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

1.1 该程序文件描述了 GEX 的关于 GEX B3 剂量计运输的接收和检查操作规程建议。
This procedure describes GEX recommended practices for receiving and inspection of shipments of GEX B3 Dosimeters.

1.2 应该对所有的 B3 剂量计产品（被称为剂量计进货或存货）的运输来货执行进货接收检查，包括新批号的首次进货和所有随后的既有批号进货。有关进货检查有三个活动内容：
Incoming receiving inspection should be performed on all shipments of B3 dosimeter products (referred to as Dosimeter Stock or Stock) including initial stock shipment of a new batch and all subsequent stock shipments of an existing batch. There are three activities associated with incoming inspection:

1.2.1 验证剂量计样品的初始吸光度，以发现会增加 B3 薄膜自然本底吸光度的可能的电离**辐射源暴露**。
Verification of the initial absorbance of dosimeter samples to detect possible exposure to a source of ionizing radiation that could increase the natural background absorbance of the B3 film.

1.2.2 验证剂量计在运输过程中没有被暴露于一个极高的**温度环境**，它会对剂量计产生不利的影响。从 GEX 运出的剂量计都附有使用不可逆温度标签或者温度数据记录器的温度监测。
Verification that the dosimeters were not exposed to an extreme maximum temperature during shipment that could have adversely impacted the dosimeters. Dosimeter shipments from GEX are accompanied by temperature monitoring using either an irreversible thermal label or temperature data logger.

1.2.2 执行来货**响应测试**，以验证新备货将和用于该批校准的剂量计库存具有相同的响应，在可接受的容许极限里。

Incoming response comparison testing is performed to verify that the new stock will respond the same as the dosimeter stock used in the batch calibration, within acceptable limits.

注意：应该注意的是，GEX 监测 B3 薄膜剂量计批的响应，以评价 B3 薄膜批随时间的响应变化情况，一旦发现任何重大（>1.0%）改变将通知用户。GEX 也鉴定用于生产 GEX B3 剂量计的 B3 薄膜卷的响应，以验证每一卷展示的每单位剂量响应、与 GEX 的批鉴定测试中建立的批基准线的差异不超过 1.0%。
NOTE: It should be noted that GEX monitors the response of its B3 film dosimeter batches to evaluate the B3 film batch response over time and advises users of any significant (>1.0%) observed change. GEX also characterizes the response of all B3 film rolls used to produce GEX B3 dosimeters to verify that each roll exhibits a response per unit dose that is not more than 1.0% different from the batch baseline established during GEX's batch characterization testing.

2.0 材料 MATERIALS

2.1 WINdose 剂量测量系统
WINdose Dosimetry System
2.2 《剂量计进货检测测试表》[GEX Doc#100-257]
Dosimeter Stock Inspection Test Form [GEX Doc#100-257]
2.3 样品剂量计（QA 保留）
Sample Dosimeters (QA retains)
注意：质量保证部门可以抽取并保留一定数量的样品用于其它类型的一些测试，或者用于执行剂量测量调查。有关这种需要的取样在本文件里没有描述。
NOTE: The QA department may elect to withhold a certain number of samples for other types of testing or for conducting dosimetry investigations. Sampling for such needs is not described in this document.

3.0 频率 FREQUENCY

该测试建议对每次剂量计进货运输执行一次，以验证送来的剂量计工作在规定的范围内。
Testing is recommended to be performed on every stock shipment of dosimeters to verify that the incoming dosimeters perform within specified limits.

注意：某些应用，譬如相对计量测量，可以不需要该文件所提出的特定性能限制。
NOTE: Some applications, such as relative dose measurements, may not require the specific performance limits called out in this document.

4.0 基本信息 GENERAL INFORMATION

一个典型的 B3 剂量计批可能会涉及到跨越 2-3 年时间（B3 剂量计批的典型寿命）的多重剂量计备货运输。
A typical batch of B3 dosimeters may involve multiple dosimeter stock shipments over a 2 to 3 year period (typical life of a B3 dosimeter batch).

