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

描述了一个使用由 GEX 公司提供的 WINdose for Excel 剂量测量软件程序来测量 GEX WINdose 和 DoseStix 剂量计的完整的、自动的方法。

To describe an integrated and automated method that can be used to measure GEX WINdose and DoseStix dosimeters using the WINdose for Excel Dosimetry Software Program provided by GEX Corporation.

忠告 Advisory:

WINdose for Excel 软件程序开发用于帮助用户准备剂量测量报告，它允许用户完成实时的屏幕计算数据的输入和填写合适的微软 Excel 工作表单元格，以及以预先格式化的剂量报告的形式查看和打印结果，该报告可以被评审和签字以正式接受并批准剂量报告记录。该软件使用内置的带有Visual Basic 代码和自定义宏指令的微软 Excel 函数。该软件的开发含有==生命周期控制==并且根据普遍接受的行业惯例进过了验证。用户必须使用为他们的加工工厂开发的并适用于他们特定应用场合的批校准特定 WINdose for Excel 工作薄。

The WINdose for Excel software program was developed to assist users in the preparation of dosimetry reports by allowing the user to complete live on-screen computer data entry and fill-in appropriate Microsoft Excel worksheet cells as well as to view and print the results in the form of pre-formatted dose reports that may be reviewed and signed to formally accept and authorize the dose report records. The software utilizes built in Microsoft Excel functions with Visual Basic code and custom macros. The software was developed under life cycle design control and has been validated in accordance with generally accepted industry practices. Users must use the batch calibration specific WINdose for Excel Workbook(s) developed for their process facility and appropriate for use in their specific application.

注意 Caution:

该软件不是设计用于、也不是旨在用于电子记录保存活动。WINdose for Excel 软件为用户的特定分光光度计（Thermo Electron Genesys 20 是标准的）和运行 Windows 2000 和 Excel 2000 或更高版本的一台 PC 提供了数据整合。该软件程序也允许直接的条码阅读器输入到自定义的 Excel 电子表格的特定的单元格。

The software was not designed nor is it intended for use in electronic record keeping activities. The WINdose for Excel software provides data integration for the user's specific spectrophotometer (Thermo Electron Genesys 20 is standard) with a PC running Windows 2000

and Excel 2000 versions or higher. The software program also allows direct barcode reader data input into specific cells in the customized Excel spreadsheet.

2.0　范围 SCOPE

2.1　该程序文件讨论了 WINdose for Excel 软件技术，它对一个校准特定微软 Excel 工作薄中的特定的 B3WINdose 产品工作表来说是很普通的。某些特色产品，比如 B3110 能量测量卡或 B3106 均匀性条带，使用的附加要求可以在 WINdose for Excel 安装与操作手册里找到。

This procedure discusses the techniques in the WINdose for Excel software that are common to the specific B3WINdose product worksheets in a calibration specific Microsoft Excel workbook. Certain specialty products, for example the B3110 energy measurement card or the B3106 uniformity strip, use additional requirements that are found in the WINdose for Excel Installation & Operation Manual.

2.2　完成后的 WINdose for Excel 工作表可以通过人工方法确认（参见 4.21.1 和 4.21.2 部分）。

Completed WINdose for Excel worksheets may be verified using manual techniques (see sections 4.21.1 and 4.21.2.).

2.3　WINdose for Excel 软件程序可以接受来自一个连接的 Genesys 20 分光光度计的数据输入或由计算机键盘手工输入。

The WINdose for Excel software program can accept data entry input from an integrated Genesys 20 spectrophotometer or by computer keyboard hand entry.

2.4　WINdose for Excel 软件程序也可以被用于打印空的工作表以便用作手工数据输入表。

The WINdose for Excel software program can also be used to print blank worksheets for use as hand data entry forms.

