## INTERNATIONAL STANDARD

### ISO/ASTM 51276

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Corrected version 2019-11

# Practice for use of a polymethylmethacrylate dosimetry system

Pratique de l'utilisation d'un système dosimétrique au polyméthylméthacrylate

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#### **Foreword**

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see <a href="https://www.iso.org/directives">www.iso.org/directives</a>).

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This document was prepared by 150/TC: 85; Nuclear senergy, nuclear technologies and radiological protection, in cooperation with ASTM E61; Radiation processing; 10 on the basis of a partnership agreement between ISO and ASTM International with the aim to create a common set of ISO/ASTM standards on additive manufacturing.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at <a href="https://www.iso.org/members.html">www.iso.org/members.html</a>.

This corrected version of ISO/ASTM 51276:2019 incorporates the following correction:

— Subclause 9.3 has been added back.

This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.





#### **Standard Practice for** Use of a Polymethylmethacrylate Dosimetry System<sup>1</sup>

This standard is issued under the fixed designation ISO/ASTM 51276; 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 polymethylmethacrylate (PMMA) dosimetry systems to measure absorbed dose in materials irradiated by photons or electrons in terms of absorbed dose to water. The PMMA dosimetry system is generally used as a routine dosimetry system.
- 1.2 The PMMA dosimeter is classified as a Type II dosimeter on the basis of the complex effect of influence quantities (see ISO/ASTM Practice 52628).
- 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 ISO/ASTM 52628 "Practice for Dosimetry in Radiation Processing for a PMMA dosimetry system. It is intended to be read in conjunction with ISO/ASTM Practice 52628. standard
- 1.4 This practice covers the use of PMMA dosimetry systems under the following conditions:

  - 1.4.1 the absorbed dose rate is  $1 \times 10^{-2}$  to  $1 \times 10^{7}$  Gy·s . 2.4 ISO Standard: 4
  - 1.4.3 the photon energy range is 0.1 to 25 MeV.
  - 1.4.4 the electron energy range is 3 to 25 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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.
- 1.6 This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.

#### 2. Referenced documents

2.1 ASTM Standards:<sup>2</sup>

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

E3083 Terminology Relating to Radiation Processing: Dosimetry and Applications

2.2 ISO/ASTM Standards:<sup>2</sup>

51261 Practice for Calibration of Routine Dosimetry Systems for Radiation Processing

51707 Guide for Estimation of Measurement Uncertainty in Dosimetry for Radiation Processing

52628 Practice for Dosimetry in Radiation Processing

52701 Guide for Performance Characterization of Dosimeters and Dosimetry Systems for Use in Radiation Processing () \ \ \

2.3 International Commission on Radiation Units and Measurements (ICRU) Reports:<sup>3</sup>

ICRU Report 80 Dosimetry Systems for Use in Radiation Processing

1.4.1 the absorbed dose range is 0.1 kGy to 150 kGy standards/sis/150 kGy to 150 kGy to

12749-4 Nuclear energy — Vocabulary — Part 4: Dosimetry for radiation processing

2.5 Joint Committee for Guides in Metrology (JCGM)

JCGM 100:2008, GUM 1995, with minor corrections Evaluation of measurement date - Guide to the Expression of Uncertainty in Measurement<sup>5</sup>

JCGM 200:2012, VIM International Vocabulary of Metrology - Basic and General Concepts and Associated Terms<sup>6</sup>

<sup>&</sup>lt;sup>1</sup> 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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<sup>&</sup>lt;sup>2</sup> 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.

<sup>&</sup>lt;sup>3</sup> Available from International Commission on Radiation Units & Measurements, 7910 Woodmont Ave., Suite 400, Bethesda, MD 20814-3095, http://www.icru.org.

<sup>&</sup>lt;sup>4</sup> Available from International Organization for Standardization (ISO), ISO Central Secretariat, BIBC II, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, http://www.iso.org.

