Food Safety Division
Food Safety Science Directorate
Science Branch

Technical Guidance Document for Resistance Temperature Detectors (RTDs) used as Indicating Thermometers for Retort Vessels and HTST Pasteurizers

Background:

Traditionally, Mercury-In-Glass (MIG) thermometers have been the only internationally recognized devices permitted for use as temperature indicating thermometers for food thermal processing systems.

The USFDA has made a rule change to CFR Title 21 -Part 113 to permit the use of other "Temperature Indicating Devices" in place of Mercury- In -Glass (MIG) temperature indicating devices for food thermal processing systems.

The CFIA has received a number of requests from the food industry for permission to replace MIG indicating thermometers with Resistance Temperature Detectors (RTDs) on food thermal processing systems. In response, CFIA formed a working group to develop a technical guidance document for the use of RTDs as indicating thermometers in food thermal processing systems. The CFIA Program and Policy Branch as well as Operation Branch contributed to the development of this policy. It has also been subject to some industry consultations.

Rationale:

The acceptance of RTDs as indicating thermometers on food thermal processing systems will allow Canadian producers to use progressive technology in monitoring their thermal food processes. RTDs and their displays have faster response times, are easier to read, are more precise and have higher frequency of recording intervals and are more sensitive to temperature changes.
Furthermore, should companies choose to replace MIGs with RTDs, this will address potential environmental and food safety concerns with respect to mercury and glass contamination due to breakage of MIGs in a food environment.

Scope:

This Technical Guidance Document is intended for those operators wishing to replace an MIG indicating thermometer with an RTD.

The intent of this document is to provide companies with requirements that must be met in order to ensure that replacement of MIG indicating thermometers with RTDs, does not in any way compromise the functioning of the thermal processing equipment in achieving the intended food safety outcome, eg. commercial sterility.

Minimum Requirements:

1. The indicating RTD thermometer is to be the official instrument for all temperature readings, including vent temperatures, come-up temperatures and process temperature during the processing of LACF(s). It shall not be used to directly control the retort or thermal processing operation.

   Here in the U. S., the FDA will not allow an output off of the reference thermometer. However, we offer a dual RTD probe option where the FDA will allow the secondary RTD to be used to send a signal to the recorder or controller. The Wahl DST610 and DST620 series uses a dual RTD sensor probe where one RTD goes to the display and that system is powered by an onboard battery. That is the reference thermometer. The second RTD goes to a terminal block, inside the meter head, for direct RTD output (DST610 series) or to a programmable 4-20mA transmitter for output (DST620 series). In either of those two series, the second RTD, in both series, and the transmitter is powered from the external control loop power. There is no common circuitry within the unit between the reference thermometer and the output circuitry.

2. The indicating RTD shall be calibrated to an official recognized standard reference thermometer*or equivalent upon installation and at least once a year thereafter or more frequently if necessary, to ensure accuracy during processing.

   * (e.g. National Research Council Canada (NRCC), National Institute of Standards and Technology (NIST), Germany Industrial Standards Organisation (DIN), American Society for Testing and Materials (ASTM) Standards)

   We can supply a NIST certified meter and probe package, used by many of the large food processing companies, here in the U. S. as well as some offshore facilities, as their internal NIST traceable reference thermometer. That is our handheld TM612 RTD meter with one of several available RTD probes (customer choice). Since every probe is slightly different, we can plot the curve of the chosen probe into the thermometer memory and get system accuracies of 0.02 to 0.03C which can be used to calibrate other temperature devices.

The RTD shall be protected against unauthorized changes by the use of seals, tags, electronic prevention or other adequate means.

No change can be made to the calibration of the unit without a calibration software kit.

