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Practice for use of a radiochromic film dosimetry system

Pratique de l'utilisation d'un système dosimétrique à film radiochromique

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75% of the member bodies casting a vote.

ASTM International is one of the world's largest voluntary standards development organizations with global participation from affected stakeholders. ASTM technical committees follow rigorous due process balloting procedures.

A pilot project between ISO and ASTM International has been formed to develop and maintain a group of ISO/ASTM radiation processing dosimetry standards. Under this pilot project, ASTM Committee E61, Radiation Processing, is responsible for the development and maintenance of these dosimetry standards with unrestricted participation and input from appropriate ISO member bodies.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. Neither ISO nor ASTM International shall be held responsible for identifying any or all such patent rights.

International Standard ISO/ASTM 51275 was developed by ASTM Committee E61, Radiation Processing, through Subcommittee E61.02, Dosimetry Systems, and by Technical Committee ISO/TC 85, Nuclear energy, nuclear technologies and radiological protection.

This third edition of ISO/ASTM 51275 cancels and replaces ISO/ASTM 51275:2004(E).

Standard Practice for Use of a Radiochromic Film Dosimetry System[1]

This standard is issued under the fixed designation ISO/ASTM 51275; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision.

1. Scope

1.1 This is a practice for using radiochromic film dosimetry systems to measure absorbed dose in materials irradiated by photons or electrons in terms of absorbed dose to water. Radiochromic film dosimetry systems are generally used as routine dosimetry systems.

1.2 The radiochromic film dosimeter is classified as a Type II dosimeter on the basis of the complex effect of influence quantities. See ASTM Practice E2628.

1.3 This document is one of a set of standards that provides recommendations for properly implementing dosimetry in radiation processing, and describes a means of achieving compliance with the requirements of ASTM E2628 "Practice for Dosimetry in Radiation Processing" for a radiochromic film dosimetry system. It is intended to be read in conjunction with ASTM E2628.

1.4 This practice covers the use of radiochromic film dosimetry systems under the following conditions:

1.4.1 The absorbed dose range is 1 Gy to 150 kGy.

1.4.2 The absorbed dose rate is 1×10^{-2} to 1×10^{13} $Gy{\cdot}s^{-1}$ **(1-4)**.[2]

1.4.3 The photon energy range is 0.1 to 50 MeV.

1.4.4 The electron energy range is 70 keV to 50 MeV.

1.5 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced documents

2.1 *ASTM Standards:*[3]

E170 Terminology Relating to Radiation Measurements and Dosimetry

E275 Practice for Describing and Measuring Performance of Ultraviolet and Visible Spectrophotometers

E2628 Practice for Dosimetry in Radiation Processing

E2701 Guide for Performance Characterization of Dosimeters and Dosimetry Systems for Use in Radiation Processing

2.2 *ISO/ASTM Standards:*[3]

51261 Practice for Calibration of Routine Dosimetry Systems for Radiation Processing

51707 Guide for Estimating Uncertainties in Dosimetry for Radiation Processing

2.3 *International Commission on Radiation Units and Measurements (ICRU) Reports:*[4]

ICRU Report 85a Fundamental Quantities and Units for Ionizing Radiation

ICRU Report 80 Dosimetry Systems for Use in Radiation Processing

2.4 *Joint Committee for Guides in Metrology (JCGM) Reports:*

JCGM 100:2008, GUM 1995, with minor corrections, Evaluation of measurement data – Guide to the Expression of Uncertainty in Measurement[5]

JCGM 200:2008, VIM, International vocabulary of metrology – Basis and general concepts and associated terms[6]

3. Terminology

3.1 *Definitions:*

3.1.1 *calibration curve*—expression of the relation between indication and corresponding measured quantity value. **(VIM)**

3.1.1.1 *Discussion*—In radiation processing dosimetry standards, the term 'dosimeter response' is generally used rather than 'indication'.

3.1.2 *dosimeter*—device having a reproducible, measurable response to radiation that can be used to measure the absorbed dose in a given system.

3.1.3 *dosimeter batch*—quantity of dosimeters made from a specific mass of material with uniform composition, fabricated in a single production run under controlled, consistent conditions, and having a unique identification code.

3.1.4 *dosimetry response*—reproducible, quantifiable effect produced in the dosimeter by ionizing radiation.

[1] This guide is under the jurisdiction of ASTM Committee E61 on Radiation Processing and is the direct responsibility of Subcommittee E61.02 on Dosimetry Systems, and is also under the jurisdiction of ISO/TC 85/WG 3.

