

# Temperature Indicating Devices for 21 CFR 113

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# Background



# Dairy Industry:

## PMO (1987 NCIMS Conference)

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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

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- ❑ 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

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- 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)

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- ❑ 1994-1997 - conducted survey of industrial MIG calibration practices – 16.8% needed at least 1°F 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

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- ❑ 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
- ❑ March 14, 2007 – published proposed rule for changes to 21 CFR 113



# Current 21 CFR 113

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- ❑ **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

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- Permit alternative temperature-indicating devices in place of the Mercury-In-Glass (MIG) thermometer
- Clarification of portions of part 113



# MIG - 21 CFR 113.40(a)(1)

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- 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)

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- ❑ 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)

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- 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

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- 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)

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- ❑ *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”

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- ❑ 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

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- ❑ 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)

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- 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)

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- ❑ 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)

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- “metering pump” replaced with the words “flow controlling device”



# Containers – 21 CFR 113.60

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- 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

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



# Processing Room – 113.87

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- 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

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- ❑ 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

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# When to Implement

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- 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

