

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 113

[Docket No. 2007N-0026]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend 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. FDA also is proposing to establish recordkeeping requirements relating to temperature-indicating devices and to clarify other aspects of low-acid canned food processing such as FDA's interpretation of some requirements of the current regulations that will, in part, allow the use of advanced technology for measuring and recording temperatures during processing. Finally, FDA is proposing to include metric equivalents of avoirdupois (U.S.) measurements where appropriate.

DATES: Submit written or electronic comments on the proposed rule by June 12, 2007. Submit comments regarding the information collection by April 13, 2007, to the Office of Management and Budget (OMB) (see **ADDRESSES**).

ADDRESSES: You may submit comments, identified by Docket No. 2007N-0026, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting

comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received may be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Information Collection Provisions: Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, OMB. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974.

FOR FURTHER INFORMATION CONTACT:

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I. Background

In the **Federal Register** of January 24, 1973 (38 FR 2398), FDA (we) issued a final rule entitled "Thermally Processed Low-Acid Food Packaged in Hermetically Sealed Containers" (low-acid canned foods) (the 1973 final rule), part 113 (21 CFR part 113)¹, which, among other things, provides for the use of an "indicating mercury-in-glass thermometer" for equipment and procedures for the following: (1) Pressure processing in steam in still retorts (§ 113.40(a)), (2) pressure processing in water in still retorts (§ 113.40(b)), (3) pressure processing in steam in continuous agitating retorts (§ 113.40(c)), (4) pressure processing in steam in discontinuous agitating retorts (§ 113.40(d)), (5) pressure processing in water in discontinuous agitating retorts (§ 113.40(e)), (6) pressure processing in steam in hydrostatic retorts (§ 113.40(f)), and (7) aseptic processing and packaging systems (§ 113.40(g)). In addition, aseptic processing systems (§ 113.40(g)) can be equipped with a mercury-in-glass thermometer or an equivalent temperature-indicating device, such as a thermocouple-recorder.

The 1973 final rule also established requirements for containers (§ 113.60), requirements for establishing scheduled processes (§ 113.83), and requirements for operations in the thermal processing room (§ 113.87). The 1973 final rule also established requirements for processing and production records, which include requirements for maintaining records of mercury-in-glass thermometer and recording thermometer readings (§ 113.100).

In the preamble to the 1973 final rule, FDA stated that two comments on a tentative final order, published November 14, 1972 (37 FR 24117), "recommended that provisions be made [in the final rule] for the use of temperature[-]indicating devices other than mercury-in-glass thermometers."

¹The low-acid canned food regulations (21 CFR part 128b) were recodified as part 113 on March 15, 1977 (42 FR 14302). The regulations were subsequently amended on March 16, 1979 (44 FR 16209) and June 11, 1997 (62 FR 31721).

FDA responded, "The Commissioner [of Food and Drugs] has determined that the mercury-in-glass thermometer is the recognized standard against which all other temperature-indicating devices are checked and calibrated. The regulation * * * retains the requirement that all retorts be equipped with mercury-in-glass indicating thermometers. However, because of the speed of the thermal process, alternate temperature-indicating devices such as thermocouples will be allowed in aseptic processing and packaging systems" (38 FR 2398 at 2400).

Since publication of the 1973 final rule, FDA has received various requests to permit use of alternative temperature-indicating devices or to permit entry into the United States of low-acid canned foods that were processed in countries that permit alternative temperature-indicating devices to be used during processing. In responding to such requests, FDA expressed concern about whether the devices were reliable and maintained accuracy under actual plant operation conditions. FDA also requested additional information relating to reliability and accuracy, including evidence to show that, if the device does not maintain its accuracy, this fact would become immediately known by the operator and would not result in underprocessed food.

FDA is aware that technological advancements in thermometry have been made since publication of the low-acid canned food regulations in 1973 and that temperature-indicating devices other than mercury-in-glass thermometers are now available that may be appropriate for use in thermal processing of low-acid foods. FDA also is aware, specifically for low-acid canned food manufacturers, of traditional concerns about ensuring that mercury from broken mercury-in-glass thermometers does not contaminate the food or the processing environment. FDA recognizes that the industry must proceed cautiously to transition from mercury-in-glass thermometers to alternative technology to ensure that accuracy and ability to function properly during processing are not compromised by replacing mercury-in-glass thermometers with alternative temperature-indicating devices. As with mercury-in-glass thermometers, manufacturers who use alternative temperature-indicating devices must conduct appropriate tests and implement procedures to ensure that the device is accurate during processing and does not result in underprocessed foods. Thus, although FDA supports elimination of mercury from the processing environment and encourages

industry to take necessary and appropriate steps to transition from mercury-in-glass thermometers to alternative temperature-indicating devices, the agency also recognizes that it may not be practical for all manufacturers to make this transition. Accordingly, FDA is proposing to revise regulations in part 113 to permit industry use of temperature-indicating devices, including mercury-in-glass thermometers, and to require maintenance of records associated with ensuring that temperature-indicating devices are accurate during processing.

FDA also is aware that the regulations from the 1973 final rule include outdated terminology and that some of the provisions are unclear. FDA is proposing to update and clarify these sections of the regulations. FDA also is proposing to clarify and establish recordkeeping requirements relating to ensuring the accuracy of temperature-indicating devices.

II. Legal Authority

FDA is proposing these regulations under sections 402(a)(3) and (a)(4) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 342(a)(3) and (a)(4)). In addition, FDA is proposing these regulations under section 361 of the Public Health Service Act (the PHS Act) (42 U.S.C. 264) that relates to communicable disease. Under section 402(a)(3) of the act, a food is deemed adulterated "if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food." Under section 402(a)(4) of the act, a food is adulterated "if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health."

A commercial processor engaged in the thermal processing of low-acid foods packaged in hermetically sealed containers must provide FDA with information about its scheduled process that includes processing method, type of retort or other thermal processing equipment employed, minimum initial temperatures, times and temperatures of processing, sterilizing value or other equivalent scientific evidence of processing adequacy, critical control factors affecting heat penetration, and source and date of the establishment of the process for each low-acid food in each container size (21 CFR 108.35(c)(2)). The scheduled process is designed to achieve commercial sterility. Commercial sterility relates to conditions achieved through the application of heat to render the food free of certain microorganisms capable

of reproducing under normal non-refrigerated conditions of storage and distribution and viable microorganisms of public health significance (§ 113.3(e)). Adhering to the scheduled process is important for preventing growth in the food of microorganisms, such as *Clostridium botulinum*. *Clostridium botulinum* produces a neurotoxin that causes botulism, a communicable disease that can result in paralysis and death (Ref. 1). The failure to use accurate temperature-indicating devices, and other measures clarified in this proposed rule, to ensure that low-acid foods are processed to achieve commercial sterility is an insanitary condition and thus renders the food adulterated under section 402(a)(4) of the act. In addition, such a food is unfit for food under section 402(a)(3) of the act based on health risks from insufficient processing.

Under section 701(a) of the act (21 U.S.C. 371(a)), FDA is authorized to issue regulations for the act's efficient enforcement. A regulation that requires measures to prevent human food from being unfit for food and from being held under insanitary conditions allows for the efficient enforcement of the act. This proposed rule requires processors of thermally processed low-acid food to establish and maintain records of the accuracy of the temperature-indicating device and reference device. Other records relating to processing and production are currently required in § 113.100. The proposed rule requires that all records under part 113, whether currently required or proposed to be required in this proposed rule, be made available to FDA for inspection and copying.

The proposed rule would require accuracy testing of temperature-indicating devices against a calibrated 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. Documentation of accuracy of such devices is necessary to determine, over time, whether each device complies with current requirements to be accurate during processing and for verifying that temperatures required by the scheduled process are met during processing. Further, such documentation is necessary for evaluating the performance of temperature-indicating devices that are technologically and operationally different from mercury-in-glass thermometers traditionally used in processing low-acid canned food. The records of accuracy testing for each temperature-indicating device and reference device will be linked to each

such device through the accuracy records so that the processor will be able to ensure that temperature-indicating devices and reference devices are tested as often as needed and will provide a means for the processor to quickly identify and correct problems that may occur. Without records documenting accuracy testing of temperature-indicating devices and reference devices, processors would not know whether they are adulterating their products. Therefore, a failure of processors to establish and maintain these records results in thermally processed low-acid canned food being prepared under insanitary conditions whereby the food may have been rendered injurious to health.

Because FDA cannot continuously observe processors' operations, the records for accuracy, and other records currently required for processing and production, are essential for FDA to know whether processors have complied with the current good manufacturing practice requirements in part 113. FDA may consider it necessary to copy records when, for example, our investigator may need assistance in reviewing a certain record from relevant experts in headquarters. If we are unable to copy the records, we would have to rely solely on our investigator's notes and reports when drawing conclusions. In addition, copying records will facilitate followup regulatory actions. We have tentatively concluded that the ability to access and copy the records is necessary to provide FDA with an enforceable regulation that will ensure public health protection. Thus, the recordkeeping requirements and access to such records would be necessary to the efficient enforcement of the act. Under the proposed rule, the failure to comply with the recordkeeping requirements would render the food adulterated under section 402(a)(4) of the act.

In addition, FDA has authority under section 361 of the PHS Act to make and enforce such regulations as "are necessary to prevent the introduction, transmission, or spread of communicable disease from foreign countries into the States * * * or from one State * * * into any other State" (section 361(a) of the PHS Act). A low-acid canned food that is not processed to achieve commercial sterility may become contaminated with microorganisms such as *Clostridium botulinum*. *Clostridium botulinum* produces a neurotoxin which, when ingested, causes botulism. Botulism is a communicable disease that is characterized by the rapid onset of paralysis. If untreated, this paralysis can

lead to death (Ref. 1). As explained previously in this document, processing and production records required by part 113, and those proposed in this rule related to accuracy testing, are necessary to ensure that low-acid foods are prepared in a manner that will prevent the spread of communicable disease. Section 361 of the PHS Act provides FDA with the authority to institute recordkeeping requirements, including access to such records to enable FDA to ensure that low-acid foods are being processed in a manner to prevent the spread of communicable disease. For these reasons, and for the reasons stated previously in this document for access and copying of records to provide for an enforceable regulation that will ensure public health protection, we have tentatively concluded that the recordkeeping requirements are necessary to prevent the spread of communicable disease.

III. Proposed Rule

A. Equipment and Procedures (§ 113.40)

1. Temperature-Indicating Devices

Current § 113.40(a)(1), (b)(1), (c)(1), (d)(1), (e)(1), and (f)(1) require that retorts used for processing low-acid foods shall be equipped with at least one mercury-in-glass thermometer. FDA is proposing to revise the regulations to provide for use of temperature-indicating devices that accurately indicate the temperature during thermal processing. Accordingly, FDA is replacing the terms "mercury-in-glass thermometer" and "thermometer" with "temperature-indicating device," as appropriate. Current § 113.40(g)(1) already allows for use of temperature-indicating devices for aseptic processing of low-acid foods. However, FDA is proposing revisions in § 113.40(g)(1) similar to proposed § 113.40(a)(1), (b)(1), (c)(1), (d)(1), (e)(1), and (f)(1) to ensure consistency in terminology, interpretation, and application of all provisions of the regulation that allow for use of temperature-indicating devices.

The term "temperature-indicating device" includes mercury-in-glass thermometers. The proposed rule provides for use of temperature-indicating devices for the following purposes: (1) Pressure processing in steam in still retorts, (2) pressure processing in water in still retorts, (3) pressure processing in steam in continuous agitating retorts, (4) pressure processing in steam in discontinuous agitating retorts, (5) pressure processing in water in discontinuous agitating retorts, (6) pressure processing in steam in hydrostatic retorts, and (7) aseptic

processing and packaging. Processors are responsible for ensuring that the temperature-indicating device is accurate during processing.

FDA is proposing 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. Currently, mercury-in-glass thermometers must be tested for accuracy against a "known accurate standard thermometer" upon installation and at least once a year thereafter, or more frequently if necessary. FDA is proposing to require similar tests for accuracy for all temperature-indicating devices. Traditionally, a "known accurate standard thermometer" was a mercury-in-glass thermometer that had been calibrated against an instrument that was traceable to a National Institute of Standards and Technology (NIST) standard or according to other standard calibration procedures that assured accuracy at the time the thermometer was used as the "standard." These thermometers are often referred to as "reference devices." (NIST is a non-regulatory Federal agency that develops and promotes measurement, standards, and technology to enhance productivity, facilitate trade, and improve the quality of life.) FDA is proposing to replace the term "known accurate standard thermometer" with the broader term "accurate calibrated reference device" to recognize that reference or "standard" devices other than mercury-in-glass thermometers are available and may be used for determining accuracy.

