**Site Information**

|  |  |
| --- | --- |
| Company Name |  |
| Address |  |
| Department/Area |  |

**Reviewed & approved before use by:**

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Name and Title | Signature | Date |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Name and Title | Signature | Date |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Name and Title | Signature | Date |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Name and Title | Signature | Date |

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**REVISION HISTORY**

|  |  |  |
| --- | --- | --- |
| **DATE** | **CHANGE DESCRIPTION** | **REVISION** |
| 12/05/18 | Initial release. | A |
| 05/30/19 | Updated to include hardware / software and system qualification instead of just software. ECO 70446. | B |

**Purpose**

To outline the planned tasks and provide the explicit procedures and reporting forms for Installation and Operational Qualification (IQ/OQ) of the GEX DoseControl dosimetry system.

**Scope**

As written this document can be used for qualification of any off-the-shelf GEX DoseControl dosimetry system. This procedure may be modified by the end user to revise planning and protocols to incorporate any hardware that is not from GEX such as locally purchased incubators. Changes must be made at the user’s discretion although GEX will gladly consult on specific customer questions in this regard.

**Description**

The DoseControl dosimetry system is a tool for generating dosimetry reports for any commercial/industrial business performing radiation processing of products. This system software integrates the spectrophotometers (measurement instruments) to control the dosimeter measurement process to achieve data integrity and to formalize an output (results) for the user.

The system includes the following components:

* GEX DoseControl software
* Thermo GENESYS 30 and/or Evolution 220 spectrophotometer(s)
* GEX Dosimeter Holder system(s) that integrate into the sample compartment of the spectrophotometer(s)
* Incubator(s) for heat-treatment of B3 dosimeters post-irradiation, prior to measurement
* Single-use chemical dosimeters such as GEX B3 WINdose and B3 DoseStix film, FWT film or Harwell Amber and Red Perspex types.
* Optional system hardware such as barcode scanners and dosimeter handling tools.
* PC’s and Servers running Microsoft Windows® operating systems as designated by the user based on the unique system implementation.

**Requirements for Execution**

* 1. A copy of all the following documents must be available during execution and the user is expected to follow the instructions therein:
* GEX Doc #100-267, Implementation Guide for the DoseControl Dosimetry System
* GEX Doc #100-269, Spectrophotometer Performance Verification Form
* GEX Doc #100-270, GENESYS 30 Performance Verification Procedure
* GEX Doc #100-271, Evolution 220 Performance Verification Procedure
* GEX Doc #100-272, Spectrophotometer Measurement Repeatability Form
* GEX Doc #100-273, Spectrophotometer Measurement Repeatability Test Procedure
* GEX Doc #100-274, Integrated Barcode Scanner IQOQ Test Form
* GEX Doc #100-275, Integrated Barcode Scanner IQOQ Test Procedure
* GEX Doc #100-276, Heat Treatment Incubator IQOQ Test Procedure
* GEX Doc #100-277, Incubator IQOQ Test Form
	1. The user may refer to internal SOP’s if they have been drafted from the documents referenced above. A rationale for any deviation from manufacturer recommendations during the execution of the protocol herein should be documented and are the responsibility of the end-user.
	2. The user has reviewed all related documents before beginning execution. Required materials or necessary prerequisites are given in the body of the protocol or procedure referenced in the protocol.
	3. The requirements for PC’s and Servers to be used as part of the system are given in *GEX Doc# 100-266, DoseControl Software User Guide* have been previously verified.
	4. Power for all applicable hardware is compliant with requirements stated in the User Guides.
	5. PC with Adobe Acrobat Reader, Microsoft Word, and Excel or equivalent is required to open all the applicable documents and forms referenced herein.

**Execution Instructions**

1. Refer to the documents listed above for detailed information regarding terms and concepts used in this Plan and Protocol document.
2. Execute each step of a qualificationTest Case in accordance with the instructions. Do not skip a step. Each step should be completed, and results recorded directly into this document or in the forms referenced herein.
3. Mark the form with a ‘N/A’ for any steps or test cases that are not applicable to the site being qualified. Do not leave fields blank.
4. Capture screenshots as required and collect printouts during each step and test case as evidence.
	1. The protocol will note when the user should be collecting evidence.
	2. Hint: use the MS Windows ‘Snipping Tool’ or equivalent screen capture tool.
	3. Label each screenshot appropriately with the test case number and step identification.
	4. All evidence pages must be signed. Ensure the signature and date of the person that created the evidence is clearly marked on each portion of the evidence.
5. Each test case contains a formal area for including comments as needed during execution. If additional space is required, refer to an attachment in this comment field and attach the detailed comments.
6. Each section contains a formal box for defining the number of pages that are attached as evidence. Include the pages of any referenced procedures that are executed in the summation of the number of pages being attached. Then attach all pages of evidence and all procedures referenced in the test case.

