changes on the conveyor shall be provided. A lock or a notice from management posted at or near the speed adjusting device that provides a warning that only authorized persons are permitted to make adjustments is a satisfactory means of preventing unauthorized changes. The surface temperature of at least one container from each conveyor channel shall be measured and recorded at the entry and at the end of the holding period at intervals of sufficient frequency to ensure that the temperatures specified in the scheduled process are maintained. Such measurements and recordings should be done at intervals not to exceed 15 minutes.

(1) *Process interruption.* In the event of process interruption wherein the temperature of the product may have dropped, an authorized, scheduled emergency plan approved by a qualified person having expert knowledge of the process requirements may be used.

(2) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process.

(i) *Equipment and procedures for thermal processing of foods wherein critical factors such as water activity are used in conjunction with thermal processing.* The methods and controls used for the manufacture, processing, and packing of such foods shall be as established in the scheduled process and shall be operated or administered in a manner adequate to ensure that the product is safe. The time and temperature of processing and other critical factors specified in the scheduled process shall be measured with instruments having the accuracy and dependability adequate to ensure that the requirements of the scheduled process are met. All measurements shall be made and recorded at intervals of sufficient frequency to ensure that the critical factors are within the limits specified in the scheduled process.

(j) *Other systems.* All systems, whether or not specifically mentioned in this part, for the thermal processing of low-acid foods in hermetically sealed containers shall conform to the applicable requirements of this part and the methods and controls used for the manufacture, processing, and packing of these foods shall be as established in the scheduled process. These systems shall be operated or administered in a manner adequate to ensure that commercial sterility is achieved. Critical factors specified in the scheduled process shall be measured and recorded at intervals of sufficient frequency to ensure that the critical factors are within the limits specified in the scheduled process.

■ 3. Amend § 113.60 by revising paragraph (d) to read as follows:

§ 113.60 Containers.

* * * * *

(d) *Postprocess handling.* Container handling equipment used in handling filled containers shall be designed, constructed, and operated to preserve the can seam or other container closure integrity. Container handling equipment, including automated and non-automated equipment, shall be checked with sufficient frequency and repaired or replaced as necessary to prevent damage to containers and container closures. When cans are handled on belt conveyors, the conveyors should be constructed to minimize contact by the belt with the double seam, *i.e.,* cans should not be rolled on the double seam. All worn and frayed belting, can retarders, cushions, *etc.* should be replaced with new nonporous material. All tracks and belts that come into contact with the can seams should be thoroughly scrubbed and sanitized at intervals of sufficient frequency to avoid product contamination.

■ 4. Revise § 113.83 to read as follows:

§ 113.83 Establishing scheduled processes.

Scheduled processes for low-acid foods shall be established by qualified persons having expert knowledge of thermal processing requirements for low-acid foods in hermetically sealed containers and having adequate facilities for making such determinations. The type, range, and combination of variations encountered in commercial production shall be

adequately provided for in establishing the scheduled process. Variations include those that occur due to seasonal or growing fluctuations, variety differences, supplier processes, reprocessing, and mixing a batch of processed product with the same unprocessed product before it is processed. Critical factors, *e.g.,* minimum headspace, consistency, maximum fill-in or drained weight, a_w, *etc.,* that may affect the scheduled process, shall be specified in the scheduled process. Acceptable scientific methods of establishing heat sterilization processes shall include, when necessary, but shall not be limited to, the use of microbial thermal death time data, process calculations based on product heat penetration data, and inoculated packs. Calculation shall be performed according to procedures recognized by competent processing authorities. If incubation tests are necessary for process confirmation, they shall include containers from test trials and from actual commercial production runs during the period of instituting the process. The incubation tests for confirmation of the scheduled processes should include the containers from the test trials and a number of containers from each of four or more actual commercial production runs. The number of containers from actual commercial production runs should be determined on the basis of recognized scientific methods to be of a size sufficient to ensure the adequacy of the process. Complete records covering all aspects of the establishment of the process and associated incubation tests shall be prepared and shall be permanently retained by the person or organization making the determination.

■ 5. Amend § 113.87 by revising paragraphs (b), (c), and (e) to read as follows:

§ 113.87 Operations in the thermal processing room.

* * * * *

(b) A system for product traffic control in the retort room shall be established to prevent unretorted product from bypassing the retort process. Each retort basket, truck, car, or crate used to hold containers in a retort, or one or more containers therein, shall, if it contains any retorted food product, be plainly and conspicuously marked with a heat-sensitive indicator, or by other effective means that will indicate visually, to thermal processing personnel, those units that have been retorted. A visual check shall be performed to determine whether or not the appropriate change has occurred in the heat-sensitive indicator as a result of retorting for all retort baskets, trucks, cars, or crates, to ensure that each unit of product has been retorted. A record of these checks should be made.