FDA is proposing 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. Although electromagnetic energy does not affect the accuracy of mercury-in-glass thermometers, temperature-indicating devices with electronic or electromagnetic components are vulnerable and must be designed to ensure that they are resistant to electromagnetic interference. Environmental conditions, such as humidity, vibrations, and air pressure, which may affect the accuracy or performance of the temperature-indicating device, also must be identified and controlled, to the extent necessary, to ensure that the temperature-indicating device is accurate during processing. The current regulations indirectly address control of the impact of environmental conditions on mercury-in-glass thermometers by requiring calibration "at least once a

year * * * or more frequently if necessary, to ensure their accuracy” (§ 113.40(a)(1), (b)(1), (c)(1), (d)(1), (e)(1), (f)(1), and (g)(1)(i)(a)) and by requiring that a mercury-in-glass thermometer that has a “divided mercury column or that cannot be adjusted to the standard shall be repaired or replaced before further use of the retort” (§ 113.40(a)(1), (b)(1), (c)(1), (d)(1), (e)(1), and (f)(1); similar requirement in § 113.40(g)(1)(i)(a)). 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. Design specificity in the regulation is not practical because of the diversity of technology associated with temperature-indicating devices that have been or may be developed and because, for each type of temperature-indicating device, different factors or parameters may need to be addressed by design. Rather, the proposed regulation would require that the design of the temperature-indicating device ensure that the accuracy of the device is not affected by electromagnetic interference and environmental conditions. Thus, the processor is responsible for ensuring that the temperature-indicating device is designed so that its accuracy during processing is not compromised due to electromagnetic interference or environmental conditions and that any malfunctions in the device that may affect accuracy will be immediately detectable.

2. Documentation and Records

Current § 113.40(a)(1), (b)(1), (c)(1), (d)(1), (e)(1), and (f)(1) recommend, but do not specifically require, maintenance of records of accuracy checks. These regulations indicate that the records should specify the date, standard used, method used, and person performing the test. The regulations also recommend, but do not require, that each thermometer should have a tag,

seal, or other means of identity that includes the date on which it was last tested for accuracy. Similar provisions in current § 113.40(g)(1)(i)(a) apply to maintenance of records of accuracy checks and to establishing a means of identity for “thermometers and temperature-indicating devices.” However, establishment and maintenance of records of the accuracy of each temperature-indicating device are essential for documenting accuracy of temperature-indicating devices throughout time, for determining that each temperature-indicating device complies with current requirements to be accurate during processing, and for verifying that temperatures required by the scheduled process are met. Further, such documentation is necessary for evaluating the performance of temperature-indicating devices that are technologically and operationally different from mercury-in-glass thermometers traditionally used in processing low-acid canned food.

FDA is proposing 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. FDA is proposing to eliminate the current recommendation in § 113.40(a)(1), (b)(1), (c)(1), (d)(1), (e)(1), (f)(1), and (g)(1)(i)(a) to include on the tag or seal the date on which each thermometer was last tested for accuracy. FDA does not object to recording the accuracy test date on the tag or seal. However, as discussed later in this document, FDA is proposing to require that the date of the last accuracy test be included as part of the record of accuracy for the temperature-indicating device. FDA believes this proposed change clarifies the process for assuring that the written record of the accuracy test can be linked to the appropriate temperature-indicating device.

FDA is proposing that a written record of accuracy for each temperature-indicating device shall be established and maintained. Documentation of the accuracy of each temperature-indicating device shall include the following information: (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 used for the accuracy test; (4) the identity of the equipment and procedures used to adjust or calibrate the temperature-indicating device; (5) the date and

results of each accuracy test; (6) the name of the person or facility that performed the accuracy test and adjusted or calibrated the temperature-indicating device; and (7) the date of the next scheduled accuracy test. Reference to the temperature-indicating device identity in the record of accuracy provides an essential link between each temperature-indicating device and the specific record associated with that device. The name of the manufacturer enables the processor to readily identify the source of the defective or deficient device and to correct or replace the device, as appropriate. Identification of the reference device used for the accuracy check and of the equipment and procedures used to adjust or calibrate the temperature-indicating device provides an essential reference for additional followup in the event the reference device is subsequently determined to be inaccurate. Documentation of the date and results of accuracy tests provides evidence that scheduled tests were performed and is essential for evaluating performance of the temperature-indicating device over time. This information can be used to determine whether more frequent accuracy tests are needed and whether a temperature-indicating device needs to be replaced. Documentation of the identification of the person or facility that performed the accuracy test and adjusted or recalibrated the temperature-indicating device is essential for appropriate followup in the event that the temperature-indicating device subsequently is determined to be inaccurate.

These records are necessary to ensure that appropriate accuracy checks are performed for each temperature-indicating device, to establish the appropriate frequency for accuracy checks, to identify when there is a problem with a temperature-indicating device and, as necessary, to repair or replace the device, and to determine and initiate appropriate followup to ensure that low-acid canned foods are appropriately processed. Because it is not possible for FDA to continuously observe processors' operations, these records are essential to ensure that the agency has the information needed to identify noncompliance and to bring a non-compliant processor into compliance. Thus, these records are essential for FDA to have an enforceable regulation that will ensure public health protection.

Current § 113.40(a)(1), (b)(1), (c)(1), (d)(1), (e)(1), and (f)(1) require that thermometers (and temperature-indicating devices in § 113.40(g)(1)(i)(a)) shall be tested for accuracy against a

known accurate standard thermometer. This requirement implies, but does not explicitly state, that the processor must be able to demonstrate, by appropriate documentation, that the reference or standard device used to determine the accuracy of the thermometers used to measure temperature during processing also is accurate. Thus, although the current regulations require documentation of the accuracy of the standard thermometer, the specific documentation FDA expects processors to maintain is not clear. FDA is proposing to clarify this requirement by specifying that a written record of the accuracy of the reference device shall be established and maintained. Documentation of the accuracy of the reference device must include the following information: (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 procedures used to test the accuracy and to adjust or calibrate the reference device; (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 the accuracy test; and (6) the traceability information. Traceability, as defined by the *International Vocabulary of Basic and General Terms in Metrology*, means a "property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties" (Ref. 2). Accordingly, records must be maintained to document that the accuracy of the reference device can be traced by comparison with a standard device, such as a NIST standard temperature device. Documentation of the traceability information for the reference device may be in the form of a guaranty of accuracy from the manufacturer of the reference device or a certificate of calibration from a laboratory. Information required in the record of accuracy for a reference device is essential for assuring that reference devices maintain their accuracy and ensures that the processor can establish an unbroken chain to trace the accuracy of the reference device to a standard device.

The requirements in proposed § 113.40(a)(1), (b)(1), (c)(1), (d)(1), (e)(1), (f)(1), and (g)(1)(i)(a) to establish and maintain written records of accuracy of temperature-indicating devices and reference devices, which include the

identity of temperature-indicating devices and reference devices, are subject to the recordkeeping requirements of § 113.100. See the discussion later in this document relating to proposed revisions to § 113.100.

FDA is proposing to revise § 113.40(g)(1)(ii)(e) by removing the requirement to observe and record the product temperature in the temperature recorder-controller at the final heater outlet in aseptic processing and packaging systems. The temperature in the final heater outlet may not be a critical factor in the scheduled process and, therefore, may not require maintenance of records. However, if the final heater outlet temperature is identified as a critical factor in the scheduled process, the temperature must be observed and recorded, as required in § 113.100(a).

3. Metric Equivalents

FDA is proposing to revise § 113.40(a), (b), (c), (d), (e), (f), and (g) to provide metric equivalents of *avoirdupois* (U.S.) measurements. Currently, these regulations express temperature measurements in Fahrenheit (°F) units, length measurements in inches and feet, and pressure measurements in pounds per square inch. The proposed metric equivalents are provided in parenthesis in the text of the proposed regulation, immediately following the *avoirdupois* measurement. FDA is proposing to modify the current regulations to not only provide the temperature measurements in Fahrenheit, but to follow the Fahrenheit (°F) measure with the units in Celsius (°C). FDA is proposing to provide measurements currently in inches also in millimeters or centimeters, measurements currently in feet also in centimeters or meters, and measurements in pounds per square inch of pressure also in kilopascals.

4. Temperature-Recording Devices

Current § 113.40(a)(2), (b)(2), (c)(2), (d)(2), (e)(2), (f)(2), and (g)(1)(i)(b) states that, "Graduations on the temperature-recording devices shall not exceed 2 °F within a range of 10 °F of the processing temperature. Each chart shall have a working scale of not more than 55 °F per inch within a range of 20 °F of the processing temperature. The temperature chart shall be adjusted to agree as nearly as possible with, but to be in no event higher than, the known accurate mercury-in-glass thermometer during the process time." When the regulations were published in the 1973 final rule, temperature-recording devices generally recorded temperatures

to paper charts and the paper charts served as the historical record of temperatures during processing. At that time, the terms "temperature-recording device" and "recording chart" were used interchangeably. However, because of advancements in technology, temperatures may now be recorded in a format other than the traditional chart that has a pre-printed time and temperature scale and may be recorded and maintained by mechanisms or devices other than recorders that use the traditional recording charts. The permanent record of temperatures may be in the form of an analog or graphical recording, such as a traditional chart with pre-printed time and temperature scale. The permanent record also may be an analog or graphical recording, for which the chart design, continuous temperature recordings or tracings, and date and time notations may be generated and printed by the temperature-recording device onto a blank paper, chart, or other medium as they are generated by the temperature-recording device. Processors also are using temperature-recording devices, such as data loggers, that record numbers or create other digital recordings at established intervals, rather than providing continuous recordings on a chart. Therefore, FDA recognizes that the term "temperature-recording device" does not necessarily imply that temperatures are being recorded to a "temperature-recording chart." Thus, the "graduation" and "working scale" requirements in the current regulation do not apply to all temperature-recording device records. The general term "temperature-recording device" should be used when referring to the entire device that records temperatures and the term "temperature-recording chart" should be used when referring to an actual chart that constitutes the mechanism by which the temperature-recording device records processing temperatures. The "graduation" and "working scale" requirements specified in the current regulation are still applicable to the "temperature-recording chart," when used as the mechanism for recording processing temperatures.

FDA, therefore, is proposing to revise § 113.40(a)(2), (b)(2), (c)(2), (d)(2), (e)(2), (f)(2), and (g)(1)(i)(b) to provide flexibility for processors to use temperature-recording device advanced technology, to update terminology to reflect current and appropriate use of terms such as "temperature-recording device" and "temperature-recording chart," to replace the terms "mercury-in-glass thermometer" and

“thermometer” with “temperature-indicating device,” to replace the term “bulb” with “sensor” (discussed later in this document), and to clarify the requirements for temperature-recording devices and the records created by the devices as follows:

Temperature-recording device. Each retort, or product sterilizer, shall have an accurate temperature-recording device that records temperatures to a permanent record, such as a temperature-recording chart.

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.

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.

5. Sensors

FDA is proposing to revise § 113.40(a), (b), (c), (d), (e), (f), and (g)(1) by replacing the term “bulb” or “bulb or sensor” with the general term “sensor” when referring generally to the sensing element of temperature-indicating devices, temperature-recording devices, and temperature-controlling devices. The sensing element of a mercury-in-glass thermometer is called a “bulb” in the current regulations. The term “sensor” encompasses “bulb” as well as other types of temperature-indicating device sensing elements, which are not bulbs. In the proposed regulation, the inclusive term “sensor” is used when referring to the sensor portion of a temperature-indicating device, which may be the bulb of a mercury-in glass thermometer, or to the sensing element or probe of a temperature-recording device or temperature-controlling device, which may include a mercury-in-glass thermometer as a component of the device.

FDA is proposing to revise § 113.40(b)(2) to clarify that, for still

retort systems that pressure process in water and are equipped with combination recorder-controller sensors, 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. Current § 113.40(b)(2) indicates specific requirements for placement of sensors for recorder-controllers, as follows: “The recording-thermometer bulb should be located adjacent to the bulb of the mercury-in-glass thermometer, except in the case of a vertical retort equipped with a combination recorder-controller. In such vertical retorts, the temperature recorder-control bulb shall be located at the bottom of the retort below the lowest crate rest in such a position that the steam does not strike it directly. In horizontal retorts, the temperature recorder-control bulb 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 control bulb.” These requirements for placement of combination recorder-controller sensors were intended to ensure accurate measurement of the scheduled process temperature and were helpful specific directives for sensor placement when the regulations were published in 1973, based on retort designs at that time. However, it may be technologically feasible to comply with the specific requirements of the current regulation, but place the sensor in a location that does not accurately measure the scheduled process temperature. Thus, although the specific sensor location requirements of current § 113.40(b)(2) are still valid, FDA believes further clarification is needed to ensure that combination recorder-controller sensors are located where the recorded temperature is an accurate measurement of the scheduled process temperature and is not affected by the heating media. FDA is proposing to provide this clarification in new § 113.40(b)(2)(iv) as follows:

- The temperature-recording device may be combined with the steam controller and may be a combination recording-controlling instrument. 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. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air.

FDA is proposing to clarify in § 113.40(b)(9) that a sensor, in addition to a gage, water glass, or petcock, may be used to determine the water level in the retort during operation. For some water level indicators, the term “sensor” may more appropriately describe the mechanism that measures or detects the water level.