**Dispositioning a Test Case**

1. Any incomplete steps shall constitute a failure of a test case.
2. A step is judged to pass if the actual result matches the expected result, and a step fails if the actual result does not match the expected result.
3. A test case is judged to pass if all tested steps in the test case pass and a test case is judged to fail if one or more steps fail.

**Test Case Failure**

1. If a step or test case is judged to fail, sometimes the subsequent steps or test cases cannot be completed. Document the failure and then make efforts to fix the cause of failure and repeat testing. Include both failed and passing evidence before moving to the next test case.
2. IQ sections must be completed before relevant OQ sections. Users may proceed with other test cases if they can justify that the failure will not cause failure of additional steps or test cases.
	1. For example, failure of hardware IQ doesn’t preclude the user from executing software IQ. Failure of software IQ will preclude software OQ from execution until the IQ is successful.
3. Please contact GEX Customer Server at cs@gexcorp.com for assistance with making determinations during any stage of execution.

**Review and Approval**

1. Upon completion of the execution, review the results of all steps within the test case for completeness and accuracy. Then, mark the appropriate test case disposition, sign and date.
2. A review is required and may be performed after completion of each test case or the entire protocol.
3. The user is encouraged to perform a subsequent PQ validation. For more information refer to *GEX Doc #100-267, Implementation Guide for the DoseControl Dosimetry System*.

**Maintaining the Qualified State**

1. Software
* The user should repeat Test Cases #3 each time the software is installed on a new PC.
* Repeat Test Case #4, steps 9-10, each time a spectrophotometer is added or moved.
1. Hardware
* The equipment must be maintained in accordance with the manufacturer recommendations, otherwise the qualification may be voided.
* All instrumentation that is calibrated must be recalibrated on a specified frequency, otherwise the qualification may be voided.
* The user should repeat applicable test cases after any parts replacement or adjustment of settings.

**DoseControl Software Configuration Plan**

**IMPORTANT:** Complete this section before you begin DoseControl software configuration.

**Procedure:** Complete the requested information or mark the answer(s) that apply.

1. **SETUP - SYSTEM CONFIGURATION**

***Reference:*** *DoseControl Software User Guide (GEX Doc #100-266), Section 1*

* 1. **Client Report Service**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Empty (no integration)** |  | **GEX (DoseControl will be integrated with another electronic system)** |

* 1. **Sign-In Manager:**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Basic**  |  | **MSSQL (Onboard)** |  | **LDAP (Active Directory)** | X | **Explicit LDAP (Active Directory)** |

* 1. **Database Location:**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **PC (SQL Express)** | X | **Local Server** |  | **Off-Site Server** |  | **Cloud Server** |

* 1. **User Management (roles and permissions):**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name** | **Username** | **System Admin** | **Application Admin** | **Technician** | **Technician Permissions**  |
| **Edit Thickness** | **Edit ID’s** | **Reread** |
| Example Smith | 12345 | X | X | X | X | X |  |
| Example Sakamura | 12346 |  | X |  |  |  | X |
| Example Bjorkman | 12347 |  | X | X |  | X | X |
|  |  |  |  |  |  |  |  |

1. **SETTINGS – DOSIMETRY CONFIGURATION**

***Reference:*** *DoseControl Software User Guide (GEX Doc #100-266), Section 2*

* 1. **Pathways**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **#** | **Pathway ID** | **Description** | **Reference ID** | **External ID** | **Produces Report (Always No)** | **Default** |
| 1 | Example Ebeam 1 | EB1 | EB1 | EB1 | No |  |
| 2 | Example Ebeam 2 | EB2 | EB2 | EB2 | No | X |
| 3 |  |  |  |  |  |  |

* 1. **Dosimeter Types**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **#** | **Dosimeter Identifier** | **Manufacturer** | **Spectral Bandwidth** | **Uses Micrometer (Yes/No)** | **Edit Thickness (Yes/No)** |
| 1 | Example B3 | GEX Corporation | Fiber | No | Yes |
| 2 |  |  |  |  |  |

* 1. **Batches**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **#** | **Batch Identifier** | **External ID** | **Type** | **Thickness (mm)** | **Description** | **Default** |
| 1 | Example DA | DA | B3 | 0.0179 | DA 0.0179 | X |
| 2 |  |  |  |  |  |  |

* 1. **Readers**

*Note: Please use the model of spectrophotometer for “Make” (example: GENESYS30), and the manufacturer name for “Model” (example: Thermo).*

