TECHNICAL MEMORANDUM

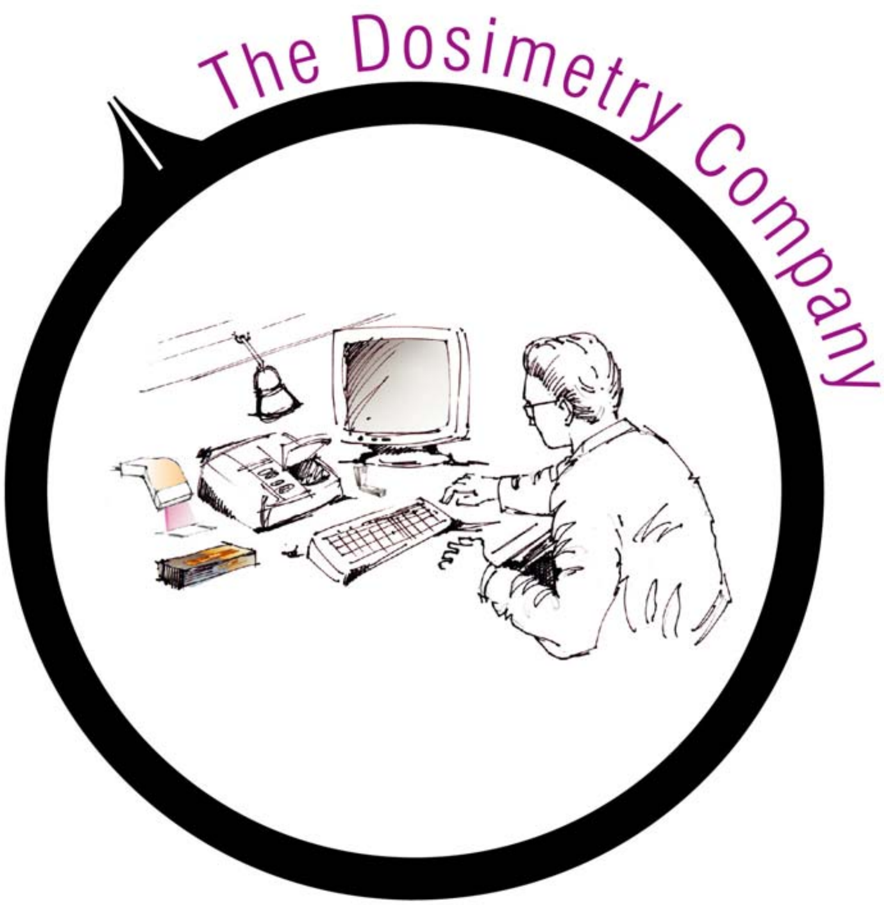
NOTICE: This document is version controlled and was produced as a part of the GEX Information Program which requires that all Series 100 documents be reviewed periodically to maintain currency and continuity of information. Appropriate Technical Memorandum are used to provide information detail in support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

REVISION HISTORY: Sept. 1, 2010 *Minor change – Corrected listing of wavelength scan range to 545nm to 559nm.*

Aug. 1, 2007 *version is a major revision and replaces and updates the 02-22-07 document version and relates to all B3 dosimeters and B3 film material effective with the introduction of the GEX B3 film batch BB and subsequent dosimeter batches. Refer to the March 5, 2004 version of this document for general information related to B3 batches prior to B3 film batch BB.*

B3 RADIOCHROMIC FILM DOSIMETRY

RELEASE DATE: September 1, 2010



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Providing Total Dosimetry Solutions Since 1991

B3 Radiochromic Film Dosimetry

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B3 Radiochromic Film Dosimetry

This document is intended to serve as an informational reference for users or potential users of B3 dosimetry. The information contained in this document supports and expands on information provided in GEX recommended procedures, technical memorandum, product data sheets and related marketing documents. GEX has developed specific dosimetry systems with proceduralized controls intended to optimize B3 film dosimeters. The information provided in this document represents the current collective knowhow of GEX as it relates to the practice of dosimetry with B3 film.

Because of our commitment to continuous improvement, we encourage B3 dosimetry users and other interested parties to visit our website frequently to obtain new or revised information documents. We review all of our customer communication information series documents on an annual basis and include a brief revision history with our version updates. GEX provides current customers with notification regarding revisions made to these information documents.

INTRODUCTION

GEX Corporation has been providing dosimetry products and services since its founding in May 1991 and is known worldwide simply as the "Dosimetry Company". GEX personnel as well as our supplier chain staff are readily available to assist our B3 dosimetry users in obtaining optimum results.

GEX applies a total vertical integration solution for B3 radiochromic film dosimetry to assure controlled uniformity from the raw chemistry stage through final dose output of the B3 dosimetry system. Every aspect of GEX B3 dosimetry is controlled and monitored by formal procedure.

The total B3 dosimetry solution provided through GEX includes B3 dosimeters and specifically designed B3 dosimetry systems including GEX recommended practices in the form of dosimetry procedures to cover all aspects of B3 dosimetry including dosimeter batch calibration.

GEX implemented numerous quality improvements throughout the B3 dosimeter manufacturing and packaging processes during the past few years. These changes were quite seamless to our B3 dosimetry user base but have resulted in noticeable reductions in overall uncertainty based on current B3 batch calibration results.

Our ability to provide complete dosimetry solutions allows us to partner with our users to better understand their specific application needs to continuously improve B3 dosimetry. Our growing user base also allows us to develop cost effective new developments.

We appreciate those early B3 dosimetry users along with our key supplier chain personnel who helped contribute information and comment that greatly aided our efforts with past improvements and look forward to working with our growing user base to further advance B3 dosimetry.

OVERVIEW OF A DOSIMETRY SYSTEM

A dosimetry system is defined as being comprised of the measurement instrumentation and its calibration references along with the dosimeters and the procedures needed to effectively use the dosimetry system. An effective dosimetry system design optimizes a specific dosimeter and the dosimetry system procedures therefore specify the details needed to achieve and maintain dose measurement performance that is specified for a given dosimetry system.

In a perfect dosimetry system, the dosimeters used to measure doses would be completely stable before and after irradiation, exhibit a linear response with a response/dose slope of 1.0 over a dose range from near zero dose to hundreds of kilogray (kGy). The mass or thickness of the dosimeters would not vary nor would the response function of the dosimeters be affected by temperature, time, humidity or any other influence quantity.

Unfortunately, in the real world, there is no such thing as a “perfect dosimetry system” or a “perfect dosimeter” for that matter. All dosimeters are problematic and require the use of specific controls and limits in order to establish a dosimetry system that can optimize the performance of the particular dosimeter being used. Even though all dosimeters impose limitations on the dosimetry system, some dosimeters are easier to manage than others and result in a simple to use dosimetry system.

In the end, the goal of a dosimetry system is to provide predictable accurate doses that optimize a particular dosimeter. The optimum performance in terms of dose accuracy of a given dosimetry system is expressed in terms of the level of uncertainty attainable with a given dosimetry system for a given range of doses. Although the specific dosimeter used in a dosimetry system imposes limitations and requirements on the dosimetry system, the actual performance of a dosimetry system depends on the metrological rigors imposed on every aspect of the system.

It is not simply the dosimeter or dosimeter material being used that controls the accuracy and reliability of the dosimetry outcomes but rather it is the metrological controls of the dosimetry system that determines the quality and accuracy of dose outcomes. It is important to be aware of the fact that two dosimetry systems using an identical dosimeter calibrated to the same range of doses can result in significantly different levels of dose accuracy or overall dose measurement uncertainty.

For example, an alanine pellet dosimetry system used at a traceable calibration standards laboratory as a transfer standard dosimetry system will generally employ a research grade EPR spectrometer measurement system costing several hundred thousand dollars. The metrology methods used would typically call for four replicate alanine pellets to be used per dose measurement and each replicate alanine pellet would be measured once and then its position in the EPR spectrometer rotated for a second measurement. The mass of each pellet would also be individually measured to determine a specific response for each pellet based on the average of its two measurements divided by its specific mass. This process is repeated for each of the four replicates with an average dose reported for the dose point. It is expected that the reported doses for transfer standard alanine pellet dosimeters will be provided with an expanded overall uncertainty statement at k=2 or 95% of 2.5 ±0.5 percent.

Contrast the metrological quality rigors of a transfer standard alanine dosimetry system with a typical routine alanine pellet based dosimetry system. With a routine alanine pellet based dosimetry system, the user will generally utilize a bench top EPR spectrometer costing fifty to sixty thousand dollars as the measurement system. The routine alanine dosimetry system user however, can purchase the alanine pellets from the same alanine batch from the same supplier used by the transfer standard alanine laboratory user. A major difference between the two users will be that the routine alanine user will typically only use a single alanine pellet per dose point and then only measure the single alanine pellet once. The typical routine alanine dosimetry system user will generally not measure the individual mass of the alanine pellet and simply rely on using the manufacturer's stated average mass of the alanine pellets that are provided with the batch shipment to estimate the dose for a given dose point. In the case of the routine alanine pellet dosimetry system using a single pellet per dose point and using an average mass one should expect an expanded overall uncertainty at k=2 or 95% confidence on the order of 5.0 ±1.0 percent.

DOSIMETRY SYSTEM SELCTION PROCESS
The selection of a dosimetry system for use in a given application should involve the establishment of formal requirements for the dosimetry system. The requirements to be considered should be:

- Irradiation process application – sterilization, food irradiation, etc.
- Dosimetry system application – reference or routine dosimetry
- Dose range(s) – routine processing, facility dose mapping, sterilization dose setting, etc.
- Type of radiation source – gamma, X-ray, high energy e-beam or low energy e-beam
- Operational environment – i.e. temperature range(s), dose rate(s), etc.
- Spatial resolution – size and flexibility of dosimeter
- Acceptable overall uncertainty level - maximum and average

The dosimetry system selection process generally begins with an initial identification and a preliminary evaluation of commercially available dosimeters that can satisfy the user's requirements.

B3 FILM DOSIMETRY SYSTEM CONSIDERATION
B3 dosimetry is a universally acceptable selection that will satisfy the requirements of most routine dosimetry system applications because of B3's outstanding pre and post irradiation stability with its extremely wide dose range, small thin size and dose rate independence. A standard GEX B3 *WINdose Dosimetry System* using GEX factory conditioned and packaged B3 *WINdose* and *DoseStix* dosimeters can typically meet or exceed the accuracy and performance requirements of any dosimetry system with a dose range requirement greater than 300 gray (Gy) and less than 160 kGy.

The GEX B3 based *WINdose Dosimetry System* has become the dosimetry system of choice, accounting for the vast majority of dosimetry systems installed since 2000 because of its operational simplicity and predictable reliability and accuracy.

B3 RADIOCHROMIC FILM
The centerpiece of any dosimetry system is always the dosimeter. A dosimeter is defined as a device that undergoes a quantifiable change when irradiated.

B3 radiochromic film material turns from clear to deepening shades of pink or magenta color associated with exposure to sources of ionizing radiation. B3 film is generally measured using a spectrophotometer, as with the GEX *WINdose Dosimetry System* to determine the post irradiated absorbance or amount of color change induced due to exposure to doses of ionizing radiation. It may also be quantifiably measured by an optical technique using bit mapped images, as is done with the RisøScan software program.

B3 radiochromic film as it is named today emerged as the result of research carried out at Risø National Laboratory between 1978 and 1980 that investigated a variety of potential radiochromic film materials. The final version of B3 film (B**3** indicates it is a third generation version) that evolved from this research uses a Risø proprietary pararosaniline dye dissolved in polyvinyl butyral (PVB).

See Appendix A for a full discussion of B3 radiochromic film including discussion of its physical, chemical and performance characteristics. Appendix B of this document provides a description of B3 film and B3 WINdose and DoseStix dosimeter manufacturing processes.

The decision by GEX to use B3 film as the dosimeter to be used for the *WINdose Dosimetry System* drove the requirements needed for the measurement instrumentation that resulted in selection of the Genesys 20 spectrophotometer. See the “Recommended Practices for Genesys 20 Instruments” Technical Memorandum (GEX Doc# 100-210) for technical detail regarding the *WINdose Dosimetry System* measurement instrument.

DOSE RANGE
The practical or usable range of B3 radiochromic film is ultimately determined by the end user based on their specific practices and the process application in which the *WINdose Dosimetry System* is used. B3 radiochromic film is currently being used in *WINdose Dosimetry Systems* over a dose range from as low as a few hundred gray (Gy) to more than 150 kilogray (kGy). The maximum irradiation temperature should be limited to 60°C and GEX has not studied B3 film below -5.0°C. In-situ calibration is recommended to best capture B3 response function.