3. The RTD shall be accurate to 0.5°C (1.0°F).

A RTD is the sensor portion of a system which includes a meter to read that sensor and any circuitry between the two. The Wahl DST600 series thermometer system, meter and RTD together, has a stated accuracy of 0.17°C (0.3°F). However, we allow no more that a maximum error of 75% of that number (0.13°C or 0.23°F) to pass inspection. A more important issue is the ambient temperature coefficient of the electronics that read the RTD. All electronic devices operate best within a specific ambient temperature range. Going below or above that band affects performance. The ideal ambient band for the DST600 series is 18° to 28°C. With the electronics mounted in places like on a hot retort, operating above or below that band could affect accuracy as much as 0.003°C per degree outside of that band. This is better than three times less error than other units on the market. We use Class A 4-wire Pt100 RTDs, the best. Others use Class B 2- or 3-wire sensors.

4. The RTD must have an easily readable display, in units of temperature degrees in graduation at least 0.2°C.

The DST600 series are all °F or °C switchable. Standard display reads in 0.1° resolution with the ability to add an optional 1.0° resolution switch, if needed. Some U. S. food processors, used to reading a MIG to 1°F and rounding down, insist on being able to do the same with the TID. We offer that as an option as that is the only way they will buy from us. The FDA is not happy about it, but so far have not done anything about it. The food processors can switch back to 0.1° resolution for calibration purposes. The DST600 display update rate is 2 second intervals as shipped. It can be set from ¼ second to 10 second update rates in ¼ second intervals. This can be changed in the field using our software kit. Update rates affect battery life. At the 2 second interval, battery life is about 2-1/2 years. At a 1 second interval, battery life is 16 to 18 months.

6. The RTD must possess self-diagnostic circuitry which provides constant monitoring of all sensing, input and conditioning circuits. The diagnostic circuitry should be capable of detecting open/short circuits, poor connections, and faulty components. Upon detection of a failure of any component, the device system must be capable of providing a warning to the operator of the thermal processing equipment. It is recommended that the self-diagnostic circuitry be able to detect if the RTD is out of calibration, through for instance the inclusion of a dual probe sensor. However, RTD's that lack this capability can be used provided that the indicating thermometer is compared frequently to a second thermometer (RTD or MIG) on the thermal processing equipment to ensure they are reading virtually the same (although the recording thermometer should not read higher than the indicating thermometer). When a significant difference is observed this may mean that the indicating RTD is out of calibration and appropriate corrective actions must be taken.

In 2007, the FDA wrote an interim protocol, outlining a "wish list" of desires and sent it out for comments. One of their desires was they wanted the electronic thermometer to alert the operator if the unit had any kind of issue. The Wahl DST600 will show CBL1 through CBL4 if 1, 2, 3, or 4 of the leads fail or the sensor itself fails. If there is a long term drift, that should be picked up during normal calibration checks. Changes of 5, 10, or 20 degrees usually indicate water is getting into the probe and will show a great difference from the recorder or controller sensor. Since the greatest possibility of unnoticed drift in these thermometers is the head electronics, we have built a series of fixed reference resistors in the head that the microprocessor cycles through about every 8 seconds to check for drift in the electronics. If head inaccuracy exceeds 0.5°F (0.3°C), ERR will appear on the display. If battery voltage gets low, a low battery indicator will appear. If the battery is not changed quickly and voltage gets low enough to cause an error, the microprocessor will show only ----- on the display. Another desire of the FDA was that no RTD of unknown accuracy be able to be attached to the meter head for use as a reference thermometer. For that reason, the DST600 series has a security chip in the probe. Without the code of that chip being programmed into the meter, the meter will not read it and will only show PRB. If a probe needs to be changed, the new probe security code can be programmed into the meter using the calibration software kit. In any of the above events, the thermometer has to be changed out.

7. It must be ensured that that the accuracy of the device is not affected by electromagnetic interference (eg. from hand-held communication devices) or

environmental conditions (eg temperature, humidity, moisture) within the processing plant. The effects of electrostatic discharge, power fluctuation, conductive emission and susceptibility, and radioactive emission and susceptibility must be tested and accounted for. The device must comply with the requirements for performance level characteristics of industrial devices. Proof of all of the above shall be documented and available to the Regulatory Agency.

