

Use of ATID's in Aseptic Processing

And the Effect of the Proposed Rule Revisions

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Outline

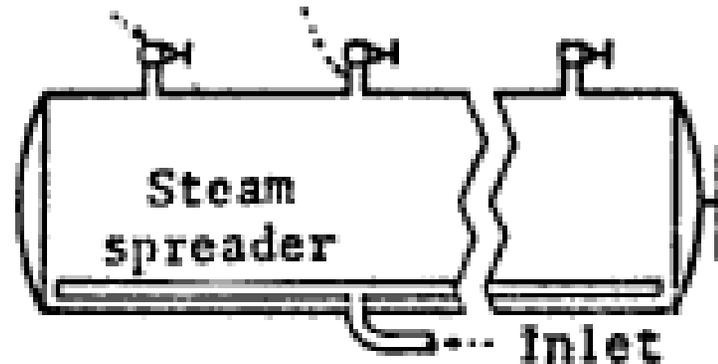
- **Brief Review of current and proposed rules**
- **TID Configurations & Considerations**
- **TID Calibration**
- **Other aspects of the proposed rule**

Industry Well Served by Current Rule

- Great results with industrial production
- HACCP Style Program
- Set a standard for the world
 - CoDex Alimentarius CAC/RAP 23 – 1979, Rev. 2 (1993)
 - Chinese Export Regulation

Vent Schedule from Part 113

1-in. gate valve 1-in. vent



Specifications. One 1-inch vent for every 5 feet of retort length, equipped with a gate or plug cock valve and discharging to atmosphere; end vents not more than $2\frac{1}{2}$ feet from ends of retort.

Venting method. Vent valves should be wide open for at least 5 minutes and to at least 225°F , or at least 7 minutes and to at least 230°F .

Vent Schedule from Chinese Export Regulation

B. 10.1 方法一 卧式杀菌锅通过 25.4 mm(1 英寸)组合式排气孔排气

每 1.52 m(5 英尺)锅长装 25.4 mm(1 英寸)排气孔 1 个,每个排气孔装 25.4 mm(1 英寸)闸阀一只,直通大气。靠近锅端的排气孔与锅体两端距离不超过 0.76 m(2.5 或 $2\frac{1}{2}$ 英尺)。

方法:排气阀全开,时间至少 5 min,温度至少达到 107.2℃,或时间至少 7 min,温度至少达到 104.4℃。示意图见图 B.1。

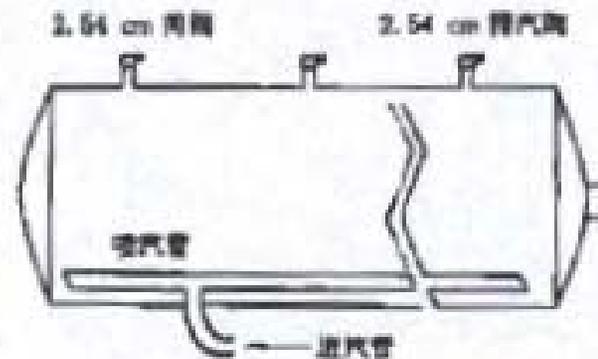


图 B.1

Mercury-In-Glass Thermometer Exception for Aseptic Processing and USDA

- Alternate temperature-indicating devices (ATID's) were recommended in comments on the 1973 rule
- MIG requirement retained for retorts
- Specific exemption for aseptic processing systems
- Not required for USDA