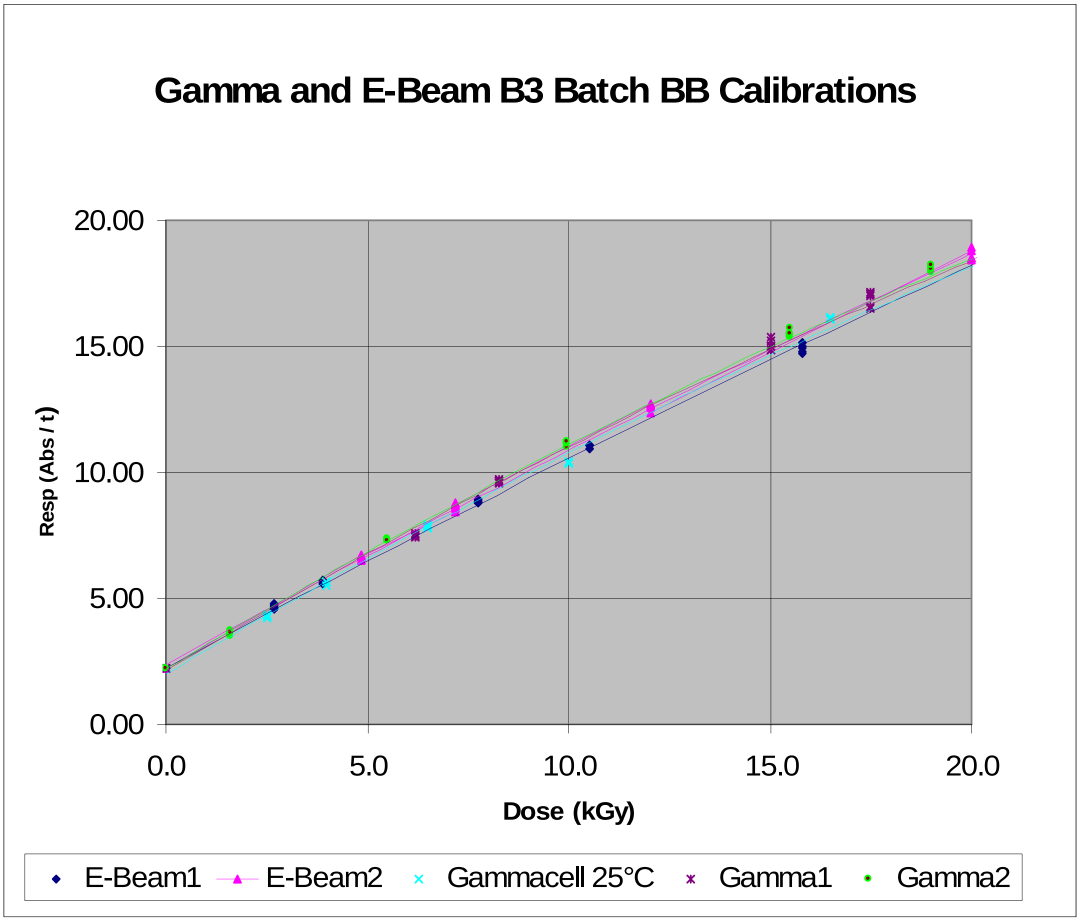
DOSE RANGE LIMITATIONS
Dosimetry system range limitations are affected by two major factors. The first limiting factor is related to instrument noise or error that imposes a lower end limit to the dose range with dosimeter response or signal saturation coming into play and limiting the high end of the range. A maximum acceptable level of dose measurement uncertainty is often used when setting actual dosimetry system calibration lower and upper dose range limits.

LOWER PORTION OF B3 DOSE RANGE
There are actions that can be taken to mitigate or minimize the impact of “instrument noise” and allow some extension of the range. For example, the B3 dose range can be extended lower by irradiating two B3 dosimeters together and using the measurement technique of placing two B3 dosimeters together inside the dosimeter holder which doubles the absorbance measurement value to reduce instrument noise (combination of error attributable to spectrophotometer drift and measurement value rounding) at the bottom of the range by approximately 50 percent. This simple measurement technique can be used to reduce measurement uncertainty sufficiently to allow a user to extend the calibration well below 1.0 kGy. This measurement technique is the equivalent of simply doubling the thickness of B3 film.

B3 RESPONSE SLOPE
The quantifiable color change in B3 film demonstrates a slope (ratio of measured B3 absorbance value/thickness or “response” to dose) of 2.0 at 2.0 kGy, reducing to a slope of 1.0 near 35 kGy, on to a slope near 0.6 at approximately 100 kGy. Noticeable saturation can be

observed near 50 kGy with full response saturation occurring at a dose of approximately 160 kGy or an absorbance value of approximately 1.600.

The influence of temperature on B3 response is not significant at the lower end of the B3 dose range. Calibrations performed under fixed temperatures in a laboratory Gammacell compared with those performed in-situ in large scale gamma and electron beam facilities result in similar calibration response functions (±1.0%) from below 1.0 kGy through approximately 20 kGy (example calibration response/dose plots are shown below).



UPPER PORTION OF B3 DOSE RANGE

The upper portion of the B3 dose range is driven almost exclusively by saturation of the B3 response signal which shows full saturation above an absorbance value of 1.600 (160 kGy with electron beam and above 180 kGy with gamma).

REGRESSION ANALYSYS CURVE FITTING

A least squares regression of the B3 response function is best described and fitted with a second order polynomial or quadratic curve that can be used over a range from below 1.0 kGy up to 80 kGy. The slope from 300 Gy to 10 kGy is nearly linear and can readily support the use of a linear fit. The slope of the B3 response beyond 80 kGy however becomes more saturated and will typically involve use of a third order polynomial or cubic fit to best describe the response function when going beyond 80 kGy.

RADIATION PROCESSING APPLICATIONS

B3 radiochromic film dosimetry is highly versatile and is used successfully in a variety of high dose radiation processing applications.

- Sterilization of Medical Devices
- Food Irradiation
- Curing and Cross Linking
- Research and Development

B3 RADIOCHROMIC FILM DOSIMETERS

B3 film is available from GEX in bare film rolls or sheets as well as in pre-packaged dosimeter formats. The B3 WINdose and DoseStix dosimeters are pre-conditioned under controlled relative humidity conditions to optimize the response uniformity of the B3 dosimeters. These factory packaged dosimeters should remain sealed until after they are irradiated to retain the uniform factory controlled conditions. Bare unpackaged B3 film strips and sheets should be used under 30% to 70% RH conditions for best results. If B3 film dosimeters are used outside of factory supplied packaging the use of factory packaged controls is recommended.

GEX B3 DOSIMETRY SYSTEM DEVELOPMENT

The historical development of GEX B3 dosimetry began when GEX founder Gary Pageau initially became acquainted with B3 radiochromic film properties in 1985 when it was used in a series of product dose mapping experiments carried out at Risø. However, serious interest in B3 film only arose with the potential of using B3 film as the cornerstone for a standardized dosimetry system following the casting of a large B3 film batch (10 million square centimeters) in 1997. An investigational effort began in 1998 to evaluate B3 film characteristics. The effort was initially based on published papers and preliminary information provided by Arne Miller based on his personal experience observed during his more than 15 years of routine use of the B3 film material that he had developed.

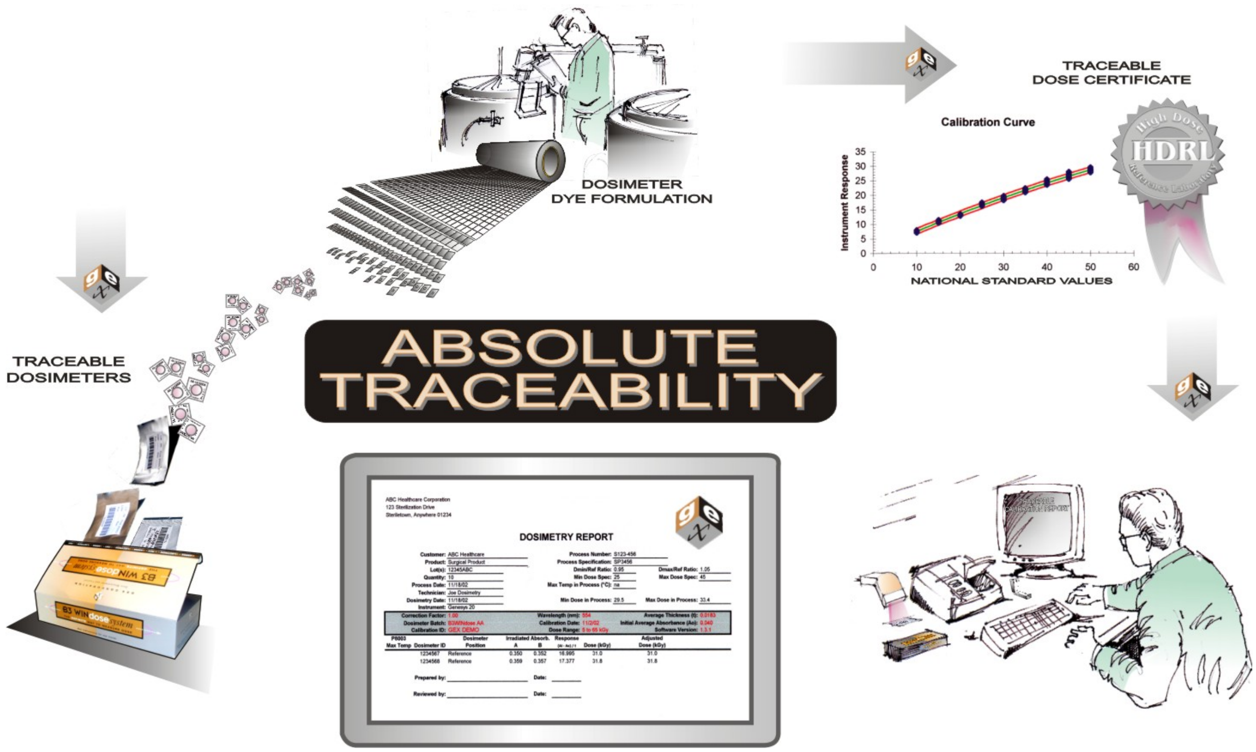
Two superior technical features associated with B3 film were immediately identified by GEX. The first was the compelling appeal of B3 film being able to cover an extremely wide dose range with measurements performed at a single wavelength. While this is an extremely important characteristic of a dosimeter, it paled in significance with the pre and post irradiation stability characteristic behavior that B3 film demonstrated.

GEX considers dosimeter stability to be the most important characteristic of a dosimeter. On the negative side however, it was also obvious that B3 film must undergo an additional post irradiation heat treatment process step in order to actually achieve the complete post irradiation stability that was so desired.

It would turn out later in the dosimetry system development process that B3 film could also serve as a reference material to monitor dosimetry system performance over time. Additionally, it was concluded from the published results and initial B3 film testing that the B3 material was affected by time, temperature and humidity changes. These influence factors affecting B3 response were identified as readily manageable by pre-conditioning B3 dosimeters in factory sealed packages combined with in-situ calibration performed under the irradiation process and environmental conditions of normal use.

GEX B3 DOSIMETRY SYSTEM CONCEPT DESIGN DEVELOPMENT EFFORT

The *WINdose Dosimetry System* design was based on the original spectrophotometer integrated design with the automated dose report generation software originally developed and used at the IOTECH, Inc. contract gamma sterilization company (IOTECH was founded in 1983 by Gary Pageau). The standardized B3 film based dosimetry system was to provide absolute traceability of dose from raw material through final dose reporting with a completely integrated approach.



The initial requirements for the GEX B3 concept dosimetry system were completed and formalized in the fall of 1998 and a B3 dosimetry system prototype development effort was initiated. Initial activities involved evaluation of spectrophotometer performance using both bare one cm^2 B3 film dosimeters as well as initial prototype one cm^2 B3 WINdose dosimeters. The prototype B3 WINdose dosimeters used a paper overlay with a 3.0 mm diameter aperture that was pre-printed with a unique dosimeter ID number as well as the B3 batch ID information.

