Temperature Indicating Devices for 21 CFR 113

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Background

Dairy Industry: PMO (1987 NCIMS Conference)

Appendix H.IV. - "Provided that types other than mercury actuated may be used when they have been: (1) recognized by the Food and Drug Administration to be equally fail-safe, accurate, reliable and meet the scale and thermometric response specifications and (2) which are approved by the regulatory agency."

Dairy Industry

- 1991 NCFST conducted a collaborative (FDA, Kraft, and Anderson Instruments Co.) study of an alternative temperature-indicating device
- In 1993 the Milk Safety Branch of FDA issued a memorandum (M-I-93-1) to regional milk specialists stipulating the criteria for acceptance of ATD's

NCFST Research

- 1993 NCFST initiated a research project on using ATD's for low-acid canned food applications
- Collaborators included: Dean Foods Vegetable Co., Dean Foods Co., Gerber Products Co., Anderson Instruments Co., Taylor Environmental Inst., Hunt-Wesson/Quaker Oats, Quaker Oats Co., and Mead Johnson

NCFST Research (cont'd)

- 1994-1997 - conducted survey of industrial MIG calibration practices – 16.8% needed at least 1ºF adjustment
- 1997 IFT presentations outlining draft protocol for implementation of an ATD for retort systems
- Developed draft drift, environmental, and EMC testing protocols. Also developed draft design criteria

FDA Actions

- FDA had numerous internal discussions on how to address requests from industry to allow for ATD's
- 2000- Started the process to revise the regulation
- 2004 – NFPA "petitioned" FDA to amend 21 CFR 113 to allow for ATD's
- March 14, 2007 – published proposed rule for changes to 21 CFR 113

Current 21 CFR 113

- **RETORTS** - 21 CFR 113.40(a)(1) *"Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer …"
- **ASEPTIC** - 21CFR113.40(g)1(i)(a) – "… or an equivalent temperature-indicating device, such as a thermocouple-recorder."

Changes

Intent

- Permit alternative temperature-indicating devices in place of the Mercury-In-Glass (MIG) thermometer
- Clarification of portions of part 113
- Added documentation requirement for reference calibration device

MIG - 21 CFR 113.40(a)(1)

- Each retort equipped with an accurate indicating device of the processing temperature
  - Tested for accuracy against “accurate calibrated reference device”
  - Tested at least yearly or more if necessary
- Designed to ensure accuracy not affected by environmental conditions and electromagnetic interference

MIG - 21 CFR 113.40(a)(1)

- Documentation of accuracy of indicating device and the reference device
- ATD's - documentation
  - Identity of device
  - Name of manufacturer of device
  - Identity of reference device, equipment used for, and procedures for calibration
  - Date and results of test
  - Name of person/facility conducting the test
  - Date of next scheduled test

MIG - 21 CFR 113.40(a)(1)

- Reference Device - documentation
  - Identity of device
  - Name of manufacturer of device
  - Identity of equipment used and procedures for calibration
  - Date and results of test
  - Name of person/facility conducting the test
  - *Traceability information*

Temperature-Indicating Device

- Accurate and easily read
- Location
  - (a)(c)(d)(f)(g) – no change
  - (b)(e) – may be in well or sleeve if adequate circulation is present, and made to agree with each other (under water, etc.)
- “Sensor” and not a “bulb”

Recorder - 21 CFR 113.40(a)(2)

- *Temperature-recorder controller*. "Each still retort shall have an accurate temperature-recording device."
- When is a chart not a chart? – When it is a Device

Temperature-recording "Device"

- Permanent record may be a chart or digital recording
- Analog, graphical or digital recording can be made
- Multipoint/digital records measured at intervals needed to record temperature
- (g) – for aseptic systems at positions that are critical to the process (i.e., particles)

Temperature Controller

- Water systems (b) sensor located to ensure accurate measurement of process temperature and not affected by heating media
- Removed end-of-heater location requirement from aseptic systems (g)

Vents – 21 CFR 113.40(a)(12)

- Specification listed in (a)(12) does not apply to systems that use divider plates – “without divider plates”

Screens – 21 CFR 113.40(b)(8)-(10)

- Drain valve “shall” have a screen (b)(8)
- Suction outlets “shall” be protected with nonclogging screens (b)(10)(ii)
- (e) was made to agree with (b) for water circulation, drain valve, and water level indicators

Flow Control – 113.40(g)(1)(i)(f)

- "metering pump" replaced with the words "flow controlling device"

Containers – 21 CFR 113.60

- Postprocess handling – “container handling equipment shall be designed, constructed, and operated to preserve the can seam or other container closure”, and check for proper operation

Scheduled Process – 113.83

- Scheduled process for a reprocessed product or blended reprocessed product must be properly designed

Processing Room – 113.87

- Accurate initial temperature of product
  - Calibrated sensor
  - Calibration against an accurate calibrated reference device
  - Calibrated at sufficient frequency to ensure accuracy
  - Maintain, dated, and signed records of calibration

Records – 21 CFR 113.100

- Signed and dated by reviewer
- Computerized records need to be in compliance with 21 CFR 11
- Records must be readily available during the retention period for inspection and copying by FDA

Implementation

When to Implement

- Proposed rule allows for immediate implementation
- FDA will use a case-by-case approach to enforcement
- Intended to provide manufacturer with time to transition to ATD's