



GEX CORPORATION

## GEX DOC# 100-263

### PERFORMING A DOSIMETER BATCH CALIBRATION

GEX Recommended Procedure

Eff. Date: 07/27/07

Rev.: C

Pg. 1 of 10


**NOTICE:** This document is version controlled and was produced as a part of the GEX Information Program which requires that all Series 100 documents be reviewed periodically to maintain currency and continuity of information. Appropriate Technical Memorandum are used to provide information detail in support of the Product Data Sheets as well as GEX Recommended Procedures and to provide technical information in support of GEX Marketing documents.

## 1.0 PURPOSE

- 1.1 Dosimetry systems must be calibrated for each new batch of dosimeters and these calibrations need to be periodically verified to assure validity of the dosimeter batch specific calibration(s). It should be understood that one calibrates the dosimetry system and not the dosimeters which are only a part of the dosimetry system.
- 1.2 This procedure describes the practices recommended by the GEX Corporation for dosimeter batch specific calibration of dosimetry systems. The calibration practices recommended by GEX were designed to conform to current industry practices and published guidance documents and demonstrate traceability to national standards through an unbroken chain with appropriate levels of uncertainty. Rationales not specified in this procedure for the methods and practices described may also be found in the referenced documents cited in Section 3.2.
- 1.3 The purpose of dosimeter batch calibration is to establish a response function that relates the change in dosimeter response to dose traceable to a national standard with an associated level of uncertainty.
- 1.4 A dosimetry system batch calibration is designed to capture the environmental conditions (i.e., temperature) and dose rates that approximate those of actual usage of the dosimeters and dosimetry systems.

## 2.0 SCOPE

- 2.1 Dosimetry System dosimeter batch specific calibrations and calibration audits.
- 2.2 GEX dosimeter calibration services with calibration curve fitting.
- 2.3 Assumes user has determined the specific processing conditions to be used in the calibration to achieve temperatures and dose targets.
- 2.4 This procedure is also supported by formal GEX Quality System work instructions related to the control and execution of GEX practices required to provide the GEX S1101 and S1102 service packages for customers that utilize this procedure. The internal GEX procedures used in support of this document are

 <b>GEX CORPORATION</b>	<b>GEX DOC# 100-263</b>		
	<b>PERFORMING A DOSIMETER BATCH CALIBRATION</b>		
	GEX Recommended Procedure	Eff. Date: 07/27/07	Rev.: C

controlled documents and are available for review during audits of GEX Corporation at the Company's Centennial, Colorado USA offices.

### 3.0 MATERIALS AND REFERENCES

3.1 Not all of these items may be needed.

- Representative dosimeter batch samples
- Reference Standard Transfer Lab dosimeters
- Spectrophotometer(s), calibrated
- Dosimeter holder fit to each instrument sample compartment
- Thickness gauge, calibrated
- Forceps, tweezers or PenVac to handle the dosimeters
- Calibration Data Workbook – GEX document QF-77-01
- Temperature monitoring labels or equivalent (i.e. calorimeter, temp recorder, etc.)
- In-situ calibration phantom holders

3.2 Definitions and References:

- *Dosimeter Batch*: Quantity of dosimeters made from a specific mass of material with uniform composition, fabricated in a single production run under controlled, consistent conditions and having a unique identification code.
- *Dosimeter Stock*: Part of a dosimeter batch held by the user.
- *Dose Point*: Also know as a Target Dose for a calibration
- *A<sub>o</sub> or A<sub>o</sub>*: Abbreviation used for Absorbance<sub>original</sub>, i.e. original absorbance, the pre-irradiation background optical density of the dosimeter film.
- *A<sub>i</sub> or A<sub>i</sub>*: Abbreviation used for Absorbance<sub>irradiated</sub>, i.e. irradiated absorbance, the post-irradiation optical density of the dosimeter film.
- *T or t*: Abbreviation used for dosimeter film thickness.
- ISO/ASTM Standard 51261: *Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing*
- ISO/ASTM Standard 51275: *Practice for Use of a Radiochromic Film Dosimetry System*
- ISO/ASTM Standard 51276: *Practice for Use of a Polymethylmethacrylate (PMMA) Dosimetry System*
- ASTM Standard E170: *Standard Terminology Pertaining to Radiation Measurements and Dosimetry*
- NPL CIRM Report 29: *Guidelines for the Calibration of Dosimeters for Use in Radiation processing*



