Regulatory Perspective on Heat Transfer Distribution in Retorts

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FDA

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Topics

- Steam and air
- Temperature distribution
- Heat transfer distribution
- The term ‘heat distribution’ in 21 CFR 113
- Testing considerations
- What does it mean for the processor?
- Problems with TDs & HDs

Steam

- Condensation of Saturated Steam provides an unlimited source of heat, relative to the rate at which a container of food can absorb the heat
- For all other Heating Media, heat transfer into packages may be limited. Based on several design and operating factors, the Heating Media may not always provide excess heat, relative to the product's ability to absorb heat

(Purohit, 2010)

Air Entrapment

"Very small quantities of air result in dramatic decreases in heat transfer rates from steam."

(Tung, Britt and Ramaswamy, 1990)

Heat Transfer Coefficients

Heating Medium	W/m^2-K
Air, free convection	6 – 30
Superheated steam or air, forced convection	30 – 300
Water, forced convection	300 – 6,000
Water, boiling	3,000 – 60,000
Steam, condensing	6,000 – 120,000

Temperature vs. Heat Transfer

- Rightly or wrongly, the terms ‘heat distribution’ and ‘temperature distribution’ have been used interchangeably (e.g., Somers, 1944; NCA, 1968)

Temperature Distribution

"Temperature distribution is, then, the *uniformity* of sterilizer temperatures and the *stability* of sterilizer temperatures at any given time during the *entire* process cycle including the come-up, holding, and cooling phases."

(Park, Cabes and Collins, 1990)

Temperature Distribution

"Temperature distribution is influenced greatly by retort design and operating procedures, and is therefore specific to the system under study. The retort size and shape, plumbing details, design and loading of the racking system, the method of achieving medium homogeniety, and other factors could influence the temperature distribution achieved."

(Tung, Britt and Ramaswamy, 1990)

Temperature Distribution Testing

"A uniform temperature distribution throughout the retort does not necessarily imply that heat transfer to the containers is also uniform. This relates to the poor heat transfer properties of air compared with steam or water."

uniform temp ≠ uniform lethality

(Tucker and Featherstone, 2011)

Heat Transfer Distribution

"However, uniformity in temperature is the minimum that should be studied and an additional heat distribution study is advisable if there are concerns about air entrapment..."

(Campden BRI, 1997b as cited in Tucker and Featherstone, 2011)

Heat Transfer Distribution

"Heat distribution studies are performed to ensure adequate lethality at any point, especially to identify the position of lowest lethality."

(Smout et al., 1998)

Scheduled Process

"…the process selected by the processor as adequate under the conditions of manufacture for a given product to achieve commercial sterility."

"…shall be at least equivalent to the process established by a competent processing authority…"

21 CFR 113.3(r)

Establishing Scheduled Processes

- by persons having expert knowledge of thermal processing… and …adequate facilities for making such determinations
- incorporate variations encountered in commercial production
- records covering all aspects of the establishment of the process

21 CFR 113.83

Heat distribution

- The term heat distribution appears 14 times in 21 CFR 113.40
  - Bleeders
  - Steam introduction
  - Water circulation
  - Air supply and controls
  - Venting and condensate removal
  - Mufflers on bleeders or vent systems
  - Other installations or operating procedures

Bleeders

- ≥1/8-inch and wide open during the entire process, including the come-up time.
- May be installed at other positions 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.

21 CFR 113.40(a)(8) & d(5)

Steam Quality

"By 'pure' steam is meant steam containing only an infinitesimal amount of air. It is realized that, except by chance, absolutely air-free steam is never obtained even in a perfectly bled retort."

(Ball and Olson, 1957)

Steam introduction

- Steam shall be distributed in the bottom of the retort in a manner adequate to provide uniform heat distribution throughout the retort.

21 CFR 113.40(b)(5)

Air supply and controls

- 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.

21 CFR 113.40(b)(9)

Water circulation

- When a water circulating system is used for heat distribution, it shall be installed [in a specific manner].
- Alternative methods for circulation of water in the retort may be used when established by a competent authority as adequate for even heat distribution.

21 CFR 113.40(b)(11) & (e)(7)

Venting and condensate removal

- 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.