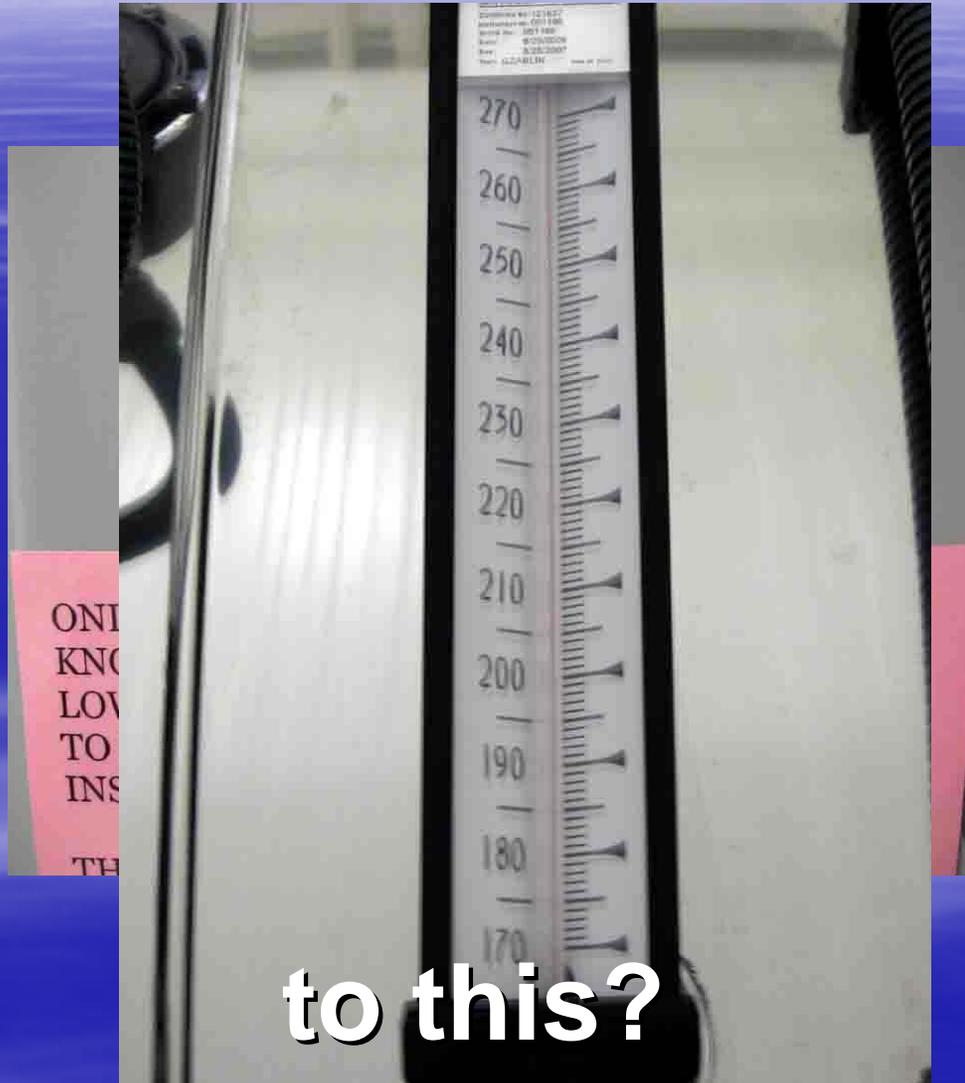
Preamble to the 1973 Final Rule

“The Commissioner ... 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).”

Preamble to the Proposed Rule Amendment

“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.”

Trouble Moving from this ...



Regulation Proposal

113.4 (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.**

Typical TID's

Resistance Temperature Detectors (RTD's)

- Mature Technology

- Very stable – repeatable performance

- High degree of interchangeability

- Very well suited for retort and aseptic processing systems

Used as part of the controller and chart recorder in aseptic and retort applications