FDA is proposing to revise § 113.40(e)(1) to clarify requirements for placement of sensors of temperature-indicating devices in discontinuous agitating retorts used for pressure processing in water, i.e., a water immersion processing system. Current § 113.40(e)(1) requires, “Bulbs of indicating thermometers shall be installed either within the retort shell or in external wells attached to the retort.” However, this basic, unqualified requirement to place sensors in the retort shell or in external wells may not be sufficient to ensure proper placement of temperature-indicating device sensors in discontinuous agitating retorts used for pressure processing in water. Current § 113.40(b)(1), relating to pressure processing in water in still retorts, also a water immersion process, clarifies that, “Bulbs of indicating thermometers shall be located in such a position that they are beneath the surface of the water throughout the process * * * this entry should be made in the side at the center, and the thermometer bulb shall be inserted directly into the retort shell * * * the thermometer bulbs shall extend directly into the water a minimum of at least 2 inches without a separable well or sleeve.” This type of clarification relating to placement of temperature-indicating device sensors in still retorts used for pressure processing in water also applies to discontinuous retorts for pressure processing in water. Thus, FDA is proposing to revise § 113.40(e)(1) (proposed § 113.40(e)(1)(v)) by adding clarifying language relating to temperature-indicating device sensor

placement, similar to current § 113.40(b)(1), as follows:

- Each temperature-indicating device shall be installed where it can be accurately and easily read. The sensor of the temperature-indicating device shall be installed either within the retort shell or in an external well attached to the retort. Sensors of temperature-indicating devices shall be located in such a position that they are beneath the surface of the water throughout the process. This entry should be made in the side at the center, and the temperature-indicating device sensor shall be inserted directly into the retort shell. The temperature-indicating device sensor shall extend directly into the water a minimum of at least 2 inches (5.1 centimeters) without a separable well or sleeve. If a separate well or sleeve is used, there must be adequate circulation to ensure accurate temperature measurements. The temperature-indicating device—not the temperature-recording device—shall be the reference instrument for indicating the processing temperature.

6. Vents

FDA is proposing to revise § 113.40(a)(12) to clarify that the “installations and operating procedures” in § 113.40(a)(12)(i)(a) through (a)(12)(i)(d) and (a)(12)(ii)(a) and (a)(12)(ii)(b) do not apply to systems that use dividers between layers of containers. Current § 113.40(a)(12) states, in part, “Some typical installations and operating procedures reflecting the requirements of this section for venting still retorts are given in paragraph (a)(12)(i)(a) through (a)(12)(i)(d) and (a)(12)(ii)(a) and (a)(12)(ii)(b) of this section.” However, the placement of dividers between layers of containers in a still retort system was not a “typical installation or operating procedure” at the time the regulations were published in 1973. The venting procedures in current § 113.40(a)(12) were based on heat penetration studies in retort systems without dividers and may be inadequate when dividers are placed between layers of containers. The dividers may interfere with heat distribution. Therefore, use of venting schedules developed for retorts without dividers may not be appropriate for retorts with dividers because such schedules may not be adequate to ensure that all areas of the retort, and thus all containers in the retort, reach the required processing temperature. FDA is proposing to add the phrase “without divider plates” to the last sentence of § 113.40(a)(12) as follows:

- Some typical installations and operating procedures reflecting the requirements of this section for venting still retorts without divider plates are given in paragraph (a)(12)(i)(a) through (a)(12)(i)(d) and (a)(12)(ii)(a) and (a)(12)(ii)(b) of this section.

As required in current § 113.40(a)(12)(iii), other installations and operating procedures, such as still retorts with divider plates, may be used if the processor has evidence, on file, in the form of heat distribution data that its installations and operating procedures accomplish adequate venting of air. Such documentation is likely to include heat distribution studies conducted and documented by the processor to show that the process temperature will be reached with the dividers in place.

7. Screens

Current § 113.40(b)(8) states, in part, “Screens should be installed over all drain openings.” Current § 113.40(b)(10)(ii) states, in part, “The suction outlets should be protected with nonclogging screens to keep debris from entering the circulating system.” These provisions are intended to advise processors that they are responsible for evaluating their water circulation systems and for ensuring that drain openings and suction outlets do not become clogged and prevent proper water circulation and proper heat distribution. Although the current regulation is expressed as a recommendation, rather than a requirement, processors are responsible for ensuring proper heat distribution during processing and, therefore, must ensure that heat distribution is not hampered by clogged drains or suction outlets. FDA is proposing to revise § 113.40(b)(8) and 113.40(b)(10)(ii) to clarify the requirement, as follows:

- *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.
- *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-section 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

equipped with a pilot light or other signaling device to warn the operator when it is not running, and with a bleeder to remove air when starting operations. 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. Air Supply and Controls and Water Circulation

FDA is proposing editorial changes to § 113.40(e)(6). At the beginning of the first complete sentence, the word “Means” is changed to “A means” and the sentence was changed from a compound sentence to two simple sentences. FDA also is proposing to renumber § 113.40(e)(6) as § 113.40(e)(6)(i), to read as follows:

- *Air supply and controls.* 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.

FDA is proposing to revise § 113.40(e)(6) to include requirements for water circulation pressure processing in water in discontinuous agitating water retorts, similar to the requirements in current § 113.40(b)(10)(ii) for pressure processing in water in still retorts. Current § 113.40(b) and (e) both establish equipment and procedures for pressure processing in water. Section 113.40(b) applies to still retorts and § 113.40(e) applies to discontinuous agitating retorts. The retort systems are operationally similar in that they use water under pressure, which must be circulated to ensure appropriate heat distribution. FDA considers the water circulation requirements in § 113.40(b) for still retorts also apply to discontinuous agitating retorts. Because they are basic procedures for assuring even heat distribution when pressure processing in water, FDA currently considers these requirements when evaluating scheduled processes for pressure processing in water in discontinuous agitating retorts. FDA is proposing to clarify the water circulation procedures for pressure processing in water in discontinuous agitating retorts by adding new § 113.40(e)(6)(ii) as follows:

- *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-section 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 equipped with a pilot light or other signaling device to warn the operator when it is not running, and with a bleeder to remove air when starting operations. Alternative methods for circulation of water in the retort may be used when established by a competent authority as adequate for even heat distribution.

9. Drain Valve and Water Level Indicator

FDA is proposing to revise § 113.40(e) to include requirements for the drain valve and water level indicator in discontinuous agitating water retorts, similar to the requirements in current § 113.40(b)(8) and (b)(9), respectively, for pressure processing in water in still retorts. As previously explained, the retort systems for which equipment and procedures are established § 113.40(b) and (e) are operationally similar in that they use water under pressure. The basic requirements for the drain valve and water level indicator in § 113.40(b) for still retorts also should apply to discontinuous agitating retorts. FDA is proposing to add new § 113.40(e)(7) for drain valve, consistent with proposed, revised § 113.40(b)(8), discussed previously in this document, and is proposing new § 113.40(e)(8) for water level indicator, consistent with proposed, revised § 113.40(b)(9), as follows:

- *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.
- *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.

Because FDA is proposing new § 113.40(e)(7) and (e)(8), as discussed previously in this document, we also are proposing to renumber current § 113.40(e)(7), relating to critical factors, as § 113.40(e)(9).

10. Temperature-Recording Device Sensors

Current 113.40(g)(1)(i)(b) requires that a temperature-recording device shall be installed in the product at the holding-tube outlet between the holding tube and the inlet to the cooler. In addition, to comply with current § 113.40(g)(4), processors must identify where temperature is a critical factor in the scheduled process and must measure and record the temperatures that are critical factors. For example, when processing a non-liquid product or a product that contains solid particles, heat penetration of the solid and liquid portions may vary and the temperature at locations other than the holding-tube outlet may be critical to ensure effective heat penetration throughout the product. Processors must determine each point in the process where temperature is a critical factor for either the solid or liquid portion of the product and must place temperature-recording device sensors at those locations. Thus, processors must determine where temperature measurements are critical, based on the size and texture of particles in the food, and must locate sensors as necessary to ensure that the process temperature is reached and maintained throughout the process. FDA is proposing to clarify the requirement for temperature-recording device sensors by adding the following statement to § 113.40(g)(1)(i)(b):

- Additional temperature-recording device sensors shall be located at each point where temperature is specified as a critical factor in the scheduled process.

11. Flow Control

FDA is proposing to revise terminology in § 113.40(g)(1)(i)(f) by changing the title of the section from “*Metering pump*” to “*Flow control*” by replacing the terms “metering pump” and “speed adjusting device” with “flow controlling device,” and by replacing the term “speed changes” with “flow adjustments.” The broad term “flow controlling device” encompasses “metering pump” and “speed adjusting device” as well as other terms that may be used, such as metering device or flow control meter, to describe or identify equipment used to control product flow in the processing system. Similarly, use of the term “flow adjustments” is consistent with and broadly describes the function of flow controlling devices. The proposed revision of the title of the section to “Flow control” is consistent with the terminology changes within the text of proposed § 113.40(g)(1)(i)(f).

B. Containers (§ 113.60)

Current § 113.60(a) requires processors to ensure proper closure and to check for closure defects. This responsibility should have extended to postprocess handling. However, current § 113.60(a) does not specifically address postprocess handling and current § 113.60(d) relating to postprocess handling recommends, but does not require, processors to design and operate automatic equipment used in handling filled containers to preserve the can seam and container closure integrity. Container handling equipment, including automated and non-automated equipment, must be of appropriate equipment design and construction, operated to ensure container closure integrity, and replaced or repaired if defective to ensure proper container closure. Otherwise, container handling equipment may be the source of damage to the can seam and may prevent proper seam closure. Improper seam closures may lead to contamination of the previously sterilized product in the can. FDA is proposing to revise § 113.60(d) to change the term “automatic equipment” to “container handling equipment,” to clarify that container handling equipment used in handling filled containers shall be designed, constructed, and operated to preserve can seam or other container closure integrity, and to clarify that processors must check and, as necessary, repair or replace the container handling equipment, including conveyors and non-automated equipment, to ensure that they do not damage the containers and container closures as follows:

- *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 at 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.

C. Establishing Scheduled Processes (§ 113.83)

Current § 113.83 states, “The type, range, and combination of variations encountered in commercial production shall be adequately provided for in establishing the scheduled process.” Reprocessing of a product and blending a previously processed product into a new formulation are variations that may affect the adequacy of the scheduled process and, therefore, must be carefully evaluated and adequately addressed in the scheduled process. For example, because starch, when heated, is gelatinized, a processed starchy food may have a different viscosity than the same starchy food prior to processing. When a previously processed starchy food is blended or reprocessed, because of physical changes in the characteristics of the food, the scheduled process used for the starchy food prior to processing may not be adequate for the same food after processing. Thus, the scheduled process must be established based on the specific food used as the starting material for each specific process, i.e., when a reprocessed or a previously processed product is blended into a new formulation, the scheduled process must be specific for that situation. FDA is proposing to clarify this requirement by revising § 113.83 to include the statement, “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.”

D. Operations in the Thermal Processing Room (§ 113.87)

FDA is proposing to revise § 113.87(c) by inserting the term “accurately” in the first sentence to clarify that “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.” FDA is adding this term to emphasize that initial temperature determinations must be accurate, as determined by sufficiently frequent tests of the temperature-indicating device for accuracy against an accurate calibrated reference device. FDA also is proposing to add in § 113.87(c), “The temperature-indicating device used to determine the initial temperature shall be tested for accuracy against an accurate calibrated reference device at sufficient frequency to ensure that initial temperature measurements are accurate. Records of the accuracy tests shall be signed or

initialed, dated, and maintained.” Although FDA believes it should be understood that initial temperature measurements are expected to be accurate when taken and, therefore, the temperature-indicating device used for initial temperatures must be accurate, the proposed clarifications ensure consistency in interpretation of the requirements of § 113.87(c).

FDA is proposing to revise § 113.87(e) to replace the term “recording-temperature charts” with “temperature-recording device records” to ensure consistency with the changes in terminology relating to the use of the term “charts,” discussed previously in this document in changes to proposed revised § 113.40. FDA also is proposing to change the recommendation for clock times to reasonably correspond to the time of the day to a requirement by changing the word “should” to “shall.” Correlation of records with the time the records were created and with the time of the processing cycle is essential for evaluating time and temperature correlations of the scheduled process. This revision also is consistent with the requirement of § 113.100(a), “Processing and production information shall be entered at the time it is observed by the retort or processing system operator * * *.” Proposed revised § 113.87(e) would read as follows:

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

E. Processing and Production Records (§ 113.100)

Current § 113.100 identifies requirements for processing and production records. FDA is proposing in § 113.100 to revise terminology, consistent with terminology used in proposed § 113.40. FDA is proposing to replace the term “mercury-in-glass thermometer” with “temperature-indicating device,” to replace “recording thermometer” with “temperature-recording device,” to replace “metering pump” with “flow controlling device,” and to replace “recording thermometer charts” with “temperature-recording device records.”

FDA is proposing to revise § 113.100(a)(4) by removing the requirement to maintain records of the product temperature in the final heater outlet as indicted by the temperature recorder-controller in aseptic processing and packaging systems. The temperature in the final heater outlet may not be critical and, therefore, may not require maintenance of records. However, if the final heater outlet temperature is

identified as a critical factor in the scheduled process, the temperature must be observed and recorded, as required in § 113.100(a).

FDA is proposing to revise § 113.100(c) by adding the statement, “The records shall be signed or initialed and dated by the reviewer.” The current regulation requires that containers closure records shall be signed or initialed by the container closure inspector and reviewed by management, but it does not explicitly state that the person in management who reviews the records must also sign or initial and date the records. FDA is proposing to add this requirement because such documentation is necessary to identify the manager who conducted the review and thus avoid any misunderstandings about who reviewed the record, to verify that the review was conducted by an individual qualified by training and expertise relating to container closures who can accept the records for the processor, to identify the person responsible for ensuring following-up to correct container closure defects, and to indicate that the records have been accepted by the processor.

