## 1.0 PURPOSE

This procedure describes the GEX methods recommended for use in investigating and evaluating suspected outlier measurements or for investigation of dosimeter measurements that differ from the expected dose, including how to re-measure dosimeters. The methods may also be used to verify a prior result by re-measurement of any dosimeter.

**NOTE**: Dosimeter measurement verification and investigation may be warranted for a variety of reasons and is considered a normal and vital activity associated with a quality dosimetry program. Keep in mind that any change to a measurement and its associated dose must be appropriately documented and supported by a strong rationale. A major advantage of using B3 radiochromic film dosimeters is that they are completely stable if properly heat treated after irradiation and can therefore be re-measured as part of an investigation with highly reproducible results.

## 2.0 MATERIALS

2.1 WINdose Dosimetry System

## 3.0 FREQUENCY

3.1 As needed.

## 4.0 PROCEDURE FOR INVESTIGATION

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

4.2 Before attempting re-measurement, inspect any suspect dosimeter for imperfections in the light beam area, such as dents, scratches, fingerprints, or bubbles, as these can cause incorrect readings. If damage is suspected, record this observation on the dosimetry worksheet. This observation in addition to the remaining steps can establish a rationale for changing a measurement result or discarding a dosimeter and its measurement because of damage.

4.3 Verify that the correct dosimetry worksheet was used. There may be different worksheets for different:

4.3.1 Calibration curves.
4.3.2 Spectrophotometers.
4.3.3 Irradiators.
4.3.4 Product groups (Verify that the correct correlation ratios were applied to the measured dose, e.g. Dmax and Dmin factors built into worksheets).

4.4 Was the spectrophotometer warmed up a minimum of 30 minutes before use? Possibly it had not stabilized. If there is any doubt, re-measure all dosimeters.

4.5 Verify that the spectrophotometer was set to the specified calibration wavelength (typically 552 nm) and is set in the Absorbance mode. The Genesys 20 is preset to start up in the absorbance mode at 552 nm, but the wavelength and the mode may have been changed for other testing (such as instrument calibration).

4.6 Were the spectrophotometer and the holder zeroed together? Instrument zero and instrument plus holder zero are different values, which will alter the apparent measurement. **NOTE**: Applies only when using WINdose dosimeters.

4.7 Was the sample compartment lid closed?

4.8 Was the dosimeter holder inserted properly? Practice inserting the holder a few times to verify that 0.000A can be achieved by the technician.

4.8 Was the dosimeter placed properly into the dosimeter holder and then the dosimeter holder seated properly in the cuvette holder?

4.9 Re-measure all dosimeters in the run or any specific dosimeter. Insert the dosimeter holder slowly and gently close the sample compartment lid. Wait for the absorbance display to stabilize. Observe the absorbance displayed on the spectrophotometer. Record this absorbance in the dosimetry worksheet. Re-compute the dose (see the WINdose for Excel Operation Manual and procedure 100-258 for detailed instruction or use the calibration Dose Estimate Table).

4.10 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.

4.11 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.

4.12 Review irradiator operation from the information on the process report for any process discrepancies.

4.13 Check with the operator on dosimeter placement at the product monitoring position in the carrier during processing. Was the dosimeter correctly placed in the correct location? A misplaced dosimeter may have accurately recorded the dose at that location, but that location may not be the correct location and therefore may not have an established relationship to the Dmax/Dmin locations.

4.14 Check that the product was properly oriented in the irradiator tote, carrier, etc. during processing. Orientation changes can affect radiation penetration to the monitoring position even in a gamma irradiator.

4.15 Check the product bulk density for variance from its specification. A materials or packaging change from those which are qualified can invalidate the correlation ratios.

4.16 Check the spectrophotometer operation and calibration. Check the lamp hours on the instrument. A lamp nearing the end of its life will result in lower readings than normal.

4.17 Was the measurement recorded too quickly before the reading had stabilized? The instrument has a ballistic response, that is, it quickly moves to near the maximum value, then slows down to find the maximum value. Additionally you may consider the impact of rounding error, there may be some flutter in the display, which shows only the nearest 0.001A.

4.18 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. Occasionally there are portions of a film dosimeter that are unusually thin or thick. Determine an appropriate calculation to adjust the response and then look up or re-calculate the dose. Contact GEX for assistance.

## 5.0 PROCEDURE FOR RESOLUTION

5.1 If the investigation demonstrates that an individual film or an entire dosimeter is physically defective, it may support and warrant that the dosimeter and its measurement value be excluded from the dosimetry report. A written statement with an appropriate level of documentation supporting this fact should be cited on and affixed with the dosimetry report itself.

5.2 If the investigation demonstrates errors in measurement or calculation, document the repeat measurements on the dosimetry report. Initiate appropriate corrective

actions and record the actions taken along with documentation supporting the rationale for the change.

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

5.4 If the investigation does not demonstrate a defective dosimeter, measurement errors, or processing deviations, accept the result(s) and close the investigation.

## 5.0 REVISION HISTORY

| Date | Change Description | Revision |
|---|---|---|
| 09/21/10 | Specified 552 nm during absorbance measurement | D |