1.0 PURPOSE

To provide guidance for evaluating the competency of a person measuring dosimeters on the DoseControl Dosimetry System.

2.0 SCOPE

A formal competency test should be performed for any person measuring dosimeters where the data will be used to make further decisions about process or product.

3.0 GENERAL INFORMATION

It is recommended that persons that do not have experience with the measurement system should prove to themselves and document a test for the repeatability of measurement of the same sample is within expected limits. Annual retesting of employees who often measure dosimeters should also be considered.

Acceptance criteria is based on the characterization and validation of the DoseControl Dosimetry System completed and on file at GEX Corporation.

The procedure can be used for GEX B3, FWT, Harwell Red and Amber PMMA, and CTA film dosimeters.

4.0 PROCEDURE

4.1 Prerequisite – IQ and OQ (or equivalent) have been completed for the dosimetry system.

4.2 Testing may be completed using either the Thermo software or using GEX DoseControl software as the software has no influence on the test result.

4.3 Testing should be completed for each dosimeter holder type that the person will utilize.

4.4 Select a dosimeter sample of each type to be tested that has an approximate absorbance value of 0.300 or higher.

4.5 Inspect the dosimeter and ensure that the surface of the dosimeter is clean and undamaged. A damaged or dirty dosimeter film may skew the test result.

4.6 Initialize (power on/power cycle) the instrument prior to testing and warm up the instrument (if required) per the documented operational instructions from GEX (see *Related Documents*).

4.7 Open the sample compartment lid and insert the dosimeter holder component that snaps into the GEX baseplate and visually confirm the holder is fully seated / installed correctly.

4.8 Insert the dosimeter into the holder and execute the first measurement.

4.9 Remove the dosimeter from the holder and then reinsert the dosimeter into the holder again. Execute the second measurement.

4.10 Repeat the process to accumulate 30 measurements for the single dosimeter.

4.11 Analyze the data (see the example of one data analysis concept using MS Excel).

4.11.1 The C.V.% should be less than 0.4 or else the system is not installed and operating correctly, or the user is negatively influencing the results due to technique. Retrain and test again.

4.12 The dosimeter may be discarded upon completion of testing.

5.0 RELATED DOCUMENTS

- GEX Doc# 100-156, Evolution 220 Spectrophotometer – Product Specifications and Usage
- GEX Doc# 100-167, GENESYS 30 Spectrophotometer – Product Specifications and Usage
- GEX Doc# 100-258, Measuring GEX B3 Dosimeters – Procedure

Example of a Measurement Competency Data Analysis Form

	A	B	C	D
1				
2	Technician Name:			
3	Date Measured:			
4	Spectrophotometer ID:			
5	Dosimeter Holder Type:			
6	Dosimeter Type:			
8	Reading		Irradiated	
9	Number		Dosimeter	
10	1			
11	2			
12	3			
13	4			
14	5			
15	6			
16	7			
17	8			
18	9			
19	10			
20	11			
21	12			
22	13			
23	14			
24	15			
25	16			
26	17			
27	18			
28	19			
29	20			
30	21			
31	22			
32	23			
33	24			
34	25			
35	26			
36	27			
37	28			
38	29			
39	30			
40				
41	Average		=AVERAGE(C10:C39)	
42	Std Deviation		=STDEV(C10:C39)	
43	C.V. (%)		=C42/C41*100	
44				
45	Circle One:		PASS/FAIL	
46	Performed By & Date:			
47	Reviewed By & Date:			

6.0 REVISION HISTORY

Date	Change Description	Revision
07/27/2021	Added explicit instrument warm –up instruction Changed language pertaining to system variance Changed test pass/fail criteria for system variance.	C
06/01/2021	New document layout to match other similar documents to include Purpose, Scope, General Info, Procedure, References, Related Documents, Revision History. Removed reference to instrument characterization – now handled in 100-272. Simplified procedure to remove ambiguity and added Related Documents. ECO 70574.	D