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Practice for dosimetry in an electron beam facility for radiation processing at energies between 80 and 300 keV

Pratique de la dosimétrie dans une installation de traitement par irradiation utilisant un faisceau d'électrons d'énergies comprises entre 80 keV et 300 keV

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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 51818 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 51818:2009), which has been technically revised.

Standard Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 80 and 300 keV[1]

This standard is issued under the fixed designation ISO/ASTM 51818; 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 covers dosimetric procedures to be followed in installation qualification, operational qualification and performance qualification (IQ, OQ, PQ), and routine processing at electron beam facilities to ensure that the product has been treated with an acceptable range of absorbed doses. Other procedures related to IQ, OQ, PQ, and routine product processing that may influence absorbed dose in the product are also discussed.

1.2 The electron beam energy range covered in this practice is between 80 and 300 keV, generally referred to as low energy.

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

1.4 Other specific ISO and ASTM standards exist for the irradiation of food and the radiation sterilization of health care products. For the radiation sterilization of health care products, see ISO 11137. In those areas covered by ISO 11137, that standard takes precedence. For food irradiation, see ISO 14470:2011. Information about effective or regulatory dose limits for food products is not within the scope of this practice (see ASTM F1355 and F1356).

1.5 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 ASTM E2232, “Practice for Dosimetry in Radiation Processing”.

1.6 *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

E2628 Practice for Dosimetry in Radiation Processing

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

F1355 Guide for Irradiation of Fresh Agricultural Produce as a Phytosanitary Treatment

F1356 Practice for Irradiation of Fresh and Frozen Red Meat and Poultry to Control Pathogens and Other Microorganisms

2.2 *ISO Standards:*[3]

11137-1:2006 Sterilization of health care products–Radiation–Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

14470:2011 Food irradiation–Requirements for the development, validation and routine control of the ionizing radiation used for the treatment of food

17025:2005 General requirements for the competence of testing and calibration laboratories

2.3 *ISO/ASTM Standards:*[2]

51261 Practice for Calibration of Routine Dosimetry Systems for Radiation Processing

51275 Practice for Use of a Radiochromic Film Dosimetry System

51607 Practice for Use of an Alanine-EPR Dosimetry System

51649 Practice for Dosimetry in an Electron Beam Facility

[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.

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[2] For referenced 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.

[3] Available from International Organization for Standardization (ISO), 1, ch. de la Voie-Creuse, CP 56, CH-1211 Geneva 20, Switzerland, http://www.iso.org.

for Radiation Processing at Energies between 300 keV and 25 MeV

51650 Practice for Use of a Cellulose Triacetate Dosimetry System

51707 Guide for Estimating Uncertainties in Dosimetry for Radiation Processing

2.4 *International Commission on Radiation Units and Measurements (ICRU) Report:*[4]

ICRU Report 85a Fundamental Quantities and Units for Ionizing Radiation

ICRU Report 80 Dosimetry Systems for Use in Radiation Processing

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 $d\bar{\varepsilon}$ by dm, where $d\bar{\varepsilon}$ is the mean incremental energy imparted by ionizing radiation to matter of incremental mass dm.

3.1.1.1 *Discussion*—Throughout this practice, "absorbed dose" is referred to as "dose".

3.1.2 *approved laboratory*—laboratory that is a recognized national metrology institute; or has been formally accredited to ISO/IEC 17025; or has a quality system consistent with the requirements of ISO/IEC 17025.

3.1.3 *average beam current*—time-averaged electron beam current.

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

3.1.5 *depth-dose distribution*—variation of absorbed dose with depth from the incident surface of a material exposed to a given radiation.

3.1.6 *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.

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

3.1.8 *electron beam energy*—kinetic energy of the accelerated electrons in the beam.

3.1.9 *traceability*—property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties.

3.1.10 *uncertainty*—parameter associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the measurand or derived quantity (see ISO/ASTM Guide 51707).

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 D_μ—absorbed dose to water in the first micrometer of water equivalent absorbing material **(1)**.[5]

3.2.1.1 *Discussion*—D_μ is a term used by an approved laboratory to specify reported surface dose values of transfer standard dosimeters based on adjustments made to account for user site specific calibration irradiation conditions.

3.2.2 *linear process rate*—product length irradiated per unit time to deliver a given dose.

3.2.3 *mass process rate*—product mass irradiated per unit time to deliver a given dose.

3.2.4 *area process rate*—product area irradiated per unit time to deliver a given dose.

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

4. Significance and use

4.1 A variety of irradiation processes uses low energy electron beam facilities to modify product characteristics. Dosimetry requirements, the number and frequency of measurements, and record keeping requirements will vary depending on the type and end use of the products being processed. Dosimetry is often used in conjunction with physical, chemical, or biological testing of the product, to help verify specific treatment parameters.

