1.0 PURPOSE

Provides instruction for qualifying an incubator, and to provide evidence that the accuracy of the temperature controller, the temperature uniformity of the device, and the temperature set point generate results within expected limits for use in the heat-treatment of GEX B3 dosimeters.

2.0 SCOPE

Any incubator to be used for the heat-treatment of GEX B3 dosimeters. The procedure provides instructions for qualifying the incubator make/models sold by GEX: Product # P4900 Microincubator, P4850/P4855 Forced Air Incubator.

NOTE: Users may modify acceptance criteria for models not listed at their discretion.

3.0 FREQUENCY

3.1 As needed for initial qualification of the unit for use in heat treatment of B3 dosimeters.

3.2 As needed for requalification of the incubator after any major servicing of the heating element.

4.0 MATERIALS

4.1 Incubator.

4.2 Timer.

4.3 P4901 Digital Thermometer (or equivalent) calibrated and included male/male thermocouple wire.

4.4 P4902 B3 Dosimeter Package Probe (or equivalent).

4.5 Copy paper for the purpose of covering the shelf.

4.6 Approximately 40 pouched dosimeters (or equivalent) for the purpose of representing a full incubator.

4.7 Masking tape (or equivalent)

5.0 PREREQUISITES

5.1 The user has the necessary documents (see Section 8 – Associated Documents) that contain the installation and usage instructions for the incubators or has written standard operating procedures to use during this test.

5.1.1 *GEX Doc# 100-277, Incubator IQOQ Test Form* in MS Excel or equivalent

5.2 The equipment has been installed in accordance with the documents referred to in Section 5.1.

5.3 The P4901 and P4902 thermometer devices (or equivalent) have been received in working condition and are calibrated.

5.4 The incubator has been turned on and has been operating for a minimum of 4 hours (forced-air incubator P4850/P4855) or 2 hours (Micro-incubator P4900).

6.0 OVERVIEW

6.1 **Calibration Verification**:

6.1.1 Purpose: To verify the accuracy of the incubator's temperature controller display temperature using a calibrated digital thermometer.

6.1.2 Rationale: The incubator's display temperature must accurately reflect the actual temperature of the incubator.

6.1.3 The end-user must verify the calibration of the temperature controller before using the incubator for the heat treatment of B3 dosimeters.

6.1.3.1 The micro-incubators (P4900) are not supplied with a Certificate of Calibration for temperature controllers.

6.1.3.2 The forced-air incubator (P4850/P4855) comes with a calibration certification from the manufacturer, but the user must verify the calibration of the temperature controller regardless.

6.1.4 Calibration verification of the temperature controllers must be completed using a calibrated digital thermometer.

6.1.5 Calibration verification test acceptance criteria:

6.1.5.1 Forced-air box-style incubator: Measured temperature must be ±0.5°C from the Displayed Temperature.

6.1.5.2 Micro-incubator: Measured Temperature must be ±0.2°C from the Displayed Temperature.

6.2 **Performance Verification**:

6.2.1 Purpose: To verify that the minimum measured temperature and maximum measured temperature in the incubator are within the expected temperature range limits.

6.2.2 Rationale:

6.2.2.1 A more uniform heat-treatment process provides an overall lower measurement uncertainty for B3 dosimetry.

6.2.2.2 The maximum temperature for heat-treatment of B3 dosimeters should not exceed 62.0 °C to avoid an increased risk of damage to the films in the treatment process. Pouched dosimeters are especially vulnerable to damage at temperatures over 62.0C.

6.2.2.3 The temperature measurement points are placed at different positions within the incubator that represent or mimic a routine use of the incubator for the purpose of B3 dosimeter heat treatment.

6.2.2.4 See *GEX Doc 100-201 Post Irradiation Heat Treatment of GEX B3 Dosimeter Products technical report* for guidance regarding set temperatures for different types of incubators and B3 dosimeter formats.