<sup>&</sup>lt;sup>5</sup> Document produced by Working Group 1 of the Joint Committee for Guides in Metrology (JCGM WG1), Available free of charge at the BIPM website (http:// www.bipm.org).

<sup>&</sup>lt;sup>6</sup> Document produced by Working Group 2 of the Joint Committee for Guides in Metrology (JCGM WG2), Available free of charge at the BIPM website (http:// www.bipm.org).





#### 3. Terminology

- 3.1 Definitions:
- 3.1.1 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.
- 3.1.2 dosimeter response (indication)—reproducible, quantifiable change produced in the dosimeter by ionizing radiation.
- 3.1.2.1 *Discussion*—The dosimeter response value (indication), obtained from one or more measurements, is used in the estimation of absorbed dose.
- 3.1.2.2 Discussion—For PMMA dosimeters, the dosimeter response value (indication) is obtained from measurement of the optical absorbance.
- 3.1.3 dosimeter stock—part of a dosimeter batch held by the user.
- 3.1.4 polymethylmethacrylate (PMMA) dosimeter—piece of specially selected or developed PMMA material, individually sealed by the manufacturer in an impermeable sachet that, when irradiated, exhibits a characterizable change in specific absorbance that can be related to absorbed dose.
- 3.1.4.1 Discussion—The piece of PMMA, when removed from the sachet after irradiation, is also commonly referred to as the dosimeter. Hen STAND
- 3.1.5 specific absorbance (k)—optical absorbance,  $A_{\lambda t}$  at a condition of the selected wavelength  $\lambda$ , divided by the optical path length, d:

  6.2 Pre-Irradiation Conditioning 6.2.1 Dosimeter Conditioning

 $k = A_3/d$ 

3.2 Definitions of other terms used in this standard that dard sist 550 369-5537-4733-bit of maintain that condition. pertain to radiation measurement and dosimetry may be found so-astm 51276 7019 in ISO/ASTM Practice 52628. Other terms that pertain to radiation measurement and dosimetry may be found in ASTM Terminology E3083 and ISO Terminology ISO 12749-4. Where appropriate, definitions used in these standards have been derived from, and are consistent with definitions in ICRU Report 85a, and general metrological definitions given in the VIM.

#### 4. Significance and use

- 4.1 The PMMA dosimetry system provides a means for measuring absorbed dose based on a change in optical absorbance.
- 4.2 PMMA 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 PMMA dosimeters may be manufactured by various methods. For example, the raw material has historically been cast, extruded, or injection molded. Fundamentally, ingredients required for the promotion and control of polymerization and stability, and, in the case of dyed dosimeters, specified quantities of dyes appropriate for the required range of response, are dissolved in methylmethacrylate, which is then polymerized. The material is then conditioned to adjust the water content, and the response to radiation is verified using appropriate sampling and testing before release for packaging, and ultimately for use.

- 5.2 Ionizing radiation induces chemical reactions in the material, which create or enhance absorption bands in the visible or ultraviolet regions of the spectrum, or both. Optical absorbance determined 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 PMMA dosimetry systems in current use.
- 5.3 The difference between the specific absorbance of unirradiated and irradiated PMMA is dependent upon the wavelength of the light which is used to make the measurement. Typically, the manufacturer specifies the recommended wavelength that optimizes sensitivity and post-irradiation stability. The wavelengths recommended for examples of commonly used systems are given in Table A1.1.

