注意：这是一个版本受控的文件，它的产生是GEX信息计划的一部分，该计划要求所有系列100的文件需要定期检查，以维持信息的最新性和连续性。恰当的技术备忘录用于提供信息细节并支撑产品数据表以及GEX推荐的操作程序，以及提供技术信息以支撑GEX的市场文件。

NOTICE: This document is version controlled and was produced as a part of the GEX Information Program which requires that all Series 100 documents be reviewed periodically to maintain currency and continuity of information. Appropriate Technical Memorandum are used to provide information detail in support of the Product Data Sheets as well as GEX Recommended Procedures and to provide technical information in support of GEX Marketing documents.

1.0 目的 PURPOSE

该程序文件描述了 GEX 推荐的用于调查和评估疑似离群值的测量或与期望的剂量不同的剂量计测量的调查的方法，包括如何重新测量剂量计。该方法也可以通过对剂量计的重新测量被用来验证先前的结果。

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.

注意：剂量计测量验证与调查可以得到保证有多个原因，它被认为是一个正常的并且至关重要的与质量剂量学计划相关的活动。请记住，任何对一个测量及其相关的剂量的改变必须被恰当的记录并由可靠的论据所支持。使用 B3 辐射变色薄膜剂量计的最大的优势在于，如果经恰当的辐照后热处理，他们是完全稳定的，所以可以作为调查的一部分被重新测量并具有很高的可重现的结果。

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 材料 MATERIALS

2.1 WINdose 剂量测量系统
WINdose Dosimetry System

3.0 频率 FREQUENCY

3.1 按需 As needed.

4.0 调查程序 PROCEDURE FOR INVESTIGATION

4.1 获取一份要调查的特定的剂量报告的拷贝件，以及来自该轮辐照的剂量计。
Obtain a copy of the specific dose report to be investigated along with the dosimeters from that run.

4.2 在试图重新测量之前，在灯光直接照射的地方检查任何可疑的剂量计是否有缺陷，比如压痕、划痕、指纹或气泡，因为这些可以导致错误的读数。如果疑似损坏的，将该观察结果记录在剂量测量工作薄中。该观察包括接下来的步骤都可以建立一个用于改变一个测量结果或由于其损坏而抛弃一个剂量计及其测量的论据。
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 确认使用了正确的剂量测量工作表。以下不同情况可能有不同的工作表：
Verify that the correct dosimetry worksheet was used. There may be different worksheets for different:

4.3.1 不同的校准曲线 Calibration curves.
4.3.2 不同的分光光度计 Spectrophotometers.
4.3.3 不同的加速器 Irradiators.
4.3.4 不同的产品组（确认对测量的剂量采用了正确的相关比率，比如固定于工作表中的 Dmax 和 Dmin 因子）
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 在使用之前分光光度计是否经过最小 30 分钟的预热？可能它还没有稳定。如果有任何怀疑，重新测量所有的剂量计。
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 确认分光光度计被设在规定的校准波长（典型的为 552 nm）并被设在吸光度模式。Genesys 20 被预设为吸光度模式下 552 nm 波长启动，但是波长和工作模式可能被更改用于其它测试（比如仪器的校准）。
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 分光光度计是否在插入支架的时候一起被置零？仪器置零和仪器+支架置零结果是不同的，这将明显改变测量结果。**注意**：仅适用于使用 WINdose 剂量计的时候。
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 样品室的盖子是否关闭？
Was the sample compartment lid closed?

4.8 剂量计支架是否恰当的被插入？由技术员练习插入支架数次以验证可以或得 0.000A。
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 剂量计是否被恰当的放进剂量计支架、然后剂量计支架被恰当的置于吸收池支架？
Was the dosimeter placed properly into the dosimeter holder and then the dosimeter holder seated properly in the cuvette holder?

4.9 重新测量该轮中的所有剂量计或任何特定剂量计。慢慢的插入剂量计支架并轻轻的关上样品室的盖子。等待显示的吸光度值稳定。观察显示在分光光度计上的吸光度。将该吸光度记录在剂量测量工作表中。重新计算剂量（详细说明请参见《WINdose for Excel 操作手册》及程序文件 100-258 或使用校准《剂量估算表》）。
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 如果第二次测量不同于最初的测量，再测量一次剂量计已验证第二次读数。验证显示由于上述的任何原因导致最初的测量是不正确的、并且记录的改变也能被测量验证证据的适度水平所支持。
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 如果第二次测量和最初的测量是相同的（±0.003A，最大可接受的操作变化），很可能该测量是正确的，并且有一些外部原因导致了该意料之外的剂量。
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 根据加工报告上的信息检查加速器操作是否有任何过程差异。
Review irradiator operation from the information on the process report for any process discrepancies.

4.13 和操作员一起检查加工过程中剂量计放置于载体里的产品监控位置。剂量计是否被正确的放置在正确的位置？错误放置的剂量计可能准确的记录了该位置的剂量，但该位置可能不是正确的位置，所以不可能有一个已经建立的与 Dmax/Dmin 位置的关系。
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 检查加工过程中产品在辐照装置的吊箱或载体等里是否是以正确的方向放置的。甚至在伽玛辐照装置中，产品放置方向的改变也会影响监控位置的辐射穿透。
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 检查产品的容积密度是否与它的规格参数不一致。材料或包装不同于验证时的情况会使相关比率无效。
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 检查分光光度计操作与校准。检查仪器灯泡的工作小时数。灯泡接近寿命末端时将导致读数低于正常值。
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 读数稳定之前测量是否记录太快？仪器有一个弹道式的相应曲线，它快速的升至接近最大值，然后慢慢找到最大值。此外，您可能要考虑化整误差的影响，显示也会有一些摆动，接近 0.001A。
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 如果合适的话，考虑测量剂量计包里的每个薄膜的各个厚度。剂量响应曲线基于批的平均厚度。偶尔，有一个薄膜剂量计的部分的厚度出现异常的薄或厚。确定一个合适的计算方法以调整该响应值，然后查阅或重新计算剂量。联系 GEX 寻求帮助。
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 解决程序 PROCEDURE FOR RESOLUTION

5.1 如果调查说明个别薄膜或整个剂量计有物理缺陷，它可以支持和证明剂量计和它的测量值被从剂量测量报告里剔除。一个含有支持该事实的一个合适水平的记录的书面陈述应该被引用并附有该剂量测量报告本身。
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 如果调查说明测量或计算错误，在剂量测量报告上记录重复测量值。发起适当的纠正措施并记录采取的措施，同时编制支持该论据的文件。
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 如果调查确定，辐照器操作偏差是导致剂量计结果的原因，发起合适的纠正措施。
If the investigation determines that there were deviations in irradiator operations that were responsible for the dosimeter results, initiate appropriate corrective actions.

5.4 如果调查没有证明一个有缺陷的剂量计、测量错误或加工偏差，接受该结果并关闭该调查。
If the investigation does not demonstrate a defective dosimeter, measurement errors, or processing deviations, accept the result(s) and close the investigation.

5.0 修订历史 REVISION HISTORY

日期 **Date**	修改描述 **Change Description**	版本 **Revision**
09/21/10	规定吸光度测量中使用552 nm波长设定值 Specified 552 nm during absorbance measurement	D