NOTE 1—In many cases dosimetry results can be related to other quantitative product properties; for example, gel fraction, melt flow, modulus, molecular weight distribution, or cure analysis tests.

4.2 Radiation processing specifications usually include a minimum or maximum absorbed dose limit, or both. For a given application these limits may be set by government regulation or by limits inherent to the product itself.

4.3 Critical process parameters must be controlled to obtain reproducible dose distribution in processed materials. The electron beam energy, beam current, beam width and process line speed (conveying speed) affect absorbed dose.

4.4 Before any electron beam facility can be routinely utilized, it must be validated to determine its effectiveness. This involves testing of the process equipment, calibrating the measuring instruments and the dosimetry system, and demonstrating the ability to consistently deliver the required dose within predetermined specifications.

4.5 In order for a dosimetry system to be effective in low-energy electron irradiation applications and to measure doses with an acceptable level of uncertainty, it is necessary to calibrate the dosimetry system under irradiation conditions that are consistent with those encountered in routine use. For example, a dosimetry system calibration conducted using

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

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

penetrating gamma radiation or high energy electrons may result in significantly inaccurate dose measurement when the dosimetry system is used at low energy electron beam facilities. Details of calibration are discussed in Section 5.

5. Selection and calibration of the dosimetry system

5.1 *Selection of Dosimetry Systems*:

5.1.1 ASTM E2628 identifies requirements for selection of dosimetry systems. For use with low-energy electron beam facilities consideration should specifically be given to the limited range of such electrons which might give rise to dose gradients through the thickness of the dosimeter. By choosing thin film dosimeters this problem can be limited (see Note 2) **(1)**.

5.1.2 When selecting a dosimetry system, consideration should be given to effects of influence quantities on the response of the dosimeter (see E2701). One such influence quantity is irradiation atmosphere, and some low-energy accelerator applications involve irradiation in oxygen-free conditions.

5.2 *Calibration of the Dosimetry System*:

5.2.1 The dosimetry system shall be calibrated prior to use and at intervals thereafter in accordance with the user's documented procedure that specifies details of the calibration process and quality assurance requirements. Calibration methods are given in ISO/ASTM 51261.

5.2.2 The calibration irradiation may be performed by irradiating the dosimeters at *(a)* an approved laboratory or *(b)* a production irradiator under actual production irradiation conditions together with transfer standard dosimeters issued and analyzed by an approved laboratory. In case of option *(a)*, the resulting calibration curve shall be verified for the actual conditions of use (see ISO/ASTM 51261). The same applies for option *(b)* if irradiation conditions different from the actual production conditions have been used for the calibration irradiation.

NOTE 2—While 5.2.2 is valid for most dosimeter calibration irradiations, it must be recognized that the irradiation of various dosimeters with low energy electrons (less than 300 keV) may lead to dose gradients through the thickness of the dosimeter. When the dosimeter response is measured, this will lead to an apparent dose that is related to the dose distribution. For a given set of irradiation conditions, the apparent dose will depend on the thickness of the dosimeter, i.e., dosimeters with different thickness will measure different apparent doses. One solution to overcome this problem is that all dose measurements are specified as dose to water in the first micrometer of the absorbing material. This is given the symbol D_μ and is independent of the dosimeter thickness **(1)**. The dose estimate for the calibration is carried out by the approved laboratory that issues the transfer standard dosimeters (5.2.2), and this dose can be given in terms of D_μ (see Annex A2).

NOTE 3—Some applications may not require dose measurements to be traceable to a national standard (see Annex A4).

5.3 *Measurement Instrument Calibration and Performance Verification*—For the calibration of the instruments, and for the verification of instrument performance between calibrations, ISO/ASTM 51261, the corresponding ISO/ASTM or ASTM standard for the dosimetry system, and/or instrument-specific operating manuals should be consulted.

6. Installation and operational qualification

6.1 Installation qualification (IQ) is carried out to demonstrate that the irradiation equipment and any ancillary items have been supplied and installed in accordance with their specifications.

NOTE 4—The dosimetric measurements carried out during IQ will often be the same as the ones carried out during Operational Qualification (OQ). IQ typically involves the use of dosimetric measurements of beam penetration and dose uniformity that can be used to calculate estimates of process throughput to verify the equipment performance specifications. A dosimetry system calibration curve obtained by dosimeter irradiation at another facility might be used for these dose measurements, but in order to ensure that the dose measurements are traceable to national standards, the calibration curve must be verified for the actual conditions of use.

6.2 Operational qualification (OQ) is carried out to characterize the performance of the irradiation equipment with respect to reproducibility of dose to product. For OQ product dose mapping guidance, see ASTM E2303.

NOTE 5—Some applications may not require OQ dose measurements to be traceable to a national standard (see Annex A4).