6.2.3 Performance verification - temperature uniformity test acceptance criteria:

6.2.3.1 Forced-air box-style incubator: +/- 2.0C from the Set Point.

6.2.3.2 Micro-incubator: +/- 2.0C from the Set Point.

6.2.4 Performance verification - temperature maximum test acceptance criteria:

6.2.4.1 The maximum temperature for any incubator should not exceed 62.0 °C for all measurements.

7.0 PROCEDURE

7.1 Open *GEX Doc# 100-277, Incubator IQOQ Test Form* in MS Excel or equivalent. Use the (a) tab to record the measurements for the Forced-Air Incubator (P4850/P4855) incubator test and the (b) tab to record the Micro-incubator (P4900) measurements.

7.2 Enter the header information located at the top of the Test Form. This section references the equipment identifiers, the date of the test, and the environmental conditions during the test.

7.3 Follow the instructions below, and complete one Test Form for each incubator.

7.4 **P4850/P4855 Forced Air Incubator (or equivalent incubator)**

7.4.1 **Calibration Verification Test**:

7.4.1.1 Record the incubator's temperature controller '**Set Point Temp'** in the 'Calibration Verification Test' section of Test Form 100-277(a). NOTE: The recommended set point for the P4850/P4855 forced-air incubator is 60.0°C, but the end-user can choose the set point based on guidance from *GEX Doc# 100-201, Post Irradiation Heat Treatment of GEX B3 Dosimeter Products Technical Report.*

7.4.1.2 Use a calibrated thermometer and probe for this step. Insert the male T-Type thermocouple of the *P4902 B3 Dosimeter Package Probe (or equivalent)* into the female T-Type port on the *P4901 Digital Thermometer (or equivalent).* Turn on the power to the thermometer using the switch on the side of the device.

7.4.1.3 Open the door of the incubator and place the P4902 B3 Dosimeter Package Probe (or equivalent) as close to the internal heat sensor of the incubator as possible without touching the heat sensor.

Figure 1: The P4902 probe is placed as close as possible to the incubator's heat sensor, without touching the sensor. The probe is secured into place using masking tape.

7.4.1.4 Secure the end of the P4902 B3 Dosimeter Package Probe (or equivalent) to the body of incubator (ceiling, floor, or walls) using tape or other means. CAUTION: Do not attach the thermometer probe directly to the incubator's heat sensor. See image above.

7.4.1.5 Carefully feed the wire of the P4902 Probe (or equivalent) out of the port on the side of the incubator. See image below. Close the incubator's glass door and outer doors securely.

Figure 2: P4902 Probe wire end placed through the incubator port.

7.4.1.6 Set the timer to count down and let the P4902 B3 Dosimeter Package Probe dwell for **15 minutes**.

7.4.1.7 Record the temperature displayed on the incubator's temperature controller into the cell for '**Displayed Temp'** in the 'Calibration Verification Test' section of Test Form 100-277(a).

7.4.1.8 Record the temperature shown on the P4901 digital thermometer (or equivalent) display into the cell for '**Measured Temp'** in the 'Calibration Verification Test' section of Test Form 100-277(a).

7.4.1.9 Test acceptance criteria: Measured Temperature 'Measured Temp' must be ±0.5°C from the Displayed Temperature 'Displayed Temp'.

7.4.1.9.1 Enter PASS in 'Result Status' if the 'Measured Temp' value is ≥ Minimum Limit value and ≤ the Maximum Limit value.

7.4.1.9.2 Enter FAIL in 'Result Status' if the 'Measured Temp' value is ≤ Minimum Limit value and ≥ the Maximum Limit value.

7.4.1.10 If the test result is "FAIL" do not continue with testing.

7.4.1.10.1 Sign and date the Test Form. Follow the appropriate internal procedure for a test deviation, if applicable. (If this Procedure is used for the *GEX Document 100-280, DoseControl IQOQ Protocol for DoseControl Dosimetry System*, see the instructions in 100-280.)

7.4.1.10.2 Make the appropriate adjustments and repeat the Calibration Verification test. Adjust the offset of the temperature controller so that the incubator display temperature matches the actual measured temperature of the calibrated thermometer. Use the temperature displayed on the P4901 digital thermometer (or equivalent) as the calibrated reference temperature to determine the offset. The manufacturer user guide for the incubator will provide instructions for executing this.

7.4.1.10.2.1 Review the placement of the P4902 Probe (or equivalent). Did the probe move from the placement position? Did the tape un-stick? Is the probe close to the heat sensor?