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[2] The boldface numbers in parentheses refer to the bibliography at the end of this standard.

[3] For referenced ASTM and ISO/ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[4] Available from the International Commission on Radiation Units and Measurements, 7910 Woodmont Ave., suite 800, Bethesda, MD 20814, USA.

[5] Document produced by Working Group 1 of the Joint Committee for Guides in Metrology (JCGM/WG 1). Available free of charge at the BIPM website (http://www.bipm.org).

[6] Document produced by Working Group 2 of the Joint Committee for Guides in Metrology (JCGM/WG 2). Available free of charge at the BIPM website (http://www.bipm.org).

3.1.4.1 *Discussion*—For radiochromic film dosimeters, the absorbance, specific absorbance or specific net absorbance is the dosimeter response.

3.1.5 *dosimetry stock*—part of a dosimeter batch held by the user.

3.1.6 *measurement management system*—a set of interrelated or interacting elements necessary to achieve metrological confirmation and continual control of measurement processes.

3.1.7 *radiochromic film dosimeter*—specially prepared film containing ingredients that undergo change in optical absorbance under ionizing radiation, which can be related to absorbed dose to water.

3.1.8 *reference standard dosimetry system*—dosimetry system, generally having the highest metrological quality available at a given location or in a given organization, from which measurements made there are derived.

3.1.9 *response*—see *dosimeter response*.

3.1.10 *routine dosimetry system*—dosimetry system calibrated against a reference standard dosimetry system and used for routine absorbed dose measurements, including dose mapping and process monitoring.

3.1.11 *specific absorbance (k)*—optical absorbance, A_λ, at a selected wavelength λ, divided by the optical path length, *d*:

$$k = A_\lambda / D \quad (1)$$

3.1.12 *specific net absorbance (Δk)*—net absorbance, ΔA_λ, at a selected wavelength, λ, divided by the optical pathlength, *d*, through the dosimeter material as follows:

$$\Delta k = \Delta A_\lambda / D \quad (2)$$

3.2 Definitions of other terms used in this practice that pertain to radiation measurement and dosimetry may be found in ASTM Terminology E170. Definitions in E170 are compatible with ICRU Report 85a; that document, therefore, may be used as an alternative reference.

4. Significance and use

4.1 The radiochromic film dosimetry system provides a means for measuring absorbed dose based on radiation-induced change in color using spectrophotometers, densitometers or scanned images.

4.2 Radiochromic film dosimetry systems are commonly used in industrial radiation processing, for example in the sterilization of medical devices and the irradiation of foods.

5. Overview

5.1 Radiochromic film dosimeters are manufactured by various methods to produce freestanding or coated films, which are flexible and transparent. They are generally supplied as small squares, strips, or long rolls or sheets that can be cut into a convenient size for dosimetry purposes. The response of the dosimeters may be influenced by water content, irradiation temperature, post-irradiation time to measurement, and other potential influence quantities that need to be taken into account. Many commercially available dosimeters are supplied in light- and vapor-tight packages, which effectively protect against light and changes in ambient humidity. The dosimeters should be calibrated under irradiation conditions that are similar to those in which they will be used.

5.2 Ionizing radiation induces chemical reactions in the material, which create or enhance absorption bands in the visible or ultraviolet regions, or both, of the optical spectrum. Absorbance determined at appropriate wavelengths within these radiation-induced absorption bands is quantitatively related to the absorbed dose. ICRU Report 80 provides technical information and historical development of the radiochromic film dosimetry systems in current use.

5.3 The radiation-induced change in absorbance of the radiochromic film depends on the wavelength of the light which is used to make the measurement.

6. Influence quantities

6.1 Factors other than absorbed dose which influence the dosimeter response are referred to as influence quantities. Examples of such factors are temperature and dose rate. See ASTM Guide E2701. See Refs **(2-14)** for examples of the types and magnitudes of the effects.

6.2 *Pre-Irradiation Conditions*:

6.2.1 *Dosimeter Conditioning and Packaging*—Dosimeters may be conditioned by the manufacturer to optimize water content in the film, and then sealed in vapor and light tight pouches to maintain that condition.

6.2.2 *Time since Manufacture*—The shelf-life of some types of radiochromic film dosimeters has been shown to exceed nine years. However, it is recommended that users carry out performance verification of pre-irradiation absorbance and post-irradiation response stability over the useful life of the dosimeter batch.