注意：当从一个新剂量计批的先前库存里取样时，需保证和保留足够数量的有代表性的样品，以保证满足执行最初批校准、预期的验证审核、将来的测试和调查需要的样品、以及支持将来另一批同批号进货运输接收检查测试需要的样品的供应。GEX 推荐保留至少 **400 个**来自先前剂量计批库存的样品。
NOTE: When sampling the initial stock shipment from a new batch of dosimeters, a sufficient quantity of representative samples should be secured and retained in order to have a supply of samples to meet the needs of performing the initial batch calibration, anticipated verification audits, samples required for future testing and investigations, as well as samples necessary to support future receiving inspection testing of other stock shipments of the same batch. GEX recommends retaining a minimum of 400 samples from the initial stock shipment of a dosimeter batch.

5.0 程序 PROCEDURE

5.1 **剂量计取样**：恰当的取样方法和从所有同批库存中获取适当的样品数量应该足以支持被测试的库存的品质的统计分析。
Dosimeter Sampling: Proper sampling technique and the procurement of the proper number of samples from all stock shipments of a batch should be sufficient to support statistical evaluation of the characteristics of the stock being tested.

注意：避免使用来自单个盒子的样品或者在任何一个盒子里选择连续的样品。
NOTE: Avoid using samples from a single box or selecting consecutive samples within any one box.

5.2 **接收和库存管理**：核实产品的标识、产品数量、剂量计批号和所有来货的剂量计平均厚度。
Receiving and Management of Stock: Verify the product identification, product quantity, dosimeter batch number, and dosimeter average thickness on all incoming shipments.

5.2.1 生产日期（DOM）在符合证书上有陈述并粘贴在所有 GEX 剂量计盒子的底部。每个盒子上的生产日期可以都不相同。盒子上生产日期最早的应该先使用，并总是在随货发送的符合证书中陈述的货架寿命期

内使用。分配一个剂量计来货标识或接收日期识别号给每一个盒子，并给盒子编号（比如：1/20，2/20 等等）。按照从老到新的顺序给盒子编号以鼓励恰当的使用存货（先入先出）。
The Date of Manufacture (DOM) is stated on the Certificate of Compliance and labeled on the bottom of all GEX dosimeter boxes. The DOM may differ from box to box. Boxes with the oldest DOM should be utilized first and always in accordance with the Shelf Life stated on the Certificate of Compliance accompanying each shipment. Assign an incoming dosimeter stock shipment identification or receiving date ID to the boxes and number the boxes (e.g. 1 of 20, 2 of 20, etc.). Number the boxes in sequence from oldest to newest to encourage proper stock utilization (FIFO).

5.2.2 一旦收到剂量计，将它存放在 15℃ 至 30℃ 的环境下。
Upon receipt, store the dosimeters between 15℃ and 30℃.

5.2.3 不要将新的剂量计备货和其它任何剂量计库存混合，直到完成接收测试。
Do not mingle the new dosimeters stock with any other dosimeter stock until acceptance testing is complete.

5.3 简单的观察由 GEX 放入所有剂量计运货里的不可逆最大温度条就应该能够发现 B3 薄膜在运输过程中是否有暴露于 45℃ 以上的温度。
Exposure of B3 film to temperatures above 45℃ during shipment should be detectable by simply observing the irreversible maximum temperature label included by GEX in all dosimeter shipments. Report any deviations observed to GEX to discuss appropriate actions.

5.4 一批剂量计的响应是通过一个正式的将剂量计响应（吸光度/厚度）与可追溯到一个国家标准的剂量关联的过程建立的，即所谓的剂量计校准。更多有关这一过程的信息，请参见 GEX 文件 100-263《执行一个剂量计批校准》。
The response of a batch of dosimeters is established through a formal process that relates the dosimeter response (absorbance/thickness) to doses traceable to a national standard, called dosimeter calibration. See GEX Document 100-263 *Performing a Dosimeter Batch Calibration* for more information on this process.