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **#** | **Make** | **Spectrophotometer ID**  | **Min Reading Value** | **Max Reading Value** | **Serial Number** | **Model Info** | **Client Machine Name** | **Zero (min)** | **COM Port** | **Baud Rate** |
| 1 | G30 | Example Spec 1 | 0 | 2.5 | 9A1WXXXXXX | Thermo | PC-1 | 5 | 1 | 9600 |
| 2 | Evo220 | Example Spec 2 | 0 | 4 | 5A2TXXXXXX | Thermo | PC-2 | 5 | 2 | 115200 |
| 3 |  |  |  |  |  |  |  |  |  |  |

* 1. **Calibrations**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **#** | **Calibration Name** | **Calibration ID** | **Pathway ID** | **Batch ID** | **Reader ID** |
| 1 | Example CAL 1 | 3601-A | Ebeam 1 | DA | Spec 1 |
| 2 | Example CAL 2 | 3601-B | Ebeam 1 | DA | Spec 2 |
| 3 |  |  |  |  |  |

* 1. **Miscellaneous**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. **User lock out managed by DoseControl? (Yes/No)**
 | Yes | **If yes, what Idle Time (minutes)** | 5 |
| 1. **Manual mode allowed to be enabled for Tech role? (Yes/No)**
 | No |
| 1. **Zero button allowed on measure screen for Tech role? (Yes/No)**
 | Yes |
| 1. **Is report search filtered by pathway? (Yes/No)**
 | No |

* 1. **Re-reads**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Default (no configuration)** | X | **Configure as specified below** |
|  |
| **Reason #** | **Reason** | **Strategy (Simple or Statistical)** |
| 1 | Check the dose | Simple |
| 2 | Out of Spec | Statistical |
| 3 |  |  |

Note: Complete one row for each reason above

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reason #** | **Limit # of Rereads****(Yes or No)** | **Number Allowed (if Yes)** | **Different User Required****(yes or no)** | **Reread Role Required****(yes or no)** | **Comment Required****(yes or no)** |
| 1 | No | N/A | No | No | Yes |
| 2 | Yes | 3 | No | Yes | Yes |
| 3 |  |  |  |  |  |

Note: Complete rows below only for Reasons that use statistical reread strategy. Do not enter a percentage. For 2% enter “0.02”.

|  |  |  |
| --- | --- | --- |
| **Reason #** | **Include Original Measurement** | **Maximum CV** |
| 2 | No | 0.02 |
|  |  |  |

* 1. **Report Headers**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **#** | **Report Header Name** | **Default** | **PDF Exporter** | **Report ID Name Structure** |
| 1 | Example Routine Dosimetry | X | Custom | PXXXXXX |
| 2 | Example Beam Testing |  | Standard 1 Pack | TEST-XXXXXX |
| 3 | Example Dose Map |  | Standard 1 Pack | MAP-XXXXXX |
| 4 |  |  |  |  |

|  |  |
| --- | --- |
| **Header No.:** | **1** |
| **Name:** | **Example Routine Dosimetry** |
| **Sequence** | **Field Label** | **Field Type** | **Description** |
| 1 | Customer | Text | The customer related to the work order. |
| 2 | Product No. | Text | The product number irradiated. |
| 3 | PCN | Text | The unique ID of the irradiation process in which the dosimeters were irradiated. |
| 4 | PSN | Text | The processing specification for the product |
| 5 | Process Date | Date | Date the irradiation of the dosimeters occurred. |
| 6 | Min Dose Specification (kGy) | Decimal | The minimum required dose for the product. |
| 7 | Max Dose Specification (kGy) | Decimal | The minimum acceptable dose for the product. |

|  |  |
| --- | --- |
| **Header No.:** | **2** |
| **Name:** | **Example Beam Testing** |
| **Sequence** | **Field Label** | **Field Type** | **Description** |
| 1 | PCN | Text | The unique ID of the irradiation process in which the dosimeters were irradiated. |
| 2 | PSN | Text | The processing specification for the product |
| 3 | Process Date | Date | Date the irradiation of the dosimeters occurred. |
| 4 | Beam Power, kW | Number | The beam power it was processed at |
| 5 | Conveyor Speed, cm/min | Decimal | The readback of the conveyor speed |
| 6 | Beam Current | Decimal | The beam current setpoint |
| 7 | Pulse Rate | Number | The frequency of the beam pulse |

|  |  |
| --- | --- |
| **Header No.:** | **3** |
| **Name:** | **Example Dose Map** |
| **Sequence** | **Field Label** | **Field Type** | **Description** |
| 1 | Customer | Text | The customer related to the work order |
| 2 | Product No. | Text | The product number irradiated |
| 3 | PCN | Text | The unique ID of the irradiation process in which the dosimeters were irradiated. |
| 4 | PSN | Text | The processing specification related to the product |
| 5 | Process Date | Date | Date the irradiation of the dosimeters occurred. |

|  |
| --- |
| **Authorization of Software Configuration Plan**Review the information for completeness and accuracy. Then sign and date below to approve this information: |
|  |  |  |
| Completed By - Name and Title | Completed By - Signature | Date |
|  |  |  |
| Approved By - Name and Title | Approved By - Signature | Date |

