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Practice for dosimetry for a self-contained dry-storage gamma irradiator

Pratique de la dosimétrie appliquée à un irradiateur gamma renfermant une source auto-protégée entreposée à sec

Reference number
ISO/ASTM 52116:2013(E)

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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 52116 was developed by ASTM Committee E61, Radiation Processing, through Subcommittee E61.04, Specialty Application, and by Technical Committee ISO/TC 85, Nuclear energy, nuclear technologies and radiological protection.

ISO/ASTM 52116:2013

An American National Standard

Standard Practice for Dosimetry for a Self-Contained Dry-Storage Gamma Irradiator[1]

This standard is issued under the fixed designation ISO/ASTM 52116; 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 dosimetric procedures to be followed with self-contained dry-storage gamma irradiators. For irradiators used for routine processing, procedures are given to ensure that product processed will receive absorbed doses within prescribed limits.

1.2 This practice covers dosimetry in the use of dry-storage gamma irradiators, namely self-contained dry-storage ^{137}Cs or ^{60}Co irradiators (shielded freestanding irradiators). It does not cover underwater pool sources, panoramic gamma sources, nor does it cover self-contained bremsstrahlung X-ray units.

1.3 The absorbed-dose range for the use of the dry-storage self-contained gamma irradiators covered by this practice is typically 1 to 10^5 Gy, depending on the application. The absorbed-dose rate range typically is from 10^{-2} to 10^3 Gy/min.

1.4 For irradiators supplied for specific applications, specific ISO/ASTM or ASTM practices and guides provide dosimetric procedures for the application. For procedures specific to dosimetry in blood irradiation, see ISO/ASTM Practice 51939. For procedures specific to dosimetry in radiation research on food and agricultural products, see ISO/ASTM Practice 51900. For procedures specific to radiation hardness testing, see ASTM Practice E1249. For procedures specific to the dosimetry in the irradiation of insects for sterile release programs, see ISO/ASTM Guide 51940. In those cases covered by ISO/ASTM 51939, 51900, 51940, or ASTM E1249, those standards take precedence.

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 E2628, “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

E1249 Practice for Minimizing Dosimetry Errors in Radiation Hardness Testing of Silicon Electronic Devices Using Co-60 Sources

E2628 Practice for Dosimetry in Radiation Processing

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

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

51707 Guide for Estimating Uncertainties in Dosimetry for Radiation Processing

51900 Guide for Dosimetry in Radiation Research on Food and Agricultural Products

51939 Practice for Blood Irradiation Dosimetry

51940 Guide for Dosimetry for Sterile Insects Release Programs

2.3 *International Commission on Radiation Units and Measurements (ICRU) Reports:*[3]

ICRU 85a Fundamental Quantities and Units for Ionizing Radiation

2.4 *ANSI Standards:*[4]

ANSI/HPS N43.7 Safe Design and Use of Self-Contained, Dry Source Storage Gamma Irradiators (Category I)

2.5 *Joint Committee for Guides in Metrology (JCGM) Reports:*

JCGM 100:2008, GUM 1995 with minor corrections, Evaluation of measurement data – Guide to the Expression of Uncertainty in Measurement[5]

[1] This practice is under the jurisdiction of ASTM Committee E61 on Radiation Processing and is the direct responsibility of Subcommittee E61.04 on Specialty Application, and is also under the jurisdiction of ISO/TC 85/WG 3.

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[2] 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.

[3] International Commission on Radiation Units and Measurements (ICRU), 7910 Woodmont Ave., Suite 800, Bethesda, MD 20810, U.S.A.

[4] Available from the Health Physics Society, http://hps.org.

[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).

JCGM 100:2008, VIM International vocabulary of metrology – Basis and general concepts and associated terms[6]

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.

3.1.2 *calibration*—[VIM, 6.11] set of operations under specified conditions, which establishes the relationship between values indicated by a measuring instrument or measuring system, and the corresponding values realised by standards traceable to a nationally or internationally recognised laboratory.