The aperture diameter used with initial B3 WINdose dosimeter prototypes proved to be too narrow and resulted in the die-cut paper overlay edges interfering with the light beam of the spectrophotometer in an irregular manner that affected absorbance measurement. The WINdose dosimeter die was replaced with a new 5.5 mm diameter die and the WINdose dosimeter holder diameter was set to a 2.5 mm width as the final specifications adopted for use in the new WINdose dosimetry system. The 3.0 mm diameter difference between paper overlay and the B3 film holder aperture provided the necessary manufacturing clearance variance to eliminate the potential of interference from the paper overlay of the B3 WINdose dosimeter containing the individual dosimeter replicate ID and the B3 batch ID data.

It was determined at the outset of the design development that B3 measurement results obtained with the Genesys 20 spectrophotometer using the same sets of B3 WINdose and bare film dosimeters were significantly more reproducible and uniform (particularly at lower doses) than results obtained with the more sensitive Genesys 5 and Genesys 2 spectrophotometers. The better results obtained with the Genesys 20 instrument were attributed at the time to the averaging effects of the Genesys 20 on absorbances around the B3 absorbance peak as a result of the wider 8nm slit width of the Genesys 20 compared with the narrower slit widths of the higher precision more sensitive and more expensive spectrophotometers.

CONTINUING B3 DOSIMETRY IMPROVEMENT
It would be several years before this conclusion to settle on the Genesys 20 instrument would be confirmed and supported. Confirmation of the Genesys 20 selection in 1999 was finally demonstrated in 2004 with evidence in the form of scans made over the B3 peak that were performed using a Cary/Varian 300 spectrophotometer. The B3 peak scan data clearly demonstrated the impact of optical interference fringes on B3 film measurements.

GEX research into the impact of these optical interference fringes on B3 film measurements made with narrow spectral band width spectrophotometers led to development of a prototype dosimetry system prototype using a Cary/Varian 300 instrument with software that can use the B3 fringing data obtained in off-peak scans of B3 dosimeters to accurately resolve and measure specific B3 film thicknesses coupled with using an average of the scanned absorbances over B3 film peak of the dosimeter to derive specific B3 dosimeter response values.

This GEX research led to use of optical thickness measurements of B3 dosimeters in 2007 that replaced traditional electro-mechanical thickness gauges as part of the GEX B3 dosimetry manufacturing process to better characterize (0.05 micron vs 0.3 micron measurement reproducibility) incoming B3 film batch roll thickness.

GEX B3 WINDOSE DOSIMETRY SYSTEM
A formal patent application with the B3 dosimetry system description was submitted in June of 1999 documenting the development effort and a patent (US 6,232,610 B1) was granted and assigned to GEX Corporation May 15, 2001. It is interesting to note that virtually all of the concepts described in the patent were actually fulfilled with the release of the initial B3 WINdose Dosimetry System in 1999 although some of the over internet actions described in the patent would take several years beyond that to be realized and demonstrated.

The actual performance characteristics of the B3 dosimeter before, during and after irradiation determined the metrological practices that GEX would use with B3 film dosimeters and the new *WINdose Dosimetry System*. GEX included a series of standard operational procedures with recommended information for control of the B3 dosimetry system including B3 dosimeter batch calibration activities with the initial release of the B3 *WINdose Dosimetry System*. These procedures have been and continue to be revised and updated periodically.

The GEX B3 *WINdose Dosimetry System* has enjoyed excellent acceptance and is already the dominant routine dosimetry system with a base of more than 100 standardized B3 *WINdose* systems now installed. The proprietary and patented *WINdose Dosimetry System* included the development of a line of pre-packaged GEX B3 dosimeters. Initial *WINdose* dosimetry systems used the GEX *WINdose* (bottom) dosimeter until the popular B3 DoseStix (top) format was introduced in 2003.

The *WINdose Dosimetry System* along with the proprietary *WINdose* dosimeters introduced in 2000 was based on proven GEX knowhow and experience gained from designing, building and operating custom one-of-a-kind dosimetry systems since 1991. GEX applied strict principals of standardization in its development of the *WINdose Dosimetry System* such that each of these systems is interchangeable and B3 response measurements can be maintained to ±1.0% from system to system (see “Daily Checks Example” data results for two Genesys 20 instruments in the back of the Technical Memorandum 100-210, Genesys 20 – General Practices and Information).

GEX developed the *WINdose Dosimetry System* to take advantage of unique characteristics found in the B3 radiochromic film. The most significant properties of B3 film that make it a quality dosimeter are its complete stability both before and after irradiation along with its ability to be used to accurately measure doses over an extremely wide range of doses (<300 Gy to more than 160 kGy).

Our working knowledge of B3 film has expanded and undergone refinement as the B3 film gained popularity with usage over the complete spectrum of ionizing radiation sources. However, the *GEX WINdose Dosimetry System* specifications of today remain little changed from our original specifications developed in 1999 and used in the first prototype systems. A software revision was validated in 2002, the *DoseStix* dosimeter format was introduced in 2003 and a micro incubator based heat treatment system was added in 2007.

The *WINdose Dosimetry System* is designed to use either the *WINdose* or *DoseStix* format of B3 film dosimeter. *WINdose* was designed as a complete dosimetry system and includes the measurement instruments and their standards along with the dosimeters and a full set of operating procedures to manage the measurement quality or performance of the dosimetry system.

WINdose is provided as a standard dosimetry system with an option to integrate the Genesys 20 spectrophotometer with a standard Microsoft Windows based PC to automate the dose measurement process. A base *WINdose* system without user specific B3 dosimeters consists of:

- Genesys 20 spectrophotometer with a national lab traceable standards set
- B3 film holder(s) for the WINdose (or bare B3 films) and DoseStix dosimeters
- GEX *WINdose Dosimetry System* procedures
- Post irradiation B3 dosimeter heat treatment system

The base *WINdose Dosimetry System* will cost the user approximately $4,200 and $7,500 depending on the heat treatment system option selected. The base *WINdose* system can be used in a manual operation along with a B3 dosimeter batch calibration dose lookup table.

However, most *WINdose Dosimetry System* users select and use the dose automation option that integrates the Genesys 20 with a PC to automate the dose measurement process and speed data input while reducing data error. The WINdose automation upgrade option will cost the user approximately $1,000 and includes:

- *WINdose* for Excel instrument integration and dose report software program
- Computer/spectrophotometer interface cable
- B3 dosimeter barcode reader

This generic *WINdose Dosimetry System* provides a uniform base system which is then tailored to the user's specific requirements with the user's selection of their specific B3 dosimeter format product(s).

USER SPECIFIC OPTIMIZATION OF THE WINDOSE DOSIMETRY SYSTEM

A *WINdose* system is made user application specific with the simple selection of the particular B3 *WINdose* or *DoseStix* dosimeter package format(s) and the number of dosimeter replicates per package to be used. Measurement uncertainty reduces by the square root of the number of replicate dosimeters used per dose point. For example, a near 30% reduction in measurement uncertainty is achieved by simply going from a single replicate to two replicates and a 50% reduction is achieved by using four replicates.

If an even greater level of precision is needed, another 35-40% reduction in dosimeter to dosimeter measurement uncertainty can be achieved with measurement of the individual thicknesses of the B3 dosimeters. Please contact GEX to discuss instrument recommendations along with technical considerations associated with thickness measurement of thin film dosimeters.

For those users that require extremely low doses (<1.0 kGy) for their application, it has been appropriately verified that two B3 *WINdose* or *DoseStix* dosimeters can be placed together and measured simultaneously. This measurement technique is useful in reducing the amount of influence from instrument noise and therefore can allow a user to extend the bottom of the B3 calibration dose range down to a few hundred Gy while still maintaining an acceptable level of dose measurement uncertainty.

The manner in which the dosimeter batch calibration is carried out and the range of the calibration also impact overall uncertainty. B3 dosimeter batch calibration is discussed in detail in the upcoming *WINdose Dosimetry System* Calibration Section. In summary, simply limiting the calibration range by using multiple calibration ranges is an effective means of optimizing a B3 dosimetry system by reducing its overall uncertainty.

EXPECTED B3 DOSIMETRY UNCERTAINTY BUDGET

Approximately 90% of all B3 based *WINdose Dosimetry System* users require a dose range from a few kGy to approximately 70 kGy for sterilization applications and almost all of these users select and use a two replicate B3 DoseStix or WINdose dosimeter package and use an average batch thickness for their dosimetry system. This set of B3 dosimetry users typically obtain an expanded overall uncertainty of 5.0% ±1.0% at k=2 or a 95% confidence level.

A user that requires a higher level of accuracy can use the same two replicate B3 packaging but measure the specific thickness of each B3 dosimeter and reduce expanded overall uncertainty to approximately 4.0% ±1.0% at k=2 or a 95% confidence level. On the other hand a user of only a single B3 dosimeter replicate per dosimeter package should only expect to obtain an expanded overall uncertainty of 6.0% ±1.0% at k=2 or a 95% confidence level.

OTHER GEX APPROVED B3 FILM DOSIMETRY SYSTEMS

In addition to the GEX *WINdose Dosimetry System*, GEX also promotes *RisøScan* for use with B3 radiochromic film. *RisøScan* is a software program that converts optically scanned computer bit map images of B3 film to dose. This software based dosimetry system was developed by Arne Miller and Jakob Helt-Hansen of Risø National Laboratory as a dosimetry system for IQ, OQ and PQ dose mapping applications using B3 film. An informational overview of RisøScan and links to more information are found at http://www.gexcorp.com/windose.html.

GEX has also approved the use of Aerial's Genesys 20 based version of their Aer'ODE dosimetry system for use with GEX B3 *WINdose* and *DoseStix* dosimeters. An information overview of the Aer'ODE dosimetry system with contact information for Aerial is available on the GEX website.

Most if not all of the posted GEX B3 *WINdose Dosimetry System* procedures may also be applied successfully when using these dosimetry systems. A user that wishes to investigate B3 on their own is encouraged to contact GEX first to discuss their requirements before attempting to evaluate B3 film and develop their own specific B3 dosimetry system.

INSTALLING AND IMPLEMENTING YOUR WINDOSE DOSIMETRY SYSTEM

Installation instructions are included with all GEX *WINdose Dosimetry Systems* to assist users with initial installation setup. A standard set of recommended operational procedures related to the use of the B3 *WINdose Dosimetry System* are readily available via the GEX website. These SOPs are reviewed and updated on a periodic basis, with revisions posted on the GEX website in PDF format at: http://www.gexcorp.com/procedures.html.

Users are encouraged to adopt these standard practices as they represent the manufacturer's current recommended practices and also provide conformance with currently published national and international guidance documents. Microsoft Word versions of the procedures can be purchased that enable easy customization of the procedures (GEX Part# S6100).

GEX DOSIMETRY TRAINING PROGRAMS

Hands-On Dosimetry workshops are conducted at the GEX manufacturing facilities in Centennial, Colorado. These four-day workshops provide comprehensive training in all aspects of establishing and running a dosimetry program with emphasis on B3 radiochromic film dosimetry. Participants walk through the dosimeter selection and calibration process and gain experience in setting up and calibrating a dosimetry system before performing dosimeter batch calibration, dose mapping, and process monitoring exercises.

In addition, GEX provides internet based training and technical support for B3 radiochromic film products using our Webex interactive conferencing capabilities.

VALIDATING YOUR WINDOSE DOSIMETRY SYSTEM BEFORE USE
Prior to placing the *WINdose* system into service it is necessary to verify performance of the measurement instrumentation. GEX will have performed preliminary factory tests of the instruments but recommends that the user perform an initial calibration verification using GEX procedure 100-254 “Genesys 20 Calibration and Maintenance” to verify that the Genesys 20 spectrophotometer is operating within its expected limits. The procedure also addresses testing of Genesys 20 and B3 dosimeter holder combination to verify they are performing within expected limits in terms of wavelength accuracy using a one nm wavelength step scan over the B3 film peak (545 - 559 nm).

After the new *WINdose* system has been incoming verification tested it can be calibrated for use with a specific batch of B3 dosimeters. The B3 batch calibration dosimeter samples should be retained and used to establish baseline references that are directly traceable to the batch calibration. These B3 dosimeter references can be used in a daily checks verification program to assure then instrument is performing within expected limits over the life of the specific B3 batch calibration.

VALIDATION OF A B3 DOSIMETER HEAT TREATMENT SYSTEM
GEX has established heat treatment criteria for B3 radiochromic film dosimeters. Heat treatment at 58.5°C ±1.0°C is the recommended temperature. See GEX Technical Memorandum 100-201 “Post Irradiation Heat Treatment of B3 Dosimeters” for informational detail.

