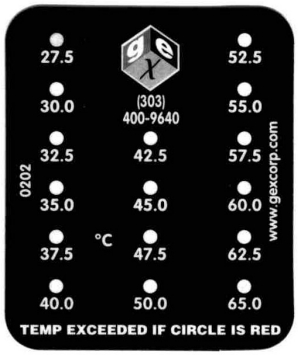
GEX Technical Information Report

Performance of P8003 Irreversible Temperature Indicator Label

PURPOSE

GEX Doc 100-219 reviews a study that evaluates the performance of the GEX P8003 Irreversible Temperature Indicator Label product. A methodical study was conducted, under in-situ conditions similar to typical applications of usage for the product, to analyze the accuracy of the chemistry and color development activation of the P8003 Irreversible Temperature Indicator Label[1].

DESCRIPTION



The P8003 Irreversible Temperature Indicator is a threshold temperature indicator with 16 temperature intervals (ranging from 27.5°C to 65.0°C), and a stated accuracy of ±1°C for each temperature interval event. Color development is activated at each temperature interval event, and the color development displays on the label window specifying the temperature event. The color changes from white to red, and the red color is irreversible and will not revert to the original state of white.

The product provides a permanent record of when the temperature reaches a point that reached (or is within ±1°C of) the listed temperature shown on the label. The labels will not de-laminate when removed for reference and can be attached to an inspection report to serve as a permanent record of attained temperature.

For complete product information, please see P8003 Irreversible Temperature Indicator PSU (GEX Doc#100-109)[2].

BACKGROUND

P8003 Irreversible Temperature Indicators are used to measure the maximum temperature of products and materials during radiation processing. The P8003 is also used during calibration irradiations where the temperature must be measured, or in dose mapping characterization of facility or product. It may also be used to monitor temperature during routine irradiation processing and also many other applications[3].

The industrial radiation processing industry did not have a sufficiently reliable study or reference that verified the in-situ precision and accuracy of the P8003 Irreversible Temperature Indicator label, or any irreversible threshold indicator product similar to the P8003. The testing method involved irradiating the labels to two different high doses, and then performing a test to evaluate the effects of the irradiation on the performance of the P8003 product.

METHOD

The product was irradiated to high doses in a fixed low-temperature field in a self-shielded gamma irradiator – see Irradiation Method below. Then, the samples were subjected to the same method of accuracy testing that is conducted on each production batch of labels – see Accuracy Test Method. The Accuracy Test Method is the same testing method conducted by the product manufacturer for each batch post-production to confirm product conformance to batch qualification standards[3]. The data obtained on a batch prior to irradiation and on the samples after irradiation is presented in Results.

Irradiation Study Test Method

1. Ten (10) representative samples of a batch production of the P8003 Irreversible Temperature Indicator label product were shipped in a Styrofoam cooler box with ice packs to a site that maintains a GammaCell 220 irradiator, with an approximate dose rate of 3.5 kGy/hour.
2. The samples received at the irradiator testing site where confirmed as received without damage or temperature elevation event.
3. The samples were placed into the sample compartment of the irradiator, and the irradiation was performed at a temperature of 20.0°C ±2.0°C (this is below the lowest activation level of the label).
4. Five samples irradiated to 20.0 kGy ±1.0 kGy.
5. Five samples irradiated to 70.0 kGy ±1.0 kGy.
6. The samples were returned using the same shipping method, and all samples verified to be un-triggered prior to performing accuracy testing of the irradiated labels.
7. Samples tested using the Accuracy Test Method.

Accuracy Test *Equipment and Materials:*

- Circulating water bath
- 75 or 100-watt, break-resistant bulb, mounted above bath
- Calibrated electronic digital thermometer
- Scissors, polyester film, and double-sided tape for waterproof pouch
- Sample mounting device
- Pantone color chart
- Timer

Accuracy Test Method:

1. Label each sample with product name, product code, and sample ID number.
2. Protect test samples in waterproof pouch.
3. Attach pouch with samples to a mounting device, and submerge in a water-bath at a temperature at least 5.0°C below the lowest temperature event to be tested.
4. Increase bath temperature to 1.5°C below the event temperature and hold for 5 minutes. Record any changes observed.
5. Increase bath temperature to 1.0°C above the event temperature and hold for 5 minutes. Record the temperature at which the samples activate as well as any other changes observed.

RESULTS

The results show that each tested product unit developed color at the specified temperature to meet Pantone 183U, in conformance with Accuracy Test methods. The results of the Accuracy Test are listed in Table 1 for the initial acceptance sampling after production, Table 2 for indicators subjected to 20 kGy irradiation, and Table 3 for indicators subjected to 70kGy irradiation.