5.5 **确认初始吸光度**：所有剂量计的备货的初始吸光度确认应该被执行以确认剂量计在接收前没有被暴露于辐射源。
Verification of Initial Absorbance: A characterization of the Initial Absorbance of all stock shipments of dosimeters should be performed to confirm that the dosimeters were not exposed to a source of radiation prior to receipt.

5.5.1 在开始初始吸光度确认之前确认分光光度计的校准（详细信息请参见 GEX Doc# 100-254《Genesys 20 校准与维护》。
Verify the calibration of the spectrophotometer(s) prior to beginning the initial absorbance verification (see GEX Doc# 100-254, *Genesys 20 Calibration and Maintenance*, for detail).

5.5.2 在 GEX Doc# 100-257《剂量计进货接收检查表》中输入标题信息。
Fill in the header information on GEX Doc# 100-257, *Dosimeter Stock Receiving Inspection Form.*

5.5.3 从需要确认的、QA 为该批进货保留的剂量计中抽取 32 个有代表性的样品（比如：16 包 B3002DS）。
Draw 32 representative samples (e.g. 16 pouches of B3002DS) from the Dosimeter QA Retains for the stock being verified.

5.5.4 于剂量计校准中使用的波长（以前是 554 nm，现在是 552 nm）测量这些剂量计的初始吸光度 Ao，剂量计在支架中没有特定的左右、上下或前后方向。将吸光度记录在 GEX Doc# 100-257《剂量计进货接收检查表》中。平均 Ao、标准偏差和变异系数是自动计算的。
Measure the initial absorbance, Ao, of the dosimeters at the wavelength used in the dosimeter calibration (historically 554 nm). There is no specific left-right, top-bottom, or front-back orientation of the dosimeter in the holder. Record the absorbances on GEX Doc# 100-257, *Dosimeter Stock Receiving Inspection Form*. The average Ao, standard deviation, and coefficient of variance are calculated automatically.

5.5.5 典型的测得的平均吸光度将发现在 0.035 – 0.041 吸光度单位 (A)。初始吸光度平均值会有略微的变化，取决于剂量计的平均厚度和使用的测量设备的类型。
Typically the measured average absorbance will be found between 0.035 – 0.041 absorbance units (A). This initial absorbance average can be expected to vary slightly depending on the average thickness of the dosimeters and the type of measurement equipment used.

5.5.6 使用从一个剂量计批的先前存货建立的平均初始吸光度，将将来的同一批号的进货的测量结果与建立的基准线比较；结果与基准线的差异不应该超过 ±0.002 A。
Using an average initial absorbance established from the initial stock shipment of a dosimeter batch, compare results from future stock shipments of the same batch against the established baseline; results should not vary by more than ±0.002 A from the baseline.

注意：较高的变异系数 CV（大于 4%）可能表明一个仪器表现失常、操作员测量过程中没有能够每次将仪器置零、或测试样品被高于平均数量的微粒污染了。
NOTE: A high measurement CV (greater than 4%) may indicate an instrument that is not performing to its potential, may indicate that the operator is not able to maintain zero during measurement, or may indicate that the test samples are contaminated with particulate amounts higher than average.

5.5.7 测试剂量计在检查测试完成后就可以丢弃了。
The test dosimeters may be discarded after the inspection testing is completed.

5.6 **剂量计响应确认：**来货响应比较测试的执行是为了确认新进货的响应、与目前剂量计库存或用于批校准的剂量计的平均响应比较、在统计学上在可接受范围里。
Verification of Dosimeter Response: Incoming response comparison testing is performed to verify that the new stock response is within statistically acceptable limits when compared against the average response of the current dosimeter stock or that used in the batch calibration.