3.0　材料 MATERIALS

3.1　WINdose 剂量测量系统
WINdose Dosimetry System

3.2　用于 B3 剂量计辐照后热处理的热处理系统（GEX P4800 或 P4900）
A heat-treatment system for post irradiation heat treatment of B3 dosimeters (e.g. GEX P4800 or P4900)

3.4　合适的 WINdose for Excel 校准特定工作薄

Appropriate WINdose for Excel Calibration Specific Workbook(s)

3.8 可选项：条码阅读器和计算机连接电缆
Optional: Bar code reader and computer connection cables

4.0 程序 PROCEDURE

注意：B3WINdose 剂量计会展现一个辐照后颜色形成过程，用户需要在最后的吸光度测量前通过对 B3 剂量计进行热处理以减小潜在的辐照后剂量计变化（详情请参见 GEX 技术备忘录 100-201《B3 薄膜剂量计产品的热处理》）。或者，用户也可以建立基于为校准建立的特定批校准测量数据的一个受控制的辐照后测量读取时间段。
NOTE: B3WINdose dosimeters may exhibit a post irradiation color development and users are highly encouraged to mitigate potential post irradiation dosimeter variance by heat treatment of the B3 dosimeters before final absorbance measurement (see GEX Tech Memo 100-201, Heat Treatment of B3 Film Dosimeter Products, for detail. Alternatively, a user may establish a controlled post irradiation time period for measurement readout based on the specific batch calibration measurement data established for the calibration.

注意：一些用户可能建立了单独的校准曲线以适应他们工厂的应用要求。这可能涉及使用多个 WINdose for Excel 校准特定工作薄或使用一个校准调节因子
NOTE: Some users may establish separate calibration curves to accommodate application requirements at their facility. This may involve the use of multiple WINdose for Excel Calibration Specific Workbooks or the use of a calibration adjustment factor.

4.1 使用前，确保被用于测量分光光度计在校准有效期内。
Ensure that the spectrophotometer being used for the measurements is in current calibration before use.

4.2 取出杯形支架（吸收池）、关闭样品室的盖子并打开分光光度计的电源。作为一项预先警告，确保每台 Genesys 20 仪器每 24 小时使用期重启一次，以允许仪器完成它的内部性能检查（大约 3 分钟），并在使用前允许仪器完成 30 分钟制造商建议的预热阶段。
Remove the cuvette cup and close the sample compartment lid and turn on the spectrophotometer. As a precaution, be sure to restart each of the Genesys 20 instruments once every 24 hour period of use to allow the instrument to cycle through its internal performance checks (approximately 3 minutes) and then allow the instrument the full 30 minute manufacturer suggested warm up period before use.

4.3 确认分光光度计设于 552 nm（或其它特定的适合于剂量计批校准使用的波长）并处于吸光度模式。

Verify that the spectrophotometer is at 552 nm (or other specified wavelength appropriate to the dosimeter batch calibration being used) and is in the Absorbance mode.

4.4   放一个空的剂量计支架在仪器里。（注意：如果测量 WINdose 剂量计，GEX 铰链式剂量计支架的锥形孔朝向仪器的本体，即远离用户。）轻轻地将支架一直压下直到不再移动。不要强制压下。关闭样品室的盖子并按一下分光光度计上的 "0 Abs" 按钮以将支架置零。 仪器显示读数应该为零。这表明仪器已经准备妥当可开始阅读剂量计。

Place an empty dosimeter holder into the instrument. (**NOTE**: If measuring the WINdose dosimeter, the conical hole of the GEX Hinged Dosimeter Holder faces into the body of the instrument, i.e. away from the user.) Gently press it all the way down until there is no further travel. Do not force it down hard. Close the sample compartment lid and press the "0 Abs" button on the spectrophotometer to zero the holder. The instrument display should read zero. This indicates that the instrument is appropriately prepared to begin reading dosimeters.

在每次剂量测量开始阶段，当将 GEX 铰链式剂量计支架用于 B3WINdose 剂量计产品时，建议用户尝试着插入支架数次并获得零读数，以使用户重新熟悉支架放置方法。

At the beginning of each dosimetry session, when using the GEX Hinged Dosimeter Holder for B3WINdose dosimeter products the user is encouraged to practice inserting the holder several times and achieving zero readings to reacquaint the user with the holder placement technique.

4.5   收集需要测量的剂量计，恰当的热处理剂量计或记录剂量计可以被恰当测量需要的控制时间。

Gather the dosimeters for measurement. Heat treat dosimeters appropriately or document the time control needed for the dosimeters to be measured appropriately.