FDA is proposing to add a new § 113.100(f) to provide for the maintenance of computerized records, in accordance with part 11 (21 CFR part 11). FDA regulations in part 11 set forth FDA criteria for electronic records and signatures. Many low-acid canned food processors currently maintain records on computers. The proposed addition of new § 113.100(f) clarifies and acknowledges that records relating to processing low-acid canned foods may be maintained electronically, provided they are in compliance with part 11.

FDA is proposing to add a new § 113.100(g) to clarify that records required under part 113, or copies of such records, must be readily available during the retention period for inspection and copying by FDA when requested. Proposed § 113.100(g) provides that, in part, “if reduction techniques, such as microfilming, are used, a suitable reader and photocopying equipment must be made readily available to FDA.” Access to such records during inspections is needed by FDA field investigators to evaluate compliance with the requirements of part 113. Copies of such records are needed for review by FDA headquarters staff experts who evaluate complex scientific and technical issues associated with processing low-acid canned foods and with compliance with the requirements of part 113.

F. Minor Revisions in Regulations

FDA is proposing to correct typographical errors, revise sentence structure, and make minor clarifying edits in the regulations, as follows:

In proposed § 113.40(a)(4), (a)(8), (b)(10)(i), (c)(5), and (e)(6)(i), we changed compound sentences to simple sentences.

In the first sentence of proposed § 113.40(b)(10)(ii), we changed the word “is” to “it.”

In the third sentence of proposed § 113.40(d)(2)(iv), we changed the phrase “bleeder opening emitting steam” to “bleeder that emits steam.”

In the second sentence of proposed § 113.40(e)(1)(v), we changed the phrase “in external wells” to “in an external well.”

In the fifth sentence of proposed § 113.40(e)(9), we corrected the spelling of “vacuum.”

In the first sentence of proposed § 113.40(g)(1)(i)(G), we corrected the spelling of “continuous.”

In the third sentence of proposed § 113.100(b), we changed the word “that” to “than.”

G. Immediate Implementation of Proposed Rule

FDA believes the proposed revisions to §§ 113.40, 113.60, 113.83, 113.87, and 113.100 will provide industry with flexibility to take advantage of technological advancements associated with temperature-indicating devices and temperature-recording devices, will clarify recordkeeping requirements for temperature-indicating devices and other aspects of processing low-acid canned foods, and will clarify provisions of the current regulations. FDA believes that the proposed rule will ensure that temperature-indicating devices that replace mercury-in-glass thermometers are accurate during processing. FDA also believes the proposed rule allows industry to voluntarily transition from mercury-in-glass thermometers to other temperature-indicating devices and to reduce potential sources of mercury contamination in food processing plants.

FDA believes that some processors are anxious to replace mercury-in-glass thermometers with alternative temperature-indicating devices. Therefore, pending issuance of a final rule, FDA intends to consider the exercise of its 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. The act’s 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 at 835 (1985); see also *Shering Corp. v. Heckler*, 779 F.2d 683 at 685–86 (D.C. Cir. 1985) (stating that the provisions of the act “authorize, but do not compel the FDA to undertake enforcement activity”). Until the agency issues a final rule for temperature-indicating devices for thermally processed low-acid foods packaged in hermetically sealed containers, the agency believes that its exercise of enforcement discretion will provide the needed flexibility to manufacturers who desire to transition to alternative temperature-indicating devices. Processors who choose to use alternative temperature-indicating devices must comply with any revised requirements established in the final rule when the final rule becomes effective.

IV. Analysis of Impacts

A. Preliminary Regulatory Impact Analysis: Flexibility in Permitting Alternative Temperature-Indicating Devices

FDA has examined the impacts of the proposed rule under Executive Order 12866, the Regulatory Flexibility Act (the RFA) (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 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 proposed rule is not a significant regulatory action as defined by the Executive order.

1. Need for the Regulation

Current regulations for thermally processed low-acid foods in hermetically sealed containers, except for aseptic packaging and processing, require 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 food industry. Moreover, NIST has developed standards for some alternative temperature-indicating devices and there is little reason to assume that alternatives are any less accurate than mercury-in-glass thermometers, given an appropriate testing regime. We request comments on the possibility that alternative temperature-indicating devices are at least as accurate as mercury-in-glass thermometers, and also that there are appropriate and established testing regimes to assure their accuracy.

Correspondence with industry representatives suggests that the current regulation requiring mercury-in-glass thermometers may be a barrier to innovation (Ref. 3). By allowing the low-acid food industry flexibility to choose alternative temperature-indicating devices, the proposed rule would allow processors to select temperature-indicating devices based on gains to labor productivity and technical considerations. Clarifying provisions in the current regulation would facilitate the voluntary adoption and safe use of alternative temperature-indicating technology, as well as replace outdated terminology.

The potential to improve productivity may be one reason firms may choose to adopt alternatives to mercury-in-glass thermometers. Correspondence with the Food Products Association (FPA) (formerly, National Food Processors Association) suggests that monitoring and analysis capabilities from using alternative temperature-indicating devices may be enhanced (Ref. 3). In addition, the potential to avoid costly remediation of hazardous mercury spills, and growing concerns by State and local governments about the health effects from the accumulation of mercury in the environment, have led to legislation that restricts the sale, manufacture, and distribution of mercury-in-glass thermometers (Ref. 4). For these reasons, FPA correspondence suggests that low-acid food processors are phasing out the use of mercury-in-glass thermometers for all other purposes except those necessary for regulatory compliance.

2. Regulatory Options Considered

Regulatory options considered include:

Option 1—No new regulation.

Option 2—Allow flexibility to use alternative temperature-indicating devices, including mercury-in-glass thermometers, that can be tested against an accurate calibrated reference device in processing low-acid canned foods without an explicit record requirements.

Option 3 (the Proposed Rule)—All of the provisions in option 2 and include explicit recordkeeping requirements for test results and explicit records access requirements for required records.

3. Costs and Benefits of Option 1 (No New Regulation)

There are neither costs nor benefits from the option of no new regulation.

4. Costs and Benefits of Option 2 (Allow the Use of Alternative Temperature-Indicating Devices Without a Record Requirement for Accuracy Tests)

The costs and benefits are estimated separately for the proposed voluntary and mandatory provisions of the rule. The voluntary provision allows low-acid canned food manufacturers to use alternatives to mercury-in-glass thermometers as temperature-indicating devices. In option 2, the mandatory provisions are considered to be clarifications of the current regulation and are primarily intended to facilitate the voluntary adoption and safe use of alternative temperature-indicating technologies. Option 2 does not consider requirements for low-acid canned food manufacturers to establish and maintain records on accuracy tests necessary to ensure that each temperature-indicating device, including each mercury-in-glass thermometer, and each reference device is accurate during processing. Nor does option 2 consider requirements for FDA access to such records upon inspection.

There are no compliance costs from allowing alternative temperature-indicating devices. The benefits from allowing alternative temperature-indicating devices are from any reduction of the risk of foodborne illness that results from the use of alternative temperature-indicating devices, the avoided cleanup and disposal costs resulting from breaking mercury-in-glass thermometers during non-production times, and the increase in labor productivity at low-acid canned food manufacturers.

a. *Costs from permitting the use of alternative temperature-indicating devices.* The proposed regulation permits, but does not require, low-acid food manufacturers to adopt alternatives to mercury-in-glass thermometers. Thus, costs associated with choosing an alternative to mercury-in-glass thermometers are voluntarily incurred. These costs would be incurred only if the expected private benefits from doing so are higher than the costs. To show our estimation method and solicit comments, we specify the determinants of the costs of alternative temperature-indicating devices.

Higher purchase prices and maintenance costs may influence a firm's decision to use alternative temperature-indicating devices. Correspondence with FPA suggests that most digital alternatives are slightly more expensive than mercury-in-glass thermometers (Ref. 3). According to FPA, after installation, there are no significant differences in maintenance costs during normal operations between mercury-in-glass thermometers and alternative temperature-indicating devices (Ref. 3). Thus, the higher cost would be a one-time capital cost. FPA also suggests that many firms are using alternative temperature-indicating device technology for purposes that are beyond the scope of the low-acid food regulations (Ref. 3). This implies that the productivity gains from their adoption are greater than the higher purchase prices.

Temperature-indicating devices must be tested against an accurate calibrated reference device, including tests relating to relevant factors such as electromagnetic interference and environmental conditions. Environmental conditions may affect the accuracy of mercury-in-glass thermometers. Thus, low-acid food manufacturers have experience with understanding and controlling these factors to ensure that mercury-in-glass thermometers are accurate and function properly during processing. Tests to ensure that alternative temperature-indicating devices are not susceptible to electromagnetic interference may result in higher costs for testing and maintaining the devices.

FPA suggests that many companies already use alternative temperature-indicating devices for unregulated purposes, and that the use of mercury-in-glass thermometers in these establishments is restricted to regulatory compliance purposes (Ref. 3). In the event that alternative temperature-indicating devices currently used by industry for unregulated purposes are tested against an accurate calibrated reference device, the experience of their use for the unregulated purpose would likely mitigate any additional learning, or adjustment costs for their testing. Nevertheless, one-time adjustment costs are likely to be incurred by all low-acid canned food manufacturers that adopt alternative temperature-indicating device technology—especially early adopters of such technology—as they adjust to new testing protocols and appropriate testing frequencies. FDA assumes that, after testing protocols and frequencies are established, the testing costs will be comparable to those required for testing mercury-in-glass

thermometers. FDA requests comments on the magnitude of the costs (if any) associated with learning about and adjusting to testing requirements for alternative temperature-indicating devices, as well as our assumption that testing costs for alternative temperature-indicating devices, subsequent to the initial establishment of testing protocols, are comparable to those for mercury-in-glass thermometers.

Finally, we assume that firms able to achieve gains in labor productivity and reduce remediation costs will phase in alternative temperature-indicating devices. One firm predicted that alternative temperature-indicating devices will be chosen for all new purchases immediately following issuance of the final rule, and that the total period for transition from mercury-in-glass thermometers to alternative temperature-indicating devices will be 5 years (Ref. 3). FDA assumes that all mid-sized and large low-acid canned food manufacturers will adopt alternative temperature-indicating device technology within 5 years after issuance of the final rule. We request comments on this assumption.

b. *Benefits from permitting the use of alternative temperature-indicating devices.*

Changes in the Risk of Foodborne Illness

The Centers for Disease Control and Prevention (CDC) report that there were 20 cases of foodborne botulism and 76 cases of infant botulism in the United States in 2003 (Ref. 5). There have been no reported cases of foodborne botulism associated with commercially canned low-acid food in recent years. CDC reported one case of botulism from food eaten at a restaurant and one case from food eaten at an unknown location in 1994, but home-canned food and Alaska Native foods consisting of fermented seafood are currently the principal sources of foodborne botulism (Ref. 5). The risk factors for infant botulism, including from food and non-food sources, remain largely unknown.

Although cases of botulism are mostly associated with food prepared or canned at home, a change to inaccurate or improperly functioning temperature-indicating devices by low-acid canned food manufacturers could potentially increase the risk of foodborne botulism. Increased risk of botulism associated with new technology could result from increased risk of device errors for indicating and recording temperatures, or an increased risk of human errors in reading alternative temperature-indicating devices. An increased risk of illness could accompany an increased risk of such errors that lead to food

being processed at unsafe low temperatures.

To acknowledge the potential for increased risk associated with the adoption of alternative technologies mentioned previously in this document, this proposed rule requires alternative temperature-indicating devices to be tested for accuracy against an accurate calibrated reference device. The proposed rule also requires tests relating to relevant factors such as electromagnetic interference and environmental conditions. Alternatives to the mercury-in-glass thermometer that meet NIST requirements are currently available to the industry and we assume that such technology is at least as accurate as mercury-in-glass thermometers given an appropriate testing regime.

There may be a period of learning and adjustment to the new temperature-indicating technology for a short period immediately following its adoption, during which the risk of inaccurate measurement may be temporarily elevated. We assume that the frequency of testing for accuracy during this adjustment period may increase for a short time to compensate for any increased risk of inaccurate measurement from the new technology. Consequently, we assume that any increases in risk during the adjustment period will be fully mitigated through appropriate or increased testing. We request comments on this assumption.

An increase in risk of illness could arise from an increase in human error in reading the alternative temperature-indicating device. However, we assume that the alternatives to the mercury-in-glass thermometer are likely to be no more difficult to read than mercury-in-glass thermometers. Thus, we expect no increase in the number of reading errors. Some alternative temperature-indicating devices may have a digital display of the temperature and may be easier to read than mercury-in-glass thermometers. However, there is also the possibility that certain digital displays with poor resolution may facilitate reading errors. In addition, the magnitude of a reading error from a digital display may be different than that from a mercury-in-glass thermometer. The relative risk of misreading a digit displayed in the "tens" and "ones" columns may be different for digital displays compared to the conventional mercury-in-glass thermometers. Although we assume no increase in the risk of reading errors for digital devices, we request comments on this assumption.

