
**Practice for dosimetry in an X-ray
(bremsstrahlung) facility for radiation
processing at energies between 50 KeV
and 7.5 MeV**

Sample Document

*Pratique de la dosimétrie dans une installation de traitement par
des rayons X (bremsstrahlung) entre 50 KeV et 7,5 MeV*

get full document from standards.iteh.ai



Reference number
ISO/ASTM 51608:2015(E)

© ISO/ASTM International 2015

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. Neither the ISO Central Secretariat nor ASTM International accepts any liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies and ASTM members. In the unlikely event that a problem relating to it is found, please inform the ISO Central Secretariat or ASTM International at the addresses given below.

Sample Document

get full document from standards.iteh.ai

© ISO/ASTM International 2015

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester. In the United States, such requests should be sent to ASTM International.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

ASTM International, 100 Barr Harbor Drive, PO Box C700,
West Conshohocken, PA 19428-2959, USA
Tel. +610 832 9634
Fax +610 832 9635
E-mail khooper@astm.org
Web www.astm.org

Published in Switzerland

Contents

	Page
1 Scope	1
2 Referenced documents	1
3 Terminology	2
4 Significance and use	3
5 Radiation source characteristics	4
6 Types of facilities	4
7 Selection and calibration of dosimetry system	4
8 Process parameters	4
9 Installation qualification	5
10 Operational qualification	5
11 Performance qualification	7
12 Routine product processing	8
13 Certification	9
14 Measurement dose uncertainty and process variability	10
15 Keywords	10
Annex	10
Figure A1.1 Beam current density distributions along the scan direction (wide curves) and perpendicular to the scan direction (narrow curves) of No. 1 accelerator of JAERI Takasaki (Fig. 2.1 from Ref (61))	11
Figure A1.2 X-ray intensity per 2 MeV electron incident perpendicularly on a tantalum target with thickness of one CSDA electron range as a function of emitting angle calculated by the ETRAN code (Fig. 3.3 from Ref (61))	11
Figure A1.3 X-ray intensity per 5 MeV electron incident perpendicularly on a tantalum target with thickness of one CSDA electron range as a function of emitting angle calculated by ETRAN code (Fig 3.4 from Ref (61))	11
Figure A1.4 X-ray emission rates from high-Z targets (Fig. E 1 from Ref (76))	12
Figure A1.5 Spectrum of transmitted photons (Fig 2a from Ref (21))	12
Figure A1.6 Spectrum of reflected photons (Fig. 2b from Ref (21))	12
Figure A1.7 Depth dose distributions (Fig. 1 from Ref (9))	12
Figure A1.8 Dose contour map, moving exposure (Fig. 3 from Ref (62))	13
Figure A1.9 Measured attenuation curves for 5 MeV X-Rays in absorbers of various densities, with moving conveyor and scanning beam (Fig. 5 from Ref (3))	13
Figure A1.10 Measurement of a high-resolution attenuation curve for 5 MeV X-rays in the heaviest absorber (chipboard) with moving conveyor and scanning (Fig. 6 from Ref (3)).	13

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 project between ISO and ASTM International has been formed to develop and maintain a group of ISO/ASTM radiation processing dosimetry standards. Under this 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 51608 was developed by ASTM Committee E61, Radiation Processing, through Subcommittee E61.03, Dosimetry Application, 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 51608:2005), which has been technically revised.



Standard Practice for Dosimetry in an X-Ray (Bremsstrahlung) Facility for Radiation Processing at Energies between 50 keV and 7.5 MeV¹

This standard is issued under the fixed designation ISO/ASTM 51608; 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 practice outlines the dosimetric procedures to be followed during installation qualification, operational qualification, performance qualification and routine processing at an X-ray (bremsstrahlung) irradiator. Other procedures related to operational qualification, performance qualification and routine processing that may influence absorbed dose in the product are also discussed.

