



Contact GEX for a MS Word copy of this document. This document was formerly published as GEX Doc. No. 100-249 Dosimetry Lab Operations (template SOP)

## 1 - Purpose

Describes the systems and related set of controls that comprise the Dosimetry Laboratory Operations which supports the overall operations for the irradiation process.

## 2 - Scope

These dosimetry laboratory operations are applicable to the irradiation process known locally as *[END USER INSERT the name of the irradiation process, e.g. "the sterilizer"]*. Any dosimetry performed by outside contractors or for any process other than specified herein is excluded.

## 3 - Definitions

- 3.1 *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 assigned by the manufacturer.
- 3.2 *dosimeter stock* – part of a dosimeter batch held by the user.
- 3.3 *dosimetry system* – interrelated elements used for determining absorbed dose, including dosimeters, instruments, associated reference standards, software, and procedures for their use.
- 3.4 *response function* – a dosimeter stock specific mathematical equation representing the relationship between the signal of the dosimeter to the radiation dose received by the dosimeter, using specified procedures and measuring instrument.
- 3.5 *routine dosimeter ('dosimeter')* – the dosimeter used for routine absorbed dose measurements, including dose mapping and process monitoring.
- 3.6 *transfer-standard dosimeter* – a dosimeter, procured from a laboratory accredited to ISO 17025, the certified measured dose of which is used for the calibration of the response function of the routine dosimeter.

## 4 - General Information

- 4.1 The dosimetry laboratory is a dedicated room or area housing furniture, equipment, computers, measurement systems, and other laboratory devices and fixtures. The laboratory is equipped with a complete Dosimetry System which is a validated and controlled system for the measurement and record keeping of radiation dose delivered by the irradiation processes specified in the Purpose.





4.2. The dosimetry laboratory ('lab') and its operation are part of a larger set of controls that are used to ensure the quality of the irradiation process and the products. The owner of the lab and associated system is the [END USER INSERT department name, e.g. 'Quality'].

4.3. The laboratory is operated and maintained in compliance with *ISO/ASTM 52628, Practice for Dosimetry in Radiation Processing* and the following standards referenced therein. Pertinent referenced documents are noted in the References section of this document.

4.4. In addition, the system is designed by the vendor to help us fulfill the requirements of *ISO 11137, FDA 21 CFR part 11, and EU Annex 11, and FDA cGMP's* in the operation and maintenance of this program, where applicable.

4.5. The dosimetry lab utilizes GEX Corporation to provide the dosimeters, system hardware, system software, and some of the accessories and fixtures along with calibration services, as described herein.

4.6. The Dosimetry System used is the GEX B3 radiochromic film dosimetry system which is a film dosimeter sold in various packaging configurations used for performing a variety of measurement tasks. The system uses a spectrophotometer to measure the optical absorbance of the films which is calibrated traceable to a national standard. The system is comprised of the following major components:

- Spectrophotometer, for measurement of optical absorbance.
- Reference standards, for performance verification of the spectrophotometer.
- GEX B3 film dosimeters, for placement in and exposure to the irradiation process.
- Incubator(s), for the post-irradiation heat treatment of the dosimeters prior to measurement.
- Software, to control and record the measurements and associated metadata.
- Procedures for the use of the system, as described in this document.
- Accessories, fixtures, and other tools to facilitate the operation and maintenance of the system.

Note: For almost all users, it is a requirement to calibrate the response function traceable to a national standard. For more information, refer to section 4.3)

## 5 - Procedure

**5.1 Purpose** - The dosimetry system used is an off-the-shelf product from GEX Corporation with the tradename "DoseControl Dosimetry System".





**5.2 Scope** - The dosimetry lab and equipment including the dosimetry system are owned by the *[END USER INSERT department name, e.g. 'Quality']* department. Unless otherwise specified in this document or related procedures, all tasks herein are the responsibility of this department.

### 5.3 Dosimetry Laboratory

5.3.1 The laboratory (“lab”) has been designed to meet the requirements for the operations and systems that it will house. Refer to *Dosimetry Lab Requirements*, for information about typical lab requirements for the dosimetry system being used.

5.3.2 Dosimetry system and other related lab equipment, fixtures, and accessories are used and operated by trained personnel only.