21 CFR 113.40(c)(6) & (d)(6)

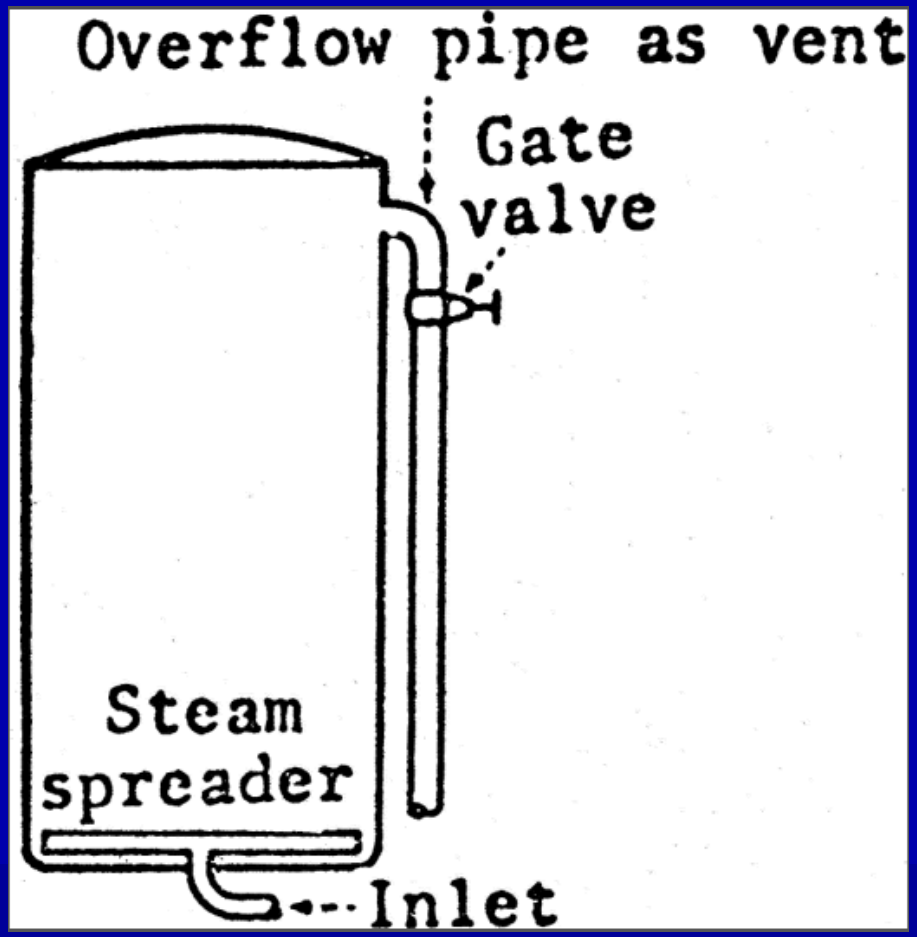
Mufflers on bleeders and vents

- If mufflers are used on bleeders or vent systems, evidence that the bleeders or vents are operated in a manner that does not significantly impede the removal of air shall be kept on file. This evidence may be in the form of heat distribution data.

21 CFR 113.87 (g)

Retort Specifications

Example: Venting vertical still steam retorts, through overflow pipe



21 CFR 113.40(a)(12)(ii)(a)

Retort Specifications

Example: Venting vertical still steam retorts, through overflow pipe

- Specifications:
  - 1½-inch overflow pipe equipped with a 1½-inch gate or plug cock valve
  - not more than 6 feet of 1½-inch pipe beyond the valve before break to atmosphere or to a manifold header

21 CFR 113.40(a)(12)(ii)(a)

Retort Specifications

Example continued

- Venting method:
  - Vent gate or plug cock valve should be wide open for at least 4 minutes and to at least 218 °F, or for at least 5 minutes and to at least 215 °F.

21 CFR 113.409(a)(12)(ii)(a)

Other installations

"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."

21 CFR 113.409(a)(12)(iii)

Additional insights

- “Other installations and operating procedures may be satisfactory. However, these should be evaluated prior to use to establish specifications for adequate air removal.”

(NFPA Bulletin 26-L, 1982)