**DoseControl System Output Plan**

**IMPORTANT:** Complete this section before you begin DoseControl software configuration.

1. **OUTPUTS LIST**

***Reference:*** *DoseControl Software User Guide (GEX Doc #100-266), Section 3.5 and 3.6.*

* 1. Enter a name for each report that is required for output and specify the output type for each report:

|  |  |  |
| --- | --- | --- |
| **#** | **Output (Report) Name** | **Output Type** |
| 1 | Example Routine Dosimetry Report | PDF |
| 2 | Example Beam Energy Test Report | Excel |
| 3 | Example Beam Scan Width Report | Excel |
| 4 |  |  |

* 1. Below, list the required data that must be on each report specified in 3.2 above. Attach an example layout if possible.

**REPORT # 1**

|  |  |
| --- | --- |
| **Report Header Name:** | **Routine Dosimetry Report** |
| **Sequence** | **Field (Column) Label** | **Description** |
| 1 | Customer | The customer related to the work order |
| 2 | Product | The product number irradiated |
| 3 | PCN | The unique ID of the irradiation process in which the dosimeters were irradiated. |
| 4 | PSN | The processing specification related to the product |
| 5 | Process Date | Date the irradiation of the dosimeters occurred. |
| 6 | Dosimetry Technician | The initials of the dosimetry technician |
| 7 | Dosimetry Date | The date the dosimeters were measured |
| 8 | Instrument | The equipment ID of the spectrophotometer |
| 9 | Dosimeter Batch | The batch ID of the dosimeters used |
| 10 | Dosimeter Calibration ID | The calibration ID from which the doses are derived |
| 11 | Min. Dose in Process (kGy) | The minimum dose received from all dosimeters in the report |
| 12 | Max. Dose in Process (kGy) | The maximum dose received from all dosimeters in the report |
| 13 | Dosimeter ID | The unique ID of the dosimeter |
| 14 | Location | The dosimeter location in the run |
| 15 | Absorbance (A) | The measured absorbance of the dosimeter |
| 16 | Thickness (t) | The average thickness for the dosimeter batch used |
| 17 | Response (A/t) | The measured absorbance divided by the average thickness |
| 18 | Dose (kGy) | The dose for the dosimeter calculated from the response using the calibration ID specified. |

**REPORT # 2**

|  |  |
| --- | --- |
| **Report Header Name:** | **Beam Energy Test Report** |
| **Sequence** | **Field (Column) Label** | **Description** |
| 1 | PCN | The unique ID of the irradiation process in which the dosimeters were irradiated. |
| 2 | PSN | The processing specification related to the product |
| 3 | Beam Power, kW | The beam power it was processed at |
| 4 | Conveyor Speed, cm/min | The readback of the conveyor speed |
| 5 | Beam Current | The beam current setpoint |
| 6 | Pulse Rate | The frequency of the beam pulse |
| 7 | Process Date | Date the irradiation of the dosimeters occurred. |
| 8 | Dosimetry Technician | The initials of the dosimetry technician |
| 9 | Dosimetry Date | The date the dosimeters were measured |
| 10 | Instrument | The equipment ID of the spectrophotometer |
| 11 | Dosimeter Batch | The batch ID of the dosimeters used |
| 12 | Dosimeter Calibration ID | The calibration ID from which the doses are derived |
| 13 | Dosimeter ID | The unique ID of the dosimeter |
| 14 | Location | The dosimeter location in the run |
| 15 | Absorbance (A) | The measured absorbance of the dosimeter |
| 16 | Thickness (t) | The average thickness for the dosimeter batch used |
| 17 | Response (A/t) | The measured absorbance divided by the average thickness |
| 18 | Dose (kGy) | The dose for the dosimeter calculated from the response using the calibration ID specified. |
| 19 | D50 | Calculated 50% of the maximum dose |
| 20 | R50 | Calculated 50% of the penetration range |
| 21 | Ea | Average beam energy per ASTM 51649 formula 4.7  |
| 22 | Depth Dose Graph | Data plot of the depth-dose profile |
| 23 | Slope | Slope of the line tangent to the depth dose descending slope |
| 24 | Y-Intercept | Y-intercept of the line tangent to the depth dose descending slope |