## 4.0 GENERAL CONDITIONS

- 4.1 Develop a calibration plan that defines the requirements of the calibration. Review and repeat this activity with all new batches of dosimeters or any change to the dosimetry system or processing system than could significantly impact the calibration response function established for the dosimetry system.
- 4.1.1 Define the type of calibration, i.e. full batch calibration or a verification audit of an existing calibration.
- 4.1.2 Define the dosimeter batch and the calibration dose range(s)
- 4.1.3 Define the radiation source to be used for the calibration: identify the specific calibration laboratory where the irradiations are to be carried out and the in-situ calibration verification audit or a full in-situ calibration including specification of the transfer dosimetry system and calibration laboratory to be used.
- 4.1.4 Define the post irradiation measurement handling specific detail including specified information regarding use of post irradiation heat treatment, specific dosimeter thickness measurement, etc.
- 4.1.5 Determine the specific dose point targets along with an estimated maximum temperature and start temperature for each dose point.
- 4.1.6 Specify the type B uncertainties to be used in the development of an expanded overall calibration uncertainty at  $k=2$  or 95% confidence based on the so called GEX “top down method”.
- 4.2 Dosimeter calibration may be performed at a certified calibration laboratory followed by performance of a minimum 3 point calibration verification audit carried out at the user’s facility under routine process conditions (in-situ) using reference transfer standard dosimeters. Alternatively, a full in-situ dosimeter calibration may be performed at the user’s facility. See ISO/ASTM 51261 and NPL CIRM Report 29 for a discussion of the two methods.

**NOTE:** GEX recommends the full in-situ calibration method because a properly designed in-situ calibration can capture and account for the various dose rates and environmental conditions of actual usage of the dosimeters within the calibration exercise itself. Use of the laboratory calibration method introduces uncertainty components associated with shipment to and from the user site along with significant time-to-measurement differences from those of normal production use.



## **GEX DOC# 100-263**

### **PERFORMING A DOSIMETER BATCH CALIBRATION**

GEX Recommended Procedure

Eff. Date: 07/27/07

Rev.: C

Pg. 4 of 10

The laboratory method will therefore generally result in a higher calibration uncertainty than the in-situ approach when these additional uncertainty components are properly taken into account.

- 4.3 The GEX Calibration Data Workbook is initially prepared by GEX and consists of a Microsoft Excel workbook with pre-formatted worksheets designed to provide a consistent data recording format for documentation and analysis.

**NOTE:** This procedure assumes user familiarity with Excel and the ability to navigate among the worksheets. When the GEX S1101 or S1102 calibration services have been purchased, only use the GEX supplied Calibration Data Workbook to record measurement data and information. The user must complete the information and measurement data entry requirements as specified for the calibration of the dosimeter batch(es).

- 4.4 Store any reference standard transfer dosimeters under temperature conditions between 15°-30°C before use. Follow instructions supplied by the calibration laboratory that were sent with the transfer dosimeters, if any. Store any accompanying irreversible 27.5°C to 65°C maximum temperature labels below 25°C before use to prevent premature triggering of the 27.5°C minimum temperature point. Use transfer standard dosimeters within 60 days from the day they are received (or sooner if stated on the accompanying shipment instructions) or advise GEX or the calibration laboratory prior to use in the event they cannot be used within the 60 day period.

**NOTE:** GEX will typically ship irreversible maximum temperature monitoring labels in special thermal cooling containers. The transfer standard dosimeters supplied through GEX are wrapped and packaged but often placed inside the thermal cooling container and shipped together with the thermal labels. The transfer standard dosimeters should be removed from the cooler upon receipt and placed under normal ambient storage temperatures to equilibrate before use so that their pre-irradiation start temperature is equivalent to that of normal use.

