Investigating B3 Dosimeter Measurements

1.0 PURPOSE

To describe the method for investigating and evaluating suspected outlier measurements or measurements that differ from the expected dose.

2.0 SCOPE

The procedure applies to the evaluation and investigation of dosimeter measurements using GEX B3 dosimeters and the DoseControl dosimetry system.

3.0 GENERAL INFORMATION

Investigation of a dosimeter result may be warranted for a variety of reasons and is considered a normal and vital activity to ensure quality of measurements from the system.

Through the dosimetry system design and the procedures employed, attempts have been made to minimize the risk of errors in the measurement results of the dosimetry system. However, there is always a risk for any system, and particularly one which has some reliance on human interface. Humans typically set the irradiation parameters, place the dosimeters, retrieve and heat treat the dosimeters after irradiation, and measure them.

There may be reasons why a dosimeter does not actually receive the expected dose, including misplacement in the irradiation process (the dosimeter wasn't where it was supposed to be) or some type of process deviation in the irradiation source or conveyor (error arises because the actual irradiation geometry or dose rate was not as expected).

There may be opportunities for deviations arising from the heat treatment or measurement processes. The handling and measurement of the dosimeters is a process that involves human interface and human error or deviations from procedure are possible.

B3 radiochromic film dosimeters are completely stable if properly heat treated after irradiation and can therefore be re-measured as part of an investigation with highly reproducible results. If a dosimeter is not heat treated properly before measurement, subsequent heat treatment should result in a rise in the optical absorbance that is measurable. Therefore, it is possible and encouraged to heat treat dosimeters a second time as part of any investigation unless there is absolute certainty the dosimeter was previously heat treated correctly. While the process can be highly controlled and validated, the heat treatment process requires human interface to insert and remove the dosimeters from the incubator.

The unintended zeroing of the spectrophotometer with an irradiated dosimeter in the sample compartment is possible. The system cannot determine this event and the process relies on the technician to successfully execute the zeroing procedure.

The dosimeters themselves can be damaged or particulate can attach to the film surface and, if not detected by the technician before measurement, film damage or particulate can affect the optical measurement of the dosimeters in a spectrophotometer.

It is highly likely that over the course of the life of any irradiator, that a very small fraction of dosimetry results is not fully explainable. Multiple errors can result in an expansion or cancelation of each other's effects, and this can lead to changes that are difficult to reproduce using trial and error.

Large deviations (>10%) in dose from expected dose are most often the result of a deviation in the irradiation, handling, or measurement and often in combination with something like particulate on the dosimeter. Small deviations (<10%) are more often attributable to issues that are more difficult to reproduce or a combination of minor issues. No matter, reproduction of events will be more valuable than reliance on the memory of even the most diligent employee. Therefore, simulating the suspected cause is encouraged whenever possible to try and prove beyond a reasonable doubt that the true reason for the deviation in the original result from the expected result has been found.

4.0 PROCEDURE

Caveat – Without specific situational knowledge, it is impossible to develop a comprehensive protocol. This document was developed with the intention of helping GEX B3 dosimeter users. Users take sole responsibility for developing their own investigation protocols and procedures and are simply encouraged to use this procedure template as a guide.

4.1 Obtain a copy of the specific dose report to be investigated along with the dosimeters from that run.

4.2 Ensure that the electronic report in DoseControl is 'processed' so that the version of the report on which the issue has been found has been locked and edits prevented.

4.3 Output and save a copy or print a copy of the dosimetry report.

4.4 Document the results of each step of the investigation noted herein.

4.5 Investigate the irradiation processing report for the process event that the dosimetry pertains to. First, determine if there is any error in the calculations performed using the measured data. Specifically, it is best to determine early in the investigation if the measured results are in question or if calculated data resulting from the measured values is in question or both.

4.5.1 As an example, if correlation ratios are used to determine minimum dose in the process load (D_{min}) or maximum dose in the process load (D_{max}) from a reference monitoring location (D_{mon}), ensure that the correlation ratios used in the report are correct for the product that was irradiated. The measured data may be correct, but it was simply processed incorrectly with ratios that were incorrect, for example.

4.6 Investigate the handling of the dosimeters by the staff that placed and retrieved the dosimeters.

4.6.1 Was anything out of the ordinary that they recall?

4.6.2 Check that the product was properly oriented in the irradiator conveyor, tote, carrier, etc. during processing if the dosimeter was on the product, and that the dosimeter was placed in the correct position.

4.6.3 If the dosimeter was in a reference monitoring location, was the dosimeter placed correctly or completely into or onto the reference position or reference fixture?

4.7 If the correct correlation factors were used, then determine if the correct dosimeter calibration recipe was used to calculate the doses on the dosimeter report.

4.7.1 Review the dosimetry report to confirm the calibration ID that was used and its associated details including:

4.7.1.1 Wavelength of measurement.

4.7.1.2 Coefficients of the calibration function (the coefficients are stored in the Calibration Configuration screen and will require an Application Administrator for review within the software).

4.7.1.3 Average Thickness of the dosimeters.

4.7.1.4 Average initial absorbance of the dosimeters.

4.8 If the results in question are not caused by use of an incorrect calibration recipe, expand the investigation to evaluate the irradiation of the dosimeters, handling and condition of the dosimeters, and the heat treatment and measurement.

4.9 Locate the dosimeters that are from the process run and the specific dosimeters in question. They will need to be inspected and remeasured.

4.10 Prior to remeasurement, continue the investigation to identify areas of probable cause. Resolving the original measurement by rereading without identifying the cause may not meet the intention of local quality procedures.

