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Standard Guide for Using Statistical Process Control Principles for Routine Dosimetry in Radiation Processing[1]

This standard is issued under the fixed designation E3239; 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.

ε[1] NOTE—References to ISO/ASTM standards were editorially updated in December 2024.

INTRODUCTION

Statistical process control (SPC) is one part of the rationale used to establish rules for conformance assessment of the radiation process and processed products. The underlying rationale for product conformance assessment as it relates to the radiation process has three components: a qualified state that is demonstrated to be capable/reliable in terms of achieving the processed product specification limits; SPC applied to routine process monitoring data demonstrating no change to the qualified state, that is, a state of statistical control, and the application of a simple acceptance rule; is the process result within the process specification limits. This document provides information on the application of SPC to radiation processing with examples which include capability/reliability assessments.

1. Scope

1.1 This document provides guidance for the statistical analysis of the irradiation process from dosimetric data.

1.2 This document is one of a set of guides and practices that provide recommendations for properly implementing dosimetry in radiation processing. It is intended to be read in conjunction with ASTM 52628 and ASTM 52303.

1.3 This document employs a set of standard statistical methods and is intended to be read in conjunction with Practice E2586, Practice E2281, Practice E2587, and ASTM Manual MNL7[2].

1.4 This guide is applicable to high-energy electron beam, X-ray and gamma-ray irradiation processes.

1.5 This document assumes user knowledge of statistics, radiation processing, and radiation dosimetry. (See Annex A6)

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

1.7 *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]

E122 Practice for Calculating Sample Size to Estimate, With Specified Precision, the Average for a Characteristic of a Lot or Process

E456 Terminology Relating to Quality and Statistics

E2281 Practice for Process Capability and Performance Measurement

E2586 Practice for Calculating and Using Basic Statistics

E2587 Practice for Use of Control Charts in Statistical Process Control

E3083 Terminology Relating to Radiation Processing: Dosimetry and Applications

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

[1] This guide is under the jurisdiction of ASTM Committee E61 on Radiation Processing and is the direct responsibility of Subcommittee E61.03 on Dosimetry Application.

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[2] S. Luko, ed., *Presentation of Data and Control Chart Analysis*, 9th ed., West Conshohocken, PA, ASTM International, 2018, https://doi.org/10.1520/MNL7-9TH-EB.

[3] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at www.astm.org/contact. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

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 Estimation of Measurement Uncertainty in Dosimetry for Radiation Processing
52303 Guide for Absorbed-Dose Mapping in Radiation Processing Facilities
52628 Practice for Dosimetry in Radiation Processing
52701 Guide for Performance Characterization of Dosimeters and Dosimetry Systems for Use in Radiation Processing

2.2 *ISO Documents:*[4]

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 11137-2 Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose
ISO 11137-3 Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects of development, validation and routine control
ISO 3534-1 Statistics — Vocabulary and symbols — Part 1: General statistical terms and terms used in probability
ISO 3534-2 Statistic-Vocabulary and symbols-Part 2: Applied statistics
ISO 11462-1 Guidelines for implementation of statistical process control (SPC) – Part 1: Elements of SPC
ISO 16269-6 Statistical interpretation of data – Part 6: Determination of statistical tolerance intervals

2.3 *ICRU Report*[5]

ICRU Report 85a Fundamental Quantities and Units for Ionizing Radiation

3. Terminology

3.1 *Definitions:*

3.1.1 *absorbed-dose mapping*—measurement of absorbed dose within an irradiated product to produce a one, two or three dimensional distribution of absorbed dose, thus rendering a map of absorbed-dose values.

3.1.1.1 *Discussion*—For a process load, such a dose map is obtained using dosimeters placed at specified locations within the process load.

3.1.2 *assignable cause*—factor that contributes to the variation in a process or process output that is feasible to detect and identify.

3.1.2.1 *Discussion*—Many factors will contribute to process output variation, but it may not be feasible (economically or otherwise) to identify some of them.

3.1.3 *common cause*—source of inherent random variation in a process (output) which is predictable within statistical limits (also called random cause and chance cause).

3.1.3.1 *Discussion*—Variation in the process output is inherent in all processes. The inherent variation of the process output results from multiple sources both dependent and independent contributing to the overall process output variation. These inherent sources which are always present to a greater or lesser extent are referred to as common causes. When only common cause sources of variation are present in the process output, the process is considered to be stable and in a state of statistical control. Other sources of the process output variation occurring intermittently result from sources that are not always present and not inherent to the process and are not predictable within statistical limits are referred to as special causes. (See 3.1.32.)

3.1.4 *confidence interval*—an interval estimate $[L,U]$ with the statistics L and U as limits for the parameter θ and with confidence level 1-α, where the probability $Pr(L \leq \theta \leq U) \geq 1-\alpha$.

3.1.4.1 *Discussion*—The confidence level, 1-α, reflects the proportion of cases that the confidence interval $[L,U]$ would contain or cover the true parameter value of θ in a series of repeated random samples under identical conditions. Once L and U are given values, the resulting confidence interval either does or does not contain it. In this sense "confidence" applies not to the particular interval but only to the long run proportion of cases when repeating the procedure many times

3.1.5 *control chart*—chart on which are plotted a statistical measure of subgroup versus time of sampling along with limits based on the statistical distribution of that measure so as to indicate how much common, or chance cause variation is inherent in the process or product.

3.1.6 *control limits*—limits on a control chart that are used as criteria for signaling the need for action or judging whether a set of data does or does not indicate a state of statistical control based on a prescribed degree of risk.

3.1.6.1 *Discussion*—For example, typical three-sigma limits carry a risk of 0.135 % of being out of control (on one side of the center line) when the process is actually in control and the statistic has a normal distribution.

3.1.7 *dose map, dose mapping*—See *absorbed-dose mapping*.

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

3.1.8.1 *Discussion*—The concept is also referred to as the max/min dose ratio. Product generally refers to the *process load*.

3.1.9 *irradiation container*—holder in which process load is transported through the irradiator.

3.1.9.1 *Discussion*—An *irradiation container* is often referred to simply as "container" and can be a carrier, cart, tray, product carton, pallet, product package or other holder.

3.1.10 *long term standard deviation,* σ_{LT},—sample standard deviation of all individual (observed) values taken over a long period of time.

[4] Available from International Organization for Standardization (ISO), ISO Central Secretariat, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, https://www.iso.org.

[5] Available from International Commission on Radiation Units and Measurements (ICRU), 7910 Woodmont Ave., Suite 400, Bethesda, MD 20841-3095, http://www.icru.org.