3.1.2.1 *Discussion*—Calibration conditions include environmental and irradiation conditions present during irradiation, storage and measurement of the dosimeters that are used for the generation of a calibration curve. To achieve stable environmental conditions, it may be necessary to condition the dosimeters before performing the calibration procedure.

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

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

3.1.5 *transit dose*—absorbed dose delivered to a product (or a dosimeter) while it travels between the non-irradiation position and the irradiation position, or in the case of a movable source while the source moves into and out of its irradiation position.

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

4. Significance and use

4.1 The design and operation of a self-contained irradiator should ensure that reproducible absorbed doses are obtained when the same irradiation parameters are used. Dosimetry is performed to determine the relationship between the irradiation parameters and the absorbed dose.

4.1.1 For most applications, the absorbed dose is expressed as absorbed dose to water (see ISO/ASTM Practice 51261). For conversion of absorbed dose to water to that to other materials, for example, silicon, see Annex A1 of ISO/ASTM Practice 51261.

4.2 Self-contained dry-storage gamma irradiators contain properly shielded radioactive sources, namely ^{137}Cs or ^{60}Co, that emit ionizing electromagnetic radiation (gamma radiation). These irradiators have an enclosed, accessible irradiator sample chamber connected with a sample positioning system, for example, irradiator drawer, rotor, or irradiator turntable, as part of the irradiation device.

4.3 Self-contained dry-storage gamma irradiators can be used for many radiation processing applications, including the calibration irradiation of dosimeters; studies of dosimeter influence quantities; radiation effects studies, and irradiation of materials or biological samples for process compatibility studies; batch irradiations of microbiological, botanical, or in-vitro samples; irradiation of small animals; radiation "hardness" testing of electronics components and other materials; and batch radiation processing of containers of samples.

NOTE 1—Self-contained dry-storage gamma irradiators contain a sealed radiation source, or an array of sealed radiation sources securely held in a dry container constructed of solid materials. The sealed radiation sources are shielded at all times, and human access to the chamber undergoing irradiation is not physically possible due to the irradiator's design configuration (see ANSI/HPS N43.7).

NOTE 2—For reference–standard dosimetry, the absorbed dose and absorbed-dose rate can be expressed in water or other material which has similar radiation absorption properties to that of the samples or dosimeters being irradiated. In some cases, the reference-standard dosimetry may be performed using ionization chambers, and may be calibrated in terms of exposure (C kg^{-1}), or absorbed dose to air, water or tissue (Gy). Measurements performed in terms of exposure apply to ionization in air, and care should be taken to apply that measurement to the sample being irradiated.

5. Types of facilities and modes of operation

5.1 *Facility Types*—Typical self-contained dry-storage gamma irradiators are illustrated in Annex A1. These irradiators house the radiation source(s) in a protective lead shield (or other appropriate material), and usually have a sample positioning mechanism tied to an accurate calibrated reset timer to lower or rotate the sample holder from the load/unload position to the irradiation position and back to the load/unload position. Details on the calibration of dosimetry systems and dose mapping in such irradiators may be found, respectively in ISO/ASTM Guide 51261 and in this practice. Details on the designs of such irradiators and on safety considerations in the use of such irradiators may be found in ANSI/HPS N43.7.

5.2 *Modes of Operation*—Three common modes of operation are described. This does not purport to include all modes of operation.

5.2.1 One method of use is to rotate the sample holder on an irradiator turntable in front of the source such that the only points that remain a fixed distance from the source are along an axis of rotation (ANSI/HPS N43.7).

5.2.2 A second method is to distribute the source in an annular array, resulting in a relatively uniform absorbed-dose distribution. In this design, the irradiator turntable normally would not be necessary.

5.2.3 A third method is to use opposed sources with appropriate beam flattening to obtain a uniform dose throughout the sample.

6. Radiation source characteristics

6.1 The radiation sources used in the irradiation devices considered in this practice consist of sealed elements of ^{60}Co

[6] Document produced by Working Group 2 of the Joint Committee for Guides in Metrology (JCGM/WG 2). Available free of charge at the BIPM website (http://www.bipm.org).

or ^{137}Cs, which are typically linear rods or pencils arranged singly or in a planar array or cylindrical array.