Avoided Cleanup Costs

The principal benefit from allowing flexibility in the use of temperature-

indicating device technology by low-acid canned food manufacturers is the reduced risk of cleanup and disposal costs resulting from breaking mercury-in-glass thermometers during non-production times (e.g., calibration, equipment maintenance, storage). Disposal and cleanup costs for mercury spills and damaged mercury-in-glass thermometers can be high. FPA estimates the cost of environmental disposal of mercury-in-glass thermometers to be about \$500 (Ref. 3). Examples of cleanup costs provided by the Northeast Waste Management Officials' Association include the \$6,000 cleanup costs paid by a school following the breakage of 12 thermometers (Ref. 6), or approximately \$500 per thermometer. According to Harvard University Operations Services, mercury spills involving thermometer breakage are one of the most common accidents involving laboratory equipment, with cleanup costs of approximately \$110 per thermometer (Ref. 7).

Mercury-in-glass thermometer breakage can occur within the processing plant during calibration, equipment maintenance, storage, and other non-production times. Because we do not have accident data from processors, we estimate mercury-in-glass thermometer breakage rates using information on accident rates involving laboratory equipment. According to a 2004 bulletin published by the Lawrence Berkeley Laboratory, the annual number of laboratory accident rates for 2002, 2003, and 2004 was 2.17, 2.51, and 1.25 per 100 employees (respectively), for an annual average of approximately 2 per 100 employees (Ref. 8).

Using 2002 U.S. Economic Census data on the number of employees in the low-acid canned food industry, we extrapolated the laboratory accident rates reported previously in this document. There were reported to be 78,016 employees in the canned food industry (North American Industry Classification System (NAICS) codes 311421, 311422, and 311514 for fruits and vegetables canning, specialty canning, and seafood canning) in 2002 (Ref. 9). We assume that half of all employees of canning manufacturers are involved in the manufacturing process. We further assume that half of the employees involved in the manufacturing process will come into direct contact with mercury-in-glass thermometers at some point during the performance of their jobs. This yields an estimate of 19,504 employees of low-acid canned food manufacturers that come into direct contact with temperature-indicating devices.

Based on the laboratory accident rates reported previously, we estimate that there are approximately 390 manufacturing process related accidents per year (i.e., $(19,504 / 100) \times \text{an accident rate of } 2$) in the low-acid canned food industry. We assume that half of these accidents involve equipment that comes directly in contact with mercury-in-glass thermometers, and half of those, or approximately 100, involve mercury-in-glass thermometer breakage and require remediation in the form of cleanup and disposal.

We estimate that all large and mid-sized low-acid canned food manufacturers will adopt alternative temperature-indicating device technology because of the potential savings in cleanup costs as well as the potential for increased productivity made possible from alternative temperature-indicating devices. There currently are approximately 1,100 domestic and 5,600 foreign-based low-acid canned food manufacturers registered with FDA that supply the domestic market (Ref. 10). Because that data does not include firm size information, we estimate the proportion of large and mid-sized domestic low-acid canned food manufacturers using U.S. Economic Census data, and assume the same proportions of large and mid-sized foreign firms as well.

Based on the 2002 U.S. Economic Census there were a total of 1,051 fruit and vegetable, specialty canning, and dry, condensed, and evaporated dairy product manufacturing establishments reported for NAICS codes 311421, 311422, and 311514, and that large and mid-sized establishments (i.e., establishments with more than 19 employees) comprise approximately half of the total. Consequently, we estimate that if half of the low-acid food manufacturers were to discontinue use of mercury-in-glass thermometers as provided in the proposed rule, approximately 50 domestic accidents per year involving mercury-in-glass thermometers would be avoided (i.e., 100 accidents divided by 2 for large and mid-sized establishments) and 255 foreign-based accidents per year involving mercury-in-glass thermometers would be avoided (i.e., 100 accidents, scaled by the ratio of foreign to domestic firms, $5,600 / 1,100$, and divided by 2 for large and mid-sized firms) that would otherwise incur cleanup and disposal costs during non-production times. Implicit in this estimate is the assumption that the accident rates for domestic and foreign-based manufacturers are the same. We request comments on this assumption.

We assume that each accident involves one mercury-in-glass thermometer. In addition, we assume that cleanup and remediation costs per accident are the same for foreign-based and domestic low-acid canned food manufacturers. Consequently, we estimate that after half of the low-acid canned foods manufacturers adopt alternative temperature-indicating device technology, between \$5,500 and \$25,000 in remediation costs (i.e., 50 accidents x \$110, and 50 accidents x \$500) would be averted by domestic manufacturers, and between \$25,000 and \$127,000 in remediation costs (i.e., 255 accidents x \$110, and 255 accidents x \$500, rounded to the nearest thousand) would be averted by foreign-based manufacturers. Total remediation costs averted would be between \$30,500 and \$152,000.

Increased Productivity from Allowing Alternative Technologies

We use U.S. Department of Labor estimates of changes in labor productivity from 1995 to 2004 to estimate the savings to large, mid-sized, and small firms from improved temperature monitoring and recordkeeping productivity that may result from using alternative temperature-indicating devices. We assume that cost savings and increases in labor productivity from adopting alternative temperature-indicating technology would be the same for domestic and foreign-based firms of similar size.

We computed the average of the U.S. Department of Labor quarterly estimates of the percent change in quarterly output per hour (expressed in annual terms) in the non-farm business sector over the 10-year period from 1996 through 2005 to be 2.8 percent (Ref. 11). We estimated that productivity gains to labor engaged in monitoring temperature sensitive processes by low-acid canned food manufacturers that adopt alternative temperature-indicating technology would be 2.8 percent as well.

We assume that monitoring temperature sensitive processes requires the equivalent of one full time job at large establishments, half a full time job at mid-sized establishments, and one quarter of a full time job at small establishments. We doubled the mean hourly wage of \$13.55 for production labor in 2002, obtained from the Bureau of Labor Statistics (Ref. 12), to account for overhead costs and estimated that adopting new temperature-indicating technology could increase labor productivity by as much as \$0.76 per hour (i.e., 2.8 percent x \$27.10) at large establishments, \$0.38 per hour at mid-

sized establishments (i.e., 2.8 percent divided by 2 x \$27.10), and \$0.19 per hour at small establishments (i.e., 2.8 percent divided by 4 x \$27.10).

5. Costs and Benefits of Option 3, the Proposed Rule (Option 2 With Added Recordkeeping and Records Access Requirements)

a. *Costs of the recordkeeping and records access requirements.* The current low-acid food regulations recommend, but do not require, that records of thermometer accuracy checks that specify date, standard used, method used, and person performing the test be maintained. The proposed rule requires, rather than recommends, maintenance of written documentation of the accuracy of the temperature-indicating device, and also written documentation of the accuracy of the reference device. The proposed rule also requires that each temperature-indicating device and reference device have a tag, seal, or other means of identity that can be referenced in the required records as the identity of the device. These proposed recordkeeping requirements apply to mercury-in-glass thermometers as well as alternative temperature-indicating devices and reference devices. Additional costs associated with the proposed revised recordkeeping requirements may be incurred for all temperature-indicating devices and reference devices.

The costs of the requirement to establish and maintain records are the setup costs required to design and establish a form for recording the required information, and the additional labor requirements needed to record the information. In addition, there will be one-time costs for training employees to comply with the requirement. We assume that one to two accuracy tests will be performed per year per device and that only a small number of forms would need to be designed. Thus, the setup costs for the recordkeeping requirement would be minimal. Moreover, we assume that the current recordkeeping practice is to maintain most, if not all, of these records and that the additional one-time training costs would be minimal as well.

We assume that additional labor costs to record the required information will be small because the current regulations recommend maintaining similar records. Thus, we assume that the current practice is to keep track of most, if not all, of the information required by the proposed rule. However, we request comments on this assumption.

Current incentives to track accuracy and performance of mercury-in-glass thermometers may vary across the

industry, and information that is currently generated during accuracy tests may not be permanently recorded, as required under this proposed rule. Thus, we assume there will be labor costs incurred from this proposed rule to record information that is currently generated, but not recorded. We assume that half of the industry currently does not have sufficient incentive to track the performance of the temperature-indicating devices necessary to permanently record all of the required information. We further assume that current practice by these firms is to leave unrecorded one to four separate pieces of information required under the proposed rule, and that each piece of information takes between 10 and 15 seconds to permanently record. Consequently, we estimated that half of all low-acid canned food manufacturers would spend between 10 seconds and 1 minute (i.e., 1 x 10 seconds and 4 x 15 seconds) per device, recording information required in the proposed rule that is currently unrecorded.

We estimated the number of temperature-indicating devices that would be subject to recordkeeping requirements using the results of a survey of the low-acid canned food industry conducted by FDA and published in 1994 (Ref. 13). Findings from that survey indicate that the number of mercury-in-glass thermometers found at establishments ranged from 1 to 65, with only 4 percent of establishments having more than 30 thermometers, and 67 percent having fewer than 10. Assuming the number of thermometers is uniformly distributed between 1 and 10 for 67 percent of establishments, between 11 and 30 for 29 percent of establishments, and between 31 and 65 for 4 percent of establishments, we estimated a weighted average of about 10 thermometers per establishment (i.e., 67 percent x 5.5 + 29 percent x 15.5 + 4 percent x 48 rounded to the nearest integer).

Based on the findings from this study, we estimated that low-acid canned food establishments use an average of 10 devices annually, for a total number of 33,500 thermometers with accuracy test results that are currently not fully recorded (i.e., $1/2 \times 6,700$ establishments x 10 thermometers) as required in the proposed rule. We assume that each device requires one to two tests per year (for a mean of 1.5), and estimated the total burden for the industry for recording the required test result information to be between 140 hours and 838 hours per year (i.e., 33,500 thermometers x 10 seconds x 1.5 tests / 3,600 seconds per hour, and

33,500 thermometers x 60 seconds x 1.5 tests / 3,600 seconds per hour). Doubling the \$13.55 mean hourly wage for production labor for 2002 from the Bureau of Labor Statistics (Ref. 11) to account for overhead costs, we computed the labor cost of recording accuracy test information required in this proposal to be between \$3,800 and \$22,700, rounded to the nearest hundred.

The costs of the requirement to allow FDA access to records documenting the accuracy of both temperature-indicating devices and reference devices include the costs of document retrieval and reproduction, as well as time spent with FDA investigators prior to, and immediately following, these activities. We assume these costs would be incurred once per year with a regular facility inspection, as well as irregularly during outbreak investigations. We assume the costs from the records access requirements would be incurred by a small number of firms that currently fail to permit FDA access to records under the current regulation.

b. *Benefits of the recordkeeping and records access requirements.* The benefits from the proposed recordkeeping and records access requirements are derived from the enhanced ability by manufacturers to track critical accuracy and performance data for temperature-indicating devices which may improve safety, as well as the ability by FDA to determine compliance with the recordkeeping requirements. Although we believe that maintenance of these records is the current industry practice, the explicit requirement in this proposed rule may increase the incentive for industry compliance with records requirements, including those related to the testing of temperature-indicating devices and reference devices, and may increase the frequency with which testing occurs. The benefits from requiring maintenance of accuracy testing records may be particularly high during the transition period following the adoption of alternative temperature-indicating devices if they are useful for learning about the performance characteristics and required testing protocols.

FDA's experience is that most manufacturers currently permit access to temperature-indicating device test results and other records under the current regulation, and we expect the benefits of the records access requirement from improving regular inspections to be small. However, the records access requirement may provide benefits from any accompanying increase in incentives to test alternative temperature-indicating devices for

accuracy that might result due to concern by a manufacturer with being in compliance with the testing requirement. Additional incentives for testing for accuracy may be particularly important during a transition period when knowledge about alternative temperature-indicating device performance characteristics may be uncertain.

In addition, there may be benefits from any increase in the degree of certainty that a manufacturer will comply with a records access request, particularly during an outbreak investigation when records of test results may be essential to determine the cause of the outbreak. However, any increase in the incentives to test alternative temperature-indicating devices for accuracy, and also in the degree of certainty that a manufacturer will comply with a records access request, may be smaller for foreign-based manufacturers compared with domestic manufacturers. This may be true if foreign-based manufacturers export their products to buyers based not only in the United States, but also in countries that do not require the maintenance and access to records documenting the accuracy of temperature-indicating device technology. Under such circumstances foreign-based low-acid canned food manufacturers may choose to sell their products in other countries rather than comply with FDA records requirements. We request comments on the possibility that the incentives for maintaining records by foreign-based low-acid canned food manufacturers that export to the United States are smaller than those for domestic manufacturers.

6. Summary

In summary, the proposed rule provides flexibility by permitting alternative temperature-indicating devices without increasing public health risks from low-acid foods. In addition, the proposed rule may result in additional or more frequent testing of alternative temperature-indicating devices, which may be particularly useful for evaluating device performance. The setup costs for designing new forms for recording the required accuracy test information and the one-time training costs are assumed to be minimal. The recurring additional labor costs are estimated to be between \$3,800 and \$22,700.

The avoided mercury cleanup costs from broken mercury-in-glass thermometers, and also the potential for enhanced labor productivity from adopting alternative temperature-indicating device technology, may be

substantial. We estimate that avoided cleanup costs from broken mercury-in-glass thermometers will be between \$30,500 and \$152,000 if all large and medium sized low-acid food firms adopt alternative temperature-indicating devices. Table 1 of this document summarizes the costs and benefits of the proposed rule, rounded to the nearest thousand.