For those users with a “box style” incubator, it will be necessary to establish specific procedures and validate the incubator settings (may involve temperature mapping of the incubator) and establish maximum and minimum heat treatment times along with the temperature setting range for the user’s specific incubator as different “box style” incubators will exhibit differing behaviors that should be characterized.

The minimum temperature of 58.5°C was determined from GEX testing and has been established by GEX as the temperature recommended to provide a sufficient temperature above the 55°C minimum threshold GEX verified that will effectively complete the color development of B3 film dosimeters. GEX testing also determined that B3 dosimeters can withstand heat treatment temperatures up to 60°C without damage to B3 film dosimeters for temperature exposure times at 60°C for a minimum time of three hours before fading in the absorbance values greater than 1.0% can be detected.

For users of the GEX P4900 Micro Incubator, it is still necessary for a user to verify use of the GEX recommended 58.5°C setting and to determine a time specification for post irradiation color development of B3 dosimeters through use of a simple post irradiation time study. The time study should involve the use of a set of irradiated B3 dosimeters (10 kGy or less) which are removed from the incubator and measured at various times from one minute 6 hours to establish both a minimum and maximum time at 58.5°C. Use data derived from the daily checks results obtained with the reference B3 dosimeters to verify the post irradiation stability of the B3 dosimeter after heat treatment to confirm effectiveness of the heat treatment process specification. See the previously cited GEX document 100-201 for more detail.

DOSIMETRY SYSTEM CALIBRATION

Calibration involves establishing the relationship of dosimeter response to dose traceable to a national standard. GEX standard operating procedure 100-263 and technical memo 100-203 (see References) are posted on the GEX website that provide detailed information appropriate for calibration of B3 dosimeter batches. It is recommended that any dosimetry system used as a routine dosimetry system be calibrated in-situ under the approximate conditions of use to best capture the radiation and environmental influence quantities during the calibration process. Temperature monitoring during routine processing is too costly and imprecise to be practical for use in routine dosimetry.

The in-situ calibration practice designed for a specific user site should be qualified before first execution to verify that the calibration practice can deliver radiations within the temperature and dose rate targets to be used in the calibration exercise and that these targets are equivalent to the doses and related temperatures that will be encountered during routine processing.

GEX provides a standardized calibration service that includes:

- calibration planning
- itemized calibration materials proposal
- calibration records workbook
- data analysis and curve fitting
- “best fit” analysis
- calibration curve dose look-up tables
- Calibration Specific workbook with batch specific coefficients for the *WINdose* for Excel software on CD.

Users can select from NIST, NPL, MDS Nordion, Risø or other appropriately ISO 17025 certified and accredited calibration laboratories. GEX also offers a full range of calibration services and products including irreversible temperature monitoring labels, calibration phantoms, etc. to assist users in developing their site specific in-situ calibration practices. Visit the GEX website (http://www.gexcorp.com/cali.html) or contact GEX directly for details.

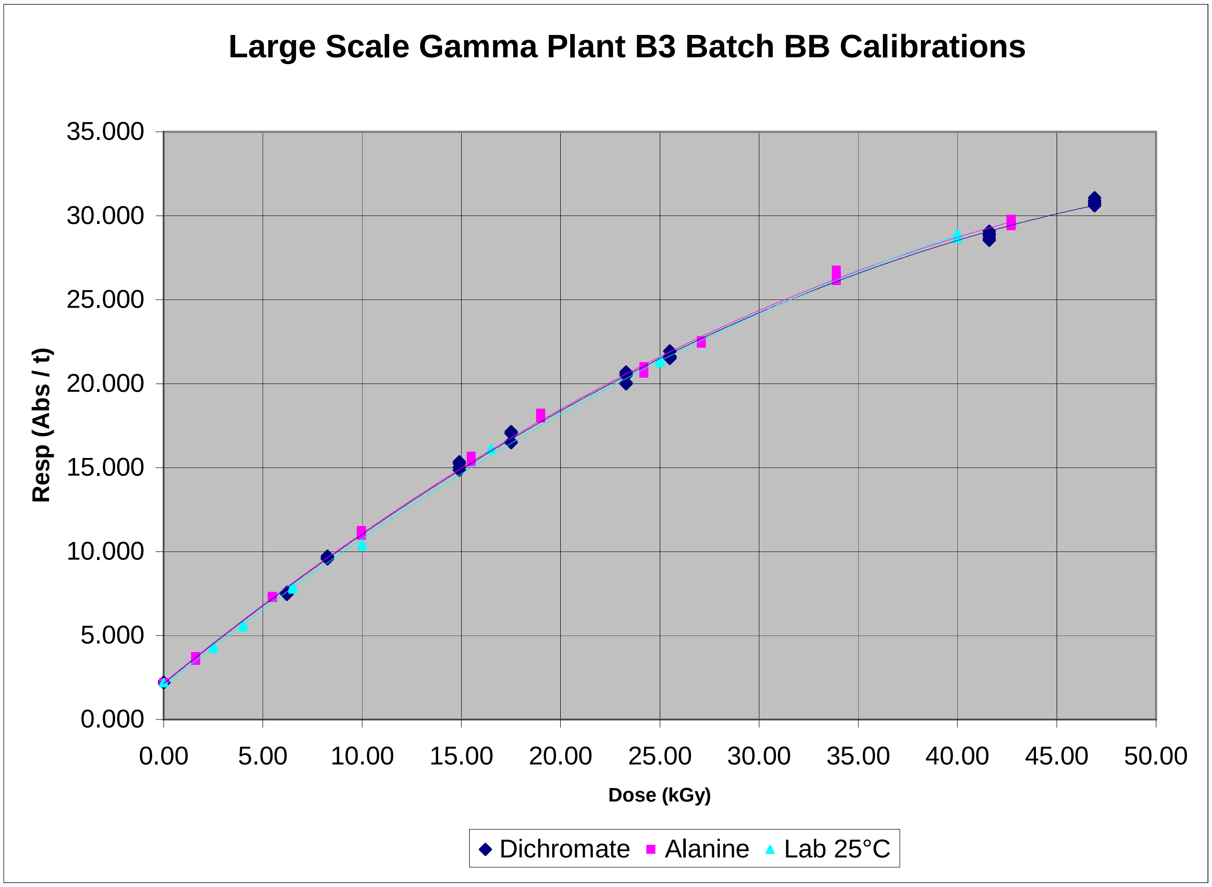
WINDOSE DOSIMETRY SYSTEM CALIBRATION RECOMMENDATIONS

GEX recommends the full in-situ method for calibration of B3 film dosimeters because it captures the dose rates, time and temperature influence quantities that affect the B3 response function. Even if a full lab calibration is performed it must still be verified by an in-situ calibration audit so most users find it more practical to simply perform the entire calibration in-situ.

GEX provides calibration holders (phantoms) designed to accommodate laboratory supplied transfer standard dosimeters and B3 batch sample dosimeters. The calibration phantoms provide holder locations designed for use with alanine pellets, dichromate and ceric-cerous ampoules in the gamma calibration phantom, as well as the factory sealed B3 dosimeter packages. These specially designed calibration holders control dosimeter placement geometry and provide electron or charged particle equilibrium conditions for gamma and electron beam processes. Visit the GEX website for details about our calibration phantom holders and our complete calibration services package.

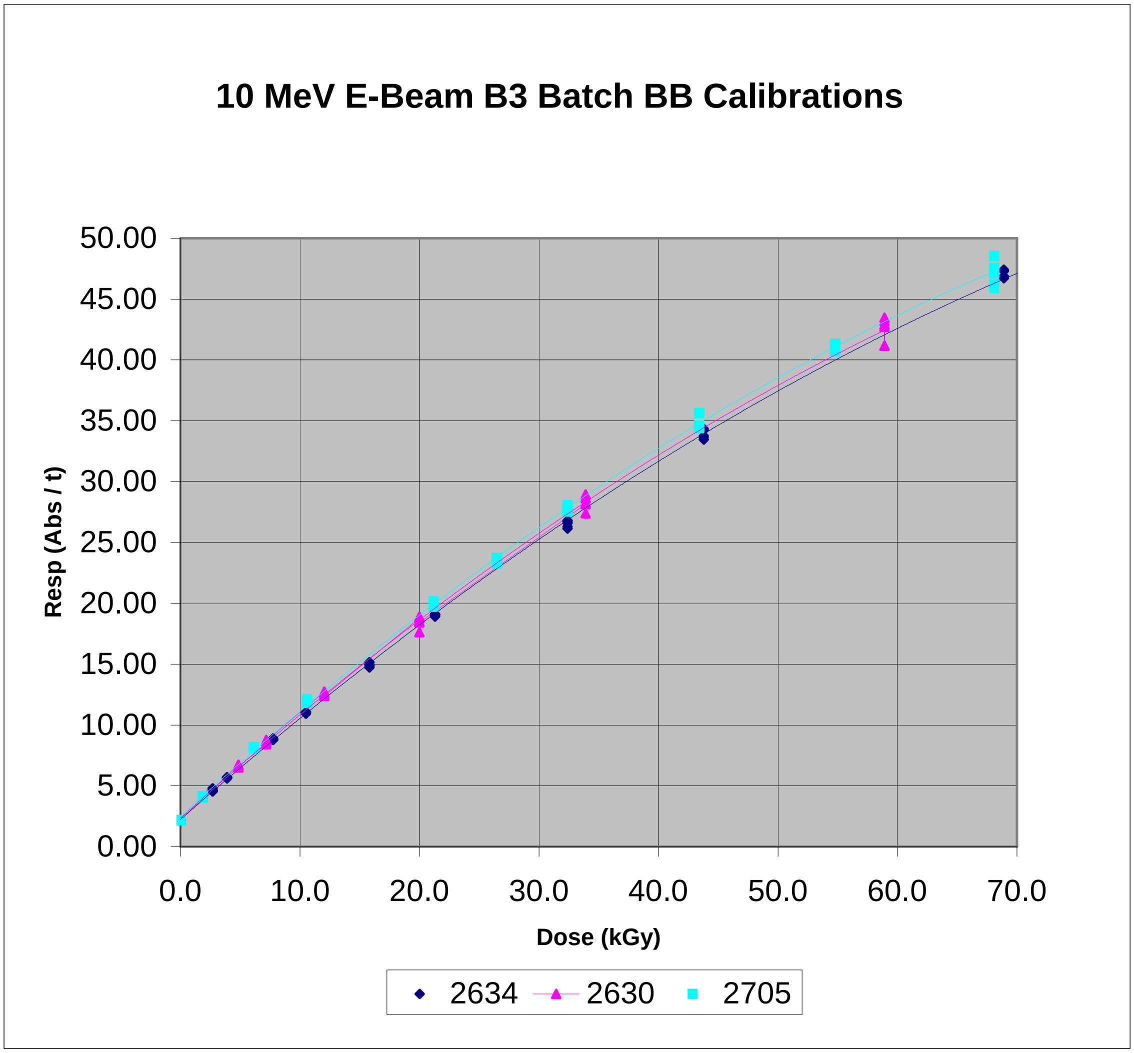
B3 CALIBRATION RESULTS

The following graph shows results of in-situ calibration data from two large scale gamma sterilization plants using different transfer standard dosimeters plotted against a low dose rate constant 25°C laboratory gamma calibration for B3 batch BB dosimeters.



The three gamma calibrations included a laboratory calibration performed at a fixed 25°C temperature and two full range in-situ calibrations with dose measurements performed on three different B3 *WINdose Dosimetry Systems*. The two in-situ calibrations represent one performed using transfer standard alanine and the other using transfer standard dichromate. The B3 batch BB radiochromic film response functions demonstrate a high level of reproducibility and also show good agreement with calibration up to approximately 40 kGy in a fixed temperature Gammacell irradiator at a dose rate below 2.0 kGy/hour.

The following graph plots calibration data sets for in-situ calibrations performed at three different 10 MeV large scale electron beam facilities also using three different *WINdose Dosimetry Systems*. These three B3 batch BB calibrations also demonstrate a highly predictable level of reproducibility.



GEX recommends use of the following procedures to provide appropriate guidance and management for calibration of B3 dosimeter batches:

- 100-256 Dosimeter Batch Receiving Inspection
- 100-263 Calibrating B3 Dosimeters

NOTE: Generic B3 dosimeter batch calibration curves are available for gamma and electron beam irradiation sources electronically from GEX at no charge to those users that do not require traceable certified calibration doses for their dosimetry application. Following is a summary calibration overview for those users that require dosimeter batch certified traceable doses.

