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Guide for use of radiation-sensitive indicators

Guide pour l'utilisation d'indicateurs sensibles aux rayonnements

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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 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 Subcommittee E10.01, Dosimetry for 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 51539 was developed by ASTM Committee E10, Nuclear Technology and Applications, through Subcommittee E10.01, and by Technical Committee ISO/TC 85, Nuclear energy.

This second edition cancels and replaces the first edition (ISO/ASTM 51539:2002), which has been technically revised.



Standard Guide for Use of Radiation-Sensitive Indicators¹

This standard is issued under the fixed designation ISO/ASTM 51539; 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 guide covers procedures for using radiation-sensitive indicators (referred to hereafter as *indicators*) in radiation processing. These indicators may be labels, papers, inks or packaging materials which undergo a visual change when exposed to ionizing radiation (1-5).²

1.2 The purpose for using indicators is to determine visually whether or not a product has been irradiated, rather than to measure different dose levels.

1.3 Indicators are not dosimeters and shall not be used as a substitute for proper dosimetry. Information about dosimetry systems for radiation processing is provided in other ASTM and ISO/ASTM documents (see ISO/ASTM Guide 51261).

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:³

E 170 Terminology Relating to Radiation Measurements and Dosimetry

2.2 ISO/ASTM Standards:³

51204 Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing

51261 Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing

51431 Practice for Dosimetry in Electron Beam and X-ray (Bremsstrahlung) Irradiation Facilities for Food Processing

51608 Practice for Dosimetry in an X-ray (Bremsstrahlung) Facility for Radiation Processing

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 Irradiation Facility for Radiation Processing

51939 Practice for Blood Irradiation Dosimetry

51940 Guide for Dosimetry for Sterile Insect Release Programs

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

ICRU Report 60 Fundamental Quantities and Units for Ionizing Radiation

3. Terminology

3.1 Definitions:

3.1.1 *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.

3.1.2 *indicator*—see *radiation-sensitive indicator*.

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

3.1.4 *radiation-sensitive indicator*—material such as coated or impregnated adhesive-backed substrate, ink, coating or other materials which may be affixed to or printed on the process loads, and which undergoes a visual change when exposed to ionizing radiation.

3.1.4.1 *Discussion*—This visual change may be as observed with the unaided eye or with an eye aid such as an optical filter.

3.1.4.2 *Discussion*—In the past, radiation-sensitive indicators have been referred to by different names (1-5) including *label dosimeters*, *label indicators*, *indicator labels*, *dose indicators*, and *radiation monitoring labels*. ASTM Subcommittee E10.01 considers a *label dosimeter* to be fundamentally different from an *indicator*, and intends to define a label dosimeter as a type of routine dosimeter (that is, quantitative) that is unique in that it is attached firmly to the product and can be read out without being removed from the product.

3.2 Definitions of other terms used in this standard that pertain to radiation measurement and dosimetry may be found in ASTM Terminology E 170. Definitions in ASTM E 170 are compatible with ICRU 60; that document, therefore, may be used as an alternative reference.

4. Significance and use

4.1 Indicators may be used to show that products have been exposed to a radiation source. They should be used only to

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

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.



provide a qualitative indication of radiation exposure and may be used to distinguish processed loads that have been irradiated from unirradiated process loads.

NOTE 1—The use of indicators does not eliminate the need for other process-control procedures, such as quantitative dosimetry or the controlled segregation of irradiated from nonirradiated products.

NOTE 2—See ISO/ASTM Standards 51204, 51431, 51608, 51649, 51702, 51939, and 51940 for information on the use of indicators in the various types of processing facilities and for unique product applications.

4.2 The indicator manufacturer is obliged to supply a statement regarding the approximate dose level at which the examiner (20/20 vision), at standard illumination (unfiltered daylight, or artificial light of the spectrum and intensity defined by the proper ASTM standard), is able to determine the visual change in the indicator.

5. Selection of indicators

5.1 Indicators should be selected that are convenient to use, will remain attached to the product, and can withstand the stresses of the irradiation process.

5.2 Indicators should be selected that have a response threshold appropriate for the range of dose experienced by the product. The visual change should occur below the minimum dose required for the product. In cases of process interruption, where product does not pass into the path of the primary radiation field and receives only some scattered radiation, the attached indicator should not show a visual change.

5.3 The indicators selected should also have a response threshold appropriate for the ranges of dose rate, radiation energy and environmental conditions experienced by the product (1).

5.4 The suitability of such indicators (under the conditions of use), from the time of purchase until their use or expiration of their shelf life, shall be determined.

5.5 Indicators used for electron beam processing should be thin enough to avoid significant influence on the dose distribution within the product.

5.6 Indicator materials may include, but are not limited to, coated or impregnated adhesive-backed substrates, inks and coatings (1-5).

6. Application

6.1 Indicators may be used to help ensure that the process load has been irradiated.

6.2 Indicators may be used to ensure segregation of irradiated product from non-irradiated product within the radiation processing facility.

6.3 In the event of interruption of the irradiation process, indicators attached to product may help to locate the specific zone of process interruption, thereby minimizing the amount of discarded product.

6.4 Indicators may be used for monitoring multiple-sided irradiation processes. In the case of such a process where the absorbed dose at the far side of the product is sufficient to affect the indicator, an unexposed indicator could be affixed to the side of the product that will face the radiation source before the first exposure and between each subsequent exposure.

NOTE 3—There are other means of monitoring multiple-sided product irradiation, such as the use of bar code labels and automatic turnover mechanisms.

7. Limitations of use

7.1 Radiation-sensitive indicators do not have suitable characteristics for quantitative, accurate dose measurement. Therefore, indicators are not dosimeters, and shall not be used as a substitute for proper dosimetry.

7.2 Exposure to environmental conditions such as heat, daylight, ultraviolet radiation, and gases produced by the irradiation process may cause undesirable changes to some of these indicator materials (1-4). Thus, indicators may only be useful within the irradiation facility where environmental conditions can be controlled. The user should be aware of and follow any special handling and storage procedures that would minimize such effects. Information about such potential environmental influences upon the indicator should be obtained from the manufacturer or from published data.

NOTE 4—Some irradiation or storage conditions may result in either an unirradiated indicator falsely indicating it was irradiated, or an irradiated indicator falsely indicating it was not irradiated (false positive or false negative observations).

7.3 For the reasons stated above, indicators shall not be used as the basis for product release.

8. Keywords

8.1 electron beam; gamma radiation; ionizing radiation; irradiation; radiation indicator; radiation processing; radiation-sensitive indicator; X-radiation; X-rays