
Practice for dosimetry in a gamma irradiation facility for radiation processing

*Pratique de la dosimétrie dans une installation de traitement par irradiation
gamma*



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.

International Standard ISO 15571 was prepared by the American Society for Testing and Materials (ASTM) Subcommittee E10.01 (as E 1702-95) and was adopted, under a special "fast-track procedure", by Technical Committee ISO/TC 85, *Nuclear energy*, in parallel with its approval by the ISO member bodies.

A new ISO/TC 85 Working Group WG 3, *High-level dosimetry for radiation processing*, was formed to review the voting comments from the ISO "Fast-track procedure" and to maintain these standards. The USA holds the convenership of this working group.

International Standard ISO 15571 is one of 20 standards developed and published by ASTM. The 20 fast-tracked standards and their associated ASTM designations are listed below:

ISO Designation	ASTM Designation	Title
15554	E 1204-93	<i>Practice for dosimetry in gamma irradiation facilities for food processing</i>
15555	E 1205-93	<i>Practice for use of a ceric-cerous sulfate dosimetry system</i>
15556	E 1261-94	<i>Guide for selection and calibration of dosimetry systems for radiation processing</i>
15557	E 1275-93	<i>Practice for use of a radiochromic film dosimetry system</i>
15558	E 1276-96	<i>Practice for use of a polymethylmethacrylate dosimetry system</i>
15559	E 1310-94	<i>Practice for use of a radiochromic optical waveguide dosimetry system</i>
15560	E 1400-95a	<i>Practice for characterization and performance of a high-dose radiation dosimetry calibration laboratory</i>
15561	E 1401-96	<i>Practice for use of a dichromate dosimetry system</i>

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15562	E 1431-91	<i>Practice for dosimetry in electron and bremsstrahlung irradiation facilities for food processing</i>
15563	E 1538-93	<i>Practice for use of the ethanol-chlorobenzene dosimetry system</i>
15564	E 1539-93	<i>Guide for use of radiation-sensitive indicators</i>
15565	E 1540-93	<i>Practice for use of a radiochromic liquid dosimetry system</i>
15566	E 1607-94	<i>Practice for use of the alanine-EPR dosimetry system</i>
15567	E 1608-94	<i>Practice for dosimetry in an X-ray (bremsstrahlung) facility for radiation processing</i>
15568	E 1631-96	<i>Practice for use of calorimetric dosimetry systems for electron beam dose measurements and dosimeter calibrations</i>
15569	E 1649-94	<i>Practice for dosimetry in an electron-beam facility for radiation processing at energies between 300 keV and 25 MeV</i>
15570	E 1650-94	<i>Practice for use of cellulose acetate dosimetry system</i>
15571	E 1702-95	<i>Practice for dosimetry in a gamma irradiation facility for radiation processing</i>
15572	E 1707-95	<i>Guide for estimating uncertainties in dosimetry for radiation processing</i>
15573	E 1818-96	<i>Practice for dosimetry in an electron-beam facility for radiation processing at energies between 80 keV and 300 keV</i>

For the purposes of this International Standard, the following amendments to the ASTM text apply.

Page 1, subclause 1.1, note 1, and subclause 1.2

Replace note 1 and subclause 1.2 by the following.

1.2 Dosimetry is only one component of a total quality assurance program for an irradiation facility. Other controls besides dosimetry may be required for specific applications such as medical device sterilization and food preservation.

1.3 For the irradiation of food and the radiation sterilization of health care products, other specific ISO standards exist. For food irradiation, see ISO 15554:1998, *Practice for dosimetry in gamma irradiation facilities for food processing* (ASTM Practice E 1204). For the radiation sterilization of health care products, see ISO 11137:1995, *Sterilization of health care products — Requirements for validation and routine control — Radiation sterilization*. In those areas covered by ISO 11137, that standard takes precedence.

Page 1, subclauses 1.3 and 1.4

Renumber these subclauses as 1.4 and 1.5 respectively.



Designation: E 1702 – 95

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If not listed in the current combined index, will appear in the next edition.

Standard Practice for Dosimetry in a Gamma Irradiation Facility for Radiation Processing¹

This standard is issued under the fixed designation E 1702; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This practice outlines dosimetric procedures to be followed in irradiator characterization, process qualification, and routine processing in a gamma irradiation facility. These procedures ensure that all product processed with ionizing radiation from isotopic gamma sources receive absorbed doses within a predetermined range. Other procedures related to irradiator characterization, process qualification, and routine processing that may influence absorbed dose in the product are also discussed. Information about effective or regulatory dose limits is not within the scope of this document.

NOTE 1—Dosimetry is one component of a total quality assurance program for adherence to good manufacturing practices. Specific applications of gamma radiation processing may require additional controls.

1.2 This practice describes general procedures applicable to all gamma radiation processing requiring absorbed doses within a predetermined range. For procedures specific to food irradiation, see Practice E 1204. The sterilization of medical devices is a regulated irradiation process with specific process control requirements. These requirements, including specific dosimetry requirements for medical device sterilization, are given in Refs (1) and (2).² Guidelines for medical device sterilization are given in Refs (3) and (4).

1.3 For guidance in the selection, calibration, and use of specific dosimeters, and interpretation of absorbed dose in the product from dosimetry measurements, see Guide E 1261 and Practices E 666, E 668, E 1026, E 1205, E 1275, E 1276, E 1310, E 1400, E 1401, E 1538, E 1540, E 1607, and E 1650. For discussion of radiation dosimetry for gamma rays, see ICRU Report 14.

1.4 *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:

- E 170 Terminology Relating to Radiation Measurements and Dosimetry³
- E 177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods⁴
- E 456 Terminology Relating to Quality and Statistics⁴
- E 666 Practice for Calculating Absorbed Dose from Gamma or X Radiation³
- E 668 Practice for Application of Thermoluminescence-Dosimetry (TLD) Systems for Determining Absorbed Dose in Radiation Hardness Testing of Electronic Devices³
- E 1026 Practice for Using the Fricke Reference Standard Dosimetry System³
- E 1204 Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing³
- E 1205 Practice for Use of a Ceriic-Cerous Sulfate Dosimetry System³
- E 1261 Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing³
- E 1275 Practice for Use of a Radiochromic Film Dosimetry System³
- E 1276 Practice for Use of a Polymethylmethacrylate Dosimetry System³
- E 1310 Practice for Use of a Radiochromic Optical Waveguide Dosimetry System³
- E 1400 Practice for Characterization and Performance of a High-Dose Radiation Dosimetry Calibration Laboratory³
- E 1401 Practice for Use of a Dichromate Dosimetry System³
- E 1431 Practice for Dosimetry in Electron and Bremsstrahlung Irradiation Facilities for Food Processing³
- E 1538 Practice for Use of the Ethanol-Chlorobenzene Dosimetry System³
- E 1539 Guide for Use of Radiation-Sensitive Indicators³
- E 1540 Practice for Use of a Radiochromic Liquid Dosimetry System³
- E 1607 Practice for Use of the Alanine-EPR Dosimetry System³
- E 1650 Practice for Use of a Cellulose Acetate Dosimetry System
- E 1707 Guide for Estimating Uncertainties in Dosimetry for Radiation Processing

2.2 ICRU Reports:

¹ This practice is under the jurisdiction of ASTM Committee E-10 on Nuclear Technology and Applications and is the direct responsibility of Subcommittee E10.01 on Dosimetry for Radiation Processing.

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² The boldface numbers in parentheses refer to a list of references at the end of this practice.

³ Annual Book of ASTM Standards, Vol 12.02.

⁴ Annual Book of ASTM Standards, Vol 14.02.