DETERMINATION OF PRACTICAL B3 APPLICATION DOSE RANGE(S)

Although B3 film can be calibrated over a dose range from <1 kGy to >160, in practice however, instrument noise at the low end of the range imposes a practical lower limit near 0.3 kGy. A practical upper dose limit is generally found between 70 - 100 kGy because this is the maximum upper dose currently certified by national laboratories or properly accredited calibration standards laboratories is in this range.

However, a user can readily establish a certified traceable dose calibration well above 100 kGy by using fractionated doses to the B3 samples within the lab certified dose ranges (e.g. 60 kGy times two or three) to extend the upper end of the usable range so that it is limited only to the extent of the B3 film's full saturation point of 1.600 absorbance.

For some users, internal quality standards may specify minimum or maximum dose limits for the dosimeter systems in use based on acceptable variance or uncertainty values associated with the use of the dosimetry system.

USE OF MULTIPLE CALIBRATION RANGES TO REDUCE UNCERTAINTY

Multiple calibration curves can be developed from the same calibration data sets and designated for specific application purposes to reduce uncertainty levels compared to fitting a single calibration curve over a large range of dose. Shortening the dose range will typically reduce the level of uncertainty associated with a specific batch calibration. For example, the radiation sterilization application involves a variety of dose range needs that can be addressed with multiple curves to reduce dose measurement uncertainty.

Radiation sterilization requires dose setting and dose audit verification testing that can require a range from approximately 1.0 kGy to 18.0 kGy whereas routine production and facility validation activities require a typical dose range from 5 kGy to 50 kGy. Although dose is cumulative in terms of radiation to destroy viable organisms or to measure damage to materials some users may also desire a high range curve that covers a range to 70 kGy or higher. By using two or three calibration curves the uncertainty associated with each of the multiple curves will be significantly lower that if a single range of dose is fitted with only a single calibration curve.

ESTIMATING DOSIMETRY SYSTEM UNCERTAINTY

An estimate of uncertainty must be prepared for each B3 dosimetry system batch calibration for applications that require traceable dose. GEX provides an uncertainty estimate upon request with each calibration report it produces for clients under the S1101 Calibration Services Package. See GEX Technical Memorandum 100-209 "Developing and Using Uncertainty Statements" for a full discussion.

WINdose Dosimetry System users that use multiple B3 dosimeter replicate packaging and observe GEX recommended procedures can expect to enjoy predictable dosimetry performance with the lowest overall uncertainty level attainable with a routine dosimetry system.

VERIFICATION OF B3 DOSIMETER BATCH CALIBRATIONS

Each new B3 dosimetry system calibration must be authorized and validated prior to use. This process should involve a verification review of the Calibration Report notebook to confirm that record data provides confirmation that the calibration requirements were achieved. Large discrepancies between the targeted calibration doses and the reported lab doses should be evaluated and understood. The maximum temperatures of the calibration should approximate those of actual production temperatures expected to be encountered during routine processing. The calibration dose look up table can be used to confirm the calibration specific GEX WINdose for Excel software file (see GEX Procedure 100-255 for instructional detail).

MAINTENANCE OF CALIBRATION

Calibration maintenance should involve the use of a daily checks program to verify the instrumentation is being maintained within expected limits. See GEX Technical Memorandum 100-210 “Recommended Practices for Genesys 20 Instruments” for information regarding establishing and using a daily checks program.

In addition, it is recommended to use GEX Procedure 100-254 “Genesys 20 Calibration and Maintenance” for use in conducting periodic dosimetry system calibration verifications.

GEX also recommends using periodic or so called “seasonal audits” to verify the dosimeter batch calibration. These are formal in-situ calibration audits that test the calibration using a minimum of three points involving low, medium and high dose test points within the calibrated range being verification audited.

GEX developed the S1102 Calibration Verification Audit Service Package to assist B3 dosimetry users with calibration audits. These audits are required to be performed approximately annually (per ISO/ASTM 51261 and NPL CIRM Report 29 documents), although GEX suggests more frequent audits with many users opting for a quarterly frequency.

Acceptance criteria should be established to be used with the audits to provide a means to verify continued use of a current calibration. In addition, the corrective action options to be used in the event of an audit failure should be developed.

GEX recommends use of the expanded overall calibration uncertainty at k=2 or an approximately 95 % confidence level as audit acceptance criteria. See GEX Technical Memorandum 100-209 “Developing and Using Uncertainty Statements” for additional detail.

Contact GEX to discuss any questions regarding B3 dosimetry or to comment on any of the material provided in this information document.

APPENDIX A

GEX B3 RADIOCHROMIC FILM DOSIMETERS

This appendix provides information related to the B3 radiochromic film developed by Risø National Laboratory used by GEX to manufacture the *WINdose* and *DoseStix* dosimeter products.

This appendix provides important discussion related to the successful use of the B3 radiochromic film manufactured by Risø National Laboratories and the B3 film dosimeters manufactured by GEX Corporation that utilize the Risø supplied B3 radiochromic film material. GEX makes the clear distinction that a dosimeter is comprised of the dosimeter in the format that it is purchased which may include the packaging material for many applications.

GEX dosimeters that are manufactured with B3 radiochromic film include specialized packaging designed to maintain controlled environmental conditions established by GEX to optimize the performance results of B3 film and to protect the B3 film from environmental influence factors that may otherwise adversely affect dose measurement results.

Important information is also provided to advise B3 users about using GEX B3 *WINdose* and *DoseStix* dosimeters outside their packaging of the potential impact of those factors that influence B3 film response. The same information also applies to the use of bare B3 film material including user conditioning and packaging of B3 radiochromic film material.

This information is designed to supplement and provide additional detail and rationale for the GEX Recommended Procedures.

B3 Dosimetry
GEX utilizes the Risø B3 radiochromic film to manufacture a variety of dosimeter products that are sold worldwide as the GEX B3 *WINdose* and *DoseStix* dosimeter brands along with B3 radiochromic film in rolls, sheets and pre-cut pieces. GEX also provides complete factory pre-validated dosimetry systems (absorbance – *WINdose,* or optical images - *RisøScan*) that are designed for use with B3 film for a variety of radiation dose measurement applications.

CAUTION: The information contained in this material assumes B3 dosimeters are to be used only with the following GEX approved dosimetry systems:

- GEX WINdose Dosimetry System
- RisøScan
- Genesys 20 version of Aerial's Aer'ODE dosimetry system

B3 RADIOCHROMIC FILM DOSIMETER INFORMATION

Physical Properties
B3 is a radiochromic film cast from polyvinyl butyral (PVB) resin mixed with the proprietary Risø National Laboratory radiochromic dye. PVB is a resin generally used for applications that require strong binding, optical clarity, adhesion to many surfaces, toughness and flexibility. It is prepared from polyvinyl alcohol by reaction with butanal. The major application is laminated safety glass for automobile windshields. PVB accounts for more than 98% of the weight by volume of B3 film.

The thin profile (18 micron nominal thickness) and toughness characteristics of B3 film combine with flexability and optical clarity to provide excellent physical properties for a dosimeter. B3 film dosimeters can be rolled or folded to allow positioning inside tubing and small apertures as well as highly irregular shapes, etc. without causing physical damage or effecting final measurement results.

B3 film is considered a small cavity dosimeter with a density of 1.12 to water with an energy abosrption property that is also near that of water. These properties make B3 film an excellent dosimeter selection for use in measuring dose at material/material and air/material interfaces.

Chemical Properties
B3 is a solid state dosimeter with the radiochromic dye (pararosaniline) held in a solid matrix of PVB along with traces of other chemicals used to provide chemical stability. The pararosaniline dye used in B3 radiochromic film belongs to a family of radiochromic dye precursors exhibiting a chemical structure in which the central carbon atom of the dye molecule is bonded to three benzene rings and a cyano group –CN. The bonding energy of the CN group is of the order of 3.8 eV and the bond is broken by energy starting near the UV portion of electromagnetic spectrum at a wavelength of 340 nm. The formation of the resultant carbonium ion is accompanied by intramolecular rearrangement leading to the formation of a double bond within one of the benzene rings. In the presence of scavenging additives, the reaction is highly irreversible and produces a stable dye in the polyvinyl butyral polymeric matrix of the B3 dosimeter material.

The chemistry of B3 film has been proven to be stable over time. A GEX follow-on batch test study of the 1997 GEX B3 Batch AA film showed no change in either the initial optical absorbance or average background of B3 film dosimeters or their original calibration response function after nearly ten years storage.

Ionizing radiation events activate the B3 dye centers which in turn cause the B3 film to undergo a predictable color change from clear to deepening shades of pink magenta. The radio chemical yield of the dye results in a color change that is easily related to absorbed dose that is independent of the dose rate. The amount of color change is influenced by temperature during irradiation. The final color change in B3 dosimeters can take a number of hours to complete dependent on the dose of ionizing radiation and the temperatures experienced during the irradiation process. Post irradiation heat treatment intervention can complete the color development process in minutes and result in B3 dosimeters that will remain stable for a year or more.

Environmental Influence Quantities

The radio-chemical yield or quantifiable color change of B3 film induced per unit dose is influenced by complex inter-related changes involving moisture and oxygen concentrations with changes in temperature over the range of dose being calibrated. These influence factors (sometimes referred to as "quantities") along with exposure to sources of light should be understood to the extent that they can be controlled and managed to minimize their effects on dose measurement outcomes.

GEX and Risø have investigated and identified a variety of factors than can affect the performance of B3 film and determined appropriate controls and recommendations to eliminate or minimize variance associated with these influence quantities.

Although most users generally do not need to carry out their own influence quantity performance characterization testing, it is useful to know and understand the impact of influence quantities on their dosimetry system in order to better investigate and resolve dosimeter measurement deviations and to impose and manage the limits and controls necessary to achieve predictable and reproducible dosimetry results.

Controlling Influence Quantities

GEX uses the approach of developing and supplying complete dosimetry systems that consider and address the various influence quantities in order to optimize dosimetry system performance.

The contribution of light, humidity and oxygen influence on the B3 dosimeter response function is readily controlled through the use of GEX factory packaging designs that provide an environmental barrier to eliminate potential for dosimeter exposure to light sources and provides dosimeters of highly uniform environmental conditioning. Additionally, the user is encouraged to calibrate B3 dosimeters in their own radiation process facility under the actual conditions of use in order to take into account the impact on dosimeter response caused by:

- pre-irradiation dosimeter handling variance,
- irradiation process influences related to differences in temperature, process dose rates, fractionation and the impact on other process induced influence quantities,
- post-irradiation variance associated with handling, storage and measurement conditions.

Using factory sealed dosimeters in accordance with GEX recommendations along with in-situ calibration and a formal set of standard operating procedures assures predictable dose measurement outcomes for B3 dosimeters by eliminating or minimizing variability due to influence quantities.

Specific Influence Quantity Information

The following information is provided by GEX to assist current and potential users with a general knowledge of the performance of B3 film that should be expected to be encountered in routine production applications. Scientific research or sophisticated industrial users conducting their own performance characterization studies are also encouraged to contact GEX and discuss their test plans in advance of the testing.

GEX and Risø have acquired substantial data related to the following influence quantities that can affect B3 radiochromic film response and dose measurement results:

- Pre-Irradiation Stability

- Light Sensitivity
- Humidity
- Dose Rate Dependence
- Temperature
- Post Irradiation Time Factors and Signal Response Stability
- Dose Fractionation
- Thickness
- Instrumentation

Pre-Irradiation Stability
Because of the large batch sizes of B3 film production, it is important to understand the stability of B3 radiochromic film chemistry over time as well as the environmental stability of the B3 dosimeters manufactured and packaged by GEX.

Initial optical absorbance and dose response testing conducted by Risø and GEX demonstrate a stable B3 film background evidenced by predictable absorbance values that do not change over time. The natural optical absorbance background of B3 film is approximately 0.0021 per micron of film thickness. Measurement of B3 film initial optical absorbance measurements are easily influenced by instrument rounding error and dosimeter placement variance at these low values.

For example, an 18 micron thick B3 film measured in a spectrophotometer with a typical variance of 0.001 would be expected to result in a reading of 0.038 ±.001 for a resulting CV of 2.6%. The impact of instrument influence on the absorbance measurement result reduces with the increased absorbance values. Therefore, GEX does not recommend subtraction of an average initial optical absorbance value when calculating a response because of the increased influence of instrument variance introduced on the measurement.