6.2 Cobalt-60 emits photons with energies of approximately 1.17 and 1.33 MeV in nearly equal proportions; cesium-137 emits photons with energies of approximately 0.662 MeV.

6.3 The radioactive decay half-lives for ^{60}Co and ^{137}Cs are regularly reviewed and updated. The most recent publication by the National Institute of Standards and Technology[7] gave values of 1925.20 (± 0.25) days for ^{60}Co and 11018.3 (± 9.5) days for ^{137}Cs. In addition, the ^{137}Cs radiation source may contain radioimpurities which should be qualified by the source manufacturer.

6.4 For pure ^{60}Co and ^{137}Cs gamma sources, the only variation in the source strength is the known reduction in the activity caused by radioactive decay. The reduction in the source strength and the required increase in the irradiation time to deliver the same dose may be calculated or obtained from tables provided by the irradiator manufacturer.

7. Dosimetry systems

7.1 The basic requirements that apply when making absorbed dose measurements are given in ASTM E2628. ASTM E2628 also provides guidance on the selection of dosimetry systems and describes the classification of dosimeters based on two criteria. Users are directed to other standards that provide specific information on individual dosimetry systems, calibration methods, and uncertainty estimation.

NOTE 3—The operation of a self-contained dry-storage irradiator, absorbed-dose measurements made in the sample under controlled environmental and geometrical conditions of calibration, testing, or processing provide an independent quality control record.

8. Installation qualification (IQ)

8.1 *Objective*—The purpose of an installation qualification (IQ) program is to obtain and document evidence that the irradiator and measurement instruments have been delivered and installed in accordance with their specifications. IQ includes documentation of the irradiator equipment and measurement instruments; establishment of testing, operation and calibration procedures for their use; and verification that the installed irradiator equipment and measurement instruments operate according to specification.

NOTE 4—Table A2.1 gives some recommended steps in the following areas: installation qualification, operational qualification, performance qualification, and routine product processing.

8.2 *Equipment Documentation*—Establish and document an IQ program that includes descriptions of the instrumentation and equipment installed at the facility. This documentation shall be retained for the life of the facility. At a minimum, it shall include:

8.2.1 A description of the irradiator's specifications, characteristics and parameters, including any modifications made during or after installation,

8.2.2 A description of the location of the irradiator within the operator's premises,

8.2.3 Operating instructions and standard operating procedures for the irradiator and associated measurement instruments,

8.2.4 Licensing and safety documents and procedures, including those required by regulatory and occupational health and safety agencies,

8.2.5 A description of a calibration program to ensure that all processing equipment that may influence absorbed-dose delivery is calibrated periodically (for example, the timer mechanism),

8.2.6 Operating procedures and calibration procedures for associated measurement instruments or systems.

8.3 *Equipment Testing and Calibration*—Test all processing equipment and instrumentation that may influence absorbed dose in order to verify satisfactory operation of the irradiator within the design specifications.

8.3.1 Implement a documented calibration program to ensure that all processing equipment and instrumentation that may influence absorbed-dose delivery are calibrated periodically.

8.3.2 If any modification or change is made to the irradiator equipment or measurement instruments during the installation qualification phase, they shall be re-tested.

8.4 For self-contained irradiators, some IQ may begin prior to the shipment of the irradiator to the customer's site.

9. Operational qualification (OQ)

9.1 *Objective*—The purpose of operational qualification (OQ) of an irradiation facility is to establish baseline data for evaluating irradiator effectiveness, predictability, and reproducibility for the range of conditions of operation for key processing parameters that affect absorbed dose in the product. As part of this process, dosimetry may be performed to: *(1)* establish relationships between the absorbed dose for a reproducible geometry and the process parameters of the irradiator, *(2)* measure absorbed-dose distributions in product (dose mapping), *(3)* characterize absorbed dose variations when irradiator and processing parameters fluctuate statistically through normal operations, and *(4)* measure the absorbed-dose rate at a reference position within the holder filled with product.