5.3.2.1 Personnel operating and using the dosimetry system exhibit the expected hygiene and cleanliness that is required per company policies for the type of work being performed.

5.3.3 *[END USER INSERT information to explain access to the dosimetry laboratory – is access controlled, who has access, etc.?)*

5.3.4 The laboratory temperature and relative humidity is monitored and recorded.

5.3.4.1 *[END USER INSERT explain details of monitoring for this site]*

5.3.5 Maintenance and cleaning

5.3.5.1 The counters are cleaned with a damp, low-lint cloth and the floor is mopped weekly.

5.3.5.2 The counter area where dosimeters are handled near the PC workstation is wiped down with a damp, low-lint cloth as needed during the week.

5.3.5.3 LED lighting is used that is free of UV. As such, maintenance to the lighting can take place in the lab while operations are ongoing, if necessary.

### 5.4 Dosimeters

5.4.1 *Procurement*

5.4.1.1 The vendor publishes detailed information about the dosimeters in *GEX B3 Dosimeters – Product Specification and Usage*.

5.4.1.2 Dosimeters are essential for the operation of the irradiation process and the laboratory must not run out of dosimeter stock.





5.4.1.3 The dosimeters must be procured with sufficient lead time for the site staff to receive, inspect and calibrate them before releasing them for use.

5.4.1.4 Accordingly, stock that is ready to use at the site should never fall below a 3-month supply, if possible.

5.4.1.5 Contact [sales@gexcorp.com](mailto:sales@gexcorp.com) to request a quote.

Note: Calibration supplies can be ordered at the same time as the dosimeters. Consult with GEX and if a new batch will be delivered, then calibration supplies should be ordered as well as the dosimeters.

#### 5.4.2 *Shipment*

5.4.2.1 The dosimeters have a low but not zero risk of adverse effects during transport when they are outside of vendor/user controls.

5.4.2.2 Preventive actions include:

5.4.2.2.1 Shipment of dosimeters from the vendor using express air freight.

5.4.2.2.2 Maximum temperature during shipment is monitored using irreversible temperature labels included by the dosimeter vendor.

5.4.2.2.3 Vendor will advise if temperature extremes in the shipping route are greater risk and recommend procurement and shipping occur only during certain months of the year.

#### 5.4.3 *Receipt*

5.4.3.1 The first stock shipment of a new batch of dosimeters is marked 'QC HOLD" while samples are pulled for receiving inspection.

5.4.3.1.1 This stock must be calibrated before use per section 5.6.

5.4.3.1.2 Upon successful completion of receiving inspection and acceptance of the calibration, the "QC HOLD" status is changed to "ACCEPTED" and the dosimeters are moved to storage per section 5

5.4.3.2 Additional stock shipments of the same batch are compared against the original stock that was calibrated and must pass the comparison testing before use.

5.4.3.2.1 Refer to *GEX Doc# 100-256, Dosimeter Stock Receiving Inspection* for complete instructions.

#### 5.4.4 *Storage and Allocation*

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5.4.4.1 Dosimeters are stored in accordance with the manufacturer’s recommendations during receipt, calibration, and ongoing use, per *GEX Doc# 100-101, B3 Film Dosimeter Products – Specifications and Usage*. Download from GEX library <https://library.gexcorp.com>

5.4.4.2 *[END USER INSERT enter site specific storage details and how they are allocated to persons or departments that use them from the storage location(s)]*

### 5.5 Dosimetry System – Qualification

5.5.1 The vendor’s general validation of the dosimetry system is helpful, but it is not sufficient for installation qualification (IQ) and operational qualification (OQ) of the system at this facility.

5.5.2 Qualification is performed before first use of the system. Refer to *DoseControl IQOQ Protocol* for a template. Contact [sales@gexcorp.com](mailto:sales@gexcorp.com) for a copy.

5.5.3 Qualification is performed if components are added, removed, or altered (i.e., ‘changed’) including requalification of processes affected by the changes.

5.5.4 Maintenance and repair of system components (hardware or software) may result in a need for requalification prior to allowing operation to resume with the equipment, for example:

- The OQ may be affected if the light source of the spectrophotometer is replaced.
- The IQ and OQ may be affected if the dosimetry system is moved, or if it is shipped offsite for service or repair.