**REPORT # 3**

|  |  |
| --- | --- |
| **Report Header Name:** | **Beam Scan Width Report** |
| **Sequence** | **Field (Column) Label** | **Description** |
| 1 | PCN | The unique ID of the irradiation process in which the dosimeters were irradiated. |
| 2 | PSN | The processing specification related to the product |
| 3 | Beam Power, kW | The beam power it was processed at |
| 4 | Conveyor Speed, cm/min | The readback of the conveyor speed |
| 5 | Beam Current | The beam current setpoint |
| 6 | Pulse Rate | The frequency of the beam pulse |
| 7 | Process Date | Date the irradiation of the dosimeters occurred. |
| 8 | Dosimetry Technician | The initials of the dosimetry technician |
| 9 | Dosimetry Date | The date the dosimeters were measured |
| 10 | Instrument | The equipment ID of the spectrophotometer |
| 11 | Dosimeter Batch | The batch ID of the dosimeters used |
| 12 | Dosimeter Calibration ID | The calibration ID from which the doses are derived |
| 13 | Dosimeter ID | The unique ID of the dosimeter |
| 14 | Location | The dosimeter location in the run |
| 15 | Absorbance (A) | The measured absorbance of the dosimeter |
| 16 | Thickness (t) | The average thickness for the dosimeter batch used |
| 17 | Response (A/t) | The measured absorbance divided by the average thickness |
| 18 | Dose (kGy) | The dose for the dosimeter calculated from the response using the calibration ID specified. |
| 19 | Average (kGy) | The average dose for the center 1/3 of the scan width |
| 20 | Std. Dev. | The Standard Deviation for the center 1/3 of the scan width |
| 21 | CV (%) | The CV for the center 1/3 of the scan width |
| 22 | Graph | Data plot of the scan width |

|  |
| --- |
| **Authorization of Software Report Output Plan**Review the information for completeness and accuracy. Then sign and date below to approve this information: |
|  |  |  |
| Completed By - Name and Title | Completed By - Signature | Date |
|  |  |  |
| Approved By - Name and Title | Approved By - Signature | Date |

|  |  |
| --- | --- |
| **Test Case #1 – System IQ Checklist** | **Page 1 of 2** |

***Procedure:*** Review the following questions for each item in the table and record any deviations:

* + 1. Enter the GEX part number, description, and quantity that is present and accounted for during this qualification.
		2. The equipment is received in operable condition, undamaged, and instruments can be powered on without errors; Pass or Fail?
		3. A user manual or equivalent product information is delivered with the item or downloaded for the item from the supplier website; yes or no?
		4. A certificate of compliance or analysis is provided with the item; yes or no?
		5. The item is supplied with a calibration certificate; yes or no?
		6. Is calibration of this item required per internal standard operating procedure; yes or no?

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **GEX Part #** | **Part Description** | **Qty** | **Condition** | **Manual** | **COC/COA** | **Cal. Cert**  | **Cal Req.**  |
| P4400-US  | GENESYS 30 Spectrophotometer  | 2 | Pass | Yes | Yes | No | Yes |
| P4220  | Spectrophotometer Calibration Standard Set. | 2 | Pass | Yes | No | Yes | No |
| P4405  | Dosimeter Holder base system for GENESYS 30  | 2 | Pass | Yes | No | No | No |
| P4410  | DoseStix Dosimeter Holder for GENESYS 30 | 2 | Pass | Yes | No | No | No |
| P4420  | WINdose Dosimeter Holder for GENESYS 30 | 2 | Pass | Yes | No | No | No |
| D2100  | DoseControl Software | 1 | Pass | Yes | No | No | No |
| P4900-US  | Micro-incubator (with separate digital timer) | 1 | Pass | Yes | No | No | No |
| P4850-US  | Forced Air Incubator (with separate digital timer) | 1 | Pass | Yes | No | No | No |
| P4901  | Digital Thermometer  | 1 | Pass | Yes | No | Yes | Yes |
| P4902  | B3 Dosimeter Package Probe (T-Type Thermocouple)  | 1 | Pass | Yes | No | No | No |
| P8006 | Dosimeter Handling Forceps - Curved | 2 | Pass | No | No | No | No |
| P8005  | PENvac Dosimeter Handling Tool  | 2 | Pass | Yes | No | No | No |
| P4701 | Risø 2-Piece Aluminum Energy Measurement Wedge  | 2 | Pass | Yes | Yes | No | Yes |
| **Test Case #1 – System IQ Checklist** | **Page 2 of 2** |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| B3110  | 10MeV Energy Card - B3WINdose Radiochromic Film Dosimeter Array  | 10 | Pass | Yes | Yes | No | Yes |
| B3001  | 1 per pouch B3WINdose Radiochromic Film Dosimeters  | 2 | Pass | Yes | Yes | No | Yes |
| **Comments:**  |  |
| (It is the judgement of the person completing this Test Case that all items are in working condition and all documentation required in present to allow testing to continue to the next Test Case.)**Result of Test Case:** | [ ]  Pass [ ]  Fail |
|  |  |  |
| Completed By - Print Name | Completed By - Tester Signature | Date |
|  |  |  |
| Reviewed By - Print Name | Reviewed By - Signature | Date |