6.2.3 *Temperature*—Exposure to extreme temperature during shipment and storage at the user's facility might affect dosimeter response. The manufacturer should be consulted for specific recommendations for dosimeter shipment and storage.

6.2.4 *Relative Humidity*—Dosimeters may be packaged so they are not affected by environmental changes in humidity; dosimeters without protective packaging might be affected. The manufacturer should be consulted for specific recommendations for dosimeter shipment and storage.

6.2.5 *Exposure to Light*—Dosimeters may be packaged so they are not affected by exposure to light; dosimeters without protective packaging might be affected. The manufacturer should be consulted for specific recommendations for dosimeter shipment and storage.

6.3 *Conditions During Irradiation*:

6.3.1 *Irradiation Temperature*—Irradiation temperature is expected to influence dosimeter response. It is recommended to calibrate the dosimetry system under the conditions of use (in-plant calibration) in order to mitigate the effect of temperature on dosimeter response.

6.3.2 *Absorbed-dose Rate*—Absorbed-dose rate might influence dosimeter response. It is recommended to calibrate the dosimetry system under the conditions of use (in-plant calibration) in order to mitigate any possible effect of dose rate on dosimeter response.

6.3.3 *Dose Fractionation*—Dose fractionation might influence dosimeter response. It is recommended to calibrate the dosimetry system under the conditions of use (in-plant calibration) in order to mitigate any possible effect of dose fractionation.

6.3.4 *Relative Humidity*—For some dosimeters, the amount of water in the dosimeter is known to influence its response. For dosimeters used outside manufacturer's sealed packaging, it is recommended to calibrate the dosimetry system under the conditions of use (in-plant calibration) in order to mitigate any possible effect of variations in the amount of water in the dosimeter and hence its response.

6.3.5 *Exposure to Light*—Dosimeters may be packaged so they are not affected by exposure to light; dosimeters without protective packaging might be affected.

6.3.6 *Radiation Energy*—The response of dosimeters has been demonstrated to be independent of energy. However, when electron energy is low enough to result in a dose gradient through the thickness of the dosimeter, difficulties in interpretation of the measured response may result **(15)**.

NOTE 1—At low energies the thickness of the packaging material might give rise to measurement errors.

6.4 *Post-Irradiation Conditions*:

6.4.1 *Time*—Dosimeters may take significant time for the absorbance to stabilize after irradiation **(10-12, 16 and 17)**. A post irradiation heat-treatment process may stabilize the absorbance sooner. Dosimeter manufacturer should be consulted for specific recommendation for post-irradiation heat treatment.

NOTE 2—The response of FWT-60 and B3 dosimeters can be stabilized by a post-irradiation heat treatment.

6.4.2 *Temperature*—Storage temperature after irradiation might influence dosimeter response. Dosimeter manufacturer should be consulted for specific recommendation for storage of irradiated dosimeters.

6.4.3 *Relative Humidity*—Water content in dosimeter after irradiation might influence dosimeter response. Dosimeter manufacturer should be consulted for specific recommendation for storage of irradiated dosimeters.

6.4.4 *Exposure to Light*—Dosimeters may be packaged so they are not affected by exposure to light; dosimeters without protective packaging might be affected.

6.5 *Response Measurement Conditions*:

6.5.1 Requirements for post irradiation conditions apply to conditions of measurement.

NOTE 3—Light used for measurement of dosimeter response might contain a UV component that can affect dosimeter response.

7. Dosimetry system and its verification

7.1 *Components of the Radiochromic Film Dosimetry System*—The following are components of radiochromic film dosimetry systems:

7.1.1 *Radiochromic Film Dosimeters*—The film may be provided in bulk or in pouches of one or more dosimeters. A pouch provides humidity and light protection.

7.1.2 *Measurement Instruments*—For each instrument used to measure dosimeter response, determine and establish the specific measurement settings capable of providing highly reproducible results over the required dose range. For example, use the peak absorbance wavelength for a specific dosimeter to optimize measurement reproducibility. Some dosimeters may require use of an off-peak wavelength to extend the usable dose range. Examples of appropriate analysis wavelengths for specific dosimetry systems are provided by the manufacturer and in Refs **(3-10, 16-21)**. Depending on the specific dosimetry system, the response may be absorbance, change in absorbance, specific absorbance or specific net absorbance.

7.1.2.1 *Spectrophotometer* (or an equivalent instrument), with appropriate traceable calibration standards.