7.4.1.10.2.2 Repeat all of Section 7.4.1 to try again.

7.4.1.10.3 If you experience repeated failure, contact GEX Customer Service support@gexcorp.com.

7.4.2 **Performance Verification Tests**:

7.4.2.1 The incubator will be tested with and without a load of dosimeters on the shelf.

7.4.2.2 The test requires placing the P4902 Probe (or equivalent) in a minimum of 5 different locations on the incubator shelf to test the uniformity of temperature.

NOTE: If your incubator has more than 1 shelf, repeat the process described in 7.5.2.2 for each additional shelf in the incubator.

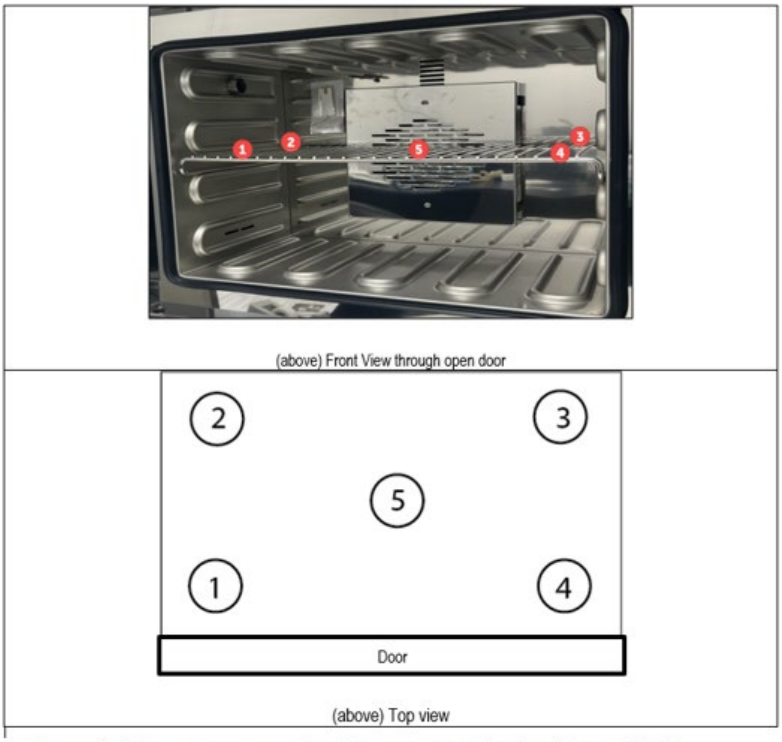

Figure 3: Temperature probe placement on the incubator shelf.

7.4.2.3 First, for the '**Empty Chamber Test'**, empty the incubator.

7.4.2.3.1 Place the P4902 Probe (or equivalent) into position on the shelf and secure with small pieces of masking tape.

7.4.2.3.2 Carefully feed the wire of the P4902 Probe (or equivalent) out of the port on the side of the incubator. Close the glass door and outer doors securely.

7.4.2.3.3 Let the P4902 Probe (or equivalent) dwell for **15 minutes**.

7.4.2.3.4 Record the temperature value in the 'Empty Chamber', Position 1, '**Measured'** cell in the 'Performance Verification Tests' section of Test Form 100-277(a).

7.4.2.3.5 Repeat the steps in 7.5.2.3.1 to 7.5.2.3.4 for each of the subsequent positions on the incubator shelf (or shelves). In Test Form 100-277(a), record the temperature measurement in the 'Empty Chamber' 'Measured' cell corresponding to its Position.

7.4.2.3.6 For all the 'Measured' temperatures at each Position, enter the Minimum measured temperature for all positions in the **'Minimum'** cell.

7.4.2.3.7 For all the 'Measured' temperatures at each Position, enter the Maximum measured temperature for all positions in the **'Maximum'** cell.

7.4.2.3.8 Test acceptance criteria: All measured temperatures must be within +/- 2.0°C from the Set Point and ≤ 62.0°C for all measurements.

7.4.2.3.8.1 Enter PASS in 'Result Status' if the 'Minimum' value and the 'Maximum' value are within +/- 2.0° C from the Set Point and the 'Maximum' value is ≤ 62.0°C.