NOTE 1—Dosimetry is only one component of a total quality assurance program for adherence to good manufacturing practices used in radiation processing applications.

NOTE 2—ISO/ASTM Practices 51649, 51818 and 51702 describe dosimetric procedures for electron beam and gamma facilities for radiation processing.

1.2 For radiation sterilization of health care products, see ISO 11137-1, *Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*. In those areas covered by ISO 11137-1, that standard takes precedence.

1.3 For irradiation of food, see ISO 14470, *Food irradiation – Requirements for development, validation and routine control of the process of irradiation using ionizing radiation for the treatment of food*. In those areas covered by ISO 14470, that standard takes precedence.

1.4 This document is one of a set of standards that provides recommendations for properly implementing and utilizing dosimetry in radiation processing. It is intended to be read in conjunction with ISO/ASTM Practice 52628, “Practice for Dosimetry in Radiation Processing”.

1.5 In contrast to monoenergetic gamma radiation, the X-ray energy spectrum extends from low values (about 35

keV) up to the maximum energy of the electrons incident on the X-ray target (see Section 5 and Annex A1).

1.6 Information about effective or regulatory dose limits and energy limits for X-ray applications is not within the scope of this practice.

1.7 *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:²

E170 Terminology Relating to Radiation Measurements and Dosimetry

E2232 Guide for Selection and Use of Mathematical Methods for Calculating Absorbed Dose in Radiation Processing Applications

E2303 Guide for Absorbed-Dose Mapping in Radiation Processing Facilities

2.2 ISO/ASTM Standards:²

51261 Practice for Calibration of Routine Dosimetry Systems for Radiation Processing

51539 Guide for Use of Radiation-Sensitive Indicators

51649 Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 300 keV and 25 MeV

51702 Practice for Dosimetry in a Gamma Facility for Radiation Processing

51707 Guide for Estimating Uncertainties in Dosimetry for Radiation Processing

51818 Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 80 and 300 keV

52628 Practice for Dosimetry in Radiation Processing

¹ This practice is under the jurisdiction of ASTM Committee E61 on Radiation Processing and is the direct responsibility of Subcommittee E61.03 on Dosimetry Application, and is also under the jurisdiction of ISO/TC 85/WG 3.

Current edition approved Sept. 8, 2014. Published February 2015. Originally published as ASTM E 1608–94. Last previous ASTM edition E 1608–00. ASTM E 1608–94 was adopted by ISO in 1998 with the intermediate designation ISO 15567:1998(E). The present International Standard ISO/ASTM 51608:2015(E) is a major revision of the last previous edition ISO/ASTM 51608:2005(E), which replaced ISO/ASTM 51608:2002(E).

² For referenced ASTM or 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.



52701 Guide for Performance Characterization of Dosimeters and Dosimetry Systems for use in Radiation Processing

2.3 ISO Standards:³

ISO 11137-1 Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

ISO 14470 Food irradiation – Requirements for the development, validation and routine control of the process of irradiation using ionizing radiation for the treatment of food

2.4 International Commission on Radiation Units and Measurements (ICRU) Reports:⁴

ICRU Report 14 Radiation Dosimetry: X Rays and Gamma Rays with Maximum Photon Energies Between 0.6 and 50 MeV

ICRU Report 34 Dosimetry of Pulsed Radiation

ICRU Report 35 Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV

ICRU Report 37 Stopping Powers for Electrons and Positrons

ICRU Report 80 Dosimetry Systems for Use in Radiation Processing

ICRU Report 85a Fundamental Quantities and Units for Ionizing Radiation

2.5 Joint Committee for Guides in Metrology (JCGM) Report:

JCGM 100:2008, GUM 1995, with minor corrections, Evaluation of measurement data—Guide to the expression of uncertainty in measurement⁵

3. Terminology

3.1 Definitions:

3.1.1 *absorbed dose (D)*—quantity of ionizing radiation energy imparted per unit mass of a specified material. The SI unit of absorbed dose is the gray (Gy), where 1 gray is equivalent to the absorption of 1 joule per kilogram of the specified material (1 Gy = 1 J/kg). The mathematical relationship is the quotient of $d\varepsilon$ by dm , where $d\varepsilon$ is the mean incremental energy imparted by ionizing radiation to matter of incremental mass dm (see ICRU Report 85a).

$$D = d\varepsilon/dm \quad (1)$$

3.1.2 *beam length*—dimension of the irradiation zone along the direction of product movement, at a specified distance from the accelerator window.