The DST600 series are all stainless steel construction and are rated NEMA-4X. The units have been thoroughly CE tested for electromagnet interference. We have all the documentation needed for such. Some of our users have found that keying the mikes on very powerful radios, very close to the thermometer display, can disrupt the signal going through the display as long as the button is held down. This causes the display to go blank. When the mike button is released, the display goes back to normal and the thermometer has not changed calibration. Calibration checks, before and after, show no changes in thermometer calibration.

8. Replacement of any component shall be regarded as a new installation and is subject to all applicable testing for calibration, in keeping with the manufacturer's recommendations, before reactivating the unit.

Wahl Instruments uses the ice point as our primary reference. Few 100 ohm RTDs are actually at 100 ohms of resistance at 0°C. Typically, they might be 99.996 or 100.003. We do a R0 and plug the tiny correction into the meter so that the initial error is offset. When a probe is changed, we supply the new R0 number for the new probe which can be plugged into the meter using the calibration software kit. You can also use an ohmmeter or an ice bath to capture the R0 for a probe at any time. Thermometer calibration can be checked in oil baths or steam logs at any point on the scale. Only the R0 ever needs to be reset if needed. If the probe is out, anywhere in the remainder of the range, it is a bad probe and needs to be changed.

9. The RTD probe and display case shall be constructed of suitable, corrosion resistant materials.

DST600 external parts are all 304 stainless steel with optional 316 stainless steel probes. Unbreakable polycarbonate lens cover over glass LCD.

10. The installation, maintenance and calibration are to be carried out in keeping with the manufacturer's recommendations, by individuals with working knowledge of the thermal processing equipment and the indicating thermometer's intended function.

Each RTD shall be installed where it can be accurately and easily read. It must be

ensured that the probe's entire length is fully exposed to a uniform heating medium, with a continuous heating medium flow past the probe.

The DST600 is available with rigid construction in bottom, back, side, or front angles, is available with an adjustable angle configuration to allow users to install the same thermometer in multiple configuration areas, or is available as a remote mount with up to 1500 foot (460 meters) cable lengths. Cables have optional waterproof (IP68) quick disconnects at each end to allow meter and probe to be removed for calibration with a short calibration cable between meter and probe. Long cables can be left in conduit or tied into other cables. Cable connections have gold-plated contacts to prevent corrosion.

Calibration and other tests are to be documented and made available to the Regulatory Agency upon request, for each specific indicating RTD outlining the following information:

- Identity of the unit, unit serial #, model #, seal or tag
- Identity of the standardized reference device used to calibrate, along with a description of the method used
- All test records are to be signed and dated by the person(s) who carried out the testing

Glossary:

Acidified Foods	Low-acid food to which an acid or an acid food is added to produce a food with a final equilibrium pH of 4.6 or less and a water activity greater than 0.85
Calibration	The standardization of a measuring instrument, by testing a measuring instrument against an accurate standard to determine any deviation and correct for errors
Commercially Sterile	The condition obtained in a food that has been processed by the application of heat, alone or in combination with other treatments, to render the food free from viable forms of microorganisms, including spores, capable of growing in the food at temperatures at which the food is designed normally to be held during distribution and storage
Hermetic Seal	A container designed and intended to be secure against the

	entry of microorganisms, including spores
HTST Pasteurizer	Thermal processing equipment used for heating liquid food
Indicating Thermometer	Thermometer used to indicate the temperature environment of the food thermal processing equipment. It used in the recording of the processing temperature to determine that an adequate thermal process temperature has been reached and maintained as set out in the processing schedule to achieve commercial sterility
Low Acid Foods	A food, other than an alcoholic beverage, where any component of the food has a pH greater than 4.6 and a water activity greater than 0.85
MIG	Mercury- In-Glass (Indicating Thermometer)
Reference Thermometer	**S**tandardized thermometer used to calibrate the Indicating Thermometer
Retort	Closed vessel used for thermally processed hermetically sealed food containers under pressure, to achieve commercially sterile food
RTD	Resistance Temperature Detector which utilizes changes in thermal resistance to measure temperature
Thermal Process	The application of heat to food either before or after sealing in a hermetically sealed container, for period of time and at a temperature scientifically determined to achieve a condition of commercial sterility

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