7.4.2.3.8.2 Enter FAIL in 'Result Status' if the 'Minimum' value and the 'Maximum' value are not within +/- 2.0°C from the Set Point and the 'Maximum' value is > 62.0°C.

7.4.2.3.9 If the test result is "FAIL" do not continue with testing.

7.4.2.3.9.1 Sign and date the Test Form. Follow the appropriate internal procedure for a test deviation, if applicable. (If this Procedure is used for the *GEX Document 100-280, DoseControl IQOQ Protocol for DoseControl Dosimetry System*, see the instructions in 100-280.)

7.4.2.3.9.2 Make the appropriate adjustments and repeat the Calibration Verification test. Assess if any adjustment to the set temperature of the incubator can be made; assess if any user errors occurred previously while performing steps in 7.5.2.3.

7.4.2.3.9.3 Repeat the Empty Chamber Test (see 7.5.2.3).

7.4.2.3.9.4 If you experience repeated failure, contact GEX Customer Service support@gexcorp.com.

7.4.2.4 Next, perform the '**Loaded Chamber Test**'.

7.4.2.4.1 Purpose: The loaded incubator test is to verify the temperature uniformity within the incubator when there are pouched dosimeters and items on the incubator shelf (or shelves) impacting the air flow and heat transfer within the incubator.

7.4.2.4.2 Acquire a quantity of dosimeters and/or pouched dosimeter samples to load on each shelf of the incubator. The quantity of dosimeters and/or pouched dosimeters should mimic the user's normal production run, or the user may determine a representative method to simulate an incubator loaded with dosimeter samples.

7.4.2.4.2.1 Place the dosimeters loosely onto a sheet(s) of thin, unprinted white paper.

7.4.2.4.2.2 Slide the piece of paper (loaded with dosimeters) onto each shelf in the incubator.

7.4.2.4.3 Repeat the temperature measurement steps as described in the Empty Chamber Test (see 7.5.2.3) for all positions on each shelf of the incubator.

7.4.2.4.4 Record the measured temperature value in the 'Loaded Chamber', Position 1, **'Measured'** cell in the 'Performance Verification Test' section of Test Form 100-277(a).

7.4.2.4.5 Repeat the steps in 7.5.2.3.1. to 7.5.2.3.4 for each of the subsequent positions on the incubator shelf (or shelves) In Test Form 100-277(a), record the temperature measurement in 'Loaded Chamber', 'Measured' cell corresponding to the appropriate Position.

7.4.2.4.6 For all the 'Measured' temperatures at each Position, enter the Minimum measured temperature for all positions in the '**Minimum**' cell.

7.4.2.4.7 For all the 'Measured' temperatures at each Position, enter the Maximum measured temperature for all positions in the '**Maximum**' cell.

7.4.2.4.8 Test acceptance criteria: All measured temperatures must be within +/- 2.0°C from the Set Point and ≤ 62.0°C.

7.4.2.4.8.1 Enter PASS in 'Result Status' if the 'Minimum' value and the 'Maximum' value are within +/- 2.0°C and the 'Maximum' value is ≤ 62.0°C.

7.4.2.4.8.2 Enter FAIL in 'Result Status' if the 'Minimum' value and the 'Maximum' value are not within +/- 2.0°C and the 'Maximum' value is > 62.0°C.

7.4.2.4.9 If the test result is "FAIL" do not continue with testing.

7.4.2.4.9.1 Sign and date the Test Form. Follow the appropriate internal procedure for a test deviation, if applicable. (If this Procedure is used for *GEX Document 100-280, DoseControl IQOQ Protocol for DoseControl Dosimetry System*, see the instructions in 100-280.)

7.4.2.4.9.2 Make the appropriate adjustments and repeat the Performance Verification test. Assess if any adjustment to the set temperature of the incubator can be made; assess if any user errors occurred previously in 7.4.2.4.