- 4.5 Record the dosimeter batch number identification on all calibration documentation. Complete all information and data sections in the appropriate Worksheets of the GEX Calibration Data Workbook
- 4.6 Calibrate all associated instrumentation prior to performing any measurements associated with the new dosimeter batch calibration or batch calibration audit.

## **5.0 DETERMINATION OF AN AVERAGE INITIAL ABSORBANCE FOR DOSIMETER BATCH**



GEX CORPORATION

## GEX DOC# 100-263

### PERFORMING A DOSIMETER BATCH CALIBRATION

GEX Recommended Procedure

Eff. Date: 07/27/07

Rev.: C

Pg. 5 of 10

- 5.1 GEX does not recommend the use of an initial absorbance value in the determination of dosimeter response when calibrating the B3 dosimeter because the B3 dosimeter is considered completely shelf stable. Reducing the final absorbance value introduces instrument error and rounding error into the calculation of response. See GEX Tech Memo #100-205 for more detail.

**NOTE:** It may be useful to perform an initial absorbance characterization exercise on each instrument, as described below, even if the value will not be used in the calculation of the dosimeter response. Such a test can identify instruments which may not be performing to expectation. C.V. results for  $A_0$  measurements should be less than 4.0%. The GEX Calibration Data Workbook (QF-77-01) has a worksheet to record these test results, although it is optional.

- 5.2 To characterize the  $A_0$ , sample a minimum of 32 unirradiated batch representative dosimeter films to obtain a statistically derived average. Inspect each dosimeter before measurement for any noticeable imperfections in the light beam area, such as scratches, fingerprints, or bubbles that could affect the measurement result, and discard as appropriate.
- 5.3 Measure and record the  $A_0$  of each dosimeter. Investigate and discard outliers as appropriate. Record the data on the 'IOD & Controls' worksheet in the GEX Calibration Data Workbook.

## 6.0 ESTABLISHING AN AVERAGE BATCH THICKNESS

- 6.1 Use of the manufacturer's stated average batch thickness is the standard practice for the use of B3 films. Record the manufacturer's stated thickness on appropriate worksheets.
- 6.2 Alternatively, perform thickness testing using a properly calibrated thickness measurement system to establish an average thickness of the dosimeter stock to replace the manufacturer's average thickness. This test is not necessary if specific thicknesses are to be used or if an average thickness is not used in the calibration calculations (i.e. if absorbance per dose is used instead of a net average response value).
- 6.3 Measure the thickness of a minimum of 32 dosimeters to establish a statistically based average. The same dosimeters used for characterization of initial absorbance may be used for this test.
- 6.4 Measure and record the thickness of each dosimeter near the center of the optical measurement area. Calculate the average, standard deviation and coefficient of



variation for the sample. Evaluate the results and remove outlier data as appropriate.

- 6.5 Record the average thickness in the appropriate spaces on the worksheet(s) in the GEX Calibration Data Workbook, if appropriate.
- 6.6 If the same dosimeters will be measured at different optical wavelengths, it is not necessary to repeat the thickness test. Simply copy the information to the appropriate worksheet(s).
- 6.7 If specific dosimeter thickness is used in dosimeter response calculations, notify GEX at the time the calibration service is ordered and simply record this information in the Calibration Data Workbook in the appropriate column.

## **7.0 LABORATORY CALIBRATION IRRADIATIONS**

- 7.1 Use representative GEX pre-packaged B3 dosimeter packages from the dosimeter batch stock when calibrating B3 films. Otherwise select representative batch samples according to company policy. Mark each package for each dose point set with the target dose. Complete the "Calibration Lab Data" sheet and send the dosimeters to the specified calibration laboratory.
- 7.2 A minimum of 4 dosimeter batch samples irradiated at each dose point is required.

**CAUTION:** Contact GEX for special instructions as to preparation of pre-packaged WINDose and DoseStix dosimeters due to physical size constraints of the GEX packages that must be accommodated differently for each 17025 certified calibration laboratory or national standards laboratory.

## **8.0 IN-PLANT CALIBRATION IRRADIATIONS**

- 8.1 Plan and conduct all irradiations such that they are reproducible for future calibration verifications and full calibrations. Document the irradiation conditions and record information related to special handling or special fixtures used in the calibration irradiations.