4.6   双击文件图表，打开并启动 WINdose for Excel 校准特定工作薄。

Open and start the WINdose for Excel Calibration Specific Workbook by double clicking on the file icon.

4.7   当 Excel 启动时，你可能被问及是否希望禁止宏指令。单击 "使能宏指令" 按钮以完成工作薄的打开。

When Excel starts you may be asked if you wish to enable macros. Click the "Enable Macros" button to finish opening the workbook.

警告：选择"禁用宏指令"将不允许 WINdose for Excel 软件程序自动操作。宏安全应该被设为"低"，即使微软的天才们应该知道病毒已经不再被隐藏在宏里边了。

WARNING: Selection of "Disable Macros" will not allow the WINdose for Excel software program to operate automatically. Macro security should be set to 'LOW' even though the geniuses at Microsoft should know that viruses are not hidden in macros anymore.
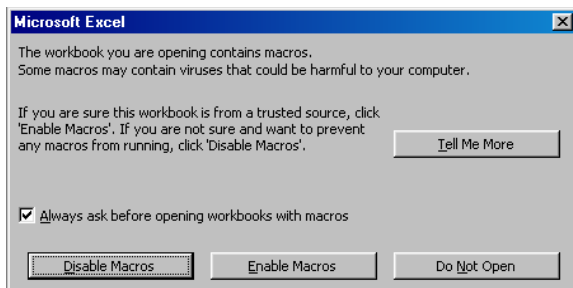

4.8   程序然后将搜索一个通过 RS232 连接的 Genesys 20 分光光度计长达 30 秒钟。在此期间不要有任何键盘输入或鼠标点击。
The program will then search for an RS232 integrated Genesys 20 spectrophotometer for up to 30 seconds. Do not make any keyboard entries or mouse clicks during this period.

4.9   如果程序不能和分光光度计通讯，一个消息窗口将出现在屏幕上。
If the program cannot communicate with the spectrophotometer, a message window will appear on the screen.
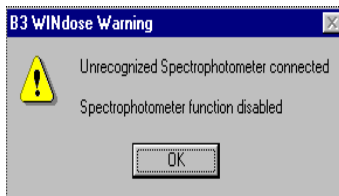
这是一个警告信息，不一定是一个出错信息。它仍然可以手动模式、使用键盘输入吸光度值、使用 WINdose for Excel 程序的剂量计算部分。有两种选择：
This is a warning message, not necessarily an error message. It is still possible to use the dose calculation portion of the WINdose for Excel program in a manual mode using keyboard entry of absorbance values. There are two options:

4.9.1 关闭程序并检查 RS-232 电缆与分光光度计和电脑的连接，重新启动程序。

Close the program and check the RS-232 cable connections on both the spectrophotometer and the computer. Restart the program.

4.9.2 在和分光光度计之间没有通讯的情况下继续进行。所有的剂量计测量必须使用计算机键盘手动进行。

Proceed without communications with the spectrophotometer. All dosimeter measurements must be made manually with the computer keyboard.

警告：WINdose for Excel 不是旨在用于电子记录保存或存档功能。存储的 WINdose for Excel 文件不符合 21 CFR Part 11 的安全责任和电子记录保管实践中的电子签名的需要。
WARNING: WINdose for Excel is not intended for use in electronic record keeping or archiving functions. Stored WINdose for Excel files do not meet 21 CFR Part 11 requirements for security liability and electronic signature in electronic record keeping practices.

打印的 WINdose for Excel 工作表，根据用户的 SOPs 的要求，经恰当的复核并由用户签字，是能满足 21 CFR Part 11 的记录要求的。
Printed WINdose for Excel worksheets that have been properly reviewed and signed by the user in accordance with the user's SOPs can satisfy the 21 CFR Part 11 record requirements.

4.11 选择合适的工作表薄中的工作表。点击屏幕底部的当中的一个标签（正规术语为"plys"）。对于每一种剂量计产品或应用都由单独的工作表。

Select the appropriate worksheet in the workbook. Click on one of the tabs (the formal term is "plys") at the bottom of the screen. There are separate worksheets for each dosimeter product or application.