5.5.4.1 Requalification needs are assessed by the owner of the dosimetry system (see section 4.2) with input from the Quality Department.

5.5.4.2 Protocols are developed on a case-by-case basis depending on the extent to which the qualified state is disturbed by the service.

### 5.6 Dosimetry System – Calibration

5.6.1 Measurements traceable to a national standard are mandatory, therefore the dosimetry system (dosimeter batch-specific response function measured on the dosimetry system) is calibrated using an accredited laboratory vendor. Refer to *GEX Doc# 100-263, Dosimeter Calibration*, for complete instructions and more information. Download from GEX library <https://library.gexcorp.com>

### 5.7 Dosimetry System - Maintenance and Calibration

5.7.1 The dosimetry system is maintained and measuring devices are all calibrated traceable to a national standard.





5.7.2 PCs are maintained in accordance with company policy by the IT Department.

5.7.3 Spectrophotometer performance (calibration) is verified and documented on a scheduled frequency.

5.7.3.1 Refer to *GENESYS 30 Spectrophotometer Performance Verification* for complete information and instructions for P.V. of the GENESYS 30 spectrophotometer. Download from GEX library <https://library.gexcorp.com>

5.7.3.2 Refer to *Evolution Spectrophotometer Performance Verification* for complete information and instructions for P.V. of the Evolution spectrophotometer. Download from GEX library <https://library.gexcorp.com>

5.7.3.3 The references (e.g. optical filters) used for the spectrophotometer P.V. are calibrated every 2 years.

Note: Contact [sales@gexcorp.com](mailto:sales@gexcorp.com) to obtain a quote for recalibration of standards or contact Thermo Fisher Scientific.

5.7.4 Static fixtures made of polymers, foams, aluminum, or other metals cannot be calibrated and are exempt from calibration requirements unless specifically addressed in a written procedure.

5.7.5 **[END USER INSERT department name or group]** are responsible for the calibration of the temperature controllers for all incubators used. They are each verified annually or after any maintenance or adjustment by the manufacturer.

5.7.6 The exterior of the equipment is wiped with a damp cloth as needed. The sample compartment and holders are cleaned with a damp cloth or compressed air is used to 'air wash' the components of the holder system and sample compartment. Refer to the vendor's information for each component for additional information.

5.7.7 **[END USER INSERT instructions for the lamp replacement on the spectrophotometer. If the spectrophotometer used has a Tungsten-Halogen lamp (e.g. GENESYS 30), then insert instructions or link to instructions such as GEX Doc# 100-169, GENESYS 30 Lamp Replacement.]** Download from GEX library <https://library.gexcorp.com>

## 5.8 Dosimetry System – Software and System Configuration

5.8.1 The PCs are built and maintained to comply with the requirements from the vendor for the dosimetry system software.

5.8.2 The software setup and use comply with the vendor's Software License Terms and Conditions.

5.8.3 The system configuration diagram is shown in Annex A.

5.8.4 Access to the PCs is in accordance with company policies.

5.8.5 The software is configured in accordance with a predetermined plan based on the internal requirements. See DoseControl User Guide for configuration instructions.





5.8.6 A general overview of the system controls:

5.8.6.1 All GxP events are captured in an audit trail that is searchable and validated.

5.8.6.2 User access to the software is controlled and user roles and permissions are used to control access to features within the software based on operational and quality assurance needs.

5.8.6.3 The Plan details the specific configurations for user access to the software.

5.8.6.4 The workflows for various tasks within the software are controlled wherever possible and necessary by the DoseControl Application Administrator and defined in The Plan including:

5.8.6.4.1 Dosimeter measurement

5.8.6.4.2 Dosimeter re-measurement

5.8.6.4.3 Information required to be input into the routine reports that are then included in system outputs (aka report metadata).

5.8.6.4.4 Spectrophotometer controls and performance verification\*.

\* Workflow control of performance verification can only be implemented for daily checks and only if using the Evolution 220. All other controls must be via procedure.

5.8.7 The software data is stored in a secure database that can be backed up regularly.

5.8.7.1 DoseControl uses Microsoft SQL Server as the database for storing application data.

5.8.7.2 The user site is responsible for using SQL Server in accordance with licensing requirements and this is determined and maintained by the IT Department.