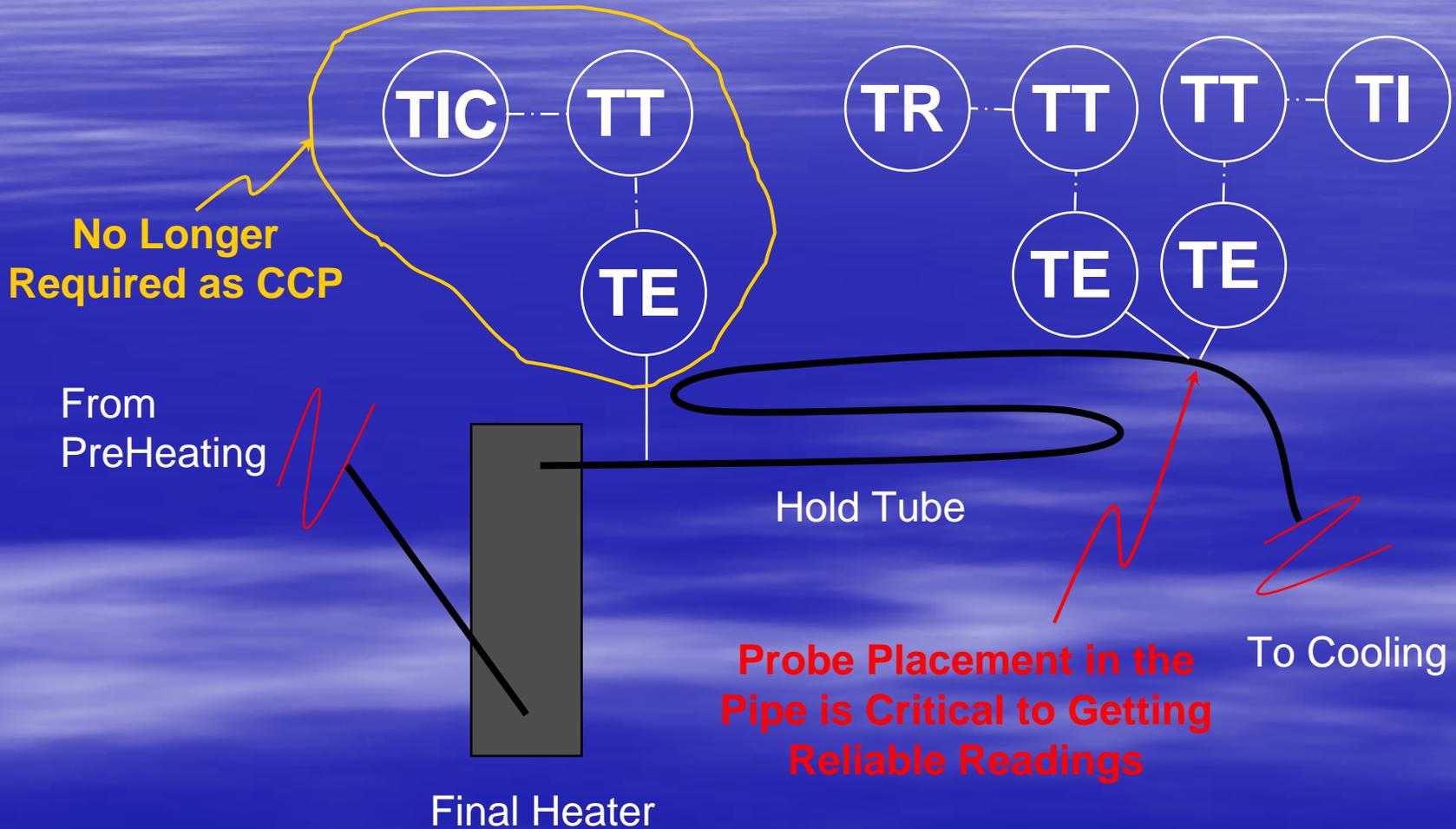
Advantages to Electronic Temperature Indicating Device

- Can be continuously monitored/recorded
- Can be Self Checking
- Location of the indicator can be *much* more convenient
- Can use standard equipment for ease of maintenance