The pre-irradiation initial optical absorbance of B3 film can be expected to remain stable over a transportation and storage temperature range from 0°C to 45°C. However, temperature extremes above 45°C have been shown to permanently increase the response function of B3 film. GEX provides irreversible thermal labels with all shipments of B3 film products as a precaution to monitor against extreme temperature excursions that can occur during shipment.

Users are urged to perform incoming receiving inspection (see GEX SOP 100-256) that tests representative samples for initial absorbance to verify the dosimeters were not inadvertently exposed to an ionizing radiation source during shipment and that the response function of the incoming stock is comparable with any prior or existing facility batch stock.

Pre-irradiation Aging Effects
There are no known aging effects. GEX conducts ongoing aging studies using retained manufacturing samples to periodically compare response function over the life of each batch. GEX has accumulated years of batch monitoring history demonstrating B3 film to be shelf stable over time when stored under temperature conditions of 15-30°C (59-86°F).

GEX performs quarterly batch response testing over a typical expected batch life of 5 years to monitor the continuity of batch response function over time. Any significant change in response function would, of course, be communicated directly with users.

The rationale for not subtracting an average B3 film background is the fact that the B3 film background is stable and does not change. Therefore, subtraction of an initial absorbance or background value does not improve the accuracy of the measurement and only increases the influence of instrument noise on the final absorbance measurement result.

The verification of B3 dosimeter response function stability is best demonstrated through the use of periodic calibration response audits by the user combined with incoming batch stock shipment response testing. Users should expect a typical batch of B3 film dosimeters to successfully pass calibration audits throughout the life of the batch when film batch stocks are maintained and stored under temperature conditions of 15-30°C.

Light Sensitivity

B3 film is sensitive to daylight and UV light and therefore must be protected from these sources before and after irradiation. Although brief exposure to UV lighting may not result in a quantifiable change to a B3 film dosimeter, it is strongly recommended that all windows and light sources in the dosimeter measurement area (Dosimetry Lab) be covered with appropriate UV light shielding material to eliminate the potential of light sources affecting B3 film.

The effectiveness of the installed light protection can be qualified by placing B3 dosimeters with pre-measured absorbance or reflectance values on area surfaces for extended time periods and then re-measuring the absorbances of these dosimeters. The user should keep in mind the 2.6% CV variance example cited above that is typical of B3 film background measurements. This exercise can be repeated periodically to verify ongoing effectiveness. See document 100-250 for detail.

GEX developed specialized packaging for B3 dosimeter products to provide protection from light sources such as daylight or UV lighting as well as to maintain uniform humidity and oxygen conditions for optimum response function performance. B3 dosimeters should remain in their factory sealed packages until they have been irradiated or just prior to irradiation depending on the application.

It should be noted that the clear window side of the *DoseStix* dosimeter package is specially laminated with a UV protective layer that allows barcode scanning and visual reading of the dosimeter identification number inside the sealed pouch.

Humidity

Testing conducted on B3 radiochromic film samples that were pre-conditioned at various controlled humidity conditions and irradiated at various temperature conditions (see Reference 2) demonstrate that the response function of B3 radiochromic film is influenced by the amount of moisture present in the film at the time of irradiation.

The influence of humidity on the response of B3 film over the range of 30% to 70% RH is shown to be relatively consistent and its impact on response considered insignificant. However, relative humidity outside this range can have significant influence on the response function of B3 film and thus can influence the accuracy of dose measurements. Correcting for this influence is not practical and, as such, the user can only make an effort to employ the dosimeter under appropriate conditions if accurate dose reporting is required. Depending on the user's application (e.g. relative dose measurements such as electron beam uniformity) using the dosimeter under conditions outside the specified range may be appropriate because all dosimeters in a test are exposed to the same conditions. However, such activities are at the user's discretion.

B3 film dosimeters have a large surface to volume ratio and will readily equilibrate to the surrounding environmental conditions. GEX equilibrates and packages its B3 *WINdose* and *DoseStix* dosimeters in a packaging cleanroom with environmental controls in order to provide pre-packed B3 dosimeters with uniform response performance.

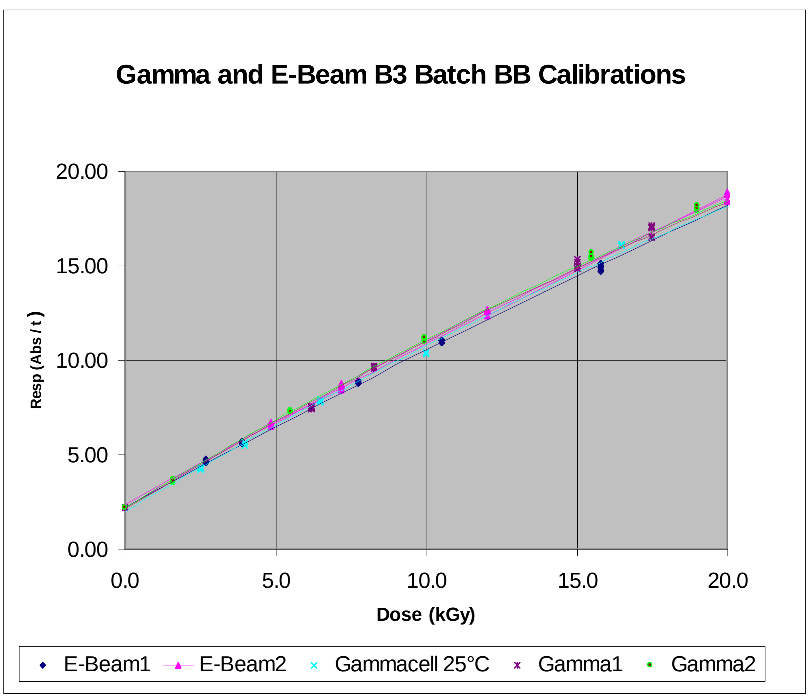
B3 *WINdose* and *DoseStix* dosimeters should remain in their factory sealed packages until after they have been irradiated. GEX has specifically designed the *WINdose* and *DoseStix* packages to maintain optimum environmental conditions over the useful life of the B3 dosimeter batch.

In the event B3 dosimeters must be used outside their original sealed factory package as in the case where the radiation energy source is too low (typically < 500 keV) to uniformly penetrate the GEX B3 factory packages, dose measurement uncertainty related to environmental influence variance should be taken into account. Refer to the Reference 2 temperature, humidity and time study or contact GEX to discuss the specific application detail.

Dose Rate

The B3 radiochromic film has no known dose rate dependency. Neither the radiation source type (gamma, electron or X-ray) nor the rate of ionizing radiation have a significant effect on the B3 film response function for doses below 20 kGy. However, the combined effects of time, temperature and humidity during the irradiation process above 20 kGy can have an influence on the B3 response function. GEX recommends use of the in-situ calibration method to properly capture or account for the combined influence quantities.

The chart below demonstrates minimal difference in the B3 response function in five different B3 Batch BB calibrations covering a wide variety of dose rates from approximately 1.0 kGy/hour in the 25°C Gammacell to several kGy per second with electron beam sources of ionizing radiation.



Temperature

The effect of temperature on dosimeters is one of the most important influence quantities to understand and manage. The response function of all dosimeters is influenced and significantly affected by temperature and B3 radiochromic film is no exception. The influence of temperature on the response function of B3 radiochromic film over a temperature range from -5.0°C to 60°C is highly complex. Because of the complex nature of temperature effects with dose on B3 dosimeter response in production irradiators, the <u>use of a</u> <u>simple temperature correction factor</u> for routine production is <u>not appropriate</u>.

The use of B3 film is not recommended above a <u>maximum 60°C</u> because the response of B3 film above that range can become erratic and unpredictable. Little information exists on the behavior of B3 film at temperatures below -5°C. GEX recommends the use of the in-situ calibration method with B3 dosimeters to properly capture and account for the specific effects of temperature for any given application.

Temperature influence becomes significant (>2.0%) in electron beam at approximately 20 kGy and in gamma radiation applications it can be expected to occur near 40 kGy.

Post Irradiation Measurement Response Stability

GEX strongly encourages use of a post irradiation heat treatment process because it completely eliminates the potential for post irradiation response change in B3 dosimeters.

Solid state chemical dosimeters (including alanine, FWT-60 and Harwell Red Perspex dosimeters) exhibit significant variance in their post irradiation response signal related to signal increase (growth) or decrease (fade) or both based on the time after irradiation. B3 radiochromic film would continue to develop color after irradiation for a number of hours (dependent on the radiation dose and the temperature during irradiation) if not heat treated.

GEX believes the post irradiation stability of B3 film that comes from the heat treatment process is the most significant feature or property that distinguishes B3 from all other dosimeters. B3 film is sufficiently stable following post irradiation heat treatment that it is used as a reference material.

However these changes in optical reflectance or absorbance measurement values are readily mitigated by either controlling the measurement time after irradiation or by post irradiation heat treatment of the B3 film dosimeters. A proper post-irradiation heat treatment process will render B3 radiochromic film completely stable regardless of the time of heat treatment intervention after processing. The response values of post irradiation heat treated B3 film dosimeters have been demonstrated to remain stable for more than one year when maintained at 15-30°C.

The early practice of post-irradiation heat treatment of B3 film dosimeters utilized standard incubators to treat unpackaged bare B3 films for 5 minutes at approximately 60°C. GEX has determined that a minimum temperature throughout the film of 55°C is required to properly treat B3 films. GEX investigated the post-irradiation heat treatment process and has determined that the optimum heat treatment of packaged dosimeters (*WINdose*/*DoseStix* irradiated in the package) requires a temperature of 58.5°C +/- 1.0°C for a minimum of 15 minutes in a “box style” incubator in order to heat the dosimeters inside the pouch to the designated temperature, which accounts for the time to heat the packaging materials as well as the dosimeter(s).

Temperatures above 60°C soften the surfaces of B3 film and multiple dosimeters may stick together in the package when the dosimeters are placed flat on an incubator shelf. Users are encouraged to implement appropriate actions or equipment to avoid heat treatment temperatures above 60°C.

GEX manufactures a unique micro-incubator post irradiation heat treatment system specifically designed to heat treat pre-packaged B3 *WINdose* and *DoseStix* dosimeters. The P4900 GEX unit operates in a batch mode and can uniformly heat treat (±0.2°C) up to 18 dosimeter packages. The P4900 uses a 58.5°C set point and because of the method it uses to heat the dosimeter packages quickly, the necessary time of incubation is greatly reduced from that of a "box style" incubator. The unit has been validated to provide stable B3 responses in as little as two minutes.

GEX testing has confirmed that dosimeters inadvertently left in an incubator for periods of time up to 3 hours showed no statistical difference from those that were incubated properly for only a few minutes. However, dosimeters incubated for more than 4 hours exhibit fading.

GEX successfully tested heat treatment intervention times from time zero up to 8 days after irradiation to verify post irradiation heat treatment intervention of B3 dosimeters can be performed without impact on measurement results even over extended time periods.

Dose Fractionation
B3 Radiochromic film has no known dose fractionation limitations. Users of B3 film dosimeters should be aware that fractionated dosing can introduce temperature influence quantities due to differences at the beginning and end of fractioned irradiation cycles dependent on changes from the starting temperature between irradiation cycles. However, the effects on B3 dosimeter response from long and short term process interruptions should not be expected to be significant.

Users of B3 film dosimeters that routinely process using multiple dose fraction cycles are encouraged to use an in-situ batch calibration designed to capture the temperature profiles that closely match those measured in or on actual product(s) during production irradiations. GEX staff is available to assist users with planning and designing an appropriate dosimeter batch calibration.

Thickness Variation
Variance in the mass or thickness of a dosimeter will affect dose measurement results. For example, a thicker dosimeter will indicate a higher dose than a thinner dosimeter when the two dosimeters are exposed to the same irradiation dose unless they are corrected for thickness differences (within the accuracy limits of the thickness measurement system). Using an average thickness will therefore result in a variation to dosimeter response values whose impact on measurement uncertainty should be evaluated and understood.

Most B3 dosimeter users elect to use an average thickness rather than measuring individual dosimeter thickness. Although the industrial B3 film casting process results in a thickness variance that is considered to be highly uniform, thickness variation is not insignificant and does impact measurement results. GEX controls and limits thickness variance from the B3 film casting process by characterizing the thickness of each individual film roll.