5.6.1 从来货中和现有库存中恰当选择的样品应该是被放于相同的位置并被辐照的，这样所有的样品在批校准范围里接收相同的低、中、高剂量。使用一个成功执行测试所需要的、能为所有的样品提供一个相同剂量的测试夹具和工艺条件。
Appropriately selected samples from the incoming stock and the existing stock should be co-located and irradiated such that all samples receive the same dose at low, medium, and high doses within the calibrated range of the batch. Use of a test fixture and process conditions that provide a uniform dose to all samples is required to successfully execute the test (see the Appendix for detail).

5.6.1.1 从需要被测试的来货中抽取有代表性的样品。
Draw representative samples from the incoming stock to be tested.

5.6.1.2 从为先前的或目前库存保留的样品中抽取有代表性的样品。
Draw representative samples from the retained samples for the initial or current stock shipment.

5.6.2 以目标剂量辐照样品。
Irradiate the sample to the target doses.

5.6.3 如果适用的话，按照公司的程序文件的要求执行恰当的剂量计辐照后热处理。
Perform appropriate post-irradiation heat-treatment of the dosimeters in accordance with company procedure, if applicable.

5.6.4 在开始剂量计测量前确认分光光度计的校准。
Verify the calibration of the spectrophotometer(s) prior to beginning the dosimeter measurements.

5.6.5 测量每个剂量点的两组样品。将吸光度记录在 GEX Doc# 100-257《剂量计进货接收检查表》中。
Measure the absorbance of both sets of samples for each dose point. Record the absorbances in GEX Doc# 100-257, *Dosimeter Stock Receiving Inspection Form*.

5.6.6 为每一组响应计算平均值、标准偏差和变异系数 CV。比较两个样品组的平均值以确认其等价性。（GEX 推荐，来货的平均响应应该落在当前库存或先前库存的平均响应的±2 倍标准偏差范围里。如果来货平均响应被发现在 3 倍标准偏差之外，结果将被认为是失败的。如果结果落在 2 和 3 倍标准偏差之间，结果需要被调查以寻找可能的异常值。剂量计可以被从新测量并考虑从新测试。
Calculate the mean average, standard deviation, and CV for each set of responses. Compare the mean averages of the two sample sets to verify equivalency. (GEX recommends that the incoming stock average response should lie within ±2 standard deviations of the average response of the current or initial stock. If the incoming stock average response is found outside 3 standard deviations, it is considered to have failed. If the results lie between two and three standard deviations, results should be investigated for possible outliers. Dosimeters may be re-measured and a repeat of the test considered.

5.6.7 如果剂量计来货确认结果失败，联系 GEX 以讨论需要采取的恰当的措施。
In the event that the incoming dosimeter stock shipment fails, contact GEX to discuss appropriate actions to be taken.

5.6.8 所有测试剂量计应该被保留，直到测试结果通过接受标准或调查已经完成。
All test dosimeters should be retained until the test results pass the acceptance criteria or investigations are completed.

注意：和该程序文件相关的测试表 100-257 可以容纳每个测试条件下最大 32 个样品，这是 GEX 推荐的样品量。用户应该放在 Risø电子束模体里的最大剂量计包数是 6 包，可是，这样的样品量还不足以支持统计显著性。
NOTE: The test form (100-257) associated with this procedure accommodates a maximum of 32 samples per test condition which is the GEX recommended sample size. Six pouches of dosimeters is the maximum number of pouches the user should place in the Risø Electron Beam Phantom. However such a sample size may not be sufficient to support statistical significance.

注意： B3 剂量计进货，具有申明的平均厚度，该厚度与当前库存平均厚度差异多达±0.0002 mm，但 GEX 不认为该差异是显著的不同，可以经受住上述的适用当前库存的平均厚度的接收确认响应测试。如果剂量计进货响应测试失败，一个建议的纠正措施是调整平均厚度到申明的进货厚度值。这需要一个特定的 WINdose for Excel 软件版本的修改及一个新的“剂量估算表”的发布，它建立了一个新的平均厚度以使现成的批校准用于新剂量计库存。
NOTE: B3 dosimeter stock shipments with stated dosimeter average thicknesses that vary as much as ±0.0002 mm from the current stock average thickness are not considered by GEX to be significantly different and may undergo receiving verification response testing described above using the average thickness of the current stock. In the event an incoming stock of dosimeters fails response testing, a suggested corrective action is to adjust the average thickness to that stated for the incoming stock. This requires a modification of the calibration specific WINdose for Excel software version and issuance of a new “Dose Estimate Table” establishing a new average thickness to be used for the new stock of dosimeters with the existing batch calibration.