7.4.2.4.9.3 Repeat the Loaded Chamber Test (see 7.4.2.4).

7.4.2.4.9.4 If you experience repeated failure, contact GEX Customer Service support@gexcorp.com.

7.5 P4900 Microincubator

7.5.1 Calibration Verification Test

7.5.1.1 Record the incubator's temperature controller **Set Point Temp** in the 'Calibration Verification Test' section of Test Form 100-277(b). NOTE: The recommended set point for the P4900 microincubator is 58.5°C, but the end-user can choose the set point based on guidance from *GEX Doc# 100-201, Post Irradiation Heat Treatment of GEX B3 Dosimeter Products Technical Report.*

7.5.1.2 Use a calibrated thermometer and probe for this step. Plug the T-Type thermocouple into the back of the P4900 Microincubator and plug the female T-Type port into the P4901 Digital Thermometer (or equivalent). Turn on the power to the thermometer using the switch on the side of the device.

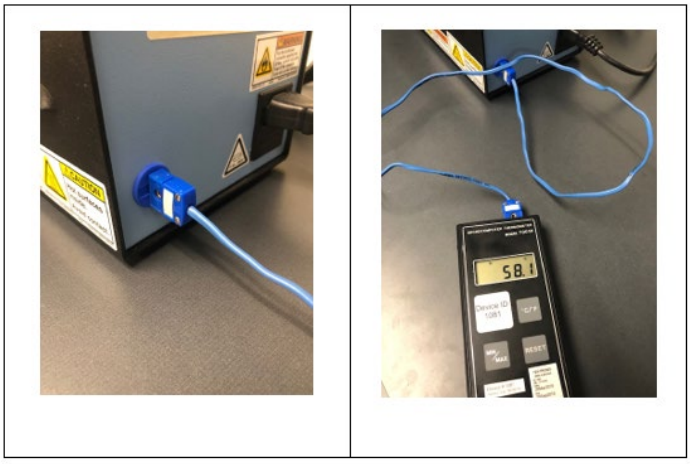

Figure 4: The T-type Probe and P4901 Digital Thermometer (or equivalent) plugged into the back of the P4900 Microincubator

7.5.1.3 Set the timer to count down and let the thermometer probe dwell for **5 minutes.**

7.5.1.4 Record the temperature displayed on the incubator's temperature controller into the cell for '**Displayed Temp'** in the 'Calibration Verification Test' section of Test Form 100-277(b).

7.5.1.5 Record the temperature shown on the P4901 digital thermometer (or equivalent) display into the cell for '**Measured Temp'** in the 'Calibration Verification Test' section of Test Form 100-277(b).

7.5.1.6 Test acceptance criteria: The Measured Temperature 'Measured Temp' must be ±0.2°C from the Displayed Temperature 'Displayed Temp'.

7.5.1.6.1 Enter PASS in 'Result Status' if the 'Measured Temp' value is ≥ Minimum Limit value and ≤ the Maximum Limit value.

7.5.1.6.2 Enter FAIL in 'Result Status' if the 'Measured Temp' value is ≤ Minimum Limit value and ≥ the Maximum Limit value.

7.5.1.7 If the test result is "FAIL" do not continue with testing.

7.5.1.7.1 Sign and date the Test Form. Follow the appropriate internal procedure for a test deviation, if applicable. (If this Procedure is used for *GEX Document 100-280, DoseControl IQOQ Protocol for DoseControl Dosimetry System*, see the instructions in 100-280.)

7.5.1.7.2 Make the appropriate adjustments and repeat the Calibration Verification test.

7.5.1.7.3 Adjust correct the microincubator's temperature controller. Adjust the offset of the temperature controller so that the incubator display temperature matches the actual measured temperature of the calibrated thermometer. Use the temperature displayed on the P4901 digital thermometer (or equivalent) as the calibrated reference temperature to determine the offset. The manufacturer user guide for the incubator will provide instructions for executing this.

7.5.1.7.4 Repeat the Calibration Verification Test (see section 7.5.1) to try again.

7.5.1.8 If you experience repeated failure, contact GEX Customer Service at support@gexcorp.com.

7.5.2 **Performance Verification Tests**

7.5.2.1 The microincubator will be tested with and without a load of dosimeters in the heat block.

7.5.2.2 There are total of 18 slot positions in the aluminum heat-block of the P4900 Microincubator.

7.5.2.3 Start at the back-left position and work towards the front-right position. See Figure 5.

7.5.2.4 All testing is completed with the lid open. (NOTE: The lid is only closed when the P4900 Microincubator is not in use as a safety precaution.)

Figure 5: Temperature probe placement in the microincubator heat block.