9.1.1 For self-contained irradiators, OQ may begin prior to the shipment of the irradiator to the customer's site. As part of release-for-shipment criteria, the irradiator manufacturer may perform absorbed-dose mapping to establish baseline data. After the unit is installed at the user's site, OQ is performed as part of the user's quality assurance plan.

9.2 *Dosimetry Systems*—Calibrate the routine dosimetry system to be used at the facility.

9.3 *Irradiator Characterization*—The absorbed dose received by any portion of product depends on the irradiator parameters (such as the source activity at the time of irradiation, the geometry of the source, the source-to-product distance and the irradiation geometry) and the processing parameters (such as the irradiation time, the product composition and density and the loading configuration).

[7] Unterweger, M. P., Hoppes, D. D., Schima, F. J., and Coursey, J. S., "Radionuclide Half-Life Measurements," National Institute of Standards and Technology, available online at http://physics.nist.gov/Halflife (updated October 5, 2010).

9.3.1 *Absorbed-Dose Rate*—A reference- or transfer-standard dosimetry system, traceable to nationally or internationally recognized standards, shall be used to measure the absorbed-dose rate within product or simulated product at a reference position (such as the center of the product or simulated product volume). For a defined irradiation geometry, the absorbed-dose rate at the reference position should have a reproducible and documented relationship to the absorbed-dose rate at locations of maximum (D_{max}) and minimum (D_{min}) dose rate.

9.3.1.1 Most manufacturers of irradiators use a reference-standard dosimetry system to measure absorbed-dose rate at a reference position within simulated product following installation of (or, in the case of some self-contained units, before shipping) the irradiator.

9.3.1.2 Reference- or transfer-standard dosimeter measurement of absorbed-dose rate at a reference position should be repeated periodically (for example, every two years for a gamma facility) and following any changes to the source, geometry, or other irradiator parameter that could affect absorbed-dose rate.

9.3.2 *Dose Mapping*—Ideally, the irradiation process is designed to irradiate product uniformly throughout the irradiated volume; in reality, a certain variation in absorbed-dose through the product will exist. The OQ process includes mapping the absorbed-dose distributions for product (or simulated product), and identifying the magnitudes and locations D_{max} and D_{min} within the product.

9.3.2.1 Map the absorbed-dose distribution by placing dosimeters throughout the actual or simulated product. Select placement patterns that can identify the locations of D_{max} and D_{min}. Dosimetry data from previously characterized irradiators of the same design or theoretical calculations may provide useful information for determining the number and locations of dosimeter sets needed for this characterization process.

NOTE 5—In the case of static irradiations (such as when the product is located at the center of an annular source array), the dose mapping should be performed in three dimensions; otherwise, two-dimensional dose mapping usually suffices. A common method for presenting the dose mapping results is to use isodose curves (lines or surfaces of constant absorbed dose through the actual or simulated product).

9.3.2.2 Changes in the product handling system (for example, irradiator turntable) requires a new absorbed-dose mapping.

9.3.3 *Transit Dose*—The transit dose and its relation to total absorbed dose should be quantified.

9.3.3.1 Dosimetry performed at the same dose level as used for product irradiation includes the transit dose contribution. Therefore, it is usually unnecessary to measure the transit dose separately.

9.3.3.2 Procedures for measuring and correcting for transit dose in terms of transit time are given in Annex A3.

9.3.3.3 In self-contained gamma irradiators, the transit dose should be small relative to the total dose delivered (for example, less than 1 %).

9.3.3.4 The absorbed-dose range of the dosimetry system used for mapping the dose distribution may not be suitable for measuring the transit dose. Thus, it may be necessary to utilize a different dosimetry system for measuring the transit dose.