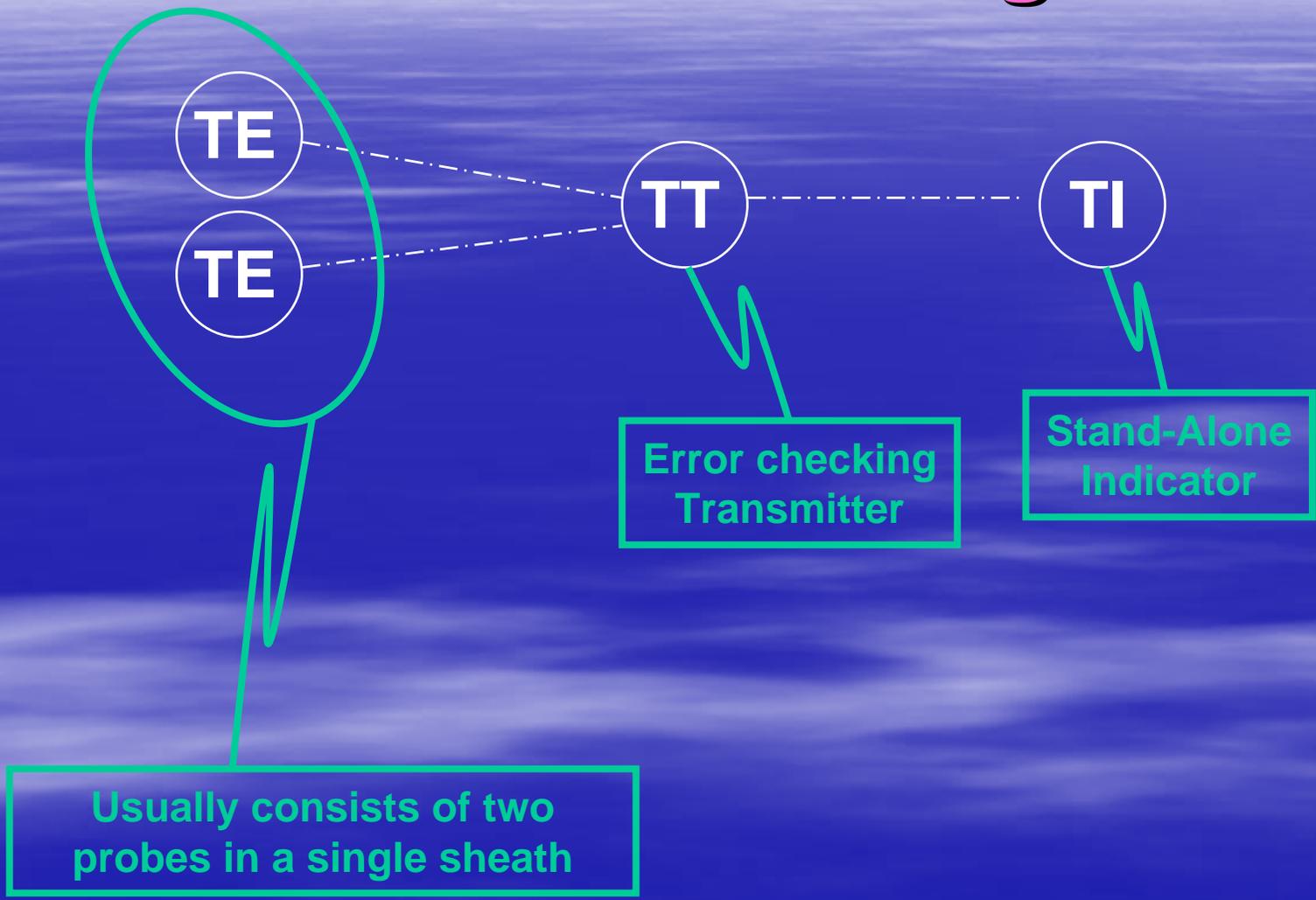
Typical TID Components

- Temperature Element (TE)
 - 100 Ohm RTD
 - 1000 Ohm RTD
- Temperature Transmitter (TT)
 - Convert resistance to analog (e.g. 4-20 ma)
- Analog-to-Digital (A/D) Converter
- Digital Display (TI)