**NOTE:** Verify that the irradiator process settings to be used can actually achieve the targeted doses and estimated temperatures prior to performing the actual calibration irradiations.

**NOTE:** The selection of a specific transfer standard dosimetry system and laboratory provider may impose special criteria on the calibration execution plan



GEX CORPORATION

## GEX DOC# 100-263

### PERFORMING A DOSIMETER BATCH CALIBRATION

GEX Recommended Procedure

Eff. Date: 07/27/07

Rev.: C

Pg. 7 of 10

in order to satisfy dose range, dose fractionation, temperature and other transfer dosimeter limitations. Contact GEX to obtain current information regarding limitations and special consideration recommendations related to specific transfer standard dosimeters.

- 8.2 Follow instructions sent with the reference transfer dosimeters and in the Calibration Data Workbook regarding handling, irradiation and documentation. Do not open the transfer dosimeter containers. A set of controls accompanies all Transfer Dosimeter orders. Keep the controls with the test samples at all times except for the irradiation.

**NOTE:** Verify that the transfer dosimeters have been properly equilibrated to the ambient start temperature of the facility prior to irradiation.

- 8.3 Place dosimeters in the appropriate calibration phantom. Different types of dosimeters may be placed in the same phantom in close proximity. Do not overload the phantom sample compartment with dosimeters or other materials that may produce shadowing or shielding of dosimeters.

8.3.1 Electron beam calibration phantom: Refer to appropriate GEX package insert and/or product data sheets for detailed instructions on use of these phantoms.

8.3.2 Gamma calibration phantom: Refer to appropriate GEX package insert and/or product data sheets for detailed instructions on use of these phantoms.

**NOTE:** Calibration phantoms should be pre-validated for use to confirm that the target doses and their associated temperatures are consistent with those specified for the calibration. This may require performance of test runs for each calibration dose point to substantiate and validate the phantom and process settings to be used. If the polystyrene phantoms result in temperatures that are higher than those encountered in routine processing of real product, it may be necessary to use a different material such as Ethafoam (lower specific heat than high density polystyrene) and to design an equivalent calibration phantom.

- 8.4 Place the phantom in the carrier/tote or its static location. Secure the phantom so that it will not be dislodged or shifted while in the irradiator. It may be necessary to support or surround the phantom with additional uniform density material to hold the phantom in place.



- 8.6 Process the phantom to the target doses according to the facility's standard procedures. The calibration dosimeters and the transfer dosimeter should be placed perpendicular to the electron beam or parallel to the gamma source rack to achieve dose uniformity.
- 8.7 Record the process temperatures for each dose point (Target Dose) on the Transfer Lab Data worksheet in the GEX Calibration Data Workbook.

**NOTE:** These are required by the transfer dosimeter laboratory in order to correct the dose of the transfer dosimeter response for the influence of temperature. Failure to report all information will delay preparation of the dose response curves.

- 8.8 After irradiation, take the calibration phantom and process documentation to the dosimeter laboratory. Open the phantom and remove the calibration dosimeters. Store all transfer dosimeters in the dosimetry laboratory until the completion of all calibration irradiations.

**NOTE:** The calibration laboratory will typically measure the transfer standard dosimeters beginning with the lowest target dose point on through the highest. It is important that the target doses on the Transfer Lab Data worksheet match the number(s) on the worksheet for the Transfer Standard Dosimeter ID#'s so that the lab can read them in the appropriate order.

- 8.9 Record the processing parameters (Gamma: source activity and timer setting; E-Beam/X-Ray: processing speed) in the Calibration Data Workbook's appropriate column. Print and retain processing records for each dose point.

## 9.0 POST-IRRADIATION HANDLING AND ABSORBANCE MEASUREMENTS

- 9.1 Open the GEX supplied Calibration Data Workbook. Record instrument information, dosimeter measurements, personnel names, dates, and process information in the pink areas of the worksheet. The transfer dosimeter numbers and target doses may be changed as necessary to reflect actual activities versus planned activities.