This thickness characterization information is provided on the label of each box of B3 dosimeter product manufactured and packaged from a specific B3 film roll with an average thickness CV of 1.4% expected. The use of two replicate B3 dosimeters will reduce the effects of thickness variance from 1.4% to approximately 0.9%.

B3 film thickness variance can be reduced further by measuring individual B3 film thickness instead of using an average thickness to reduce thickness variance another 35-40% depending on the instrumentation equipment and measurement practices used.

Highly reproducible B3 film thickness measurement can be achieved with appropriate equipment. An electro-mechanical thickness gauge such as one manufactured by Solartron can offer a resolution of 0.05 micron with thickness measurement uncertainty of 0.3 micron at k=2 or 95% confidence attainable. GEX uses an optical thickness gauge system from Filmetrics that has a resolution of 0.001 micron and thickness measurement uncertainty of 0.05 micron at k=2 or 95% confidence is attainable with this unit.

Measurement Instrumentation

Factors that effect B3 radiochromic film dose measurements, directly or indirectly, also include measurement instrumentation components of variance and the specific instrument measurement setting factors. Some instrumentation can have unintended adverse results and be inappropriate for use with the B3 radiochromic film. Please consult with GEX before specifying or purchasing any other measurement instrumentation for use with B3 film than that which is listed on Page 20 of this document.

GEX has developed stringent requirements and specifications for measurement instrumentation approved for use with B3 film and GEX B3 dosimeters. Performance characterization testing should be performed by the user to establish initial baseline instrumentation variance used to maintain the instrumentation within established limits.

B3 film dosimeters may be measured effectively by absorbance measured in a Genesys 20 spectrophotometer or by using optically scanned bit map images with RisøScan. These complete systems include: instrumentation, instrument calibration standards, dosimeters and procedures.

The wide (8nm) SBW of the Genesys 20 is well suited for measurement of thin film dosimeters and eliminates the potential of optical interference fringes that are introduced with the use of a narrow slit width. GEX expects B3 users with a GEX WINdose system to achieve a reproducible CV level of 0.2% or better for B3 film measurements.

B3 radiochromic film has a rather broad absorption peak found between 550-554 nm with the maximum peak occurring at approximately 552 nm. B3 dosimeters have historically been calibrated with dosimeter measurements made at a fixed 554 nm wavelength but any of the wavelengths between 550nm and 554nm may be established and used successfully as the measurement wavelength. The Genesys 20 instrument can be used in single nm steps to perform a wavelength scan over the peak from 545nm to 559nm to identify the peak wavelength of the B3 for a specific Genesys 20 instrument. The stated wavelength accuracy for the Genesys 20 is ±2.0 nm.

Post irradiation heat treated B3 dosimeters are stable and are recommended for use as references that can be used in a Daily Checks Program to measure the photometric scale performance reproducibility of Genesys 20 spectrophotometers. See the 100-210 “Genesys 20 – General Practices and Information” Technical Memorandum and GEX procedure 100-254, Genesys 20 Calibration and Maintenance for detail.

GEX has also determined that it is appropriate to perform spectrophotometric scans over the peak using summed or average values to measure absorbance. This latter method can be used to minimize the influence of interference fringes on B3 film dosimeter measurements when using a spectrophotometer with a spectral bandwidth less than ±8 nm.

B3 Radiochromic Film Summary Recommendations

Dosimeter Batch Stock Shipments
B3 dosimeters will tolerate extreme temperatures up to 45°C during shipment without concern for damage. GEX provides an irreversible maximum temperature indicator with each shipment and advises the use to contact GEX to report a temperature indication of 45°C and to discuss appropriate actions to be taken.

Pre-Irradiation Handling
Store B3 dosimeters at temperature conditions of normal use and similar to those used in the calibration. Storage between 15-30°C is recommended.

Irradiation Conditions
Avoid irradiation temperatures above 60°C. GEX also recommends that dosimeters be irradiated in their factory sealed packages in order to maintain the constant manufacturing packaging environment until after irradiation. If dosimeters must be irradiated outside the sealed package, the sealed package conditions should be maintained until just prior to use.

Post Irradiation Handling
Observe post irradiation storage temperatures between 15-30°C. B3 film dosimeters will typically continue their color development for a number of hours after irradiation. This is typical of low dosed dosimeters irradiated at low temperatures. Heat treatment will eliminate the post irradiation color change and associated measurement response variance. Heat treat B3 dosimeters at 58.5°C using 15-20 minutes when using a box style incubator or 2 minutes or more in the GEX P4900 micro incubator.

Summary
B3 radiochromic film can be used over a broad range of dose and is currently used successfully in a wide variety of ionizing radiation processes, and can be calibrated for use with any and all types of radiation sources.

B3 radiochromic film dosimeters are well established with a proven history of stable long-term results. Predictable and consistent response to dose performance should be expected over the life of the batch when used in accordance with GEX recommended practices.

APPENDIX B

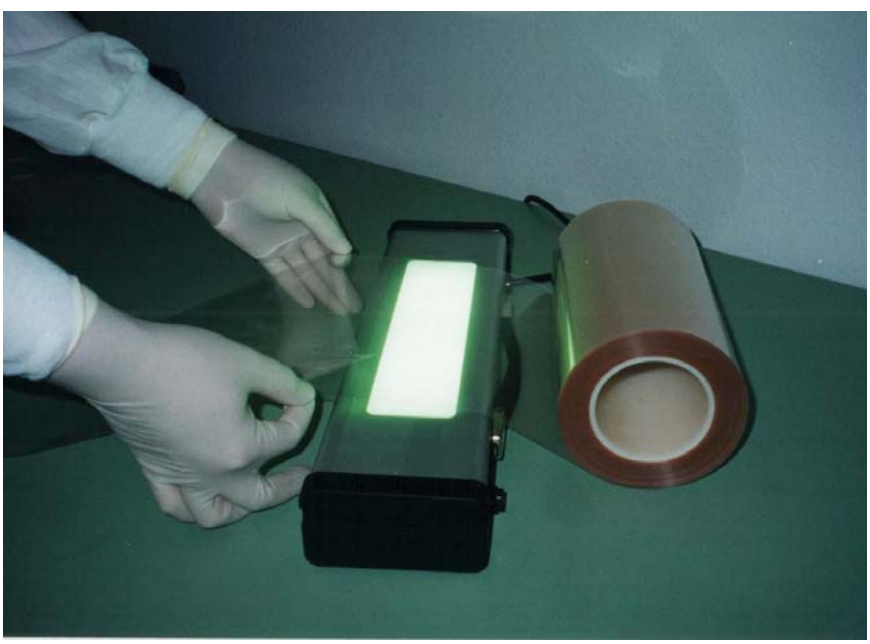
B3 FILM BATCH MANUFACTURING

This Appendix provides an overview of the Risø B3 film batch manufacturing process along with details related to the manufacture and packaging of GEX B3 film dosimeter products.

B3 Radiochromic Film Manufacture
B3 radiochromic films were initially produced from the proprietary B3 dye synthesized at Risø. The dye was dissolved in PVB and poured onto smooth sheets of glass where they were allowed to dry. The dried sheets were then hand cut with a knife and straight edge into usable pieces of dosimeter material. This old laboratory style batch process was replaced with a more robust manufacturing process in 1988.

The current manufacture of B3 film still begins with the synthesis of a proprietary pararosaniline dye that is performed at Risø. The B3 dye is dissolved in PVB but the sheets of glass have been replaced with a continuous industrial film casting process to produce large batches of highly uniform film. A typical batch will produce 1,000 square meters or more of B3 film in a single batch cast.

A typical B3 film batch today produces a continuously cast 400 mm wide master roll of B3 film that is thousands of meters in length. This continuous cast roll is wound and cut at approximate 200 meter intervals to provide manageable batch master film rolls. Each master roll is sampled during the cast process at approximate 200 meter intervals to verify that specified mass uniformity specifications are achieved.



200 meter long 200 mm wide B3 film roll prior to final film roll slitting

Film master rolls that meet mass uniformity specification are then final sliced to the GEX specified widths and lengths that are used to produce our popular GEX B3 *WINdose* or *DoseStix* dosimeter products.

Risø B3 Film Batch Characterization
Risø examines and samples each of these final sliced rolls for an entire batch of B3 film in order to verify that film batch thickness uniformity is acceptable for release and shipment to GEX. The Risø batch characterization testing includes thickness measurements of each roll along with response function testing and post irradiation stability analysis with temperature and humidity studies. Batch to batch comparison is accomplished by including batch samples from prior batches along with the new batch being characterized.

GEX reviews the Risø batch characterization data along with the individual roll thickness information to authorize the release of the batch rolls for shipment to GEX. All B3 film shipments to and from Risø and to and from GEX are monitored for maximum temperature to verify that the maximum shipment temperature does not exceed 45°C as a precaution against extreme transportation temperature that could affect the response function.

GEX B3 Film Batch Characterization
GEX performs incoming inspection upon receipt of the new B3 film rolls verifying external appearance, shipment temperature labels or data loggers and matching roll identification numbers against the incoming shipment paperwork.

Film strip samples are initially taken from each roll before release for roll characterization. These sample strips are in turn used to manufacture standard GEX B3 *WINdose* and *DoseStix* dosimeters under written procedures. This provides a single production lot of GEX *DoseStix* and *WINdose* dosimeters representing all batch rolls that are used for initial GEX batch response characterization and also will provide the source of samples for continuing batch response monitoring & testing over an expected 5 year plus period.

An initial B3 dosimeter batch response baseline is established by irradiating representative samples from each of the B3 film roll sample product. Final B3 dosimeter absorbances and individual thicknesses are measured and specific responses are calculated for each dosimeter. Measurement results are used to determine an overall batch average baseline response as well as to compare the uniformity of response of all individual rolls corrected for specific thickness.

GEX B3 Dosimeter Manufacturing Traceability
Each of the B3 film batch rolls receives a batch specific roll identification number at the time it is initially sliced and created during the film batch casting process. Batch film rolls go through receiving inspection at GEX where their individual roll identifications are verified against the incoming shipment inventory paperwork.

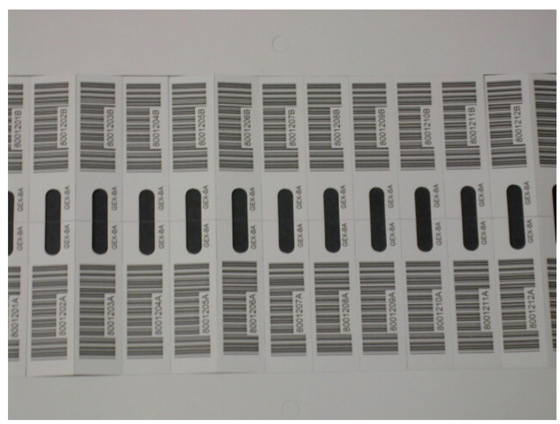
GEX maintains and uses the specific B3 film roll identification numbers to trace and document each roll at every step in the manufacturing process from the time of receipt through final dosimeter packaging and boxing. This provides the means to trace the unique identification number of each and every *WINdose* or *DoseStix* dosimeter to a batch specific roll of B3 film along with its detailed manufacturing and packaging history. A label on every dosimeter box or package identifies the packaging lot number which references the Work Order number and B3 film roll number and other pertinent information about the packaging lot.

Individual B3 Film Roll Thickness and Response Uniformity Characterization
All incoming B3 film batch rolls are cleaned and placed in quarantine awaiting the outcome of the initial sampling and baseline response testing. Incoming B3 film batch rolls remain in quarantine until they are drawn for manufacturing slicing and roll thickness and response characterization. Statistically representative sample slices are laminated to B3 dosimeter cards, die-cut, and packaged into standard B3 *WINdose* or *DoseStix* dosimeter packages creating representative samples that are used to characterize a given B3 film roll. These sample dosimeters are irradiated alongside benchmark or baseline rolls that have already passed characterization testing. In addition, the individual thickness of each dosimeter is measured to determine a specific response. These characterization tests establish the specific roll thickness specifications and verify the roll exhibits the same response per average unit thickness as other rolls from the same batch.

Assigning Average Roll Thickness
The thickness data of the roll samples are used to establish thickness characterization for each B3 film roll as well as to verify that the roll's thickness variability meets established GEX quality specifications. Rolls which do not satisfy GEX acceptance criteria for thickness and response are rejected and placed back in quarantine pending final disposition.

Rolls that conform to GEX specifications for thickness and response are approved and released to raw material manufacturing inventory. These approved film rolls are maintained in segregated containers marked with their roll ID and are stored awaiting lamination.