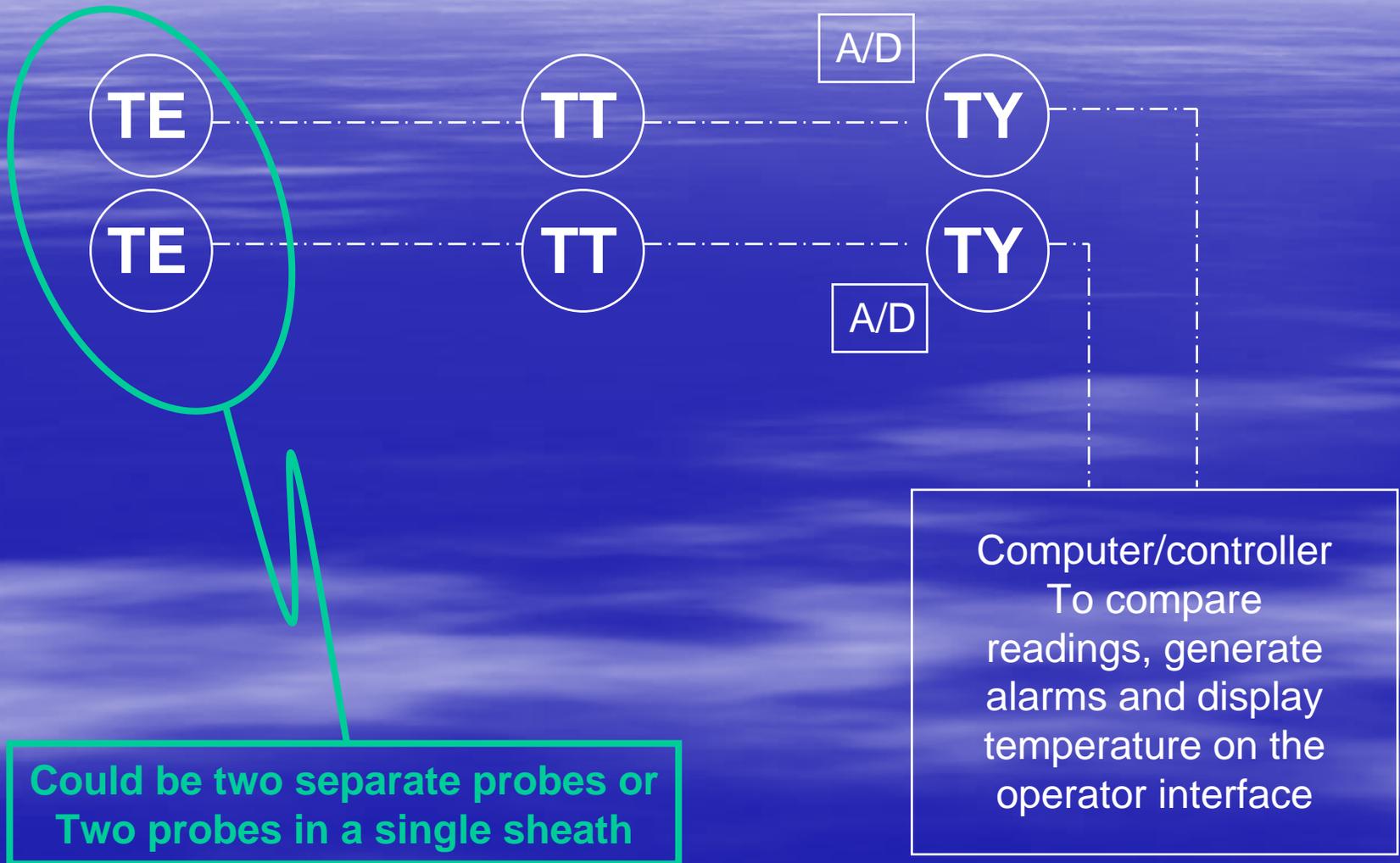
TID Placement



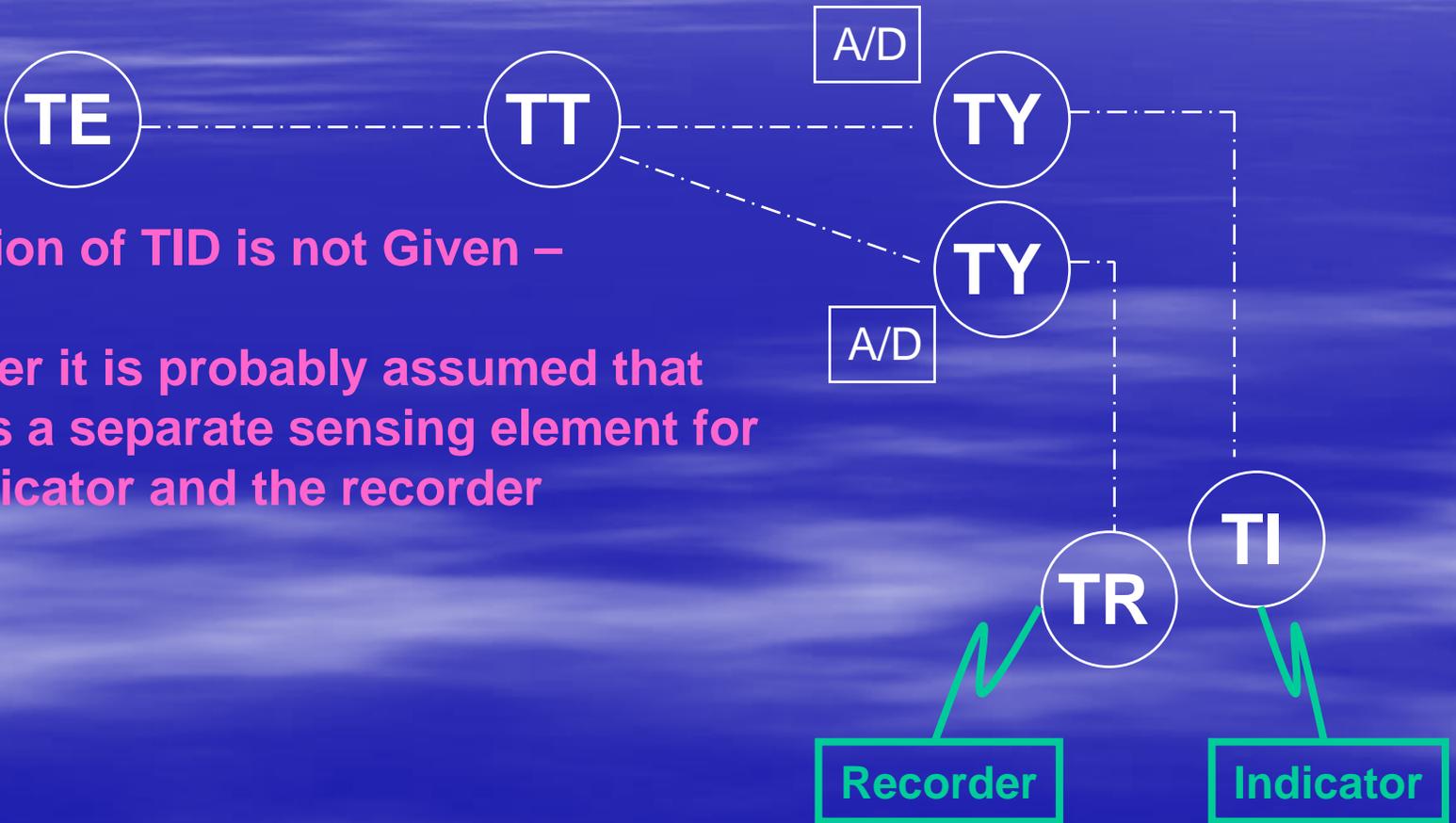
Possible TID Configurations



Possible TID Configurations



Is This a Possible TID Configuration?