3.1.2.1 *Discussion*—Beam length is perpendicular to beam width and to the electron beam axis. In case of product that is stationary during irradiation, ‘beam length’ and ‘beam width’ may be interchangeable.

3.1.3 *beam width*—dimension of the irradiation zone perpendicular to the direction of product movement, at a specified distance from the accelerator window.

3.1.3.1 *Discussion*—For graphic illustration, see ISO/ASTM Practice 51649. This term usually applies to electron irradiation.

3.1.4 *bremsstrahlung*—broad-spectrum electromagnetic radiation emitted when an energetic charged particle is influenced by a strong electric or magnetic field, such as that in the vicinity of an atomic nucleus.

3.1.4.1 *Discussion*—In radiation processing, bremsstrahlung photons with sufficient energy to cause ionization are generated by the deceleration or deflection of energetic electrons in a target material. When an electron passes close to an atomic nucleus, the strong coulomb field causes the electron to deviate from its original motion. This interaction results in a loss of kinetic energy by the emission of electromagnetic radiation. Such encounters are uncontrolled and they produce a continuous photon energy distribution that extends up to the maximum kinetic energy of the incident electron. The bremsstrahlung energy spectrum depends on the electron energy, the composition and thickness of the X-ray target, and the emission direction of photon angle of emission with respect to the incident electron.

3.1.5 *charged-particle equilibrium* (referred to as electron equilibrium in the case of electrons set in motion by photon-beam irradiation of a material)—condition in which the kinetic energy of charged particles (or electrons), excluding rest mass, entering an infinitesimal volume of the irradiated material equals the kinetic energy of charge particles (or electrons) emerging from it.

3.1.6 *dose uniformity ratio*—ratio of the maximum to the minimum absorbed dose within the irradiated product.

3.1.6.1 *Discussion*—The concept is also referred to as the max/min dose ratio.

3.1.7 *dosimeter*—device that, when irradiated, exhibits a quantifiable change that can be related to absorbed dose in a given material using appropriate measurement instrument(s) and procedures.

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

3.1.9 *dosimetry system*—system used for measuring absorbed dose, consisting of dosimeters, measurement instruments and their associated reference standards, and procedures for the system’s use.

3.1.10 *electron energy*—kinetic energy of an electron.

3.1.10.1 *Discussion*—Unit is usually electron volt (eV), kiloelectron volt (keV), or megaelectron volt (MeV). 1 eV is the kinetic energy acquired by a single electron accelerated through a potential difference of 1 V. 1 eV is equal to energy of 1.602×10^{-19} joules.

3.1.11 *electron energy spectrum*—particle fluence distribution of electrons as a function of energy.

3.1.12 *installation qualification (IQ)*—process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specifications.

³ Available from the International Organization for Standardization, 1 Rue de Varembe, Case Postale 56, CH-1211, Geneva 20, Switzerland.

⁴ Available from the International Commission on Radiation Units and Measurements, 7910 Woodmont Ave., Suite 800, Bethesda, MD 20814, U.S.A.

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>).



3.1.13 *irradiation container*—holder in which product is placed during the irradiation process.

3.1.13.1 *Discussion*—“Irradiation container” is often referred to simply as “container” and can be a carrier, cart, tray, product carton, pallet, product package or other holder.

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

3.1.15 *operational qualification (OQ)*—process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures.

3.1.16 *performance qualification (PQ)*—process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields product meeting its specification.