4.12 在屏幕顶部有填充色的单元格里输入加工信息。信息输入后，单元格变成白色。在任何空单元格里填入"N/A"。

Enter the processing information in the colored cells at the top of the screen. As information is entered, the cell turns white. Fill in any empty cells with "N/A".

注意：该程序文件提供了一个使用 *WINdose for Excel* 软件记录剂量计测量结果的一般描述。详细说明，请参见 *WINdose for Excel* 安装与操作手册的相关部分。

NOTE: *This procedure provides a general description of use the WINdose for Excel software to record dosimeter measurements. For detailed instructions, see the appropriate sections of the WINdose for Excel Installation & Operation Manual.*

4.13 将剂量计号码输入到标题为"Dosimeter ID"下的恰当的单元格，如果使用条码阅读器，将剂量计包装通过条码阅读器下方，号码将被读出并输入到单元格，并且右边的下一个单元格变成活动单元格。
Enter the dosimeter number in the appropriate cell under the heading "Dosimeter ID". If using a barcode reader, pass the dosimeter package under the barcode reader. The number will be read and entered in the cell, and the next cell to the right highlighted.

18	P8003		Dosimeter	Irradiated Absorb.		Response			Adjusted
19	Max Temp	Dosimeter ID	Position	A	B	(Ai - Ao) / t	Dose (kGy)		Dose (kGy)
20		1234567		0.000	0.000	0.000	na		

4.14 输入一个剂量计位置于合适的单元格。这可以是载体的编号或一个特殊的测试位置或其它任何描述性的文本，比如"参考位置"。
Enter a dosimeter position in the appropriate cell. This can be the carrier number or a special test location or any other descriptive text, such as "reference position".

4.15 打开剂量计包装，小心不要损坏剂量计或用裸手指触摸薄膜区域。
Open the dosimeter package, taking care not to damage the dosimeters or touch the film area with bare fingers.

4.16 从分光光度计里取出剂量计支架（如果需要）并打开（注意：测量 GEX DoseStix 剂量计不涉及从分光光度计里取出支架。）
Remove the dosimeter holder (if needed) from the spectrophotometer and swing it open. (NOTE: Measurement of the GEX DoseStix dosimeters does not involve removal of the holder from the spectrophotometer.)

4.17 将剂量计放在合适的剂量计支架里并合上剂量计支架（如果需要的话）。为测量的剂量计选择工作表 "Irradiated Absorbance" 单元格。插入装有剂量计的支架到分光光度计里，关闭样品室的盖子。
Place the dosimeter in the appropriate dosimeter holder and close the dosimeter holder if necessary. Select the "Irradiated Absorbance" cell of the worksheet for the dosimeter replicate being measured. Insert the loaded dosimeter holder into the spectrophotometer. Close the sample compartment lid.

4.18 将剂量计剂量点组的每一个剂量计的 "辐照后的吸光度" 输入到合适的单元格，重复次数取决于 B3WINdose 产品工作表的使用。同时压下"Ctrl & Shift"两格键并保持，再压下字母"a"键。吸光度将被拷贝到剂量工作表，然

后右侧的下一个单元格将变成活动单元格。进行完一个测量后不要按 "Enter" 键。

Enter the "Irradiated Absorbance" in the appropriate cell for each dosimeter replicate in the dosimeter dose point set. The number of replicates may vary depending on the B3WINdose product worksheet being used. Simultaneously press the two keys "Ctrl & Shift" and while holding them down press the "a" letter key. The absorbance will be copied into the dose worksheet, and then the next cell to the right will be highlighted. Do not press the "Enter" key after making a measurement.

18				Irradiated Absorb		Response
19	Dosimeter ID	Position	A	B	
20	AA- 1234567	sample			#DIV/0!
21					

重要提示：与分光光度计显示的值比较以核实单元格中的值。视情而定使用计算机键盘覆盖计算机工作表中的数据以修改任何差异。

IMPORTANT: Verify the value in the cell against the value of the spectrophotometer display. Correct any discrepancies using the computer keyboard to overwrite the data in the computer worksheet as appropriate.