6.0 参考资料 REFERENCES

- ISO/ASTM 51261
- NPL CIRM Report 29

7.0 修订历史 REVISION HISTORY

日期 Date	版本 Revision	修改描述 Change Description
06/19/07	C	重大修订，完全重写。 Major Revision. Complete re-write.

附录
APPENDIX

剂量计测试夹具的鉴定
CHARACTERIZATION OF A DOSIMETER TEST FIXTURE

测试夹具应该被鉴定用于剂量计比较测试，以确保剂量计组以相同的剂量被辐照，±2.0%或更低，以比较测试结果。
A test fixture should be characterized for dosimeter comparison testing that will assure sets of dosimeters are irradiated to the same dose, ±2.0% or less, in order to compare test results.

测试夹具验证测试应该涉及到夹具的剂量分布，以验证夹具或模体的剂量分布的均匀性。
Test fixture verification testing should involve dose mapping of the fixture to verify the dose distribution uniformity of the fixture or phantom.

1.1 电子束工厂剂量计测试夹具的鉴定涉及到支架的开发，比如一个“三明治”式的，由一种低或中密度的均匀的吸收材料（比如聚乙烯泡沫）制成。当需要较多的用于测试的样品并超过 Risø电子束模体所能容纳的数量时，需要选择另一种夹具以避免 Risø模体内的过度拥挤。
Characterization of a dosimeter test fixture in an Electron Beam facility can involve development of a fixture, such as a ‘sandwich’, made from a low to medium density uniform absorber material such as Ethafoam (polyethylene foam). When more samples are required for dose testing than can be fit into the Risø Electron Beam Phantom, an alternative fixture to avoid overcrowding the Risø phantom is needed.

1.2 夹具应该设计为置于产品的载体里并与电子束的方向垂直，设计还要能确保它辐照过程中不要移动。
The fixture should be designed to sit in the product carrier perpendicular to the direction of the beam and should be designed so that it can be secured in place during irradiation.

1.3 做夹具的剂量分布以确认 ±2.0%或更好的剂量分布。
Dose map the fixture to verify a dose distribution of ±2.0% or better.

1.4 标准的 Risø校准模体通常可以容纳足够数量的 B3 剂量计包并应该被使用，除非验证测试证明它不能维持 ±2.0%的剂量均匀度。

The standard Risø gamma calibration phantom can typically hold an adequate number of B3 dosimeter packages and should be used unless verification testing demonstrates an inability to maintain a ±2.0% uniformity of dose.

1.5 和 1.1 中描述的相同的低或中密度均匀吸收材料可以被用来为伽玛辐照剂量计比较测试制作一个模体支架测试夹具。
The same low to medium density uniform absorber material described in 1.1 can be used to construct a phantom holder test fixture for gamma irradiation dosimeter comparison testing.

1.6 设计模体以在测试过程中牢固的固定住剂量计
Design the phantom to securely hold the dosimeters secure during testing.

注意：对于伽玛夹具的设计，多层剂量计包可以节省夹具里的空间，以使它在满足需要的情况下尽可能的小。对于电子束，将剂量计朝着移动的方向排列在束线的中心，在很多情况下能获得最佳的结果。在测试夹具中随机的放置样品可能有助于减小偏差引入。
NOTE: In the design of a gamma fixture, multiple layering of dosimeter pouches can save space in the fixture allowing it to be as small as necessary. In electron beam, arraying the dosimeters at the center of the beam line in the direction of travel in many cases provides an optimum result. Randomizing sample placement in the test fixture can help reduce the introduction of a bias.