(c) The initial temperature of the contents of the containers to be processed shall be accurately determined and recorded with sufficient frequency to ensure that the temperature of the product is no lower than the minimum initial temperature specified in the scheduled process. For those operations that use water during the filling of the retort or during processing, provision shall be made to ensure that the water will not, before the start of each thermal process, lower the initial temperature of the product below that specified in the scheduled process. The temperature-indicating device used to determine the initial temperature shall be tested for accuracy against a reference device for which the accuracy is traceable to a National Institute of Standards and Technology (NIST), or other national metrology institute, standard reference device, by appropriate standard procedures, with sufficient frequency to ensure that initial temperature measurements are accurate. Records of the accuracy of the temperature-indicating device and of a reference device that is maintained by the processor shall be established and maintained in accordance with § 113.100(c) and (d).

* * * * *

(e) Clock times on temperature-recording device records shall reasonably correspond to the time of day on the processing records to provide correlation of these records.

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■ 6. Section 113.100 is amended by:

■ a. Revising paragraphs (a) introductory text, (a)(4), (b);

■ b. Redesignating paragraphs (c), (d), and (e), as paragraphs (e), (f), and (g), respectively;

■ c. Adding new paragraphs (c), (d), and (h); and

■ d. Revising newly redesignated paragraph (e).

The revisions and additions read as follows:

§ 113.100 Processing and production records.

(a) Processing and production information shall be entered at the time it is observed by the retort or processing system operator, or other designated person, on forms that include the product, the code number, the date, the retort or processing system number, the size of container, the approximate number of containers per coding interval, the initial temperature, the actual processing time, the temperature-indicating device and temperature-recording device readings, and other appropriate processing data. Closing machine vacuum in vacuum-packed products, maximum fill-in or drained weight, or other critical factors specified in the scheduled process shall also be recorded. In addition, the following records shall be maintained:

* * * * *

(4) *Aseptic processing and packaging systems.* Product temperature in the holding tube outlet as indicated by the temperature-indicating device and the temperature-recording device; differential pressure as indicated by the differential pressure recorder-controller, if a product-to-product regenerator is used; product flow rate, as determined by the flow controlling device or by filling and closing rates; sterilization media flow rate or temperature or both; retention time of containers, and closures when applicable, in the sterilizing environment; and, when a batch system is used for container and/or closure sterilization, sterilization cycle times and temperatures.

* * * * *

(b) Temperature-recording device records shall be identified by date, retort number, and other data as necessary, so they can be correlated with the record of lots processed. Each entry on the processing and production records shall be made by the retort or processing system operator, or other designated person, at the time the specific retort or processing system condition or operation occurs, and this retort or processing system operator or other designated person shall sign or initial each record form. Not later than 1 working day after the actual process, and before shipment or release for distribution, a representative of plant management who is qualified by suitable training or experience shall review all processing and production records for completeness and to ensure that the product received the scheduled process. The records, including temperature-recording device records, shall be signed or initialed and dated by the reviewer.

(c) Records of the accuracy of a temperature-indicating device shall include:

(1) A reference to the tag, seal, or other means of identity used by the processor to identify the temperature-indicating device;

(2) The name of the manufacturer of the temperature-indicating device;

(3) The identity of the reference device, equipment, and procedures used for the accuracy test and to adjust the

temperature-indicating device or, if an outside facility is used to conduct the accuracy test for the temperature-indicating device, a guarantee, certificate of accuracy, certificate of calibration, or other document from the facility that includes a statement or other documentation regarding the traceability of the accuracy to a National Institute of Standards and Technology (NIST) or other national metrology institute standard;

(4) The identity of the person or facility that performed the accuracy test and adjusted or calibrated the temperature-indicating device;

(5) The date and results of each accuracy test, including the amount of calibration adjustment; and

(6) The date on or before which the next accuracy test must be performed.

(d) Records of the accuracy of a reference device maintained by the processor shall include:

(1) A reference to the tag, seal, or other means of identity used by the processor to identify the reference device;

(2) The name of the manufacturer of the reference device;

(3) The identity of the equipment and reference to procedures used for the accuracy test and to adjust or calibrate the reference device or, if an outside facility is used to conduct the accuracy test for the reference device, a guarantee, certificate of accuracy, certificate of calibration, or other document from the facility that includes a statement or other documentation regarding the traceability of the accuracy to a NIST or other national metrology institute standard;

(4) The identity of the person or facility that performed the accuracy test and adjusted or calibrated the reference device;

(5) The date and results of each accuracy test, including the amount of calibration adjustment; and

(6) The date on or before which the next accuracy test must be performed.

(e) Records of all container closure examinations shall specify the product code, the date and time of container closure inspections, the measurements obtained, and all corrective actions taken. Records shall be signed or initialed by the container closure inspector and reviewed by management with sufficient frequency to ensure that the containers are hermetically sealed. The records shall be signed or initialed and dated by the reviewer.

* * * * *

(h) Records of this part may be maintained electronically, provided they are in compliance with part 11 of this chapter.

Dated: February 23, 2011.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2011–4475 Filed 3–2–11; 8:45 am]

BILLING CODE 4160–01–P