5.8.7.3 The specific detail about the server is defined in The Plan.

5.8.8 The *GEX Doc# 100-266, DoseControl Software User Guide* is the vendor's (GEX's) primary document describing the software, configuration options, and recommendations for the software.

## 5.9 Dosimeter Irradiation and Processing

5.9.1 Dosimeters are used for different tasks and the specifics of each are detailed in an operational procedure or work instruction not referenced herein. Refer to those documents for specific details related to handling dosimeters for the application.





5.9.2 The dosimeter packaging is designed to protect them during normal usage. Care is still exercised to the extent possible with packaged dosimeters as they are a measuring/monitoring device.

5.9.3 Dosimeters are all heat treated after irradiation to stabilize the color change (dosimeter response).

5.9.3.1 The vendor publishes detailed information about heat treatment and recommendations:

5.9.3.1.1 See Post Irradiation Heat Treatment of B3 film dosimeters. Or download *GEX Doc# 100-201, Post Irradiation Heat Treatment of GEX B3 Dosimeter Products – Technical Information Report* provides extensive information and guidance. Download from GEX library <https://library.gexcorp.com>

5.9.3.1.2 Users of incubators purchased from GEX or its distributors should reference the product information provided for the model of incubator being used.

5.9.3.2 Dosimeters are typically heat treated in groups (or however they are received after irradiation) within the time window noted in the application instruction.

*[NOTE TO BE REMOVED BY USER - Users may have different time windows for different applications. For example, dosimeters from Ebeam testing require processing quickly after irradiation so that the engineers can get the information they need. Alternatively, it can take hours to disassemble PQ dose map of a product and thus the time window may be different due to operational needs. Therefore, it is suggested that each application instruction should dictate the window for heat treatment and expected time to get dosimetry reports completed]*

5.9.3.3 Heat treated dosimeters can be measured or re-measured up to 14 days after irradiation but typically, dosimetry is complete within *[END USER INSERT value, e.g. '6 to 8']* hours.

5.9.3.4 When using a box-style incubator, dosimeters are never placed in a large pile on the interior shelf. Dosimeters are laid out in a single layer on the shelf or on a piece of paper that is then inserted into the incubator. Pouches may slightly overlap but they are not stacked one on top of the other.

5.9.3.5 The minimum incubation time is *[END USER INSERT value, e.g. '15']* minutes and the maximum incubation time is *[END USER INSERT value, e.g. '120']* minutes.

5.9.3.5.1 If there is a deviation in the time of incubation, the following information is important for the investigation:

5.9.3.5.1.1 If the time is less than the minimum, the risk is that the dosimeter response is not fully completed which means the measured value should be lower than expected if there is any effect from the nonconforming treatment.

5.9.3.5.1.2 If the time is greater than the maximum, the risk is that the heat induces a fading of the dosimeter response, so again the value should be lower than if the dosimeter was incubated properly.





5.9.3.5.1.3 Therefore, there is no risk of an actual underdose that would not be observed. The risk is that an overdose may have occurred, and it cannot be determined from the nonconforming dosimeter.

5.9.3.5.1.4 Conduct a study of dosimeters irradiated to a similar dose; treat some dosimeters in accordance with procedure and another group using the incubation dwell time of the nonconforming dosimeter. Determine any actions to take in accordance with the site's nonconformance SOP.

5.9.4 Personnel measuring dosimeters must demonstrate the ability to generate repeatable results – for more information refer to *GEX Doc# 100-251, Measurement Competency*. Download from GEX library <https://library.gexcorp.com>

5.9.5 For complete instructions for handling dosimeters outside of their packaging, see *GEX Doc# 100-258, Measuring GEX B3 Dosimeters* for more information. Download from GEX library <https://library.gexcorp.com>

5.9.6 The following types of measurement activities or “tests” are performed:

5.9.6.1 Routine Monitoring Dosimetry tests consist of the measurement of dosimeters that are irradiated at specified intervals in the ongoing irradiation process. The measurement data is used to monitor the process and to determine product conformity with dose specifications.