|  |  |
| --- | --- |
| **Test Case #2 – Dosimeters IQ** | **Page 1 of 2** |

***Objective:*** Verification that dosimeters are received with the information that will be required before their use (operation).

|  |  |  |  |
| --- | --- | --- | --- |
| **Dosimeters Batch ID:**  |  | **Shipment Receipt Date:** |  |
|  **Step**  | **Instruction** | **Expected Result** | **Actual Result** | **Result of Step** |
|  | Complete for all GEX B3 Dosimeter shipments. For other dosimeters mark test case result “N/A”.1. Locate all irreversible temperature labels or data logging of temperature that were included in the shipment.
2. Attach to a sheet of paper with shipment date labeled on the paper.
3. Make a color scan of all labels and ***attach as evidence.***
 | The maximum temperature is equal to or less than 45°C. | The Maximum temperature was \_\_\_\_\_\_\_\_\_\_\_\_\_°C | [ ]  Pass[ ]  Fail[ ]  N/A |
|  | Review the Certificate(s) of Compliance accompanying the dosimeters and compare the certificate(s) to the actual product. Make copies of the certificate(s) of compliance and ***attach as evidence.*** | 1. The boxes received are all accounted for on the certificate(s)
2. There is no discrepancy of any information about the dosimeters on the box labels versus the certificate(s).
 |  | [ ]  Pass[ ]  Fail |
|  | 1. Examine each box of dosimeters to find a labeled expiration date.
2. If no label of expiration date exists, create a label for each box showing the expiration date. Refer to the certificate of compliance and product literature for the dosimeters to determine the expiration date if no label exists from the vendor.
 | The expiration date is labeled on every box of dosimeters. |  | [ ]  Pass[ ]  Fail |
| **Comments:**  |  |

|  |  |
| --- | --- |
| **Test Case #2 – Dosimeters IQ** | **Page 2 of 2** |

|  |  |  |  |
| --- | --- | --- | --- |
| **No. of Pages of Evidence Attached:**  |  | **Result of Test Case:** | [ ]  Pass [ ]  Fail |
|  |  |  |
| Completed By - Print Name | Completed By - Tester Signature | Date |
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| --- | --- |
| **Test Case #3 – Software IQ** | **Page 1 of 1** |

***Complete one copy for each PC workstation.***

**Objective –** To verify that DoseControl and other required software are installed and operable on the specified PC workstation.

|  |  |
| --- | --- |
| **Windows PC Name:** |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  **Step**  | **Instruction** | **Expected Result** | **Actual Result** | **Result of Step** |
|  | Log into the MS Windows PC with a valid username and password.  | The user is logged into the PC. |  | [ ]  Pass[ ]  Fail |
|  | Open the DoseControl Application by the GEX icon and login to the software with a valid username and password with Application Administrator privilege. | The user is logged into DoseControl. |  | [ ]  Pass[ ]  Fail |
|  | Record the version ID from the bottom right corner of the application in the space below:1. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 | The version ID is recorded.***(Attach screenshot as evidence showing PC name and DoseControl Software Version.)*** |  | [ ]  Pass[ ]  Fail |
|  | Locate and open any PDF file to verify that Adobe Reader (or equivalent) is installed on the PC. | Adobe Reader or equivalent is installed on the PC. |  | [ ]  Pass[ ]  Fail |
|  | Locate and open any MS Excel file to verify that MS Excel is installed on the PC. | MS Excel is installed on the PC. |  | [ ]  Pass[ ]  Fail |
| **Comments:**  |  |
| **No. of Pages of Evidence Attached:**  |  | **Result of Test Case:** | [ ]  Pass [ ]  Fail |
|  |  |  |
| Completed By - Print Name | Completed By - Tester Signature | Date |
|  |  |  |
| Reviewed By - Print Name | Reviewed By - Signature | Date |
| **Test Case #4 – Software OQ** | **Page 1 of 2** |

