1.0 PURPOSE

1.1 This procedure describes GEX recommended practices for receiving and inspection of shipments of GEX B3 Dosimeters.

1.2 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:

1.2.1 Verification of the initial absorbance of dosimeter samples to detect possible exposure to a source of ionizing radiation that could increase the natural background absorbance of the B3 film.

1.2.2 Verification that the dosimeters were not exposed to an extreme maximum temperature during shipment that could have adversely impacted the dosimeters. Dosimeter shipments from GEX are accompanied by temperature monitoring using either an irreversible thermal label or temperature data logger.

1.2.2 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.

NOTE: It should be noted that GEX monitors the response of its B3 film dosimeter batches to evaluate the B3 film batch response over time and advises users of any significant (>1.0%) observed change. GEX also 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.

2.0 MATERIALS

2.1 WINdose Dosimetry System
2.2 Dosimeter Stock Inspection Test Form [GEX Doc#100-257]
2.3 Sample Dosimeters (QA retains)

NOTE: The QA department may elect to withhold a certain number of samples for other types of testing or for conducting dosimetry investigations. Sampling for such needs is not described in this document.

3.0 FREQUENCY

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

NOTE: Some applications, such as relative dose measurements, may not require the specific performance limits called out in this document.

4.0 GENERAL INFORMATION

A typical batch of B3 dosimeters may involve multiple dosimeter stock shipments over a 2 to 3 year period (typical life of a B3 dosimeter batch).

NOTE: 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.

5.0 PROCEDURE

5.1 **Dosimeter Sampling:** Proper sampling technique and the procurement of the proper number of samples from all stock shipments of a batch should be sufficient to support statistical evaluation of the characteristics of the stock being tested.

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

5.2 **Receiving and Management of Stock:** Verify the product identification, product quantity, dosimeter batch number, and dosimeter average thickness on all incoming shipments.

5.2.1 The Date of Manufacture (DOM) is stated on the Certificate of Compliance and labeled on the bottom of all GEX dosimeter boxes. 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).

5.2.2 Upon receipt, store the dosimeters between 15°C and 30°C.

5.2.3 Do not mingle the new dosimeters stock with any other dosimeter stock until acceptance testing is complete.

5.3 Exposure of B3 film to temperatures above 45°C during shipment should be detectable by simply observing the irreversible maximum temperature label included by GEX in all dosimeter shipments. Report any deviations observed to GEX to discuss appropriate actions.

5.4 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, called dosimeter calibration. See GEX Document 100-263 *Performing a Dosimeter Batch Calibration* for more information on this process.

5.5 **Verification of Initial Absorbance:** A characterization of the Initial Absorbance 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.

5.5.1 Verify the calibration of the spectrophotometer(s) prior to beginning the initial absorbance verification (see GEX Doc# 100-254, *Genesys 20 Calibration and Maintenance*, for detail).

5.5.2 Fill in the header information on GEX Doc# 100-257, *Dosimeter Stock Receiving Inspection Form.*

5.5.3 Draw 32 representative samples (e.g. 16 pouches of B3002DS) from the Dosimeter QA Retains for the stock being verified.

5.5.4 Measure the initial absorbance, Ao, of the dosimeters at the wavelength used in the dosimeter calibration (historically 554 nm). There is no specific left-right, top-bottom, or front-back orientation of the dosimeter in the holder. Record the absorbances on GEX Doc# 100-257, *Dosimeter Stock Receiving Inspection Form*. The average Ao, standard deviation, and coefficient of variance are calculated automatically.

5.5.5 Typically the measured average absorbance will be found between 0.035 – 0.041 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.

5.5.6 Using an average initial absorbance established from the initial stock shipment of a dosimeter batch, compare results from future stock

shipments of the same batch against the established baseline; results should not vary by more than ±0.002 A from the baseline.

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.

5.5.7 The test dosimeters may be discarded after the inspection testing is completed.

5.6 **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 that used in the batch calibration.

5.6.1 Appropriately selected samples from the incoming stock and the existing stock should be co-located and irradiated such that all samples receive the same dose at low, medium, and high doses 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 Appendix for detail).

5.6.1.1 Draw representative samples from the incoming stock to be tested.

5.6.1.2 Draw representative samples from the retained samples for the initial or current stock shipment.

5.6.2 Irradiate the sample to the target doses.

5.6.3 Perform appropriate post-irradiation heat-treatment of the dosimeters in accordance with company procedure, if applicable.

5.6.4 Verify the calibration of the spectrophotometer(s) prior to beginning the dosimeter measurements.

5.6.5 Measure the absorbances of both sets of samples for each dose point. Record the absorbances in GEX Doc# 100-257, *Dosimeter Stock Receiving Inspection Form*.

5.6.6 Calculate the mean average, standard deviation, and CV 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 a repeat of the test considered.

5.6.7 In the event that the incoming dosimeter stock shipment fails, contact GEX to discuss appropriate actions to be taken.

5.6.8 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 is 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 are 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 specific WINdose for Excel software version and issuance 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.

6.0 REFERENCES

- ISO/ASTM 51261
- NPL CIRM Report 29

7.0 REVISION HISTORY

Date	Revision	Change Description
06/19/07	C	Major Revision. Complete re-write.

APPENDIX

CHARACTERIZATION OF A DOSIMETER TEST FIXTURE

A test fixture should be characterized for dosimeter comparison testing that will assure sets of dosimeters are irradiated to the same dose, ±2.0% or less, in order to compare test results.

Test fixture verification testing should involve dose mapping of the fixture to verify the dose distribution uniformity of the fixture or phantom.

1.1 Characterization of a dosimeter test fixture in an Electron Beam facility can involve development of a fixture, such as a 'sandwich', made from a low to medium density uniform absorber material such as Ethafoam (polyethylene foam). When more samples are required for dose testing than can be fit into the Risø Electron Beam Phantom, an alternative fixture to avoid overcrowding the Risø phantom is needed.

1.2 The fixture should be designed to sit in the product carrier perpendicular to the direction of the beam and should be designed so that it can be secured in place during irradiation.

1.3 Dose map the fixture to verify a dose distribution of ±2.0% or better.

1.4 The standard Risø gamma calibration phantom can typically hold an adequate number of B3 dosimeter packages and should be used unless verification testing demonstrates an inability to maintain a ±2.0% uniformity of dose.

1.5 The same low to medium density uniform absorber material described in 1.1 can be used to construct a phantom holder test fixture for gamma irradiation dosimeter comparison testing.

1.6 Design the phantom to securely hold the dosimeters secure during testing.

NOTE: In the design of a gamma fixture, multiple layering of dosimeter pouches can save space in the fixture allowing it to be as small as necessary. In electron beam, arraying the dosimeters at the center of the beam line in the direction of travel in many cases provides an optimum result. Randomizing sample placement in the test fixture can help reduce the introduction of a bias.