9.3.4 *Timer Setting Calculation*—An important calculation in the use of gamma sources is the correction for radioactive decay. For a pure radionuclide source, the reduction in activity with time is exponential. For an initial activity of A_0(at time = 0 which is usually specified as the date of the last reference dose-rate measurement), the activity at some later time, *t*, is given by:

$$A_t = A_0 \cdot e^{-\lambda t} \tag{1}$$

where A_t is the source activity at time *t*, and the decay constant, λ, for a given radionuclide, is defined as:

$$\lambda = \frac{\ln(2)}{t_{1/2}} \tag{2}$$

where:

$t_{1/2}$ is the half-life for a given radionuclide. The half-lives used in these examples for gamma emission by ^{60}Co and ^{137}Cs are 1925.20 (±0.25) days and 11018.3 (±9.5) days, respectively (see 6.3). The values for λ in Eq 2 for ^{60}Co and ^{137}Cs are as follows:

$$\text{For } ^{60}\text{Co}, \lambda = 3.60076 \times 10^{-4}\ \text{day}^{-1} \tag{3}$$

$$\text{For } ^{137}\text{Cs}, \lambda = 6.29087 \times 10^{-5}\ \text{day}^{-1} \tag{4}$$

where no round-off occurs until the final answer. The decay factor is defined as follows:

$$\text{Decay Factor} = \frac{A_t}{A_0} = e^{-\lambda t} \tag{5}$$

NOTE 6—Examples of using these equations to obtain decay factors are given as follows: for an elapsed time period of 500 days and using the decay constants according to Eq 3 and Eq 4, Eq 5 gives decay factors for ^{60}Co and ^{137}Cs of 0.835238 and 0.969035, respectively. The decay factor can be used to correct a known dose rate or source activity for time. Refer to http://physics.nist.gov/Halflife for up-to-date radionuclide half lives.

Since the absorbed-dose rate due to a radionuclide source also varies exponentially with the decay time, *t*, the dose rate, *dR*, is given by:

$$DR_t = DR_0 \cdot e^{-\lambda t} \tag{6}$$

where: DR_t is the dose rate at time *t*; D_0 is the dose rate at some earlier time (t = 0). The timer setting, *TS*, necessary to deliver the targeted central dose varies inversely with the dose rate or source activity, and is given by:

$$(TS)_t = (TS)_0 \cdot e^{-\lambda t} \tag{7}$$

where: $(TS)t$ is the timer setting necessary to deliver the required target dose, for example, D_{min}, at a time *t*; $(TS)_0$ is the timer setting at some earlier time, t = 0, to deliver the same target dose. Typically for free-standing irradiators with a ^{137}Cs radionuclide source, the timer setting is adjusted (increased) by ~1.1 % every six months. Typically, for free-standing irradiators with a ^{60}Co radionuclide source, the timer setting is adjusted (increased) by ~1.1 % every month.

NOTE 7—Calculations of source decay, and therefore adjustments of timers, always should be done as referenced to the date of last dose-rate measurement (t = 0), to avoid compounding error.

9.3.4.1 Although the output of gamma sources is expected to be constant (except for radioactive decay), errors may be introduced by the existence of radioactive impurities. For example, ^{134}Cs may be an impurity in ^{137}Cs sources. This could lead to an error in the manufacturer's measurement of source activity. In addition, the dose measurements cannot differentiate the dose contributions from ^{134}Cs and ^{137}Cs. Although the original dosimetry measurements take this into account, ^{134}Cs and ^{137}Cs decay at different rates, which may lead to an error in the timer setting calculations. If the contribution to the central dose rate from the radioimpurity is greater than 1 %, the irradiator manufacturer should provide a timer setting methodology to accurately account for source decay. Periodic re-measurement of the central dose rate using a reference-standard dosimetry system may help to minimize the uncertainty introduced by the presence of radio-impurities.

10. Performance qualification (PQ)

10.1 *Objective*—For irradiators to be used for routine processing, performance qualification (PQ) dosimetry shall be performed to ensure that all products processed within specified parameters receive the required absorbed dose.

10.1.1 Minimum and maximum absorbed-dose limits are often associated with the irradiation application. In addition, for many applications, one or both of these limits may be prescribed by government regulations. Dosimetry is used in performance qualification (PQ) to determine the appropriate process parameters (including timer setting and product loading configuration) to help ensure that the absorbed-dose requirements for a particular product can be satisfied. This is accomplished by absorbed-dose mapping of specific product. The purpose of the mapping is to determine the magnitudes and locations of the minimum and maximum absorbed doses and their relationships to the absorbed doses at locations used for monitoring during routine product processing.