**Complete one copy for each shared database installation of DoseControl (not required on each PC in a multiple PC system).**

**Objective –** To verify that DoseControl is configured according to the specifications in the Software Configuration Plan.

|  |  |  |  |
| --- | --- | --- | --- |
| **Windows PC Name:** |  | **Spectrophotometer S/N:** |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  **Step**  | **Instruction** | **Expected Result** | **Actual Result** | **Result of Step** |
|  | a. Login to the software as Application Administrator. b. Expand the Pathways configuration section of the Setup Screen. | The software is configured according to the Configuration Plan section 2.1.***Attach screenshot as evidence.*** |  | [ ]  Pass[ ]  Fail |
|  | Expand the Dosimeter Types configuration section of the Setup Screen. | The software is configured according to the Configuration Plan section 2.2.***Attach screenshot as evidence.*** |  | [ ]  Pass[ ]  Fail |
|  | Expand the Batches configuration section of the Setup Screen. | The software is configured according to the Configuration Plan section 2.3.***Attach screenshot as evidence.*** |  | [ ]  Pass[ ]  Fail |
|  | Expand the Readers configuration section of the Setup Screen.  | The software is configured according to the Configuration Plan section 2.4.***Attach screenshot as evidence.*** |  | [ ]  Pass[ ]  Fail |
|  | Open the Calibrations configuration section of the Setup Screen.  | The software is configured according to the Configuration Plan section 2.5.***Attach screenshot as evidence.*** |  | [ ]  Pass[ ]  Fail |
|  | Expand the Miscellaneous configuration section of the Setup Screen.  | The software is configured according to the Configuration Plan section 2.6.***Attach screenshot as evidence.*** |  | [ ]  Pass[ ]  Fail |
|  | Open the Rereads configuration section of the Setup Screen. | The software is configured according to the Configuration Plan section 2.7.***Attach screenshot as evidence.*** |  | [ ]  Pass[ ]  Fail |

*Continued on next page*

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| **Test Case #4 – Software OQ** | **Page 2 of 2** |

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| --- | --- | --- | --- | --- |
|  | Expand the Report Headers configuration section of the Setup Screen.  | The software is configured according to the Configuration Plan section 2.8.***Attach screenshot as evidence.*** |  | [ ]  Pass[ ]  Fail |
|  | 1. Create a new report using any available irradiation pathway and batch that has an active calibration for this spectrophotometer (reader).
2. The message appears asking to zero the instrument.
3. Ensure the correct holder is installed for the irradiated dosimeter you will need to measure.
4. Remove any samples from the spectrophotometer sample compartment
5. Press ‘OK’.

***Reference*** *GEX Doc# 100-266 DoseControl User Guide Section 3.2* | The “Status” of the instrument on the screen is “Ready” in green font. |  | [ ]  Pass[ ]  Fail |
|  | 1. Enter a unique dosimeter ID number.
2. Insert an irradiated dosimeter into the dosimeter holder in the spectrophotometer.
3. Press the ‘Measure’ button.
4. Repeat for 2 more dosimeters for a total of 3 measurements.

***Reference*** *GEX Doc# 100-266 DoseControl User Guide Section 3.3* | An absorbance value registers in the software for each of the 3 dosimeters that were measured.***(Attach screenshot of DoseControl Measure screen as evidence.)*** |  | [ ]  Pass[ ]  Fail |
| **Comments:**  |  |
| **No. of Pages of Evidence Attached:**  |  | **Result of Test Case:** | [ ]  Pass [ ]  Fail |
|  |  |  |
| Completed By - Print Name | Completed By - Tester Signature | Date |
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| Reviewed By - Print Name | Reviewed By - Signature | Date |
| **Test Case #5 – Hardware OQ - Part 1: Spectrophotometer** | **Page 1 of 1** |

***Complete one copy for each spectrophotometer.***

***Objective:*** Verification of wavelength and photometric accuracy of a spectrophotometer, repeatability of measurements, and integration of a barcode scanner.

