1.0 PURPOSE

Describes GEX recommended practices for the receipt and inspection of GEX B3 Dosimeter shipments.

2.0 APPLICATION(S)

Incoming receiving inspection should be performed on all shipments of B3 dosimeter products (referred to as Dosimeter Stock or Stock) including initial stock shipment of a new batch and all subsequent stock shipments of an existing batch.

There are three activities associated with incoming inspection:

- Verification of the initial absorbance of dosimeter samples to detect possible exposure to a source of ionizing radiation which could increase the un-irradiated background absorbance of the B3 film.
- Verification that the dosimeters were not exposed to an extreme maximum temperature during shipment which could have adversely impacted the dosimeters. Dosimeter shipments from GEX are temperature monitored by using either an irreversible temperature indicator or temperature data logger.
- Incoming response comparison testing is performed to verify that the new stock will respond the same as the dosimeter stock used in the batch calibration, within acceptable limits.

3.0 GENERAL INFORMATION

A batch of B3 dosimeters may involve multiple dosimeter stock shipments over a two (2) to three (3) year period, which is the typical lifespan of a B3 dosimeter batch.

NOTE: The response of a batch of dosimeters is established through a formal process that relates the dosimeter response (absorbance/thickness) to doses traceable to a national standard, known as a dosimeter calibration. For more information on dosimeter calibration process, see *GEX Doc# 100-263, Performing a Dosimeter Batch Calibration*. GEX characterizes the response of all B3 film rolls used to produce GEX B3 dosimeters to verify that each roll exhibits a response per unit dose that is not more than 1.0% different from the batch baseline established during GEX's batch characterization testing.

3.1 Materials

- WINdose Dosimetry System, DoseControl dosimetry system, or similar
- GEX Doc# 100-257, Dosimeter Stock Receiving Inspection Form
- Sample dosimeters (QA retains)

3.2 Frequency

Testing is recommended to be performed on every incoming shipment of stock dosimeters to verify that the dosimeters perform within specified limits.

NOTE: Some applications (such as relative dose measurements) may not require the specific performance limits specified in this document.

4.0 PROCEDURE

4.1 Dosimeter Sampling:

A proper sampling technique and obtaining the proper number of samples from all stock shipments of a batch must be sufficient to support statistical evaluation of the characteristics of the stock being tested.

When sampling the initial stock shipment from a new batch of dosimeters, a sufficient quantity of representative samples should be secured and retained in order to have a supply of samples to meet: the needs of performing the initial batch calibration, anticipated verification audits, samples required for future testing and investigations, as well as samples necessary to support future receiving inspection testing of other stock shipments of the same batch. GEX recommends retaining a minimum of 400 samples from the initial stock shipment of a dosimeter batch to perform these activities.

NOTE: Avoid using samples from a single box or selecting consecutive samples within any one box.

4.2 Receiving and Management of Stock

Verify the product identification, product quantity, dosimeter batch number, and dosimeter average thickness on all incoming shipments.

- The Date of Manufacture (DOM) is stated on the Certificate of Compliance (CoC) and labeled on the bottom of each GEX dosimeter box. The DOM may differ from box to box. Boxes with the oldest DOM should be utilized first and always in accordance with the Shelf Life stated on the Certificate of Compliance accompanying each shipment. Assign an incoming dosimeter stock shipment identification or receiving date ID to the boxes, and number the boxes (e.g. 1 of 20, 2 of 20, etc.). Number the boxes in sequence from oldest to newest to encourage proper stock utilization (FIFO).
- Upon receipt, store the dosimeters between 15°C - 30°C (59°F – 86°F). Exposure of B3 film to temperatures above 45°C during shipment is detectable by observing the maximum temperature triggered on the P8003 Irreversible Temperature Indicators, which are included by GEX in all dosimeter shipments. Report any deviations observed to GEX Customer Service to discuss appropriate actions.
- Do not intermix the new dosimeter stock with any other dosimeter stock until acceptance testing is complete.

4.3 Verification of Initial Absorbance (A)

Characterization of the initial absorbance (A) of all stock shipments of dosimeters should be performed to confirm that the dosimeters were not exposed to a source of radiation prior to receipt.