TABLE 1.—A SUMMARY OF THE COSTS AND BENEFITS OF THE PROPOSED RULE

Description	Impact
One-time Costs	
Design of new record-keeping forms	minimal
Recordkeeping training	minimal
Recurring Costs	
Recordkeeping	\$5,000–\$23,000
Records access (incurred by a small number of firms that currently fail to permit FDA access)	minimal
Purchase and additional testing of alternative devices	voluntarily incurred
Benefits	
Change in risk from low-acid canned foods	no change
Avoided mercury cleanup costs	\$31,000–\$152,000
Enhanced labor productivity	not quantified, but may be substantial

B. Regulatory Flexibility Analysis

The RFA requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities.

FDA has examined the economic implications of this proposed rule as required by the RFA. If a rule has a significant economic impact on a substantial number of small entities, the RFA requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. The voluntary provisions of this proposed rule would not generate any compliance costs for any small entities because they do not require small entities to undertake any new activity. A small business will not

choose alternative temperature-indicating device technology unless it believes that doing so will increase private benefits by more than it increases private costs.

The per-firm costs of the mandatory recordkeeping requirement of this proposed rule will be small. The additional labor costs from the recordkeeping requirements are estimated to be between \$3,800 and \$22,700 or between approximately \$1.00 and \$4.00 per firm (i.e., \$3,800 / 6,700 firms and \$22,700 / 6,700 firms, rounded up). Moreover, costs for small firms will be at the lower end of this range since they will have fewer temperature-indicating devices and reference devices to test. We assume the costs from the records access requirement would be small and incurred by a small number of firms that currently fail to grant FDA access to records under the current regulation. Accordingly, FDA certifies that this proposed rule will not have a significant impact on a substantial number of small entities. Under the RFA, no further analysis is required.

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, before proposing "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 one year." The current threshold after adjustment for inflation is \$122 million, using the most current (2005) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule, if finalized, to result in any 1-year expenditures that would meet or exceed this amount and has determined that this proposed rule does not constitute a significant rule under the Unfunded Mandates Reform Act of 1995.

V. Environmental Impact

The agency has determined under 21 CFR 25.30(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Paperwork Reduction Act

This proposed rule contains information collection provisions that are subject to review by OMB under the

Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). A description of these provisions is given in the following paragraphs with an estimate of the annual recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on the following topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Recordkeeping Requirements for Temperature-Indicating Devices

Description: The information proposed to be collected contains the results of tests of the accuracy of temperature-indicating devices used by low-acid food firms. Much of this information is currently generated from the accuracy "checks" recommended under current regulations, and some of it may not be permanently recorded as required under this proposed rule.

Current low-acid food regulations recommend that records of thermometer accuracy checks that specify date, reference device used, method used, and person performing the test be maintained. The proposed rule requires maintenance of written documentation of the accuracy of the temperature-indicating device and also written documentation of the accuracy of the reference device. The required documentation of accuracy is necessary to track the performance of devices, and may be particularly important for new temperature-indicating device technology during the transition period following its adoption. By requiring permanent records of the accuracy test results, manufacturers may have incentive to test temperature-indicating devices for accuracy more frequently than they would under the current regulations.

Description of Respondents: All commercial low-acid canned food processors. Based on FDA low-acid canned food manufacturers' registration

data, we estimate that there are approximately 6,700 low-acid canned food processing establishments.

Burden: The costs of the recordkeeping requirement are the setup costs required to design and establish a form for recording the required information, and the additional labor requirements needed to record the information. The initial setup costs for designing a new record form are assumed to be minimal since only one to two accuracy tests will be performed on an average of 10 devices per firm.

We assume that labor costs to record the required information will be small because current 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, information that is currently generated during accuracy tests may not be permanently recorded as required under the proposed rule. Thus, we assume there will be labor costs incurred from this proposed rule to record information that is currently generated, but not recorded.

We assume that half of the industry currently does not have sufficient incentive to track the performance of the temperature-indicating devices and reference devices necessary to permanently record all of the required information. We further assume that current practice by these firms is to leave unrecorded one to four separate pieces of information required under the proposed rule, and that each piece of information takes between 10 and 15 seconds to permanently record. Consequently, we estimate that half of all low-acid canned food manufacturers would spend between 10 seconds and 1 minute (i.e., 1 x 10 seconds and 4 x 15 seconds) per device, recording information required in the proposed rule.

Based on a survey conducted by FDA between 1992 and 1993, we estimate that low-acid food firms use an average of 10 devices, including reference devices. We estimate that 3,350 low-acid canned food manufacturers currently do not fully record the accuracy test results required by the proposed rule. We assume that each device requires one to two tests per year (midpoint of 1.5 tests per year). We estimate the annual frequency per recordkeeping to be 15 (i.e., 10 devices x 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). Table 2 of this document reports the

average annual burden described previously in this document.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
113.40(a)(1), (b)(1), (c)(1), (d)(1), (e)(1), and (f)(1)	3,350	15	50,250	0.0097	487

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

In compliance with the PRA (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection to OMB (see **DATES** and **ADDRESSES**).

VII. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the proposed rule does not contain policies that have substantial direct effects on 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, we have tentatively concluded that the proposed 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.

VIII. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IX. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. FDA has verified the Web site addresses, but is not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**.

1. Heymann, David L., "Control of Communicable Diseases," 18th ed., 2004, An

Official Report of the American Public Health Association, American Public Health Association, Washington, DC, p. 612, 2001.

2. *International Vocabulary of Basic and General Terms in Metrology (VIM)*, BIPM, IEC, IFCC, ISO, IUPAC, IUPAP, OIML, 2d ed., p. 47, definition 6.10, 1993.

3. Letter from Sia Economides, FPA, to Mischelle Ledet, FDA, August 23, 2004.

4. Smith, Brandie, *King County Passes Mercury Thermometer Sales Ban*, Washington Free Press, #63, May/June 2003, accessed online January 25, 2007, at <http://www.washingtonfreepress.org/63/kingCountyPassesMercury.htm>.

5. CDC, "Summary of Notifiable Diseases—United States, 2003," *Morbidity and Mortality Weekly Report*, April 22, 2005, accessed online January 25, 2007, at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5254a1.htm>.

6. Great Lakes Regional Pollution Prevention Roundtable, "Mercury-Thermometers: Spills," Mercury-Thermometer Topic Hub, Northeast Waste Management Officials' Association, accessed online January 25, 2007, at <http://www.glrppr.org/hubs/subsection.cfm?hub=101&subsec=17&nav=17>, last updated July 13, 2006.

7. University Operations Services, Harvard University Web site, accessed online January 25, 2007, at http://www.uos.harvard.edu/ehs/onl_fac_env_mer.shtml.

8. "Accident Prevention Urged for Final Weeks of Fiscal Year '04," *Today at Berkeley Lab—Friday, August 27, 2004*, accessed online January 25, 2007, at http://www.lbl.gov/today/2004/Aug/27-Fri/safety_page.html.

9. U.S. Census Bureau, "2002 Economic Census", accessed online January 25, 2007, at http://factfinder.census.gov/servlet/IBQTable?_bm=y&-geo_id=&-ds_name=EC023113&-lang=en.

10. FDA/Center for Food Safety and Applied Nutrition, "Acidified and Low-Acid Canned Food Registration Data," December 2005.

11. U.S. Department of Labor, Bureau of Labor Statistics, Output Per Hour—Non-farm Business Productivity—PR85006092, accessed online January 25, 2007, at <http://data.bls.gov/cgi-bin/survey/most?bls>.

12. U.S. Department of Labor, Bureau of Labor Statistics, accessed online January 25, 2007, at <ftp://ftp.bls.gov/pub/news.release/History/ocwage.11192003.news>.

13. Stringer, L.W., *Proceedings of Advances in Instrumentation and Control*, Vol. 49, part 2, pp. 715–723, 1994.

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, it is proposed that 21 CFR part 113 be 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. Temperature-indicating devices shall be tested for accuracy against an accurate calibrated 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 reference device 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) Written documentation of the accuracy of the temperature-indicating device and the reference device shall be established and maintained.

(A) Documentation of the accuracy of the temperature-indicating device shall include a reference to the tag, seal, or other means of identity used by the processor to identify the temperature-indicating device, the name of the manufacturer of the temperature-indicating device, the identity of the reference device used for the accuracy test and of equipment and procedures

used to adjust or calibrate the temperature-indicating device, the date and results of each accuracy test, the name of the person or facility that performed the accuracy test and adjusted or calibrated the temperature-indicating device, and the date of the next scheduled accuracy test.

(B) Documentation of the accuracy of the reference device shall include a reference to the tag, seal, or other means of identity used by the processor to identify the reference device, the name of the manufacturer of the reference device, the identity of the equipment and procedures used to test the accuracy and to adjust or calibrate the reference device, the identity of the person or facility that performed the accuracy test and adjusted or calibrated the reference device, the date and results of the accuracy test, and the traceability information. Documentation of the traceability information for the reference device may be in the form of a guaranty of accuracy from the manufacturer of the reference device or a certificate of calibration from a laboratory.

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

(iv) A temperature-indicating device shall be easily readable 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 sensor of the temperature-indicating device 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 3/4-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 that records 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 to agree as nearly as possible with, but to be in no event higher than, the temperature-indicating device during the process time. 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 recording-controlling instrument. 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 which emits steam continuously during the processing period. 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 should be graduated in divisions of 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 recording-controlling instrument 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. 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 this 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.

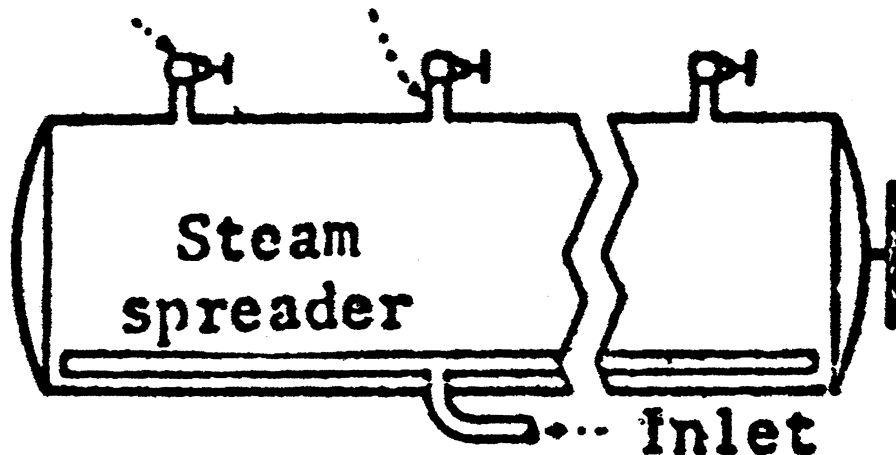
(11) *Water valves.* Retorts using water for cooling shall be equipped with a suitable valve to prevent leakage of water into the retort during processing.

(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 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 paragraph (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-in. gate valve 1-in. vent



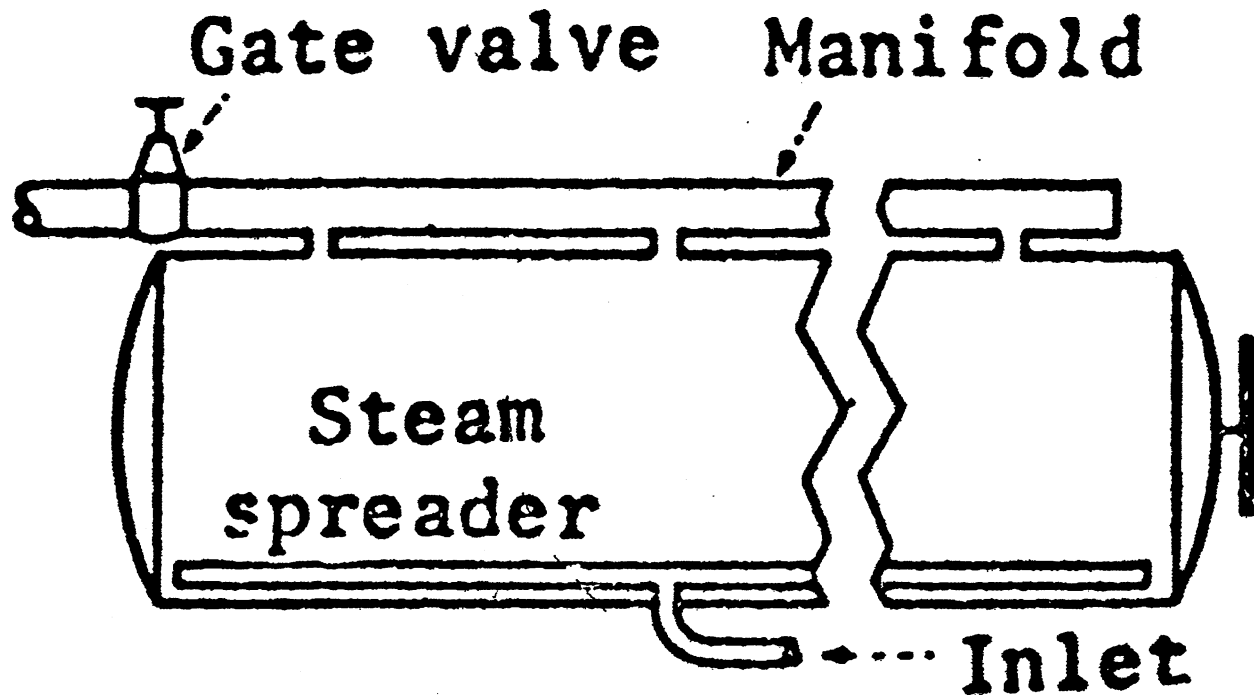
Specifications. One 1-inch (2.5 centimeters) vent for every 5 feet (1.5 meters) of retort length equipped with a gate or plug cock valve and discharging to atmosphere; end vents not more than

2.5 feet (76 centimeters) from ends of retort.