7.5.2.5 **First, perform the Empty Heat Block Test with the <u>empty incubator</u>.**

7.5.2.5.1 Place the P4902 B3 Dosimeter Package Probe into position #1 in the heat block.

7.5.2.5.2 Set the timer to count down and let the P4902 Probe dwell for **5 minutes.**

7.5.2.5.3 Record the temperature value in the 'Empty Heat Block', Position 1, **'Measured'** cell in the 'Performance Verification Test' section of Test Form 100-277(b).

7.5.2.5.4 Repeat for each of the subsequent positions in the microincubator heat block. In Test Form 100-277(b), record the temperature measurement in the 'Empty Chamber' 'Measured' cell corresponding to its Position.

7.5.2.5.5 For all the 'Measured' temperatures at each Position, enter the Minimum measured temperature for all positions in the **'Minimum'** cell.

7.5.2.5.6 For all the 'Measured' temperatures at each Position, enter the Maximum measured temperature for all positions in the **'Maximum'** cell.

7.5.2.5.7 Test acceptance criteria: All measured temperatures must be within +/- 2.0°C from the Set Point and ≤ 62.0°C for all measurements.

7.5.2.5.7.1 Enter PASS in 'Result Status' if the 'Minimum' value and the 'Maximum' value are within +/- 2.0°C and the 'Maximum' value is ≤ 62.0°C.

7.5.2.5.7.2 Enter FAIL in 'Result Status' if the 'Minimum' value and the 'Maximum' value are not within +/- 2.0°C and the 'Maximum' value is > 62.0°C.

7.5.2.5.8 If the test result is "FAIL" do not continue with testing.

7.5.2.5.8.1 Sign and date the Test Form. Follow the appropriate internal procedure for a test deviation, if applicable. (If this Procedure is used for *GEX Document 100-280, DoseControl IQOQ Protocol for DoseControl Dosimetry System*, see the instructions in 100-280.)

7.5.2.5.8.2 Make the appropriate adjustments and repeat the Performance Verification test. Assess if any adjustment to the set temperature of the incubator can be made; assess if any user errors occurred while performing the steps in 7.5.2.5.

7.5.2.5.8.3 Repeat the Empty Heat Block Test (see 7.5.2.5).

7.5.2.5.8.4 If you experience repeated failure, contact GEX Customer Service support@gexcorp.com.

7.5.2.6 **Next, perform the Loaded Heat Block Test with a loaded incubator.**

7.5.2.6.1 Purpose: The Loaded Incubator Test is to verify the temperature uniformity within the incubator when there are pouched dosimeters in the incubator heat block.

7.5.2.6.2 Place the thermometer P4902 B3 Dosimeter Package Probe into position #1 in the heat block. Insert a B3 dosimeter package (pouched B3 dosimeter) into positions 2 through 18 of the heat-block of the P4900. See Figure 6.

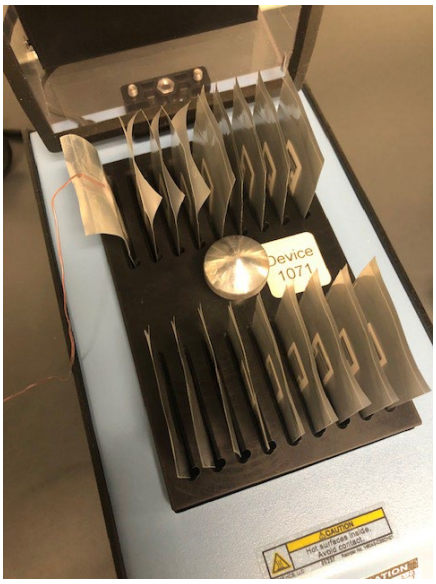

Figure 6: Heat block loaded with B3 dosimeters in package. P4902 B3 Dosimeter Package Probe into position #1

7.5.2.6.3 Repeat all steps. Move the thermometer Probe into Positions 1-18 and ensure all slots in the heat block are filled with a dosimeter pouch.

7.5.2.6.4 For each measured Position, record the measured temperature values in the **'Measured'** cell corresponding with the appropriate Position of the probe in the ''Loaded Heat Block' section of Test Form 100-277(b).