B3 Film Roll Lamination
Manufacturing pulls approved rolls from raw materials and assigns them a numbering sequence for film card printing and lamination. A GEX Work Order is prepared and the specially designed *WINdose* or *DoseStix* dosimeter cards are printed with a range of specified dosimeter numbers that were assigned to each roll to account for the total number of dosimeter cards and film pieces to be the laminated. The individual film slices are then laminated onto these pre-printed GEX *WINdose* and *DoseStix* film overlay cards containing the unique individual dosimeter number and batch identification information.



GEX B3 Individual Dosimeter Traceability
Unique dosimeter identification numbering is the centerpiece of our GEX dosimeter manufacturing quality program. Every GEX manufactured *WINdose* or *DoseStix* dosimeter is not only marked with a dosimeter batch number but each dosimeter is also printed with its own unique identification number within a specific batch. This proprietary and patented GEX dosimeter manufacturing process assures that a user can readily distinguish every GEX *WINdose* or *DoseStix* dosimeter from one another and provides a means of absolute dosimeter traceability back through each segment of the dosimeter manufacturing and packaging process.

Environmental Controls
All B3 film rolls and B3 dosimeters are stored and maintained under controlled and monitored conditions for relative humidity and temperature throughout the manufacturing process and their storage time at the GEX facility.

Dosimeter Die Cutting

The laminated dosimeters are sent to an outside supplier for final die cutting prior to the packaging operation. GEX uses temperature and humidity data loggers to monitor the product while dosimeter cards are at the die cut facility. Dosimeter cards returning from die cut are quarantined pending a review of the data logger results. Excursions from the allowable relative humidity and temperature limits require a minimum period of re-equilibration prior to release of the roll of die cut cards for packaging.

Dosimeter Packaging
Dosimeters are packaged into a variety of application specific configurations for GEX standard products or special order packaged to specific customer specifications. GEX supplies the B3 radiochromic film in a variety of configurations ranging from bare film in rolls or sheets to finished pre-packaged bar-coded dosimeter pouches.

APPENDIX C

B3 DOSIMETRY SUMMARY INFORMATION TABLES

PHYSICAL PROPERTIES

B3 Physical Properties	Tough, thin and flexible polymeric films with embedded radiochromic dye precursor. Composition is >98% polyvinyl butyral (PVB) matrix <2.0% proprietary Risø National Laboratory pararosaniline radiochromic dye.
Handling	Avoid handling B3 film surfaces directly with bare fingers – films can be bent or folded for placement in small irregular locations without damage to the optical properties.
Optical	B3 PVB film dosimeters are optically clear in the visible part of the spectrum before irradiation. The major non dosimetry related application of PVB films is in laminated safety glass for automobile windshields.
Density	The average density of B3 radiochromic film is 1.120 g/cm^3.
Thickness	B3 dosimeters have a nominal 18 micron thickness with the measured average thickness specifications provided on each box of GEX dosimeters.
Energy Absorption	B3 film dosimeters are a low atomic number material with ionizing energy absorption properties similar to water.

CHEMICAL PROPERTIES

B3 Chemical Properties	Solid state chemical dosimeter with the radiochromic dye (pararosaniline) held in a solid matrix of PVB along with traces of other chemicals used to provide chemical stability
Pre-Irradiation Stability	The chemistry of B3 film is extremely stable over time – stability testing covering a range from 0°C– 45°C simulating shipment and storage indicate no change in the initial optical absorbance or response of B3 film. Storage or shipment temperatures greater than 45°C will permanently increase the response of B3 film that may be cause for re-calibration.
Color Change	Ionizing radiation events activate the B3 dye centers which in turn cause the B3 film to undergo a predictable color change from clear to deepening shades of pink magenta. The radio chemical yield of the dye results in a color change that is easily related to absorbed dose that is independent of the dose rate. The pararosaniline dye used in B3 radiochromic film belongs to a family of radiochromic dye precursors exhibiting a chemical structure in which central carbon atom of the dye molecule is bonded to three benzene rings and a cyano group –CN. The bonding energy of the CN group is of the order of 3.8 eV and the bond is broken by energy starting near the UV portion of electromagnetic spectrum at a wavelength of 340 nm. The formation of the resultant carbonium ion is accompanied by intramolecular rearrangement leading to the formation of a double bond within one of the benzene rings. In the presence of scavenging additives, the reaction is highly irreversible and produces stable dye in the polyvinyl butyral polymeric matrix of the B3 dosimeter material.

INFLUENCE QUANTITIES

Factors that Can Influence B3 Response – before irradiation	The recommended storage temperature for B3 film is 15-30°C. Testing over a temperature range from 0°C – 45°C simulating shipment and storage temperatures indicate no change in the initial optical absorbance or response of B3 film. Storage or shipment at extreme temperatures above 45°C can affect the response of B3 film and should be avoided. GEX includes irreversible temperature labels with all B3 shipments.
Pre-Irradiation Optical Background Stability	The chemistry of B3 film is shown to be extremely stable over time. The natural unirradiated background absorbance of B3 film is approximately .0021 per one micron of film thickness. Subtraction of an average background value is not recommended when calculating dosimeter response. Measurement of an average background should be performed with incoming dosimeter batch stock shipments to confirm the dosimeters were not inadvertently exposed to ionizing radiation sources during shipment.
Light	B3 film is sensitive to the UV component present in most man-made and natural sources of illumination and it should remain in factory sealed packaging during storage, irradiation and post irradiation. Light fixtures and windows in the dosimeter measurement area should be covered with UV filter material to eliminate the presence of undesirable part of the spectrum.
Humidity	Response of B3 film is influenced by the amount of moisture content available in the film during irradiation. GEX pre-conditions and packages B3 film in a temperature and relative humidity controlled clean room where dosimeter packages are sealed in environmentally secure and UV light protected packages. Storage at room temperature prior to irradiation will maintain the factory environmental conditions for five years or more when maintained in these specially designed factory sealed packages.
Temperature	Storage prior to irradiation at temperatures between 15°C and 30°C is recommended.

Factors that Can Influence B3 Response – during irradiation	The radio-chemical yield or quantifiable color change induced per unit dose in the B3 film is influenced by complex and inter-related reactions involving moisture and oxygen concentrations, compounded with the concurrent changes in temperature over the range of dose.
Dose Rate Dependence	There are no known dose rate dependencies for B3 film.
Light	Films should remain in their factory packaging during irradiation. In the event B3 film is used outside the factory package, the B3 film should remain covered from inadvertent exposure to light sources and the impact of ambient light should also monitored and taken into account.
Humidity	Films should remain in their factory packaging during irradiation. In the event B3 film is used outside the factory package, the impact of change in humidity should be monitored and taken into account. Because of the large surface to volume ratio, B3 film dosimeters will readily equilibrate to the new environment outside the package. Relative humidity (RH) influence between 30% and 70% is minimal but RH levels outside this range can be significant.
Temperature	B3 film response has a complex temperature dependency and all batches of B3 film should be calibrated in-situ under process conditions that approximate those of actual use. Temperature correction factors should not be used with B3. GEX recommends a maximum 60°C temperature during irradiation.

Factors that Can Influence B3 Response – after irradiation	B3 film response is post-irradiation time dependent as the color development of B3 film will continue for a number of hours. B3 film dosimeters should undergo a post-irradiation heat treatment to complete and stabilize the B3 color change.
Light	All light fixtures and windows in the dose measurement area require UV light protection to minimize inadvertent UV or daylight contamination of B3 films during all B3 bare film handling activities. Periodic testing should be performed using bare unpackaged B3 dosimeters as control references to verify effectiveness of light protection measures.
Humidity	The stability of B3 film response is not moisture dependent after irradiation and post-irradiation relative humidity does not need to be controlled.
Temperature	Post irradiation heat treated B3 film dosimeters are not affected by temperature when maintained at temperatures between 15-30°C.
Time After Irradiation	Non heat treated B3 film dosimeters will continue their color development for a number of hours after irradiation. Post irradiation heat treatment is recommended to uniformly complete the color development and render B3 film stable. If heat treatment is not used then B3 dosimeters should be calibrated and used with post-irradiation time periods.
Instrumentation and Measurement	B3 film has a known broad peak wavelength that is typically found between 550nm and 554nm. The historically recommended measurement wavelength has been 554nm. Each spectrophotometer can be individually evaluated by simply using any B3 film dosimeter as a reference film to determine its specific peak wavelength by either scanning over the peak from 545nm to 559nm or by performing individual measurements over this range at single nm intervals.

B3 CALIBRATION AND USE

Dosimetry System Application	B3 film and B3 *WINdose* and *DoseStix* dosimeters are intended for use in routine dosimetry systems. In addition, because B3 radiochromic film can be heat treated after irradiation to complete the color development and stabilize response it can also serve as a reference material that can be used for daily checks of the dose measurement system.
B3 Radiation Source Applications	B3 radiochromic film is successfully calibrated and used with a broad array of ionizing radiation sources that include: gamma rays (cesium-137 and cobalt-60), X-ray photons, high energy electrons 1 - 20 MeV, low energy electrons (80 – 600 keV) and UV.
Process Applications	B3 is one of the most popular and fastest growing dosimeters and is used in wide variety of radiation process applications although the bulk of B3 use is found in sterilization process applications followed by crosslinking and curing application. Because of its low profile, B3 film is placed directly on to material surfaces and used to measure dose at product material/material and material/air interfaces as well as for measurements using pre-packaged dosimeters affixed to the outer product packages and box surfaces.
Dose Range Applications	B3 dosimetry systems are calibrated and used to cover dose from well below 1.0 kGy to greater than 150 kGy. Optimum results are achieved by limiting the calibration range.
Calibration	GEX recommends in-situ calibration of B3 *WINdose* and *DoseStix* for optimum performance with lowest overall uncertainty. GEX assists its customers with development of an in-situ calibration practice that can be validated to appropriately capture the temperature and dose rate conditions of routine process conditions for either full calibrations or calibration verification audits of a lab calibration. Uncertainty can be significantly reduced by limiting the curve fit dose range to cover specific application needs. GEX is pleased to assist B3 dosimeter users in designing and planning batch calibrations.
Uncertainty Expectations	An effectively designed and executed dosimeter batch calibration should be expected to result in a calibration that meets predictable uncertainty expectations that can be maintained and re-validated over time. Overall expanded uncertainties at approximately 95% confidence (k=2) should be expected to range from 3.5% to 6.0% dependent on the user's specific metrological practices with their B3 dosimetry system.

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PUBLICATIONS
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2.) Abdel-Fattah A. A. and Miller A. (1996); *Temperature, Humidity, and Time. Combined Effects on Radiochromic Film Dosimeters*; Radiation Physics and Chem. Vol. 47, No. 4 pp 611-621, Elsevier Science Ltd. Pergamon Press, Great Britain.

GEX RECOMMENDED GUIDANCE DOCUMENTS
3.) NPL CIRM REPORT 29 – *Guidelines for the Calibration of Dosimeters for use in Radiation Processing,* Peter Sharpe and Arne Miller, 1999; National Physical Laboratory, Teddington, UK.

4.) *Standards on Dosimetry Processing*; September 2004; ASTM International, West Conshohocken, PA; ISBN # 0-8031-4057-6 Stock # RADPR2004.

GEX RECOMMENDED PROCEDURES
100-250 UV Control and Monitoring
100-251 Instruments and Personnel Characterization
100-252 Instruments and Personnel Characterization Form
100-253 Dosimetry Lab Requirements
100-254 Windose System Calibration
100-255 Windose for Excel Verification
100-256 Dosimeter Batch Receiving Inspection
100-257 Dosimeter Ao Characterization Form
100-258 Measuring GEX Dosimeters
100-259 Investigation of B3 Windose Measurements
100-260 Energy Estimation
100-261 Uniformity Measurement
100-262 Genesys 20 Spectrophotometer Calibration Form
100-263 Calibrating B3 Dosimeters

GEX TECHNICAL MEMORANDA
100-201 Post Irradiation Heat Treatment of B3 Dosimeters
100-203 Comparison of ASTM Calibration Method and Dose On Response Method
100-204 High Energy Electron Beam Energy Determination through
100-205 B3 Radiochromic Film Dosimetry
100-207 Low Energy Electron Beam
100-208 Calibration Analysis
100-209 Developing and Using Uncertainty Statements
100-210 Genesys 20 – General Practices and Information