NOTE 6—Dose measurements for OQ may have to be carried out using a dosimetry system calibration curve obtained by irradiation at another facility. This calibration curve should be verified as soon as possible, and corrections applied to the OQ dose measurements as needed.

6.2.1 The performance of the low-energy electron beam facility depends on the energy of the electrons. It may therefore be necessary to carry out separate OQ measurements for each energy selected for the operation of the facility.

6.2.2 The relevant dosimetric OQ measurements are described in more detail in Annex A1. They typically include the following:

6.2.2.1 *Dose as Function of Average Beam Current, Beam Width and Conveying Speed*—Dose to the product irradiated in an electron beam facility is proportional to average beam current (I), inversely proportional to conveying speed (V), and inversely proportional to beam width (W_b). The last relationship is valid for product that is conveyed through the beam zone perpendicular to the beam width. This is expressed as:

$$\text{Dose} = (K \cdot I) / (V \cdot W_b) \tag{1}$$

where:

D = absorbed dose (Gy),
I = average beam current (A),
V = conveying speed (m s^{-1}),
W_b = beam width (m), and
K = slope of the straight line relationship in Eq 1 $(Gy \cdot m^2) / (A \cdot s)$.

This straight-line relationship shall be determined for each energy selected for the operation of the facility. In order to determine the relationship, dose shall be measured at a specific location using a number of selected parameter sets of beam current, conveying speed and beam width to cover the operating range of the facility.

6.2.2.2 *Beam Width*—The beam width is measured by placing dosimeter strips or discrete dosimeters at selected intervals over the full beam width. Whenever possible dosimeters should be placed beyond the expected beam width to identify the limits of the full beam width.

6.2.2.3 *Beam Penetration*—The beam penetration is measured using a stack of thin dosimeters or by placing a dosimeter strip under thin layers of plastic foils.

(1) Calculation Methods—Beam penetration can be calculated using mathematical modeling (see ASTM E2232).

6.2.2.4 *Dose Distribution on Reference Material*—It may be needed to measure the distribution of dose on or in a reference material.

6.2.2.5 *Process Interruption*—A process interruption can be caused by, for example, failure of beam current delivery or by the conveyor stopping. The effect of a process interruption shall be determined, so that decisions about possible product disposition can be made.

6.2.3 The measurements in 6.2.2 shall be repeated a sufficient number of times (three or more) to allow determination of the operating parameter variability based on a statistical evaluation of the dose measurements.

NOTE 7—The operating parameter variability can be determined from the scatter between repeated dose measurements made at different times using identical operating parameter settings. Determination of this variability forms part of operational qualification. Operating parameter variability contributes to uncertainty of measured doses. It is often difficult to separate operating parameter variability and dosimeter reproducibility and the variability determined will often be a combination of the two **(2)**.

6.2.4 Based on the measured variability of the operating parameters, limits for their acceptable variation can be determined.

6.2.5 *Requalification*—OQ measurements shall be repeated at intervals specified by the user's documented procedure. The intervals shall be chosen to provide assurance that the irradiator is consistently operating within specifications. Requalification is typically carried out on an annual cycle, with specific parts of requalification at shorter time intervals within this cycle. If requalification measurements show that the OQ status of the irradiator has changed, then PQ might have to be repeated.

6.2.6 OQ measurements shall be repeated after assessment of changes of the irradiation facility that might affect dose or dose distribution. The extent to which requalification is carried out shall be justified.

NOTE 8—Activities that might affect the OQ status of the irradiation facility include, but are not limited to:

replacement of accelerator emitter
replacement of accelerator window
replacement of window support grid
replacement of conveyor parts
change in electron energy
change in distance of accelerator window to product surface

7. Performance qualification

7.1 Performance Qualification (PQ) is the stage of validation which uses defined product to demonstrate that the facility consistently operates in accordance with predetermined criteria to deliver specified doses, thereby resulting in product that meets the specified requirements.

7.2 PQ dose mapping is carried out to demonstrate that minimum dose to product exceeds the dose required for the intended effect and that maximum dose to product does not exceed a maximum acceptable dose. For PQ product dose mapping guidance, see ASTM E2303.

NOTE 9—Dose mapping exercises do not have to be carried out at the same dose as used for product irradiations. The use of higher doses, for example, can enable the dosimetry system to be used in a more accurate part of its operating range, thereby improving the overall accuracy of the dose mapping.

NOTE 10—Some applications may not require PQ dose measurements to be traceable to a national standard (see Annex A4).

7.3 OQ dose mapping can in some cases be used as PQ dose mapping. For example, this is the case for irradiation treatment of wide webs of infinite length. In other cases, such as sterilization of complex product, it may be required to carry out specific PQ product dose mapping.

7.4 During PQ dose mapping the locations and magnitudes of minimum and maximum doses, as well as the dose at a routine monitoring position are determined.

