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Practice for use of a cellulose triacetate dosimetry system

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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. ISO/ASTM 51650.2013

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 51650 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 cancels and replaces the second edition (ISO/ASTM 51650:2005), which has been technically revised.

ISO/ASTM 51650:2013(E)



Standard Practice for Use of a Cellulose Triacetate Dosimetry System¹

This standard is issued under the fixed designation ISO/ASTM 51650; 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 a cellulose triacetate (CTA) dosimetry system to measure absorbed dose in materials irradiated by photons or electrons in terms of absorbed dose to water. The CTA dosimetry system is classified as a routine dosimetry system.

1.2 The CTA dosimeter is classified as a type II dosimeter on the basis of the complex effect of influence quantities on its response (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 CTA dosimetry system. It is intended to be read in conjunction with ASTM E2628.

Reports: 1.4 This practice covers the use of CTA dosimetry systems under the following conditions:

1.4.1 The absorbed dose range is 10 kGy to 300 kGy. sion of Uncertainty in Measurement⁵ 1.4.2 The absorbed-dose rate range is 3 Gy/s to $4{\times}10^{10}$

ISO/ASTM 51650JCGM 200:2008, VIM, International vocabulary of metrol-Gy/s (1).² 1.4.3 The photon energy ranges is 0.1 dtod 50. MeV atalog/standards/sist/82957eBasis and general concepts and associated terms⁶

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) JCGM 100:2008, GUM 1995, with minor corrections,

1.4.4 The electron energy range is 0.2 to 506MeV b43a5/iso-astr3-51650-2013

3.1 Definitions:

3.1.1 absorbed-dose mapping-measurement of absorbed dose within an irradiated product to produce a one-, two- or three-dimensional distribution of absorbed dose, thus rendering a map of absorbed-dose values.

3.1.1.1 Discussion-The CTA dosimeter strip with appropriate length provides the opportunity for high resolution measurement of dose distribution, such as depth dose distribution.

3.1.2 absorbed-dose rate (\dot{D}) —absorbed dose in a material per incremental time interval, i.e., the quotient of dD by dt. Also see E170. The SI unit is Gy s^{-1} . (ICRU-60, 4.2.6)

$$\dot{D} = dD/dt \tag{1}$$

3.1.2.1 Discussion—(1) The absorbed-dose rate is often specified in terms of its average value over longer time intervals, for example, in units of Gy·min⁻¹ or Gy·h⁻¹. (2) In

¹ This practice 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).



gamma industrial irradiators, dose rate may be significantly different at different locations. (3) In electron-beam irradiators with pulsed or scanned beam, there are two types of dose rate: average value over several pulses (scans) and instantaneous value within a pulse (scan). These two values can be significantly different.

3.1.3 *calibration curve*—expression of the relation between indication and corresponding measured quantity value. (VIM:2008)

3.1.3.1 *Discussion*—In radiation processing standards, the term "dosimeter response" is generally used for "indication".

3.1.4 *cellulose triacetate dosimeter*—piece of CTA film that, during exposure to ionizing radiation, exhibits a quantifiable change in specific net absorbance as a function of absorbed dose.

3.1.5 *dosimeter*—device that, when irradiated, exhibits a quantifiable change that can be related to absorbed dose in a given material using appropriate measurement instruments and procedures.

3.1.6 *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.

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

3.1.7.1 *Discussion*—For CTA dosimeters, the specific net absorbance is the dosimeter response.

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

3.1.9 *measurement management system* set of interrelated near or interacting elements necessary to achieve a metrological so-a confirmation and continual control of measurement processes.

3.1.10 *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.

3.1.11 response—see dosimeter response.

3.1.12 *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.

3.1.13 *specific net absorbance* (Δk) —net absorbance, ΔA_{λ} , at a selected wavelength, λ , divided by the optical pathlength, d, through the dosimeter as follows:

$$\Delta k = \Delta A_{\lambda}/d \tag{2}$$

3.1.14 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 CTA dosimetry system provides a means for measuring absorbed dose based on a change in optical absorbance in the CTA dosimeter following exposure to ionizing radiation (5, 7-14).

4.2 CTA dosimetry systems are commonly used in industrial radiation processing, for example in the modification of polymers and sterilization of health care products.

4.3 CTA dosimeter film is particularly useful in absorbed dose mapping because it is available in a strip format and if measured using a strip measurement device, it can provide a dose map with higher resolution than using discrete points.

5. Overview

5.1 CTA dosimeters are manufactured by casting cellulose triacetate with a plasticizer, triphenylphosphate, and solvents, for example, a methylene chloride–methanol mixture (5, 11).

5.2 The commercially available dosimeter film is in the format of 8 mm width and 100 m length rolled on a spool, which is described in the informative annex.