4.19　将剂量计从分光光度计中取出。重复步骤 4.13 至 4.18 直到该轮所有剂量计包测量完毕。遵照 WINdose for Excel 安装与使用手册中为特定的产品工作表提供的特定说明。

Remove the dosimeter from the spectrophotometer. Repeat steps 4.13 through 4.18 until all dosimeter packages for that run have been measured. Follow the specific instructions provided for the specific product worksheet in the WINdose for Excel Installation & Operation Manual.

18			Irradiated Absorb		Response	Calculated		Adjusted	Avg. Ref.	Avg. Ref.
19	Dosimeter ID	Position	A	B		Dose (kGy)	Formula	Dose (kGy)	Min Dose	Max Dose
20	AA- 1234567	sample	0.396	0.334	17.568	21.3		21.3	18.1	27.6
21	AA- 1234568	sample	0.249	0.411	15.676	18.8		18.8	15.9	24.4
22	AA- 1234569	sample	0.424	0.232	15.568	18.6		18.6	15.8	24.2
23	AA- 1234570	sample	0.240	0.515	18.243	22.2		22.2	18.9	28.8
24	AA- 1234571	sample	0.512	0.395	22.351	28.0		28.0	23.8	36.3
25	AA- 1234572	sample	0.593	0.555	28.865	38.1		38.1	32.4	49.6

4.20　加工运行的 最小剂量和最大剂量被自动计算，它们的值也被显示在工作表顶部恰当的单元格。

Minimum doses and maximum doses for the process run are automatically calculated and their values displayed in the appropriate cells in the top portion of the worksheet.

4.21　打印并复核剂量计测量报告。

Print and review the dosimetry report.

4.21.1 复核可以包括通过手工计算对计算值的验证。
The review can include verification of calculated values by hand calculation.

4.21.2 剂量可以通过使用和特定剂量计批校准报告一起提供的《剂量表》进行验证。详情请参见 GEX 推荐的程序文件 100-255《WINdose for Excel 验证》。
Doses can be verified by using the Dose Tables supplied with the specific dosimeter batch calibration report. See GEX Recommended Procedure 100-255, WINdose for Excel Verification, for detail.

注意：如果 WINdose for Excel 软件操作失败，剂量测量报告可以使用从分光光度计获得并记录的吸光度读数完全由手工产生，参考 4.1 至 4.4 部分提供的信息（以及 4.5，如果适合的话）。使用《剂量估算表》以确定记录的剂量计吸光度的剂量估算值。
NOTE: In event of operational failure of the WINdose for Excel software, dose measurement reports may be generated entirely by hand using the absorbance readouts obtained and recorded from the spectrophotometer using the information provided in sections 4.1 through 4.4 (and 4.5 if appropriate). Use a "Dose Estimate Table" to determine the dose estimate values for the recorded dosimeter absorbances.

4.22 关闭剂量测量工作薄。
Close the dosimetry workbook.

4.23 视情而定重新打开主工作薄以创建更多的报告。
Reopen the master workbook to create additional reports as appropriate.

4.24 设备关机
Equipment Shutdown

4.24.1 将空的剂量计支架放入分光光度计，关闭样品室的盖子并关闭分光光度计电源。
Place the empty dosimeter holder in the spectrophotometer, close the sample compartment lid and turn off the spectrophotometer.

4.24.2 几分钟后，放置防尘罩于仪器上。
After a few minutes, place the dust cover on the instrument.

4.24.3 如果使用的话，让恒温箱一直处于开机状态，因为通常来说，当从室温开始加热时，恒温箱需要几个小时才能稳定于工作温度。
If utilized, leave the incubator on at all times because an incubator typically requires several hours to stabilize at operating temperature when coming up from ambient room temperature.

注意：Genesys 20 仪器可以连续处于开机状态，需要每天一次简单的重启。和许多类型的设备一样，该仪器设计用于连续运行。每天 24 小时运行将需要大约每月更换一次灯泡。
NOTE: The Genesys 20 instrument may be left "On" continuously, requiring a simple restart each day. Like many types of equipment the instrument was designed for continuous operation. 24 hour a day operation will require that the lamp be changed approximately once every month.

5.0 修订历史 REVISION HISTORY

日期 Date	修改描述 Change Description	版本 Revision
09/21/10	规定吸光度测量使用552nm Specified 552 nm during absorbance measurement	D