CONCLUSIONS

When exposed to gamma radiation at both 20.0 and 70.0 kGy, the GEX P8003 Irreversible Temperature Indicator remains accurate to within ±1.0°C and exhibits the required color change. This study demonstrates that the P8003 product performance is not impacted by irradiation, and the product conforms to the stated product accuracy claims at each of the 16 temperature intervals (ranging from 27.5°C to 65.0°C), and conforms to the stated accuracy of ±1.0°C for each temperature interval event.

Table 1 - Batch Sample Testing Before Irradiation

Event °C	No Change Temperature °C	No Change Reading	Change By Temperature °C	Change by Reading °C
27.5	26.0	NC=No Change	28.5	27.3-27.5
30.0	28.5	NC	31.0	30.3-30.5
32.5	31.0	NC	33.5	32.2-32.4
35.0	33.5	NC	36.0	35.1-35.3
37.5	36.0	NC	38.5	37.7-37.9
40.0	38.5	NC	41.0	40.2-40.4
42.5	41.0	NC	43.5	41.9-42.1
45.0	43.5	NC	46.0	44.8-45.0
47.5	46.0	NC	48.5	47.2-47.4
50.0	48.5	NC	51.0	50.1-50.3
52.5	51.0	NC	53.5	52.5-52.7
55.0	53.5	NC	56.0	55.4-55.5
57.5	56.0	NC	58.5	57.4-57.6
60.0	58.5	NC	61.0	60.4-60.7
62.5	61.0	NC	63.5	62.5-62.7
65.0	63.5	NC	66.0	65.6-65.8

Table 2 - Batch Sample Testing After Irradiation to 20 kGy

Event °C	No Change Temperature °C	No Change Reading	Change By Temperature °C	Change by Reading °C
27.5	26.0	NC=No Change	28.5	27.3-27.5
30.0	28.5	NC	31.0	30.2-30.4
32.5	31.0	NC	33.5	32.2-32.4
35.0	33.5	NC	36.0	35.1-35.3
37.5	36.0	NC	38.5	37.6-37.8
40.0	38.5	NC	41.0	40.3-40.4
42.5	41.0	NC	43.5	42.3-42.5
45.0	43.5	NC	46.0	45.3-45.5
47.5	46.0	NC	48.5	47.4-47.5
50.0	48.5	NC	51.0	50.3-50.4
52.5	51.0	NC	53.5	52.7-52.8
55.0	53.5	NC	56.0	55.4-55.5
57.5	56.0	NC	58.5	57.3-57.4
60.0	58.5	NC	61.0	60.5-60.6
62.5	61.0	NC	63.5	62.5-62.6
65.0	63.5	NC	66.0	65.6-65.7

Table 3 - Batch Sample Testing After Irradiation to 70 kGy

Event °C	No Change Temperature °C	No Change Reading	Change By Temperature °C	Change by Reading °C
27.5	26.0	NC=No Change	28.5	27.2-27.4
30.0	28.5	NC	31.0	30.2-30.4
32.5	31.0	NC	33.5	32.1-32.3
35.0	33.5	NC	36.0	35.0-35.1
37.5	36.0	NC	38.5	37.6-37.7
40.0	38.5	NC	41.0	40.1-40.2
42.5	41.0	NC	43.5	42.2-42.4
45.0	43.5	NC	46.0	45.2-45.4
47.5	46.0	NC	48.5	47.2-47.3
50.0	48.5	NC	51.0	50.1-50.2
52.5	51.0	NC	53.5	52.5-52.6
55.0	53.5	NC	56.0	55.2-55.3
57.5	56.0	NC	58.5	57.2-57.3
60.0	58.5	NC	61.0	60.3-60.4
62.5	61.0	NC	63.5	62.4-62.5
65.0	63.5	NC	66.0	65.5-65.6

REFERENCES

- [1] R&D Report No. 2019-005, Evaluation of I-16027 Indicators Sterilized by Gamma Radiation – 2019, Yeager, Steve. Dayton, OH: American Thermal Instruments.
- [2] GEX Doc# 100-109, P8003 Irreversible Temperature Indicators - Product Specifications and Usage (PSU).
- [3] NPL CIRM 29 – 2009, Sharpe, Peter, and Arne Miller. *Guidelines for the Calibration of Routine Dosimetry Systems for Use in Radiation Processing*.

REVISION HISTORY

DATE	CHANGE DESCRIPTION	REVISION
05/14/19	Initial release.	A