#### 6. Influence quantities

- 6.1 Factors other than absorbed dose which influence the dosimeter response are referred to as influence quantities and are discussed in the following sections. (See also ISO/ASTM Guide 52701.) Examples of such influence quantities are temperature and dose rate.
- 6.2.1 Dosimeter Conditioning and Packaging—Pieces of PMMA are pre-conditioned by the manufacturer to optimize water concentration, and sealed in impermeable aluminum foil
- Since Manufacture—With appropriate manufacturing, packaging and storage conditions, the shelf-life of some types of PMMA dosimeters has been shown to exceed ten years (1).
- 6.2.3 Temperature—Exposure to temperatures outside the manufacturer's recommended range should be minimized to reduce the potential for adverse effects on dosimeter response.
- 6.2.4 Relative Humidity-The effect of humidity is eliminated by the isolation provided by the sachet.
- 6.2.5 Exposure to Light—The effect of light exposure is eliminated by the isolation provided by the sachet.
  - 6.3 Conditions during Irradiation:
- 6.3.1 Irradiation Temperature—the dosimeter response is affected by temperature and shall be characterized.
- 6.3.2 Absorbed-Dose Rate—the dosimeter response is affected by the absorbed-dose rate and shall be characterized.
- 6.3.3 Dose Fractionation—the dosimeter response may be affected by incremental exposures and should be characterized.
- 6.3.4 Relative Humidity—the effect of humidity is eliminated by the isolation provided by the sachet.
- 6.3.5 Exposure to Light—the effect of light exposure, if any, is eliminated by the isolation provided by the sachet.

<sup>&</sup>lt;sup>7</sup> The boldface numbers in parentheses refer to the bibliography at the end of this





- 6.3.6 Radiation Energy—the dosimeter response is dependent upon the radiation energy and the dosimeters shall be irradiated for calibration under the conditions of use.
  - 6.4 Post-Irradiation Conditions:
- 6.4.1 Time—the time between irradiation and dosimeter reading shall be standardized and should conform to the manufacturer's recommendations.
- 6.4.2 *Temperature*—Exposure to temperatures outside the manufacturer's recommended range should be minimized to reduce the potential for adverse effects on dosimeter response.
- 6.4.3 Conditioning Treatment—Post-irradiation treatment is not applicable.
- 6.4.4 Relative Humidity—Prior to opening the sachet, the effect of humidity is eliminated by the isolation provided by the
- 6.4.5 Exposure to Light—Prior to opening the sachet, any effect of light exposure is eliminated by the isolation provided by the sachet.

Note 1—Two categories of post-irradiation change are of concern when devising a practical operational protocol for the use of dosimeters: the changes which occur if the sachet is left unopened; and those which occur after it is opened. It is good practice to assess the post-irradiation change of dosimeters under both of these conditions. Examples of results obtained by a manufacturer are given in (2).

- 6.5 Response Measurement Conditions:
- 6.5.1 Exposure to Light—After opening the Sachet, exposure to light may affect the response of the dosimeter. Users should
- 6.5.2 Temperature—Exposure to temperatures outside the manufacturer's recommended range should be minimized to reduce the potential for adverse effects on dosimeter response.
- 6.5.3 Relative Humidity—Afters opening stheh sachet, sprandard longed exposure to extreme humidity conditions may affect the so-ast response of the dosimeter. Therefore, the time between opening the sachet and dosimeter reading should be minimized.
- 6.5.4 *Handling*—Handle dosimeter by its edges. Skin oils, dirt and debris on the surface of dosimeters that are perpendicular to the analyzing light beam, may affect the absorbance of light, therefore impacting the dose measurement.

#### 7. Dosimetry system and its verification

- 7.1 Components of the PMMA Dosimetry System—The following are components of PMMA dosimetry systems:
  - 7.1.1 Polymethylmethacrylate Dosimeters.
- 7.1.2 Calibrated Spectrophotometer (or an equivalent instrument), capable of measuring optical absorbance at the analysis wavelength and having documentation specifying analysis wavelength range, accuracy of wavelength selection and absorbance determination, spectral bandwidth, and stray light rejection.
- 7.1.2.1 Means of verifying the accuracy of optical absorbance-measurement, for example through the use of certified optical absorption filters, covering more than the range of absorption encountered.
- 7.1.2.2 Means of verifying wavelength calibration, for example through the use of certified filters.
- 7.1.3 Holder, to position the dosimeter reproducibly in, and perpendicular to, the analyzing light beam.
  - 7.1.4 Calibrated Thickness Gauge.