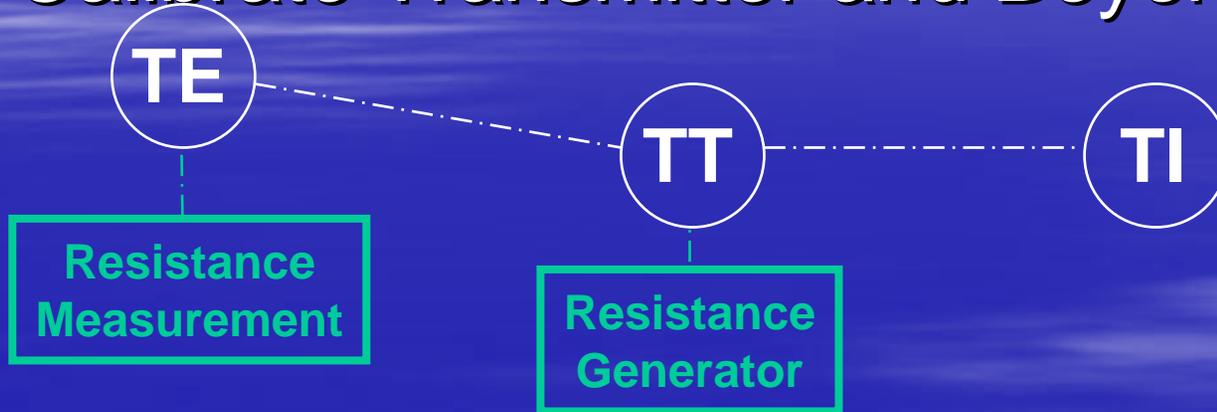


Definition of TID is not Given –

However it is probably assumed that there is a separate sensing element for the indicator and the recorder

Calibration Technique

- Calibrate Transmitter and Beyond



- Calibrate Complete System



TID Experiences/Considerations

- **RTD systems are very reliable**
 - Temperature elements are very repeatable
 - Component failures are rare
 - Failure mode can be set for 'Failsafe'
 - Indicators and Recorders fail low
 - Controllers fail high
 - Drift on transmitters is very small
- **Calibration Frequency**
 - Once per year required
 - Usually have more frequent 'verification' checks
- **Redundant systems generally not an issue**
 - Similar components and probe placements
- **Calibration Technique**
 - Ensure stable calibration device
 - Ensure good thermal contact between device and probe

TID Requirements

“(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.”

This statement is nebulous, unenforceable and does not achieve the desired end result.

TID Requirements

What Processors need to do –

Design and install the temperature-indicating device in a manner that produces reliable and accurate readings under the operating environmental conditions.

Installation Considerations

- Appropriate wire size
- Minimize termination points
- Proper grounding
- Isolate signal and power wires

Detection of Failure

“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.”

Detection of Failure – TID Dual Probe design

- Suggested in preamble but not required
- Also suggested in FPA Guidance
- Often used in design of self-checking systems
- Easily configured with normal components

TID Documentation

“(2) Written documentation of the accuracy of the temperature-indicating device and the reference device shall be established and maintained.”

- Why “Written”? –
- Written should be eliminated to remove a technology inhibitor.

TID Accuracy Test Documentation

1. Name of the TID (usually a tag number),
2. Name of the TID manufacturer,
3. Identity of the reference device,
4. Have a documented procedure,
5. The date and results of each accuracy test,
6. Name of the person or facility that performed the test, and
7. The date of the next scheduled accuracy test

TID Accuracy Test Documentation

- Proposed requirements are typical for calibration records except;

7. “The date of the next scheduled accuracy test”

- #7 is part of the calibration plan, not part of routine records

Other Aspects of the Proposed Revisions

- Other TID Recording Means
- dP Recording

This is Good

“(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.”

This is Not so good

- No change to the verbiage for differential pressure recording
- Reads like a pasteurizer application (very antiquated)
- Calibration frequency is 3 months versus 1 year for TID
- Should be updated with common language and calibration timeframes

Summary

- **ATID's have been very successfully used in aseptic systems**
 - Systems have proven to be very reliable
 - Readings can be made more reliably and accurately
 - Maintenance and calibration is simpler due to commonality of components used in other parts of the system
- **ATID's for FDA filed retorts long overdue and very welcome**
- **Industry will fast adapt and end up with more accurate and reliable systems as has been proven in aseptic systems**