7.5.2.6.5 For all the 'Measured' temperatures at each Position, enter the Minimum measured temperature for all positions in the **'Minimum'** cell.

7.5.2.6.6 For all the 'Measured' temperatures at each Position, enter the Maximum measured temperature for all positions in the **'Maximum'** cell.

7.5.2.6.7 Test acceptance criteria: All measured temperatures must be within +/- 2.0°C from the Set Point and ≤ 62.0°C.

7.5.2.6.7.1 Enter PASS in 'Result Status' if the 'Minimum' value and the 'Maximum' value are within +/- 2.0°C and the 'Maximum' value is ≤ 62.0°C.

7.5.2.6.7.2 Enter FAIL in 'Result Status' if the 'Minimum' value and the 'Maximum' value are not within +/- 2.0°C and the 'Maximum' value is > 62.0°C.

7.5.2.6.8 If the test result is "FAIL" do not continue with testing.

7.5.2.6.8.1 Sign and date the Test Form. Follow the appropriate internal procedure for a test deviation, if applicable. (If this Procedure is used for *GEX Document 100-280, DoseControl IQOQ Protocol for DoseControl Dosimetry System*, see the instructions in 100-280.)

7.5.2.6.8.2 Make the appropriate adjustments and repeat the Calibration Verification test. Assess if any adjustment to the set temperature of the incubator can be made; assess if any user errors occurred previously while performing steps in 7.5.2.6.

7.5.2.6.8.3 Repeat the Loaded Heat Block Test (see 7.5.2.6).

7.5.2.6.8.4 If you experience repeated failure, contact GEX Customer Service support@gexcorp.com.

7.6 When the Test Procedure for Forced-Air Incubator (section 7.4) or for Microincubator (section 7.5) is completed, enter your name below the signature line, and then sign and date the Test Form(s).

7.7 Obtain a review by a qualified reviewer, who also enters their name, and sign and date the Test Form(s).

8.0 ASSOCIATED DOCUMENTS

- GEX Doc# 100-123, P4900 Microincubator System Product Specifications and Usage
- GEX Doc# 100-142, P4850/P4855 Forced Air Incubator Product Specifications & Usage
- GEX Doc# 100-201, Post Irradiation Heat Treatment of GEX B3 Dosimeter Products Technical Report
- GEX Doc# 100-277, Incubator IQOQ Test Form
- GEX Doc# 100-280, IQOQ Protocol for DoseControl Dosimetry System
- Memmert Forced Air Incubator Operators Manual
- SciGene Microincubator User Guide

9.0 REVISION HISTORY

DATE	CHANGE DESCRIPTION	REVISION
04/12/2021	- 8.6.1.3 for language clarification. - 8.6.1.5 removed reference of the P4902 probe. - 8.6.2.5.3 changed cell reference from G12 to D12. ECO 70569	D
04/27/2021	9.0 Associated documents – updated manufacturer user guides. Memmert Operation Manual for P4850/P4855. ECO 70571	E
05/03/2024	- Updated with new pictures detailing specific instructions on setting the P4902 B3 Dosimeter Package Probe within 4cm of the thermocouple inside the P4850 incubator. - Updated pictures with P4902 probe placement with a minimum of 5 different locations.	F

	- Materials – changed number of dosimeters for loaded incubator test to be an approximate number. - Updated forced-air incubator GEX product number to consistently be P4850/P4855. - Changed Overview section to clearly delineate the Calibration Verification Test and Performance Verification Test with acceptance criteria for each. - Clarified the Calibration Verification Test and Performance Verification Test section to make the steps and acceptance criteria clear, and what to do in case of a test failure/deviation. - Updated Associated Documents to include the manufacturer user manuals. ECO 70676 *Note corrections made on 5/14/24 to step 6.2.2.2, "....to damage at temperatures over 62.0C", and steps 7.4.2.3.8.2, 7.4.2.4.8.2, 7.5.2.5.7.2, 7.5.2.6.7.2, “Enter FAIL in ‘Result Status’ if the ‘Minimum’ value and the ‘Maximum’ value are not within +/- 2.0°C and the ‘Maximum’ value is **>** 62.0°C.”	

REVISED
2:41 pm, May 14, 2024
Dominique Taylor