5.9.6.2 Qualification Dosimetry tests are measurements used to verify some of the irradiation process specifications or to validate products to be irradiated, and include:

5.9.6.2.1 Electron beam energy estimation testing to verify and monitor the penetration range of the electrons from the Ebeam.

5.9.6.2.2 Electron beam scan width and scan uniformity to verify and monitor the physical length/distance covered by the Ebeam and the uniformity of dose over that distance.

5.9.6.2.3 Dose mapping of material (products) to verify and validate the distribution of dose within the material and the relationship between the irradiation process parameters and dose magnitude and repeatability to the product (i.e., Performance Qualification or PQ Dose Mapping).

5.9.7 Measurements are performed in “sessions” that are typically segregated by the type of testing and are typically measured by a single employee, on a single instrument, and are stated with a defined level of measurement uncertainty.

5.9.8 There are times when a measured result may be brought into question at some point in the lifecycle of the dosimeter or dosimetry report. A process is followed to investigate, which is based on the probability and known characteristics of the measurement system – refer to *GEX Doc# 100-259, Investigation of Dosimeter Measurements* for more details. Download from GEX library <https://library.gexcorp.com>

5.9.9 All possible error is not engineered out of the dosimetry system. There are instances where rereading dosimeters (otherwise called ‘remeasuring’) may be required either during the measurement process (e.g. a technician determines a





known problem such as particulate on the dosimeter in the path of the spectrophotometer light beam) or after the fact (e.g. operations or quality personnel determine that the result is significantly different than expected).

5.9.9.1 The dosimetry system software has optional configuration of restricted workflows for rereading dosimeters based on a type of event. Refer to The Plan for details of the configuration in use.

5.9.9.2 When rereading dosimeters, sample integrity is of utmost importance to ensure integrity of the remeasured data. Barcode scanning is used wherever possible and is available with the system from the vendor.

#### 5.9.10 Storage of Irradiated Dosimeters

5.9.10.1 Dosimeters are stored in the lab for [END USER INSERT value, e.g. '14 days'] after irradiation and may only be remeasured during this time interval.

5.9.10.2 After [END USER INSERT value, e.g. '14 days'] the dosimeters and their packaging may be disposed of in general waste receptacles.

### 5.10 **Reporting Results**

5.10.1 Reporting is discussed in GEX's user guide for the software, *DoseControl Software User Guide*.

5.10.2 The dosimetry system output is the "Dosimetry Report" for a specified purpose which often includes some data analysis included in the report or performed separately.

5.10.3 The following is a list of the dosimetry report forms that are used to report the results of the various tests used at this site:

[END USER INSERT modify list below for user site specifics]

5.10.3.1 Routine Dosimetry Report

5.10.3.2 Ebeam Energy Wedge Test Report

5.10.3.3 Ebeam Scan Test Report

5.10.3.4 Dose Mapping Test Report

5.10.3.5 Dosimeter Calibration Raw Data Report

5.10.4 The required information for each dosimetry report named above is defined in The Plan.





5.10.5 Each “Report” listed above must be validated by the user to verify the correctness of any data analysis used. The system vendor, GEX Corporation, provides support and guidance but validating the outputs is the responsibility of the user.

## 5.11 **Troubleshooting**

5.11.1 When experiencing error messages on the equipment or software screens or performance issues with the system, please consult with department manager(s), review the references noted herein, and refer to the published information in text and video form from the supplier, GEX Corporation.

5.11.1.1 Consult the Troubleshooting section of *GEX Doc# 100-266, DoseControl Software User Guide* for information about specific error messages.

5.11.1.2 Follow a process when troubleshooting dosimeter measurements that are out of specification or otherwise different than expected. Refer to *Investigation of Dosimeter Measurements*, for more information.

5.11.2 For customer support with any of GEX’s products or services, please contact [support@gexcorp.com](mailto:support@gexcorp.com) or call +1 303-400-9640. Email is the preferred method of communication.

5.11.3 *[END USER INSERT customers with a priority support contract with GEX may consider inserting language here with related information.]*

## 6 - References

1. ISO/ASTM 51275, Practice for Use of a Radiochromic Film Dosimetry System
  2. ISO/ASTM 52628, Practice for Dosimetry in Radiation Processing
  3. ANSI/AAMI/ISO 11137, Sterilization of health care products – Radiation
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