3.1.17 *process load*—volume of material with a specified loading configuration irradiated as a single entity.

3.1.18 *processing category*—group of different product that can be processed together.

3.1.18.1 *Discussion*—Processing categories can be based on, for instance, composition, density or dose requirements.

3.1.19 *reference material*—homogeneous material of known radiation absorption and scattering properties used to establish characteristics of the irradiation process, such as scan uniformity, depth-dose distribution, throughput rate, and reproducibility of dose delivery.

3.1.20 *simulated product*—material with radiation attenuation and scattering properties similar to those of the product, material or substance to be irradiated.

3.1.20.1 *Discussion*—Simulated product is used during irradiator characterization as a substitute for the actual product, material or substance to be irradiated. When used in routine production runs in order to compensate for the absence of product, simulated product is sometimes referred to as compensating dummy. When used for absorbed-dose mapping, simulated product is sometimes referred to as phantom material.

3.2 Definitions of Terms Specific to This Standard:

3.2.1 *X-radiation*—ionizing electromagnetic radiation, which includes both bremsstrahlung and the characteristic radiation emitted when atomic electrons make transitions to more tightly bound states. See *bremsstrahlung*.

3.2.1.1 *Discussion*—In radiation processing applications, the principal X-radiation is bremsstrahlung.

3.2.2 *X-ray*—of or relating to X-radiation.

3.2.2.1 *Discussion*—X-ray is used as an adjective while X-radiation is used as a noun.

3.2.3 *X-ray converter*—device for generating X-radiation (bremsstrahlung) from an electron beam, consisting of a target, means for cooling the target, and a supporting structure.

3.2.4 *X-ray target*—component of the X-ray converter that is struck by the electron beam and which produces X-radiation.

3.2.4.1 *Discussion*—The X-ray target is usually made of

metal with a high atomic number (such as tantalum), high melting temperature, and high thermal conductivity.

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

4. Significance and use

4.1 A variety of products and materials are irradiated with X-radiation to modify their characteristics and improve the economic value or to reduce their microbial population for health-related purposes. Dosimetry requirements might vary depending on the type and end use of the product. Some examples of irradiation applications where dosimetry may be used are:

4.1.1 Sterilization of health care products;

4.1.2 Treatment of food for the purpose of parasite and pathogen control, insect disinfestation, and shelf life extension;

4.1.3 Disinfection of consumer products;

4.1.4 Cross-linking or degradation of polymers and elastomers;

4.1.5 Curing composite material;

4.1.6 Polymerization of monomers and oligomer and grafting of monomers onto polymers;

4.1.7 Enhancement of color in gemstones and other materials;

4.1.8 Modification of characteristics of semiconductor devices; and

4.1.9 Research on materials effects of irradiation.

NOTE 3—Dosimetry with measurement traceability and with known measurement uncertainty is required for regulated irradiation processes, such as the sterilization of health care products and treatment of food. Dosimetry may be less important for other industrial processes, such as polymer modification, which can be evaluated by changes in the physical properties of the irradiated materials. Nevertheless, routine dosimetry may be used to monitor the reproducibility of the radiation process.

4.2 Radiation processing specifications usually include a pair of absorbed-dose limits: a minimum value to ensure the intended beneficial effect and a maximum value that the product can tolerate while still meeting its functional or regulatory specifications. For a given application, one or both of these values may be prescribed by process specifications or regulations. Knowledge of the dose distribution within irradiated material is essential to help meet these requirements. Dosimetry is essential to the radiation process since it is used to determine both of these limits and to confirm that the product is routinely irradiated within these limits.

4.3 Several critical parameters must be controlled to obtain reproducible dose distributions in the process load. The absorbed-dose distribution within the product depends on the overall product dimensions and mass and irradiation geometry. The processing rate and dose distribution depend on the X-ray intensity, photon energy spectrum, and spatial distribution of the radiation field and conveyor speed.