10.2 *Product Loading Configuration*—A loading configuration for the irradiation should be established for each product type. The documentation for this loading configuration shall include specifications for parameters that influence the absorbed-dose distribution. These parameters typically include volume of the product and packaging. The product holder shall not be loaded beyond its designed maximum volume.

10.3 *Product or Simulated Product Absorbed-dose Mapping*—For each type of irradiated product, there is a minimum dose to achieve the desired effect and a maximum dose that the product can tolerate without unacceptable degradation in quality. Both these limits are usually defined by the facility. Establish the locations of the regions of D_{max} and D_{min} for each selected product-loading configuration by placing dosimeter sets throughout the product volume or simulated product. Concentrate the dosimeters in expected regions of D_{max} and D_{min} with fewer dosimeters placed in areas likely to receive intermediate absorbed dose. In many applications, the product is relatively close to the radiation sources, resulting in pronounced absorbed-dose gradients near the periphery of the volume of the sample. It is important, therefore, to choose a dosimeter that is small enough to detect these gradients. Dosimeter film in strips or sheets may be employed to obtain useful information.

NOTE 8—One of the primary design intents for dry-storage gamma irradiators is a highly reproducible dose distribution. As such, it is often straight-forward for the user to demonstrate that one dose mapping is adequate for OQ and PQ and to determine the locations for D_{max} and D_{min}.

10.3.1 Results of absorbed-dose mapping will be used to determine the degree of dose uniformity. In the case when the measured dose uniformity is close to the acceptable dose uniformity, irradiator or processing parameters can be adjusted to improve dose uniformity (for example, installing an irradiator turntable or reducing the product volume to exclude product from areas with low or high dose rates).

10.3.2 If any changes are made to the irradiator or mode of operation that could affect the magnitude or location of the absorbed-dose extremes, repeat the absorbed-dose mapping to the extent necessary to establish the effect. In addition, the established dose rate should be re-verified.

10.3.3 *Reference Position*—Identify a reference position for each loading configuration. This may be, for example, the location of D_{min} or D_{max}, or a location in or on the product holder. The absorbed dose at this location shall have a reproducible and documented relationship to the absorbed dose at the locations of D_{min} and D_{max}.

10.4 *Establishing Process Parameters*—Values of process parameters that yield absorbed dose within specified limits should be established for each product and loading configuration. Value(s) of all parameters that affect absorbed dose are established based on results of the absorbed-dose mapping in

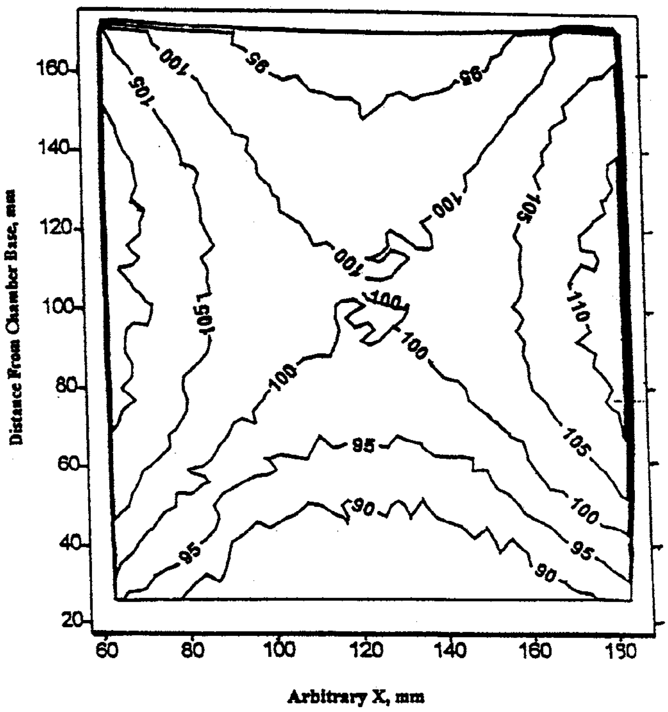

FIG. 1 Example of two-dimensional dose mapping results normalized to a central dose of 100 %