- Verify the calibration of the spectrophotometer(s) prior to beginning the initial absorbance verification.
- Complete the header information on *GEX Doc# 100-257, Dosimeter Stock Receiving Inspection Form* 'Analysis' tab.
- Draw 32 representative samples (e.g. 16 pouches of B3002DS) from the Dosimeter QA Retains for the stock being verified.
- Measure the initial absorbance of the dosimeters at the wavelength used in the dosimeter calibration (historically 552 nm for B3). There is no specific left-right, top-bottom, or front-back orientation of the dosimeter in the dosimeter holder. Record dosimeter ID's and their absorbance values on *GEX Doc# 100-257, Dosimeter Stock Receiving Inspection Form* 'Raw Data' tab. The average absorbance, standard deviation (stdev), and coefficient of variance are automatically calculated on the 'Analysis' tab.
- Typically, the measured average absorbance will be found between 0.038 – 0.048 absorbance units (A). This initial absorbance average can be expected to vary slightly depending on the average thickness of the dosimeters and the type of measurement equipment used.
- Using an average initial absorbance established from the initial stock shipment of a dosimeter batch (entered into the "Baseline Ave. Value" on the 'Analysis' tab), as well as the standard deviation value established from the initial stock shipment (entered into the "Baseline St. Dev." on the 'Analysis' tab), compare results from future stock shipments of the same batch against the established baseline. The results should not vary by more than ±2 standard deviations from the baseline.
    - If the initial absorbance fails two standard deviations but passes three standard deviations, response testing results may be used to determine if the dosimeter stock is statistically equivalent.

NOTE: A high measurement CV (greater than 4%) may indicate an instrument that is not performing to its potential, may indicate that the operator is not able to maintain zero during measurement, or may indicate that the test samples are contaminated with particulate amounts higher than average.

- The test dosimeters may be discarded after verification testing is complete.

4.4 Verification of Dosimeter Response

Incoming response comparison testing is performed to verify that the new stock response is within statistically acceptable limits when compared against the average response of the current dosimeter stock or dosimeters used in the batch calibration.

Appropriately selected samples from the incoming stock and the existing stock should be co-located and irradiated so that all samples receive the same doses (low, medium, and high) within the calibrated range of the batch. Use of a test fixture and process conditions that provide a uniform dose to all samples is required to successfully execute the test (see the NOTE below for detail).

- Draw representative samples from the incoming stock to be tested, and label accordingly.
- Draw representative samples from the retained samples for the initial or current stock shipment, and label accordingly.
- Irradiate the samples to the target doses.
- Perform appropriate post-irradiation heat-treatment of the dosimeters in accordance with company procedure, if applicable.
- Verify the calibration of the spectrophotometer(s) prior to beginning the dosimeter measurements.
- Measure the absorbance values of both sets of samples for each dose point. Record the absorbance values into *GEX Doc# 100-257, Dosimeter Stock Receiving Inspection Form* 'Raw Data' tab.
- The mean average, standard deviation, and CV will automatically calculate on the 'Analysis' tab for each set of responses. Compare the mean averages of the two sample sets to verify equivalency. GEX recommends that the incoming stock average response should lie within ± 2 standard deviations of the average response of the current or initial stock. If the incoming stock average response if found outside 3 standard deviations, it is considered to have failed. If the results lie between two and three standard deviations, results should be investigated for possible outliers. Dosimeters may be re-measured and/or a repeat of the test considered.
- In the event that the incoming dosimeter stock shipment fails, contact GEX to discuss appropriate actions to be taken.
- All test dosimeters should be retained until the test results pass the acceptance criteria or investigations are completed.

NOTE: The test form (100-257) associated with this procedure accommodates a maximum of 32 samples per test condition which is the GEX recommended sample size. Six pouches of dosimeters are the maximum number of pouches the user should place in the Risø Electron Beam Phantom. However, such a sample size may not be sufficient to support statistical significance.

NOTE: B3 dosimeter stock shipments with stated dosimeter average thicknesses that vary as much as ±0.0002 mm from the current stock average thickness is not considered by GEX to be significantly different and may undergo receiving verification response testing described above using the average thickness of the current stock. In the event an incoming stock of dosimeters fails response testing, a suggested corrective action is to adjust the average thickness to that stated for the incoming stock. This requires a modification of the calibration in the DoseControl software and creation of a new "Dose Estimate Table" establishing a new average thickness to be used for the new stock of dosimeters with the existing batch calibration.

5.0 REFERENCES

- ISO/ASTM 51261: Practice for calibration of routine dosimetry systems for radiation processing
- NPL CIRM 29 Guidelines for the Calibration of Dosimeters for use in Radiation Processing, Peter Sharpe and Arne Miller, 1999; National Physical Laboratory, Teddington, UK.

GEX Documented Information:

- 100-254, Genesys 20 Calibration and Maintenance
- 100-257, Dosimeter Stock Receiving Inspection Form
- 100-263, Performing a Dosimeter Batch Calibration
- PSU# 100-109, Irreversible Temperature Indicators

6.0 REVISION HISTORY

Date	Change Description	Revision
06/19/2007	Major Revision. Complete re-write.	C
10/12/2016	Revised to reference addition of newly added column to #100-257. ECO 70245.	D
02/01/2021	Revised to update the average initial absorbance values from 0.035-0.041 to 0.038-0.048 found on currently offered G30 and Evo220 spectrophotometers. ECO 70554.	E

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