Venting method. Vent valves should be wide open for at least 5 minutes and to at least 225 °F (107.2 °C), or at least

7 minutes and to at least 220 °F (104.4 °C).

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



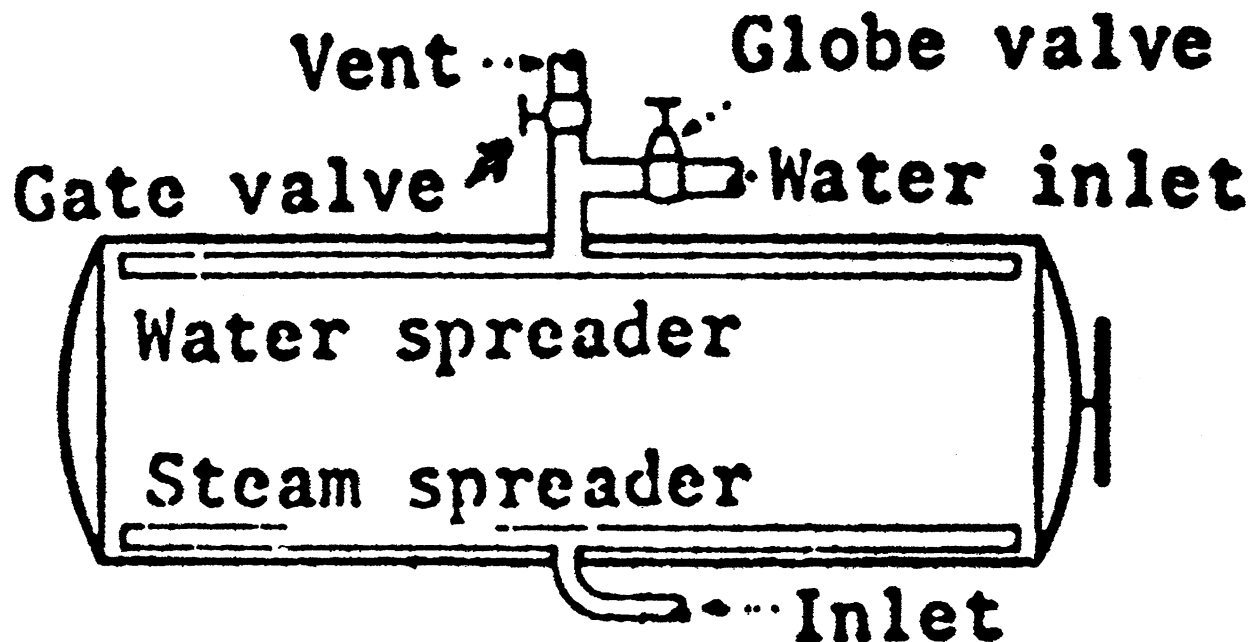
Specifications. One 1-inch (2.5 centimeters) vent for every 5 feet (1.5 meters) of retort length; and vents not over 2.5 feet (76 centimeters) from ends of retort: Size of manifold—for retorts less than 15 feet (4.6 meters) in length,

2.5 inches (6.4 centimeters); for retorts 15 feet (4.6 meters) and over in length, 3 inches (7.6 centimeters).

Venting method. Manifold vent gate or plug cock valve should be wide open for at least 6 minutes and to at least 225

°F (107.2 °C), or for at least 8 minutes and to at least 220 °F (104.4 °C).

(C) Venting through water spreaders.



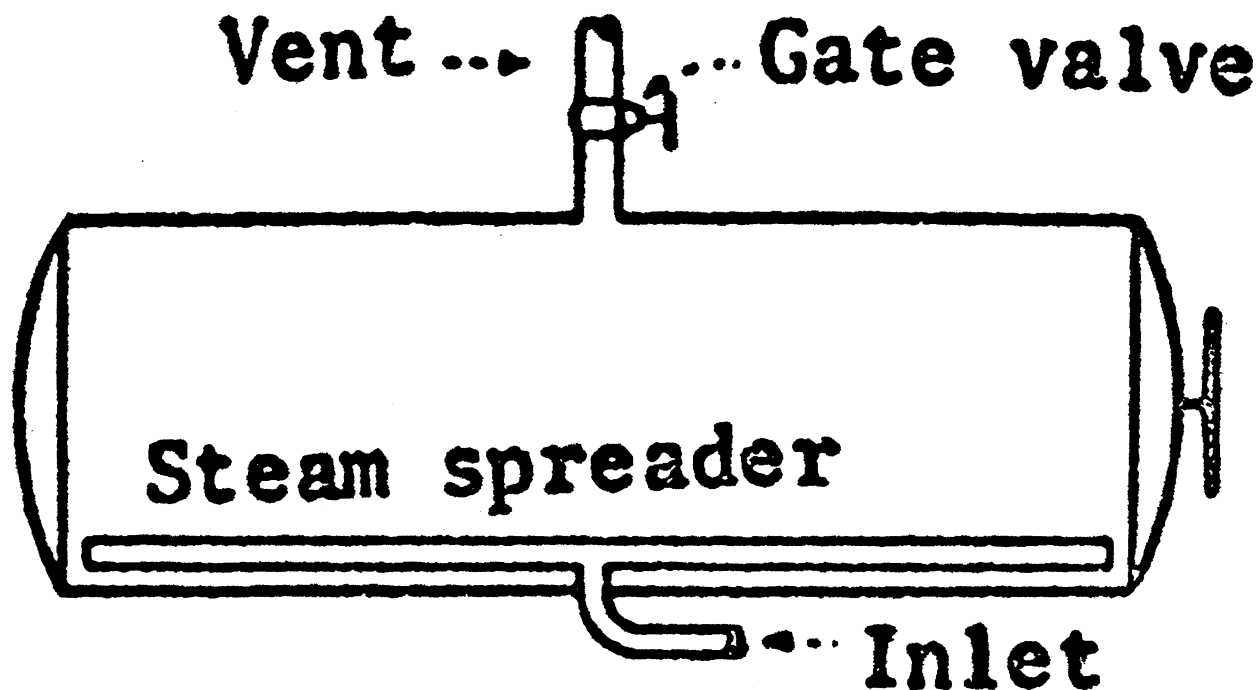
Size of vent and vent valve. For retorts less than 15 feet (4.6 meters) in length, 2 inches (5.1 centimeters); for retorts 15 feet (4.6 meters) and over in length, 2.5 inches (3.8 centimeters).

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.

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 (107.2 °C), or for at least 7 minutes and to at least 220 °F (104.4 °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).

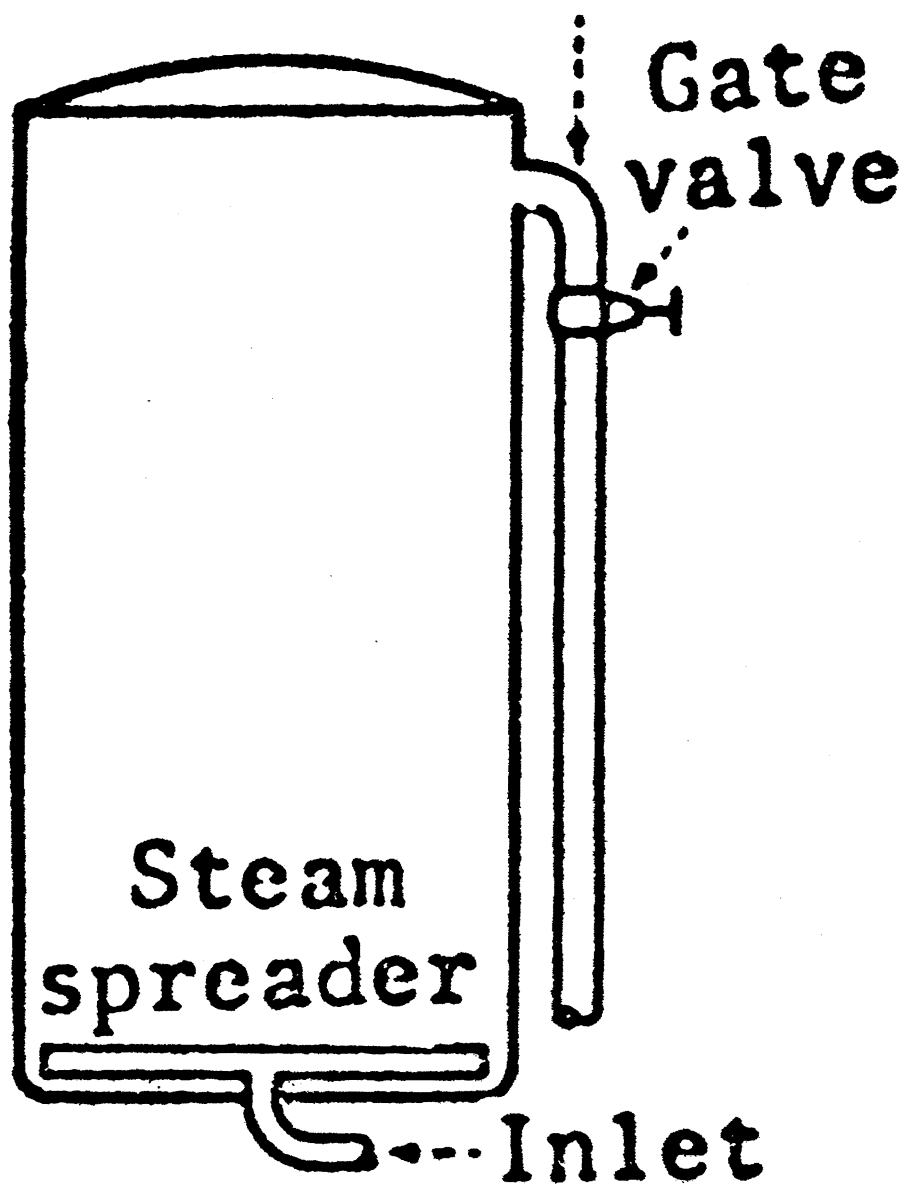


Specifications: A 2.5-inch (6.4 centimeters) vent equipped with a 2.5-inch (6.4 centimeters) gate or plug cock valve and located within 2 feet (61 centimeters) of the center of the retort.

Venting method: Vent gate or plug cock valve should be wide open for at least 4 minutes and to at least 220 °F (104.4 °C).

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

Overflow pipe as vent



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

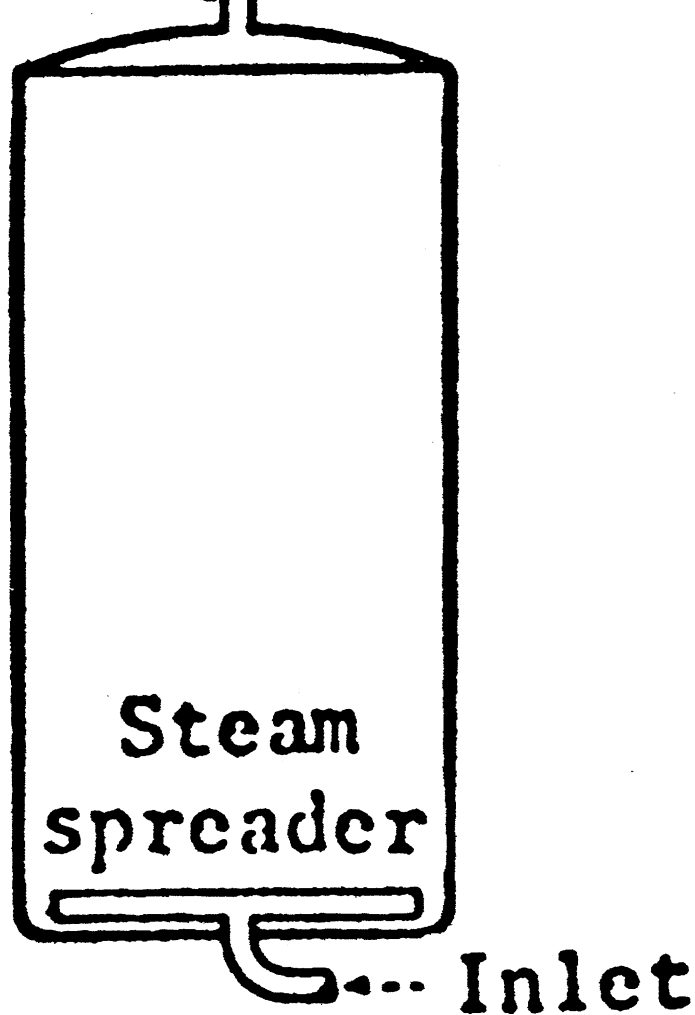
centimeters) pipe beyond the valve before break to the atmosphere or to a manifold header.