- 7.1.4.1 Means of verifying thickness gauge calibration, for example through the use of certified thickness gauge blocks, exceeding the range of thicknesses encountered.
- 7.2 Measurement Management System, including the dosimeter batch calibration curve resulting from calibration according to ISO/ASTM Practice 51261, and the procedures for use.
  - 7.3 Performance Verification of Instrumentation:
- 7.3.1 At prescribed time intervals, and 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 documented. 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 protocol shall be established for the purchase, receipt, acceptance and storage of dosimeters.
- 8.2 For dosimeters received, the user shall perform an follow manufacturer's recommended practices standard incoming inspection of a representative sample to verify, for example, batch designation against the manufacturer's certification, sachet integrity, and that the sample's thickness range, pre-irradiation absorbance, and radiation response, are within documented specifications.
  - 8.3 Retain sufficient dosimeters for investigations, or for use during verification, or recalibration.
  - 8.4 Store dosimeters according to the manufacturer's written recommendations, or as justified by published data or experience.

Note 2—For some industries or uses of PMMA dosimeters, where the dose delivered to product is a defined specification, the monitoring and documentation of storing conditions is recommended in order to prevent storage conditions being a cause of influence quantities.

#### 9. Calibration

- 9.1 Prior to use of each batch of dosimeters, the dosimetry system shall be calibrated in accordance with the user's procedures, which shall detail the calibration process and quality assurance requirements in compliance with ISO/ASTM Practice 51261.
- 9.2 The user's dosimetry system calibration procedures 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 3-If prior experience, manufacturer's recommendations, or scientific literature (see Refs 1-29), suggest that the conditions experienced by the dosimeters are likely to influence dosimeter response and increase the uncertainties beyond what is considered acceptable for the given irradiation application, the calibration irradiation of the dosimeters should be performed under conditions similar to those in routine use (2,27,28).





9.3 Multiple calibration curves may be required to accommodate particular dose ranges or post-irradiation measurement intervals.

#### 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 and manufacturer's written recommendations, and that they are within shelf life and calibration expiration dates.
- 10.1.2 Inspect each dosimeter sachet for external imperfections, for example sachet seal integrity and presence of PMMA piece. Discard any dosimeters that show unacceptable imperfections.
- 10.1.3 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.
- 10.1.4 Place the unopened dosimeters at specified locations for irradiation.
  - 10.2 Post-Irradiation Analysis Procedure:
  - 10.2.1 Retrieve the dosimeters.
- 10.2.2 Maintain the PMMA pieces in their sealed packages in an approved location under specified conditions prior to measurement. See 6.4 and 6.5.
- 10.2.3 Optical absorbance of dosimeters should be measured within a specified time interval (see 6.4.1 and Ref (26)) and under conditions (6.5) which take account of potential 12.1 All dose measurements need to be accompanied by an post-irradiation changes.
- mented procedures. See 7.3. https://standards.iteh.ai/catalog/standardsakso//GUM)9e-b537-473a-bd29-
- example, compromised sachet integrity. Document any imperfections.
  - 10.2.6 For each dosimeter, perform the following:
- 10.2.6.1 Open the package and remove the PMMA piece, handling it by its edges.
- 10.2.6.2 Inspect the PMMA piece for any imperfections, such as scratches. Document any imperfections.

Note 4—If a dosimeter is found to be scratched, a reliable measurement can usually be obtained by repositioning the PMMA piece, for example by inverting it, so that the scratch is not in the light beam path of the spectrophotometer.