NOTE 4—Select a spectrophotometer capable of satisfying specified precision and dose range requirements. For example, in thin film dosimetry, the spectral bandwidth setting must be appropriate for a given dosimeter thickness in order to avoid introducing optical interference fringes that adversely affect measurement reproducibility and can severely limit the lower end of achievable dose range.

7.1.2.2 *Densitometer*, with appropriate traceable calibration standards.

7.1.2.3 *Film Image Scanner*, with appropriate traceable calibration standards.

7.1.3 *Dosimeter Holder*, to position the dosimeter reproducibly during the absorbance measurement process.

7.1.4 *Calibrated Thickness Gauge (Optional)*, with appropriate calibration standards.

NOTE 5—Most users will elect not to implement an on-site thickness measurement capability due to the technical difficulty associated with performing highly reproducible thickness measurements on soft surfaced film dosimeters. Instead, most users will either ignore thickness (treating it as a constant) or utilize the average thickness as stated by the manufacturer.

7.2 *Measurement Management System*, including the dosimetry system calibration curve resulting from calibration according to ISO/ASTM Practice 51261, and the procedures for its use.

7.3 *Performance Verification of Instrumentation*:

7.3.1 At prescribed time intervals, or in the event of suspected performance issues during periods of use, check measurements against their calibration standards.

7.3.2 Implementation of a daily check program intended to verify instrument performance before and after measurement sessions is also recommended.

8. Incoming dosimeter stock assessment

8.1 A protocol shall be established for the purchase, receipt, acceptance and storage of dosimeters.

8.2 The user shall perform an incoming inspection and acceptance testing for each shipment of dosimeters received. Samples should be randomly selected from the incoming stock as is possible.

8.2.1 Verify and document details such as batch, quantity, date received, miscellaneous descriptions (such as average thickness) and status of any shipping controls (such as temperature device's indication of whether temperature limits may have been exceeded during shipping).

8.2.2 Perform random sampling per documented procedures to verify dosimeter and pouch integrity and, if appropriate, to determine average thickness and average pre-irradiation absorbance.

8.2.3 It is also recommended that the user conduct dosimeter response testing at or near the planned high, medium and low doses either to determine that the batch samples respond within expectation or to verify the batch response of a new stock shipment against the results obtained with samples from a prior shipment.

8.3 Retain sufficient dosimeters for additional investigations, for use during verification or for recalibration.

8.4 Store dosimeters according to the manufacturer's recommendations, or specific user determined practices.

9. Calibration

9.1 Prior to initial use of each batch of dosimeters, the dosimetry system shall be calibrated in accordance with ISO/ASTM Practice 51261, and the user's procedures, which specify details of the calibration and quality assurance requirements.

9.2 The user's dosimetry system calibration shall take into account the influence quantities associated with pre–irradiation, irradiation, and post-irradiation conditions applicable to the process in the user's facility (see Section 6).

NOTE 6—Successful calibration of radiochromic film dosimetry systems requires use of calibration conditions that approximate those expected to be encountered during use. If large seasonal temperature differences are anticipated, then the calibration should be conducted during periods that may better reflect the middle of the temperature range expected to be encountered over the life of the calibration. Periodic or seasonal calibration verification is also recommended to determine any effects of seasonal variation and confirm continued use of a batch specific calibration.

9.3 Multiple calibration curves can be used instead of using a single calibration curve over the entire dose range as a means of reducing the level of calibration uncertainty.

10. Routine use

10.1 *Before Irradiation*:

10.1.1 Ensure that the dosimeters are selected from an approved batch stored according to user's procedures. These procedures should be based on manufacturer's written recommendations or user specific performance characterization results.

10.1.2 Use only dosimeters that are within shelf life and calibration expiration dates.

10.1.3 Inspect each dosimeter package for external imperfections. For example, seal integrity along with verification of the presence of radiochromic film dosimeter within the package. Discard any dosimeters that indicate possible damage.

10.1.4 Mark the packaged dosimeters appropriately for identification, or if preferred and if provided by the manufacturer, use the unique reference or bar-code of the dosimeter.

10.1.5 Place the packaged dosimeters at the specified locations for irradiation.

10.2 *Post-Irradiation Analysis Procedure*:

10.2.1 Retrieve and account for all dosimeters, verifying the placement location of each dosimeter.

10.2.2 Maintain the radiochromic film dosimeters in their sealed packages, if applicable, in an approved location under specified conditions prior to measurement. See 6.4 and 6.5.