5.3 Ionizing radiation induces chemical reactions in CTA and the plasticizer, which create or enhance optical absorption bands in the ultraviolet regions of the spectrum. Optical absorbance at appropriate wavelengths within these radiation-induced absorption bands is quantitatively related to the absorbed dose. ICRU Report 80 provides information on the scientific basis and historical development of the CTA dosimetry systems in current use.

5.4 The difference between the specific net absorbance of un-irradiated and irradiated CTA dosimeter depends significantly on the analysis wavelength used to make the absorbance measurement. Typically, the manufacturer recommends the analysis wavelength that optimizes sensitivity and postirradiation stability. The analysis wavelengths recommended

t management system darst ich air at a base and after some commonly used systems are given in Table A1.1.

-astm-51650-2013 6. Influence quantities

6.1 Factors other than absorbed dose which influence the dosimeter response are referred to as influence quantities. These influence quantities include those related to the dosimeter before, during, and after irradiation and those related to the dosimeter response measurements (see ASTM Guide E2701). Influence quantities affecting dosimeter response are discussed below.

6.2 Pre-Irradiation Conditions:

6.2.1 *Dosimeter Conditioning and Packaging*—The dosimeter may require conditioning and packaging, particularly for low dose rate (gamma) irradiation. See 6.3.4.

NOTE 1—Conditioning CTA film and packaging pieces of it in environmentally impermeable pouches under controlled relative humidity conditions will provide for the most consistent dosimeter response, however the film is often used with no packaging.

6.2.2 *Time Since Manufacture*—The pre-irradiation absorbance increases very slowly with time and depends on the access to air (oxygen). The pre-irradiation absorbance of the outer layer(s) of a roll of CTA film may, therefore, increase more than the inner layers; hence, it may be advisable to discard the outer layer(s) of the film. Measure the pre-irradiation absorbance before using the dosimeter. Alternatively, compare the pre-irradiation absorbance to the average value noted at the time of calibration to determine if there is any significant change that should be taken into account.

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NOTE 2—The pre-irradiation absorbance to be used in the calculation of specific net absorbance will either be the value as measured before irradiation by the user, or a user-determined average pre-irradiation absorbance.

6.2.3 *Temperature*—Avoid exposure to temperatures outside the manufacturer's recommended range to reduce the potential for adverse effects on dosimeter response.

6.2.4 *Relative Humidity*—There is no known effect on dosimeter response.

6.2.5 *Exposure to Light*—The dosimeter is insensitive to visible light; however, exposure to UV light may have an effect and should be characterized. Exposure to UV prior to irradiation may increase the pre-irradiation absorbance of the film, and depends on the intensity of the UV (6).

6.3 Conditions During Irradiation:

6.3.1 *Irradiation Temperature*—The dosimeter response is affected by temperature, particularly at low dose rates, and this effect shall be characterized (**3**, **6**, **13**, **14**).

6.3.2 *Absorbed-Dose Rate*—The dosimeter response is affected by the absorbed-dose rate and this effect shall be characterized (2, 4-8, 11-13).

6.3.3 *Dose Fractionation*—The dosimeter response is affected by dose fractionation and shall be characterized (4).

6.3.4 *Relative Humidity*—The dosimeter response is affected by relative humidity, particularly at low dose rates and R relative humidity extremes. This effect shall be characterized (3, 6, 8, 11, 13).

6.3.5 *Exposure to Light*—The dosimeter is insensitive to visible light, however, exposure to UV light may have an effect and should be characterized. Exposure to UV during irradiation may increase the optical absorbance of the film, and likely depends on the intensity of the UV (6).

6.3.6 *Radiation Energy*—There is no known effect on dosimeter response, however, the irradiation of 125 micron thick CTA film using electron energies below 300 keV can result in a dose gradient through the film.

6.4 Post-Irradiation Conditions:

6.4.1 *Time*—The dosimeter response varies with the time interval between radiation exposure and dosimeter measurement (**3**, **4**, **6**, **8**, **14**). This effect shall be characterized and the measurement time standardized.

NOTE 3—The absorbance first decreases and then slowly increases with storage time longer than fifteen minutes after high dose-rate electron beam irradiation. The dosimeter response will become more stable about two hours after irradiation. Therefore, it is recommended that the absorbance of the dosimeter be measured at a constant time period, for example, two hours after irradiation (6, 8, 11).

6.4.2 *Temperature*—The temperature of CTA film storage after irradiation does have an effect and shall be characterized. The user may need to control the post-irradiation storage temperature within a defined range (6).

6.4.3 *Conditioning Treatment*—No advantageous post-irradiation treatment has been found (8).