4.11 Verification of Spectrophotometer

4.11.1 Check the following. If any of the items are in question, remeasurement is recommended after remediation of any issues found.

4.11.1.1 If using a GENESYS 30 or other spectrophotometer with a Tungsten-Halogen light source, was the spectrophotometer warmed up a minimum of 30 minutes before use? There is the possibility that it had not stabilized. If there is any doubt, re-measure all dosimeters.

4.11.1.2 Check the lamp hours on the instrument. A lamp nearing the end of its life may result in lower readings than normal.

4.11.1.3 Was the instrument warmed up with a dosimeter holder or dosimeter in the light path that interfered with the light beam and would affect the power-on self-test that the instrument performed to check itself?

4.11.1.4 When was the last instrument P.V. testing performed and is the instrument calibration current?

4.11.1.5 Is there visible evidence that the dosimeter holder was not fully seated?

4.12 Condition of the Dosimeters

4.12.1 Inspect all or a sampling of dosimeters in the run for imperfections in the light beam area, such as dents, scratches, fingerprints, or bubbles. Include inspection of all dosimeters being investigated as well as others from the run whose result is not in question.

4.12.1.1 Is there any observable difference in the condition of the dosimeters being investigated versus those that are not under investigation? Document any observed differences or if there are specific issues with dosimeters being investigated.

4.12.1.2 If damage or particulate is found, record this observation for the dosimeter serial number on which it is found. Dosimeters will be remeasured after confirmation of the possibility of other potential causes.

4.12.2 Document any findings or correlations drawn from the findings (e.g. 'the dosimeter in question has visible surface imperfection that is not present on the samples not in question').

4.13 Verification of Heat Treatment

4.13.1 Verify that the dosimeters were heat treated and that the correct treatment parameters were used including:

4.13.1.1 Treatment temperature.

4.13.1.2 Treatment duration (dosimeter dwell time in the incubator).

4.13.1.3 Time between irradiation and heat-treatment was within proceduralized or normal range.

4.14 After reviewing the dosimeter condition, heat treatment history, and the spectrophotometer per steps 4.11 to 4.13, prepare the dosimetry system to remeasure samples.

4.14.1 Correct any issues with the instrumentation (reboot and warm up the instrument if required, check dosimeter holders are properly seated, etc.).

4.14.2 Remove any particulate from the dosimeter film surface using a dry lint-free wipe.

4.14.3 Heat treat any dosimeters that were surely not heat treated before the original measurement that is in question.

4.15 Re-measure all dosimeters in the run or any specific dosimeter in question within the investigation and document a rationale for the decision to remeasure or not.

4.15.1 If the second measurement is different than the original measurement, measure the dosimeter a third time to verify the second reading. Verification implies that the original measurement was incorrect due to any of the problems described above and that a documented change is supported by an appropriate level of measurement verification evidence.

4.15.2 If the second measurement is the same as the original measurement (±0.003A, maximum acceptable handling variation), it is likely that the measurement is correct and there is some external cause for the unexpected dose.

4.16 If appropriate, consideration can be given to measure individual thickness of each film in the dosimeter package. The dose response curve is based on the average thickness of the batch. There could be portions of a film dosimeter that are unusually thin or thick, but history has shown this to be highly unlikely. However, if nothing else has resolved the issue, then the thickness should be checked. GEX offers to measure the thickness on our optical gauges or users can measure themselves. Consult with GEX support for guidance.

4.17 Resolution and Documentation

4.17.1 If the investigation demonstrates that a dosimeter is physically defective, it may support and warrant that the dosimeter and its measurement value be excluded from the data used to disposition the product to which the dosimetry report pertains. A written statement with an appropriate level of documentation supporting this fact should be cited on and affixed with the dosimetry report itself.

4.17.2 If the investigation demonstrates errors in measurement or calculation, document the repeat measurements on the dosimetry report. Initiate immediate corrective actions to resolve the issue and record the actions taken along with documentation supporting the rationale for the change.

4.17.3 If the investigation determines that there were deviations in irradiator operations that were responsible for the dosimeter results, initiate appropriate corrective actions.

4.17.4 If the investigation does not demonstrate a defective dosimeter, measurement errors, or processing deviations, discarding the measurement may be possible if the irradiation process is validated and appropriate documentation and evidence based on statistics is utilized. Disregarding a measurement without determining cause is highly discouraged.

4.17.4.1 A detailed statistical evaluation of the results along with a process control chart analysis may support such efforts.

4.17.4.2 Consult ASTM 178 (see *Section 5: References*) for an example of a practice for handling outlier observations that are not assignable to identifiable causes. The user must assign the criteria; 1% is a reasonable criteria (approximately k=3) but the user must define and justify their selection.

5.0 REFERENCES

1) ASTM E178 – Standard Practice for Dealing with Outlier Observations

6.0 RELATED DOCUMENTS

- GEX Doc# 100-249, Dosimetry Lab Operations
- GEX Doc# 100-258, Measuring GEX B3 Dosimeters

7.0 REVISION HISTORY

Date	Change Description	Revision
21-Sep-2010	Specified 552 nm during absorbance measurement instead of 554nm.	D
05-Nov-2021	Major revision. Completely re-written. Changed title from 'Reread of B3 WINdose Dosimeters' to 'Investigating Dosimeter Measurements'. Moved to new procedure template format. Changed scope for DoseControl from WINdose dosimetry system and removed all details of rereads in DoseControl which are moved to 100-258 Rev E. Revised all instruction based on the past 10 years of supporting customers for events described herein. ECO 70590.	E