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| --- | --- | --- | --- |
| **Spectrophotometer Model:** |  | **Spectrophotometer S/N:** |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  **Step**  | **Instruction** | **Expected Result** | **Actual Result** | **Result of Step** |
|  | Execute only one of the following procedures, as applicable for the spectrophotometer model type listed above:1. *GEX Doc# 100-270, GENESYS 30 Performance Verification Procedure*

**OR**1. *GEX Doc# 100-271, Evolution 220 Spectrophotometer Performance Verification Procedure*
 | All tests meet the acceptance criteria and display “Pass” as applicable on the test form, *GEX Doc# 100-269, Spectrophotometer Performance Verification Form****(Attach printed copy of completed test form as evidence.)*** |  | [ ]  Pass[ ]  Fail |
|  | Execute *GEX Doc# 100-273, Spectrophotometer Measurement Repeatability Test Procedure.* | All tests “Pass” as applicable on the test form, *GEX Doc#100-272, Spectrophotometer Measurement Repeatability Form*.***(Attach printed copy of completed test form as evidence.)*** |  | [ ]  Pass[ ]  Fail |
|  | Execute *GEX Doc# 100-275, Integrated Barcode Scanner IQ/OQ Test Procedure*. | All tests “Pass” on the test form, *GEX Doc# 100-274, Integrated Barcode Scanner IQOQ Test Form.****(Attach printed copy of completed test form as evidence.)*** |  | [ ]  Pass[ ]  Fail[ ]  N/A |
| **Comments:**  |  |
| **No. of Pages of Evidence Attached:**  |  | **Result of Test Case:** | [ ]  Pass [ ]  Fail |
|  |  |  |
| Completed By - Print Name | Completed By - Tester Signature | Date |
|  |  |  |
| Reviewed By - Print Name | Reviewed By - Signature | Date |
| **Test Case #6 – Hardware OQ - Part 2: Incubator** | **Page 1 of 1** |

***Complete one copy for each incubator.***

***Objective:*** Verification of the calibration of the temperature controller and the temperature uniformity of an incubator for heat-treatment of B3 dosimeters.

***Rationale:***

* + - 1. Calibration Verification: The incubators are not supplied with a certificate of calibration for the temperature controllers. Calibration verification of the temperature controllers using a calibrated digital thermometer is required until such time as the controller is calibrated.
			2. Performance Verification: GEX recommends that the minimum temperature should not be less than 58.0 °C and the maximum should not exceed 62.0 °C to establish this heat treatment process with the least amount of risk. Temperatures less than 58.0 °C may not be sufficient to fully treat B3 dosimeters in the time specified that will be qualified in the PQ phase for this process. Temperatures more than 62.0 °C will increase the risk of damage to the B3 dosimeters during the treatment, potentially impacting dosimeter performance.

|  |  |  |  |
| --- | --- | --- | --- |
| **Incubator Model:** |  | **Incubator S/N:** |  |

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|  **Step**  | **Instruction** | **Expected Result** | **Actual Result** | **Result of Step** |
|  | Execute *GEX Doc# 100-276 Incubator OQ Qualification Procedure.* | All tests “Pass” as applicable on the test form, *GEX Doc# 100-277 Incubator OQ Qualification Form.****(Attach printed copy of completed test form as evidence.)*** |  | [ ]  Pass[ ]  Fail[ ]  N/A |
| **Comments:**  |  |
| **No. of Pages of Evidence Attached:**  |  | **Result of Test Case:** | [ ]  Pass [ ]  Fail [ ]  N/A |
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| Completed By - Print Name | Completed By - Tester Signature | Date |
|  |  |  |
| Reviewed By - Print Name | Reviewed By - Signature | Date |
| **Test Case #7 – System OQ** | **Page 1 of 1** |

***Complete one copy for each dosimetry system workstation.***

**Objective –** To verify that the system produces the required outputs. Complete once for each PC workstation.

**Reference:** *GEX Doc #100-266, DoseControl Software User Guide*, Section 3.

|  |  |
| --- | --- |
| **Windows PC Name:** |  |

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| --- | --- | --- | --- | --- |
|  **Step**  | **Instruction** | **Expected Result** | **Actual Result** | **Result of Step** |
|  | 1. Following the instructions for use for the DoseControl System, create one example of each of the output dosimetry reports specified in the *Software Output Plan*.
2. Where an integrated barcode scanner will be utilized, it should be activated and tested, if applicable.
3. Use the appropriate Report Header when creating the report and include a minimum of 3 measured dosimeter samples.
4. Process the report upon completion.
5. Output the specified type of report and print it or save and print, as applicable.
 | The report can be output from the system.***(Print and attach DoseControl PDF or MS Excel Report as evidence.)*** |  | [ ]  Pass[ ]  Fail |
| **Comments:**  |  |
| **No. of Pages of Evidence Attached:**  |  | **Result of Test Case:** | [ ]  Pass [ ]  Fail |
|  |  |  |
| Completed By - Print Name | Completed By - Tester Signature | Date |
|  |  |  |
| Reviewed By - Print Name | Reviewed By - Signature | Date |