6.4.4 *Relative Humidity*—The rate of change of the postirradiation absorbance may be affected by relative humidity and shall be characterized. The user may need to control the post-irradiation storage relative humidity within a defined range (3, 6, 11, 13). 6.4.5 *Exposure to Light*—The dosimeter is insensitive to visible light, however, exposure to UV light may have an effect and should be characterized. Exposure to UV after irradiation may increase the post-irradiation absorbance of the film, and likely depends on the intensity of the UV (**6**).

NOTE 4—The post-irradiation absorbance of the film has been shown to change over longer storage periods (greater than 24 hours) and is dependent on the temperature and relative humidity during post-irradiation storage. The user should characterize longer term effects and define storage conditions if measurements will be made outside of the time interval used during calibration of the dosimetry system (see 6.4.1) (6, 13).

6.5 Response Measurement Conditions:

6.5.1 *Exposure to Light*—The dosimeter is insensitive to visible light, however, exposure to UV light may have an effect and should be characterized. Exposure to UV after irradiation may increase the post-irradiation absorbance of the film, and likely depends on the intensity of the UV (**6**).

6.5.2 *Temperature*—The temperature conditions used during routine measurement shall be consistent with the conditions during calibration.

6.5.3 *Relative Humidity*—The relative humidity conditions used during routine measurement shall be consistent with the conditions during calibration.

7. Dosimetry system

7.1 *Components of the CTA Dosimetry System*—The following are components of a CTA dosimetry system:

7.1.1 Cellulose Triacetate Dosimeter Film.

S1650720.2 Calibrated Spectrophotometer (or an equivalent inrdsstrument), capable of determining optical absorbance at the istranalysis-2wavelength and having documentation specifying wavelength range, accuracy of wavelength selection and absorbance determination, spectral bandwidth, and stray light rejection.

7.1.2.1 Means of verifying optical absorbance, for example using certified optical absorption filters, covering more than the range of absorption encountered.

7.1.2.2 Means of verifying wavelength calibration, for example using certified filters.

7.1.3 *Holder*, to position the dosimeter reproducibly in, and perpendicular to, the analyzing light beam during absorbance measurement.

NOTE 5—Automatic dosimeter strip reading equipment is commonly used to measure long strips of CTA film (see Table A1.3 for more information).

7.1.4 Calibrated Thickness Gauge (optional).

7.1.4.1 Means of verifying thickness gauge calibration, for example through Certified Thickness Gauge Blocks, exceeding the range of thicknesses encountered.

7.2 *Measurement Management System*, including the dosimetry system calibration curve resulting from calibration according to ISO/ASTM Practice 51261 (see Section 9).

7.3 Performance Verification of Instrumentation:

7.3.1 At prescribed time intervals, or whenever there are indications of poor performance during periods of use, the wavelength and absorbance scales of the spectrophotometer shall be checked at or near the analysis wavelength, and the



results documented. This information should be compared with the instrument specifications to verify adequate performance, and the result documented (see ASTM Practice E275).

7.3.2 At prescribed time intervals the calibration of the thickness gauge shall be checked and the result recorded. The thickness gauge shall also be checked before, during, and, if considered appropriate, after use, to ensure reproducibility and absence of zero drift.

8. Incoming dosimeter stock assessment

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

8.2 On receiving a new dosimeter stock, the user shall check the batch designation against the manufacturer's certification and perform an incoming inspection. The user should verify, for example, that the thickness, pre-irradiation absorbance, and variability of response are within documented specifications.

NOTE 6-CTA dosimetry system users often accept the manufacturer's stated thickness and do not perform such verification.

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

8.4 Store dosimeters according to the manufacturer's recommendations, or as justified by published data or experience.

9. Calibration

9.1 Prior to initial use of each dosimeter stock the dosimetry ommendations). system shall be calibrated in accordance with ISO/ASTM 10.2.5.5 Measure the thickness of the dosimeter in the Practice 51261, and the user's procedures, which should region traversed by the analyzing light beam, if applicable. specify details of calibration and quality assurance require-Note 9-3-Alternatively, the manufacturer's stated average or a userments.

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 7-If prior experience, manufacturer's recommendations, or scientific literature (see references) suggest that the conditions experienced by the dosimeters are likely to influence dosimeter response and increase the uncertainties significantly, the calibration irradiation of the dosimeters should be performed under conditions similar to those of routine use (see ISO/ASTM 51261 for details).

9.3 Multiple calibration curves may be required, for example, to accommodate particular dose ranges or postirradiation measurement intervals.

10. Routine use

10.1 Preparation for Use:

10.1.1 Ensure that the dosimeters are selected from an approved stock stored according to user's procedures and manufacturer's written recommendations, and that they are within shelf life and calibration expiration dates.