10.2.3 Response of dosimeters should be measured during an interval (section 6.4.1) and under conditions (section 6.5) which account for potential post-irradiation changes. If appropriate, perform post-irradiation heat treatment per established procedure.

10.2.4 Verify instrument performance according to documented procedures. See 7.2.

10.2.5 Inspect each dosimeter package for imperfections, for example, compromised seal and package material integrity. Document any imperfections.

10.2.6 For each dosimeter, perform the following:

10.2.6.1 If the dosimeter is packaged, open the package and remove the dosimeter, handling it by its edges or corners with a pair of tweezers.

10.2.6.2 Inspect the dosimeter for any imperfections, such as scratches. Document any imperfections.

NOTE 7—If a dosimeter is found to be scratched, a reliable measurement may be obtained by repositioning the dosimeter, for example by inverting or rotating it, so that the scratch is not in the light beam path of the spectrophotometer.

10.2.6.3 If necessary, clean the dosimeter before analysis.

10.2.6.4 Position the dosimeter in the holder in the instrument, taking care to align it properly and to position it perpendicular to the analyzing light beam.

10.2.6.5 Measure and record the absorbance at the specified analysis wavelength (see Table A1.1 for manufacturer's recommendations).

10.2.6.6 Measure the thickness of the dosimeter in the region traversed by the analyzing light beam or use an average value specified by the manufacturer or determined by sampling.

NOTE 8—For some type of dosimeters, it is not possible to measure the thickness of the active layer of the dosimeter (for example, Gafchromic).

10.2.6.7 Calculate the response.

10.2.6.8 Calculate the absorbed dose from the response using the appropriate calibration curve of the dosimetry system (see 9.3).

11. Documentation requirements

11.1 Record details of the measurements in accordance with the user's measurement management system.

12. Measurement uncertainty

12.1 All dose measurements need to be accompanied by an estimate of uncertainty. Appropriate procedures are recommended in ISO/ASTM Guide 51707. See also GUM.

12.2 All components of uncertainty should be included in the estimate, including those arising from calibration, dosimeter reproducibility, instrument reproducibility, and the effect of influence quantities. A full quantitative analysis of components of uncertainty may be referred to as an uncertainty budget, and is then often presented in the form of a table. Typically, the uncertainty budget will identify all significant components of uncertainty, together with their methods of estimation, statistical distributions and magnitudes.

12.3 The estimate of the expanded uncertainty achievable with measurements made using a routine dosimetry system such as radiochromic film is typically of the order of ±6 % ($k = 2$), which corresponds approximately to a 95 % level of confidence for normally distributed data.

13. Keywords

13.1 absorbed dose; dose; dosimeter; dosimetry system; electron beam; gamma radiation; ionizing radiation; irradiation; radiation; radiation processing; radiation sterilization; radiochromic film

ANNEX

(Mandatory Information)

A1. INFORMATION ON RADIOCHROMIC FILM DOSIMETERS

A1.1 This information is intended to serve as a guide only, since available sources of dosimeters and dosimeter performance may change.

A1.2 A general list of available radiochromic film dosimeters is given in Table A1.1.

A1.3 Note that the absorbed dose ranges are recommended ranges. In some cases it may be possible to extend the lower and upper dose limits with possible consequent loss of dosimetric accuracy.

A1.4 Some suppliers are listed in Table A1.2.

TABLE A1.1 Basic properties of available radiochromic film dosimeters

Dosimeter Type	Nominal Thickness, µm	Analysis Wavelength, nm	Usable Dose Range, kGy
FWT-60	50	605, 600, or 510	5 to 100
B3	18	552 ± 2	<1.0 to >120
GAFCHROMIC (various models)	Depends on model	Depends on model	Depends on model

TABLE A1.2 Some suppliers of radiochromic film dosimeters

Type	Supplier Address
Far West Technology, Inc.	330 S Kellogg Ave Suite D Goleta, CA 93117 USA
GEX Corporation	7330 South Alton Way Suite 12i Centennial, CO 80112 USA
International Specialty Products	1361 Alps Road Wayne, NJ 07470 USA

A1.5 The response of some types of radiochromic film dosimeters is known to be dependent on water content, so these dosimeters are normally supplied in sealed leak-tight packages. These packages protect the dosimeters, ensure stable water content, and prevent undue exposure to light before absorbance measurements.

A1.6 Information on environmental effects and their possible influence on dosimetric accuracy may be obtained from the dosimeter manufacturers.

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