**NOTE:** GEX recommends use of a post irradiation heat treatment of B3 film dosimeters in a properly validated heat treatment system. Refer to GEX Technical Memorandum 100-201 "Post Irradiation Heat Treatment of B3 Dosimeter Products" or contact GEX directly for instruction on how to establish an effective post irradiation heat treatment process.





GEX CORPORATION

## GEX DOC# 100-263

### PERFORMING A DOSIMETER BATCH CALIBRATION

GEX Recommended Procedure

Eff. Date: 07/27/07

Rev.: C

Pg. 9 of 10

- 9.2 Several post irradiation final absorbance ( $A_i$ ) measurements, one before heat-treatment and one after, may be required if a non-heat treatment calibration curve is a requirement.
- 9.3 Measure the irradiated absorbance ( $A_i$ ) of each dosimeter. Record this value in the appropriate column.
- 9.4 Retain all dosimeters under controlled conditions until the calibration curve fitting is complete and accepted for use in the event they may need to be re-read or investigated for anomalies.

**NOTE:** GEX recommends retention and use of the B3 dosimeter batch specific calibration dosimeters in an instrument(s) “Daily Checks” program. See GEX Technical Memorandum 100-210 “Recommended Practices for Genesys 20 Instruments used to Measure B3 Dosimeters” for more information.

- 9.5 Record any informational comments, deviations or abnormalities that GEX technical personnel should be advised of before preparing the calibration curves.
- 9.6 Print a copy of the Transfer Lab Data worksheet and the Calibration Data worksheet. Review these documents for accuracy and completeness.

## 10.0 RETURN TRANSFER DOSIMETERS and GEX WORKBOOK

- 10.1 If performing an in-situ calibration, immediately send the transfer dosimeters and the completed “Transfer Lab Data” worksheet to the specified calibration laboratory at the address shown on the “Transfer Lab Data” sheet. The reference transfer standard dosimeters will be analyzed and the calibration report issued. The results are reported to GEX for curve fitting purposes.
- 10.2 Send a copy of the completed Calibration Data Workbook and any other relevant process data to GEX. Use e-mail if possible to transmit the Workbook data. The data will be reviewed for completeness and analyzed prior to the performance of the curve fitting process. The calibration curve fitting will be performed according to the specifications provided to GEX.
- 10.3 GEX will prepare the expanded overall uncertainty for each calibration curve using the specified type B uncertainties combined in quadrature with the “average” calibration uncertainty determined from the Dose Estimate Table of each calibration curve.
- 10.4 A draft of the Calibration Data Workbook complete with curve fitting from GEX is emailed back to the facility contact and should be reviewed for data accuracy



GEX CORPORATION

# GEX DOC# 100-263

## PERFORMING A DOSIMETER BATCH CALIBRATION

GEX Recommended Procedure

Eff. Date: 07/27/07

Rev.: C

Pg. 10 of 10

and content approval and authorization should be given to GEX to prepare the formal printed "Calibration Report" which is shipped to the facility contact for final review and authorization by the user. The Calibration Report contains the full documentation of the calibration including:

- Calibration Lab Report
- Completed "Calibration Data Workbook" with individual worksheet curve fit results or calibration audit analysis
- "Dose Look-up Table(s)"
- "Summary Calibration Report"
- CD with the dosimeter batch specific WINdose for Excel software update containing the embedded "best fit" calibration curves, if applicable
- Software Verification statement and testing review

10.5 In addition to verification of the data accuracy and completeness of the calibration records, the calibration review includes verification that the specified calibration target doses and maximum temperatures are within specified limits before the calibration can be approved and authorized for use at the facility.

10.6 Prior to actual implementation, it is appropriate to perform side-by-side comparisons on actual production irradiations as a final verification and to determine whether process setting adjustments will be required in order to successfully achieve dose targets with the new dosimetry system calibration(s).

### 11.0 REVISION HISTORY

Date	Revision	Change Description
07/27/07	C	Major revision. No major new topics or ideas were added, however, many previous recommendations were expanded on. Lengthy notes were added on some topics and the procedure was revised to be applicable to more than just the B3 dosimeter, although some specifics regarding B3 were retained or expanded upon.