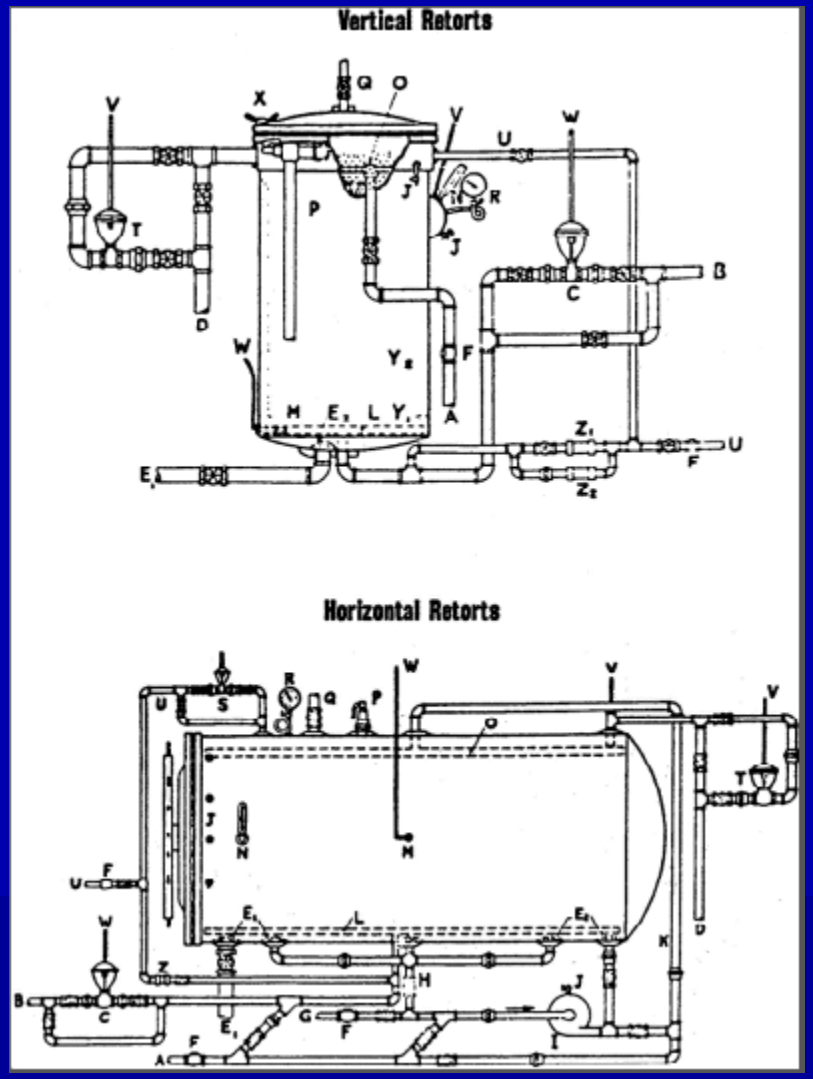
Additional insights

- “THESE VENTING SCHEDULES ARE NOT TO BE USED WHERE DIVIDER PLATES ARE EMPLOYED BETWEEN CONTAINER LAYERS, UNLESS PROVEN EFFECTIVE.”

(NFPA Bulletin 26-L, 1982)

Retort Specifications

Example:
Pressure processing in water in still retorts



21 CFR 113.409(a)(12)(ii)(a)

Vertical and horizontal retorts Other installations

- Should follow the arrangements in the diagrams in this paragraph.
- Other installations and operating procedures that deviate from these arrangements may be used, as long as there is evidence in the form of heat distribution data, which shall be kept on file, which demonstrates that the heat distribution is adequate.

21 CFR 113.40(b)(14)

Why test?

- TD: To establish reproducible and reliable heating and cooling performance of the retort system
  - Temperature distribution may vary with individual installations of identical equipment
- HD: To demonstrate uniformity of the heat transfer medium within the retort

When to test?

- New retort design
- New installation
- Maintenance changes –Change Control
- Retort modifications
- Changes to baskets/crates, divider plates, package size/arrangement
- Deviation analysis
  - e.g., blocked nozzles for water spray retort

Before you test…

- Make a record of the current state of the system
  - Verify instrumentation is calibrated
  - Plant utilities capabilities
  - Conduct a retort survey
  - Conduct a product survey

The role of the TID

"The 'official reference instrument' against which all other sterilizer temperature control devices are adjusted is the [TID]. All thermocouple lead readings must also be compared to the [TID] readings."

(Park, Cabes and Collins, 1990)

Heat Input Unit (HIU) for HD

- Consistent response (across all test units)
- Repeatable response (repeated tests)
- Definitive thermo-physical properties
- Appropriate geometry
- Appropriate characteristics for heating profile
  - (e.g. concentration of bentonite solution)

Records are critical!

- Thermocouple locations
- Retort settings (e.g. RPM, if agitated)
- Retort operation actions (e.g. time & temp vent closed)

TD and HD Reports

- The need to develop TD and HD data *may not* necessitate its submission along with process filings.
  - Temperature distribution data must be submitted for cascading-water retorts to establish minimum CUT
  - Heat distribution data must be submitted for steam/air retorts to demonstrate the ability of the retort process to uniformly mix and distribute the heating medium.

What do I do with data that I used to establish retort procedures?

- **Do not submit with process filing**.
- Keep it on file at the plant.

Problems with TDs

- Locations of thermocouples (TC) not mapped
- Not enough TCs
- Not all TCs at process temp at end of CUT
- *Only* average temperatures reported
- Translation of ‘worst case’ pouch size
  - Not clear whether big or small pouch is worst case
  - Which occupies most area on tray and volume in retort?
- Assumption that plastic trays follow response for rigid containers

Problems with HDs

- Highly variable f_h
- Highly variable F_o
- No f_h
- *Only* F_o -values reported
- Inappropriate HIU used
  - e.g. food for which the heat transfer rate changed during process

Questions?