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Guidance for use of radiation-sensitive indicators

Lignes directrices pour l'utilisation d'indicateurs sensibles aux rayonnements

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Contents

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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 www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by ASTM Committee E61, *Radiation processing* (as ASTM E1539-93), and drafted in accordance with its editorial rules. It was assigned to Technical Committee ISO/TC 85, *Nuclear energy, nuclear technologies and radiological protection*.

This fourth edition cancels and replaces the third edition (ISO/ASTM 51939:2013) which has been technically revised.

The main changes are as follows:

— Editorial corrections throughout the document.

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 www.iso.org/members.html.

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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.

ISO/ASTM 51539:2023(E)

Standard Guidance for Use of Radiation-Sensitive Indicators[1]

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 document 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 should 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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.5 *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:*[3]

E170 Terminology Relating to Radiation Measurements and Dosimetry

E3083 Terminology Relating to Radiation Processing: Dosimetry and Applications

2.2 *ISO/ASTM Standards:*[3]

51261 Practice for Calibration of Routine Dosimetry Systems for Radiation Processing

51608 Practice for Dosimetry in an X-ray (Bremsstrahlung) Facility for Radiation Processing at Energies between 50 keV and 7.5 MeV

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

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 85 Fundamental Quantities and Units for Ionizing Radiation

3. Terminology

3.1 *Definitions:*

3.1.1 *dosimetry system*—interrelated elements 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*, and *radiation monitoring labels*. ASTM Subcommittee E61 considers a *label dosimeter* to be fundamentally different from an *indicator*, and intends to define a label dosimeter as a type of

[1] This document is under the jurisdiction of ASTM Committee E61 on Radiation Processing and is the direct responsibility of Subommittee E61.04 on Specialty Application, 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 document.

[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.

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routine dosimeter (that is, quantitative) that is unique in that it is attached firmly to the product and absorbed dose can be determined 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 E170 and E3083. Definitions in ASTM E170 and E3083 are compatible with ICRU 85; 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 provide a qualitative indication of radiation exposure and may be used to distinguish process loads that have been irradiated from unirradiated 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 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 that will be experienced by the product. The visual change should begin to 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, should 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 facilitate 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 should 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 should 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

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