7.5 The relationship between minimum and maximum doses and the dose at a routine monitoring position is determined.

7.6 PQ dose mapping measurements shall be repeated a sufficient number of times (three or more) to allow statistical evaluation and characterization of the dose distribution data.

7.7 Based on the measured uncertainties of this relationship (see 7.5) acceptable limits for variation of the dose at the routine monitoring position to be measured during process irradiations can be determined **(2)**.

7.8 Repeat of PQ dose mapping shall be considered if product is changed (thus affecting dose or dose distribution), or if the OQ status of the irradiation facility is changed.

8. Routine process control

8.1 *Monitoring of Operating Parameters*—The operating parameters (beam energy, beam current, beam width and conveying speed) shall be monitored and recorded continuously during the process or at intervals specified by the operator of the facility. The intervals shall be chosen to provide assurance that the irradiator is consistently operating within specifications.

NOTE 11—Beam energy, beam current and beam width are usually not measured directly, but are obtained through indirect measurements.

8.2 *Measurement of Routine Dose*—The dose at the routine monitoring position shall be measured at intervals specified by the operator of the facility. The intervals shall be chosen to verify the irradiator operated within limits, and thereby ensuring that the product specifications were achieved.

NOTE 12—Some applications may not require routine dose measurements to be traceable to a national standard (see Annex A4).

8.3 *Process Control Limits*—Acceptance limits for the variation of the monitored process parameters (8.1) and measured routine dose (8.2) should be selected based on the measured uncertainties (see 6.2.3 and 7.6). The selection of acceptance limits can be based on the principles for statistical process control **(2)**.

9. Measurement uncertainty

9.1 All dose measurements shall be accompanied by an estimate of uncertainty. Appropriate procedures are recommended in ISO/ASTM Guide 51707 (see also **(3)**).

9.2 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 is referred to as an uncertainty budget, and 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.

9.3 The expanded uncertainty for dose to product in a low-energy electron process depends on the facility and product variabilities, and on the combined uncertainty of the dosimetry system.

10. Documentation

10.1 Data and measurement results shall be recorded and stored in accordance with the operator's measurement management system. Data to be recorded and stored include:

10.1.1 Data from initial IQ and from any changes to the irradiation facility.

10.1.2 Data from maintenance of the irradiation facility.

10.1.3 Data from OQ of the irradiation facility.

10.1.4 Data from PQ for products irradiated at the facility.

10.1.5 Process control data.

10.1.6 Calibration data for the dosimetry system(s) used.

10.1.7 Calibration data for measurement systems used at process control of the irradiation facility.

10.2 *Review and Approval*—All data and dosimetry records shall be reviewed in accordance with the operator's measurement management system.

11. Keywords

11.1 absorbed dose; dosimeter; dosimetry system; electron beam; electron beam accelerator; ionizing radiation; radiation crosslinking; radiation curing; radiation processing; radiation sterilization

ANNEXES

(Mandatory Information)

A1. DOSE MEASUREMENTS FOR OPERATIONAL QUALIFICATION

A1.1 This annex describes dose measurements carried out in connection with operational qualification of a low-energy electron beam facility.

NOTE A1.1—Multiple beam systems can be characterized individually or as the combined facility.

A1.2 Dose as function of beam current, beam width and conveying speed

A1.2.1 Absorbed dose to product depends on average beam current, beam width, conveying speed and beam energy. Measurement of dose as a function of these parameters constitutes effectively a calibration of the electron beam facility. There is no simple relationship between dose and energy, and measurement of dose as a function of the three other parameters should therefore be made for each operating energy.

A1.2.1.1 The relationship is expressed as:

$$D = (K \cdot I) / (V \cdot W_b) \quad \text{(A1.1)}$$

where:

D = absorbed dose (Gy),
I = average beam current (A),
V = conveying speed (m s^{-1}),
W_b = beam width (m), and
K = slope of the straight line relationship in Eq A1.1 (Gy · m^2) / (A · s)

(1) D is dose at the point of measurement. It would often be the surface dose at the center of the beam. It can be expressed as D_μ, see Annex A2.

(2) I is the average beam current as monitored by the facility. This monitored current is often the current going to the emitting cathode(s), while the beam current reaching the product is less.

(3) V is the speed of product through the irradiation zone.

(4) W_b is the width of the beam at a specified fraction of dose at the center of the beam (see A1.3).

A1.2.1.2 See Fig. A1.1 for example of measurement of Dose = *f* (*I*, *V*, W_b).

A1.2.2 Dose depends on beam window thickness, distance between the beam window and the product surface, and on the composition and temperature of the gas between the beam window and the product surface. These should therefore be kept constant during the measurements.

A1.2.3 The relationship in Eq A1.1 can be established by dose measurements with different combinations of the parameters *I*, *V*, and W_b. Showing that this relationship is a straight line passing through (0,0)—within uncertainties—proves that