10.1.2 Measure the pre-irradiation absorbance of the film (see 6.2.2).

10.1.3 Inspect each dosimeter piece for external imperfections, for example the presence of scratches on the CTA film. Discard any film pieces or sections that show unacceptable imperfections.

10.1.4 Mark the dosimeters appropriately for identification.

10.1.5 Place the dosimeters at specified locations for irradiation.

10.2 Post-Irradiation Analysis:

10.2.1 Retrieve the dosimeters.

10.2.2 Store the dosimeters in an approved location under specified conditions prior to measurement (see 6.4).

10.2.3 Measure the specific absorbance of dosimeters at a time (see 6.4.1) and under conditions (see 6.5) which take account of potential post-irradiation changes.

10.2.4 Verify instrument performance according to documented procedures (see 7.2).

10.2.5 For each dosimeter, perform the following:

10.2.5.1 Inspect it for any imperfections, such as scratches. Document any imperfections.

NOTE 8-If a dosimeter is found to be scratched, a reliable measurement can sometimes be obtained by repositioning the dosimeter in the spectrophotometer holder, for example by inverting it, so that the scratch is not in the light beam path of the spectrophotometer.

10.2.5.2 If necessary, clean the dosimeter before analysis. An accepted method is wiping the film with a dry, low-lint or lint-free cloth.

10.2.5.3 Position the dosimeter in the holder in the spectrophotometer.

ileh SIAND 10.2.5.4 Measure and record the absorbance at the selected analysis wavelength (see Table A1.1 for manufacturer's rec-

adetermined average should be used.

10.2.5.6 Calculate the specific net absorbance using the measured or average thickness.

10.2.5.7 Determine the absorbed dose from the specific net absorbance and the appropriate calibration curve (see Section 9).

10.3 Additional Information:

10.3.1 The dosimeter film irradiated to doses exceeding 200 kGy becomes brittle to some degree and must be handled with care. This may limit the practical dose range depending on the type of testing and handling required.

10.3.2 During the preparation and measurement, to avoid transmission of finger-prints or other residue, do not touch the dosimeter surface with bare fingers. These kinds of surface contaminations can affect the measurement. Use a pair of tweezers for handling the dosimeter, holding it at a corner or a side, or use powder free gloves.

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 response reproducibility, instrument reproducibility, and the effect of influence quantities. A full quantitative analysis of components of uncertainty, referred to as an uncertainty budget, is 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 CTA dosimetry system and

used as per this practice is typically of the order of $\pm 6 - 8$ % for a coverage factor k = 2 (which corresponds approximately to a 95 % level of confidence for normally distributed data).

13. Keywords

13.1 absorbed dose; cellulose triacetate; CTA; dose; dosimeter; dosimetry system; electron beam; gamma radiation; ionizing radiation; irradiation; radiation; radiation processing; radiation sterilization

ANNEX

(informative)

A1. INFORMATION ON (CTA) FILM DOSIMETERS

A1.1 This information is intended to serve as a guide only,	TABLE A1.2 Known suppliers of CTA dosimeters		
since available sources of dosimeters and dosimeter perfor-	Туре	Supplier Address	
mance may change.	FTR-125	FujiFilm Corporation 7-3 Akasaka 9-Chome,	
A1.2 A list of available CTA dosimeters is given in Table R	D PREV	Minato-Ku, Tokyo, 107-0052 Japan	
A1.1.	FTR-125	GEX Corporation	
(standards,	iteh.ai)	(distribution for Fuji)	
A1.3 The absorbed dose range is the recommended range.		7330 S. Alton Way, Suite 12-I,	
In some cases it may be possible to extend the lower and upper		Centennial, CO 80112 USA	
dose limits with possible consequent loss of dosimetric accu-	0:2013 FTR-125	Aérial—Centre de Ressources Technologiques	
racy https://standards.iteh.ai/catalog/standards/	sist/82357ee6-66	516-4 (distribution for Fuji)	
a6f47a1b43a5/iso-astm	⊦51650-2013	Parc d'Innovation, Rue Laurent Fries,	
		BP 40443	
A1.4 Some suppliers of the film are listed in Table A1.2.		F-6/412 Illkirch, Cedex, France	

TABLE A1.1	Basic properties of available CTA dosimeters

	Busic propert		TA desineters
Dosimeter	Nominal Thickness, mm	Analysis Wavelength, nm	Absorbed Dose Range, kGy
FTR-125	0.125	280 ^A	10 to 300

^A Other analysis wavelengths near 280nm have been suggested and demonstrated **(13)**.

A1.5 Some suppliers of specialized CTA strip reading equipment are shown in Table A1.3.

A1.6 Information on environmental and post-irradiation effects and their possible influence on dosimetric response may be obtained from the supplier and information is published in the references listed in this standard.