Venting method. Vent gate or plug cock valve should be wide open for at

least 4 minutes and to at least 218 °F (103.3 °C), or for at least 5 minutes and to at least 215 °F (101.7 °C).

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

1-in vent... Gate valve



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.

Venting method. Vent gate or plug cock valve should be wide open for at least 5 minutes and to at least 230 °F (110.0 °C), or for at least 7 minutes and to at least 220 °F (104.4 °C).

(iii) **Other procedures.** Other installations and operating procedures that deviate from the above specifications 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. Temperature-indicating devices shall be tested for accuracy against an accurate calibrated 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 reference device 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) Written documentation of the accuracy of the temperature-indicating device and the reference device shall be established and maintained.

(A) Documentation of the accuracy of the temperature-indicating device shall include a reference to the tag, seal, or other means of identity used by the processor to identify the temperature-indicating device, the name of the manufacturer of the temperature-indicating device, the identity of the reference device used for the accuracy test and of equipment and procedures used to adjust or calibrate the temperature-indicating device, the date and results of each accuracy test, the name of the person or facility that performed the accuracy test and adjusted or calibrated the temperature-indicating device, and the date of the next scheduled accuracy test.

(B) Documentation of the accuracy of the reference device shall include a reference to the tag, seal, or other means of identity used by the processor to identify the reference device, the name of the manufacturer of the reference device, the identity of the equipment and procedures used to test the accuracy and to adjust or calibrate the reference device, the identity of the person or facility that performed the accuracy test and adjusted or calibrated the reference device, the date and results of the accuracy test, and the traceability information. Documentation for the reference device may be in the form of a guaranty of accuracy from the manufacturer or a certificate of calibration from a laboratory.

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

(iv) A temperature-indicating device shall be easily readable 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. Sensors of temperature-indicating devices shall be located in such a position that they are beneath the surface of the water throughout the process. On horizontal retorts, this entry should be made in the side at the center, and the temperature-indicating device sensor shall be inserted directly into the retort shell. In both vertical and horizontal retorts, the temperature-indicating device sensor shall extend directly into the water a minimum of at least 2 inches (5.1 centimeters) without a separable well or sleeve. If a separate well or sleeve is used, there must be adequate circulation to ensure accurate temperature

measurements. 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 that records 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 to agree as nearly as possible with, but to be in no event higher than, the temperature-indicating device during the process time. 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 recording-controlling instrument. 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. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air.

(3) *Pressure gages.* (i) Each retort should be equipped with a pressure gage that should be graduated in divisions of 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.

(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) *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.

(10)(i) *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.

(ii) *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-section 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 equipped with a pilot light or other signaling device to warn the operator when it is not running, and with a

bleeder to remove air when starting operations. Alternative methods for circulation of water in the retort may be used when established by a competent authority as adequate for even heat distribution.

(11) *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.

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

(13) *Vertical and horizontal still retorts.* Vertical and horizontal still retorts should follow the arrangements in the diagrams below 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.

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Legend for Vertical and Horizontal Still Retorts

A—Water line.
 B—Steam line.
 C—Temperature control.
 D—Overflow line.
 E₁—Drain line.
 E₂—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.
 Y₁—Crate support.
 Y₂—Crate guides.
 Z—Constant flow orifice valve.
 Z₁—Constant flow orifice valve used during come-up.
 Z₂—Constant flow orifice valve used during cook.

(14) *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. Temperature-indicating devices shall be tested for accuracy against an accurate calibrated 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 reference device 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) Written documentation of the accuracy of the temperature-indicating device and the reference device shall be established and maintained.

(A) Documentation of the accuracy of the temperature-indicating device shall include a reference to the tag, seal, or other means of identity used by the processor to identify the temperature-indicating device, the name of the manufacturer of the temperature-indicating device, the identity of the reference device used for the accuracy test and of equipment and procedures used to adjust or calibrate the temperature-indicating device, the date and results of each accuracy test, the name of the person or facility that performed the accuracy test and adjusted or calibrated the temperature-indicating device, and the date of the next scheduled accuracy test.

(B) Documentation of the accuracy of the reference device shall include a reference to the tag, seal, or other means of identity used by the processor to identify the reference device, the name of the manufacturer of the reference device, the identity of the equipment and procedures used to test the accuracy and to adjust or calibrate the reference device, the identity of the person or facility that performed the accuracy test and adjusted or calibrated the reference device, the date and results of the accuracy test, and the traceability information. Documentation for the reference device may be in the form of a guaranty of accuracy from the manufacturer or a certificate of calibration from a laboratory.

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

(iv) A temperature-indicating device shall be easily readable 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 sensor of the temperature-indicating device 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 3/4-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 that records 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 to agree as nearly as possible with, but to be in no event higher than, the temperature-indicating device during the process time. 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 recording-controlling instrument. 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 opening emitting steam continuously during the processing period. 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, which should be graduated in divisions of 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 recording-controlling instrument 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.

(5) *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. 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 marked on the recording chart 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 marked 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. Temperature-indicating devices shall be tested for accuracy against an accurate calibrated 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 reference device 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) Written documentation of the accuracy of the temperature-indicating device and the reference device shall be established and maintained.

(A) Documentation of the accuracy of the temperature-indicating device shall include a reference to the tag, seal, or other means of identity used by the processor to identify the temperature-indicating device, the name of the manufacturer of the temperature-indicating device, the identity of the reference device used for the accuracy test and of equipment and procedures used to adjust or calibrate the temperature-indicating device, the date and results of each accuracy test, the name of the person or facility that performed the accuracy test and adjusted or calibrated the temperature-indicating device, and the date of the next scheduled accuracy test.

(B) Documentation of the accuracy of the reference device shall include a

reference to the tag, seal, or other means of identity used by the processor to identify the reference device, the name of the manufacturer of the reference device, the identity of the equipment and procedures used to test the accuracy and to adjust or calibrate the reference device, the identity of the person or facility that performed the accuracy test and adjusted or calibrated the reference device, the date and results of the accuracy test, and the traceability information. Documentation for the reference device may be in the form of a guaranty of accuracy from the manufacturer or a certificate of calibration from a laboratory.

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

(iv) A temperature-indicating device shall be easily readable 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 sensor of the temperature-indicating device 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 3/4-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 that records 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 to agree as nearly as possible with, but to be in no event higher than, the temperature-indicating device during the process time. 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 recording-controlling instrument. 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. 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 should be graduated in divisions of 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 recording-controlling instrument 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.

(5) *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. 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 containing 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. Temperature-indicating devices shall be tested for accuracy against an accurate calibrated 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 reference device 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) Written documentation of the accuracy of the temperature-indicating device and the reference device shall be established and maintained.

(A) Documentation of the accuracy of the temperature-indicating device shall include a reference to the tag, seal, or other means of identity used by the processor to identify the temperature-indicating device, the name of the manufacturer of the temperature-indicating device, the identity of the reference device used for the accuracy test and of equipment and procedures used to adjust or calibrate the temperature-indicating device, the date and results of each accuracy test, the name of the person or facility that performed the accuracy test and adjusted or calibrated the temperature-indicating device, and the date of the next scheduled accuracy test.

(B) Documentation of the accuracy of the reference device shall include a reference to the tag, seal, or other means of identity used by the processor to identify the reference device, the name of the manufacturer of the reference device, the identity of the equipment and procedures used to test the accuracy and to adjust or calibrate the reference device, the identity of the person or facility that performed the accuracy test

and adjusted or calibrated the reference device, the date and results of the accuracy test, and the traceability information. Documentation for the reference device may be in the form of a guaranty of accuracy from the manufacturer or a certificate of calibration from a laboratory.

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

(iv) A temperature-indicating device shall be easily readable 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 sensor of the temperature-indicating device shall be installed either within the retort shell or in an external well attached to the retort. Sensors of temperature-indicating devices shall be located in such a position that they are beneath the surface of the water throughout the process. This entry should be made in the side at the center, and the temperature-indicating device sensor shall be inserted directly into the retort shell. The temperature-indicating device sensor shall extend directly into the water a minimum of at least 2 inches (5.1 centimeters) without a separable well or sleeve. If a separate well or sleeve is used, there must be adequate circulation to ensure accurate temperature measurements. 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 that records 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 to agree as nearly as possible with, but to be in no event higher than, the temperature-indicating device during the process time. 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 recording-controlling instrument. The temperature-recording device sensor shall be installed either within the retort shell or in a well attached to the shell. 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 should be graduated in divisions of 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 recording-controlling instrument when combined with a temperature-recording device.

(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)(i) *Air supply and controls.* 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) *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-section 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 equipped with a pilot light or other signaling device to warn the operator when it is not running, and with a bleeder to remove air when starting operations. Alternative methods for circulation of water in the retort may be used when established by a competent authority as adequate for even heat distribution.

(7) *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.

(8) *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.

(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. Temperature-indicating devices shall be tested for accuracy against an accurate calibrated 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 reference device 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) Written documentation of the accuracy of the temperature-indicating device and the reference device shall be established and maintained.

(A) Documentation of the accuracy of the temperature-indicating device shall include a reference to the tag, seal, or other means of identity used by the processor to identify the temperature-indicating device, the name of the manufacturer of the temperature-indicating device, the identity of the reference device used for the accuracy test and of equipment and procedures used to adjust or calibrate the temperature-indicating device, the date and results of each accuracy test, the name of the person or facility that performed the accuracy test and adjusted or calibrated the temperature-indicating device, and the date of the next scheduled accuracy test.

(B) Documentation of the accuracy of the reference device shall include a reference to the tag, seal, or other means of identity used by the processor to identify the reference device, the name of the manufacturer of the reference device, the identity of the equipment and procedures used to test the accuracy and to adjust or calibrate the reference device, the identity of the person or

facility that performed the accuracy test and adjusted or calibrated the reference device, the date and results of the accuracy test, and the traceability information. Documentation for the reference device may be in the form of a guaranty of accuracy from the manufacturer or a certificate of calibration from a laboratory.

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

(iv) A temperature-indicating device shall be easily readable 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 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 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 that records 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 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 to agree as nearly as possible with, but to be in no event higher than, the temperature-indicating device during the process time. 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 recording-controlling instrument. 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 which emits steam continuously during the processing period. Additional temperature-recording device sensors shall be installed in the hydrostatic water legs if the scheduled process specifies maintenance of particular temperatures in the hydrostatic water legs. 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 should be graduated in divisions of 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 recording-controlling instrument 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.

(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 1/4-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. Temperature-indicating devices shall be tested for

accuracy against an accurate calibrated 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 reference device 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) Written documentation of the accuracy of the temperature-indicating device and the reference device shall be established and maintained.

(i) Documentation of the accuracy of the temperature-indicating device shall include a reference to the tag, seal, or other means of identity used by the processor to identify the temperature-indicating device, the name of the manufacturer of the temperature-indicating device, the identity of the reference device used for the accuracy test and of equipment and procedures used to adjust or calibrate the temperature-indicating device, the date and results of each accuracy test, the name of the person or facility that performed the accuracy test and adjusted or calibrated the temperature-indicating device, and the date of the next scheduled accuracy test.

(ii) Documentation of the accuracy of the reference device shall include a reference to the tag, seal, or other means of identity used by the processor to identify the reference device, the name of the manufacturer of the reference device, the identity of the equipment and procedures used to test the accuracy and to adjust or calibrate the reference device, the identity of the person or facility that performed the accuracy test and adjusted or calibrated the reference device, the date and results of the accuracy test, and the traceability information. Documentation for the reference device may be in the form of a guaranty of accuracy from the manufacturer or a certificate of calibration from a laboratory.

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

(4) A temperature-indicating device shall be easily readable 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 that records temperatures to a permanent record, such as a temperature-recording chart. A temperature-recording device 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 to agree as nearly as possible with, but to be in no event higher than, the temperature-indicating device during the process time. 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, there shall be an accurate differential pressure recorder-controller installed on the regenerator. The scale divisions shall not exceed 2 pounds per square inch (13.8 kilopascals) on the working scale of not more than 20 pounds per square inch per inch of scale (55 kilopascals per centimeter). The controller shall be tested for accuracy against a known accurate standard pressure indicator upon installation and at least once every 3 months of operation thereafter, or more frequently if necessary, to ensure its accuracy. 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.

(F) *Flow control.* A flow controlling 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 1/4-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 and shall be reprocessed or destroyed. 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 metering pump 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 instrumented 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 and 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, 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 at 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. 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. 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, 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 (c) and (e) to read as follows:

§ 113.87 Operations in the thermal processing room.

* * * * *

(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 an accurate calibrated reference device at sufficient frequency to ensure that initial temperature measurements are accurate. Records of the accuracy tests shall be signed or initialed, dated, and maintained.

* * * * *

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

* * * * *

6. Amend § 113.100 by revising paragraphs (a) introductory text, (a)(4), (b), and (c) and by adding paragraphs (f) and (g) to 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 written 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) Written 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.

* * * * *

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

(g) All records required under this part, or copies of such records, must be readily available during the retention period for inspection and copying by FDA when requested. If reduction techniques, such as microfilming, are used, a suitable reader and photocopying equipment must be made readily available to FDA.

Dated: March 4, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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