- 10.2.6.3 If necessary, clean the PMMA piece before analysis. An accepted method is wiping with a lint-free cloth or paper tissue moistened with an appropriate solvent such as ethanol or propanol. Examine the dosimeter to ensure the cleaning did not cause scratches in the dosimeter.
- 10.2.6.4 Position the PMMA piece 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 selected analysis wavelength (see Table A1.1 for manufacturer's recommendations).
- 10.2.6.6 Measure the thickness of the PMMA piece in the region traversed by the analyzing light beam.
  - 10.2.6.7 Calculate the specific absorbance.
- 10.2.6.8 Determine the absorbed dose from the specific absorbance and the appropriate calibration curve (see 9.3).
- 10.2.6.9 Re-reading of dosimeters at a later date is not recommended since over time the properties of the dosimeter may change from when the dose was delivered. If re-reading of dosimeters at a later date may occur, then testing should be done to determine when these dosimeter properties change over time and it is recommended that procedures for re-reading dosimeters be established.

10.2.6.10 In some industries, reusing open dosimeters occurs, such as topping of product that was under-dosed. Reusing open dosimeters is not recommended due to temperature, light and relative humidity influence quantities (see Section 6). Rather than reuse open dosimeters, new dosimeters in a sealed sachet are recommended.

#### 11. Documentation requirements

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

#### 12. Measurement uncertainty

- estimate of uncertainty. Appropriate procedures are recom-10.2.4 Verify instrument performance according to docur 51mended in ISO/ASTM Guide 51707 and Practice 51261 (see
- 10.2.5 Inspect each dosimeter sachet for imperfections for imperfections as made and a support of the sachet for imperfections for imperfections as made and a support of the sachet for imperfections as made and a support of the sachet for imperfections as made and a support of the sachet for imperfections as made and a support of the sachet for imperfections as made and a support of the sachet for imperfections as made and a support of the sachet for imperfections as made and a support of the sachet for imperfections as made and a support of the sachet for imperfections as made and a support of the sachet for imperfections as made and a support of the sachet for imperfections as made and a support of the sachet for imperfections as made and a support of the sachet for imperfections as made and a support of the sachet for imperfections as made and a support of the sachet for imperfections as made and a support of the sachet for imperfections as made and a support of the sachet for imperfection as made and a support of the sa the estimate, including those arising from calibration, dosimeter variability, instrument reproducibility, and the effect of influence quantities. A full quantitative analysis of components of uncertainty is 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.
  - 12.1.2 The estimate of the expanded uncertainty achievable with measurements made using a routine dosimetry system such as PMMA is typically of the order of  $\pm 6\%$  (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; PMMA; polymethylmethacrylate; radiation; radiation processing; radiation sterilization



#### (informative)

#### A1. INFORMATION ON POLYMETHYLMETHACRYLATE (PMMA) 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 PMMA 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 PMMA dosimeters

| Dosimeter<br>Type       | Nominal<br>Thickness<br>mm | Analysis<br>Wavelength,<br>nm | Absorbed  Dose Range,  kGy |
|-------------------------|----------------------------|-------------------------------|----------------------------|
| Harwell Red 4034        | 3                          | 640                           | 5 to 50                    |
| Harwell Amber 3042      | 3                          | 603 or 651                    | 5 to 50<br>12 11 30 2 T (  |
| Harwell Gammachrome YR® | 2.5                        | 530                           | 0.1 to 3                   |
| Radix W                 | 1.5                        | 280 or 320                    | 1 to 150                   |

TABLE A1.2 Suppliers of polymethylmethacrylate (PMMA) dosimeters

| Dosimeter | Address   |
|-----------|---|
| Harwell   | Harwell Dosimeters Ltd.,<br>Unit 4 Moorbrook,<br>Southmead Industrial Estate    |
|           | DIDCOT Oxfordshire, OX11 7HP, England   |
| Radix     | Radia Industry Co., Ltd.,<br>168 Ooyagi<br>Takasaki<br>Gunma 370-0072,<br>Japan |

A1.5 The radiation response of some types of PMMA 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 a stable water content, and prevent undue exposure to light before absorbance measurements.

1 to 30 and S. A1.6 Information on environmental and post-irradiation 0.1 to 3 effects and their possible influence on dosimetric accuracy may 150/ASTM 5 be obtained from the suppliers.

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