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Invited Paper

DOSIMETRY STANDARDS FOR RADIATION PROCESSING

H. FARRAR IV
Bell Canyon, California,
United States of America

Abstract

For irradiation treatments to be reproducible in the laboratory and then in the commercial environment, and for products to have certified absorbed doses, standardized dosimetry techniques are needed. This need is being satisfied by standards being developed by experts from around the world under the auspices of Subcommittee E10.01 of the American Society for Testing and Materials (ASTM). In the time period since it was formed in 1984, the subcommittee has grown to 150 members from 43 countries, representing a broad cross-section of industry, government and university interests. With cooperation from other international organizations, it has taken the combined part-time effort of all these people more than 13 years to complete 24 dosimetry standards. Four are specifically for food irradiation or agricultural applications, but the majority apply to all forms of gamma, x-ray, bremsstrahlung and electron beam radiation processing, including dosimetry for sterilization of health care products and the radiation processing of fruits, vegetables, meats, spices, processed foods, plastics, inks, medical wastes and paper. An additional 6 standards are under development. Most of the standards provide exact procedures for using individual dosimetry systems or for characterizing various types of irradiation facilities, but one covers the selection and calibration of dosimetry systems, and another covers the treatment of uncertainties. Together, this set of standards covers essentially all aspects of dosimetry for radiation processing. The first 20 of these standards have been adopted in their present form by the International Organization of Standardization (ISO), and will be published by ISO in 1999.

1. INTRODUCTION

Today, radiation processing is an expanding technology with numerous applications in, for example, health care products sterilization, sewage and hospital waste treatment, polymer modification, and food processing. In the time since dosimetry standards were discussed at the previous IAEA High-Dose Symposium in 1990 [1], public perception and media coverage about food irradiation have shifted dramatically from *generally negative* to *usually positive*, and it appears increasingly likely that large amounts of meat (to reduce the possibility of contamination) and fruits (to inactivate insects) will be processed in the next few years. The effectiveness of the irradiation process depends, however, on the proper application of dose and its measurement. Regulatory authorities generally require the processor to control the irradiation process so that all parts of the product receive an absorbed dose within certain prescribed limits. This required absorbed dose range will depend on the product and the desired effect, such as total sterilization of medical products, extended shelf-life of food, or insect disinfestation. The lower limit must be high enough to accomplish this desired effect, but the upper limit should not be so high as to cause adverse effects. Adequate dosimetry with proper statistical controls and documentation is the key part of the Quality Control (QC) process which is necessary to assure the products are properly treated.

Recognizing the importance of standards, several national and international organizations such as ISO, CEN, and the Association for the Advancement of Medical Instrumentation (AAMI) have been involved in the development of guidelines and standards related to various aspects of radiation processing. Amongst them, ASTM is the principal player for the development of standards for dosimetry.

2. ASTM SUBCOMMITTEE E10.01 ON DOSIMETRY FOR RADIATION PROCESSING

To address the needs of industry, ASTM Subcommittee E10.01 "*Dosimetry for Radiation Processing*" was formed in 1984 with the principal objective of developing dosimetry standards. Membership has grown to about 150 individuals from 43 countries, representing industry, government laboratories, radiation equipment manufacturers, dosimeter manufacturers, regulatory agencies, universities, medical companies, food companies, and irradiator operators. This membership includes most groups in the world known to be active in the development of dosimetry for radiation processing. The international composition of this subcommittee is reflected in the fact that 14 of the 32 task groups that are writing or revising these standards are chaired by individuals from countries ***other*** than the United States of America.

Individual ASTM standards are developed by task groups consisting of both members and non-members, including anyone in the world who wants to participate. The standards pass through a series of ballot steps where all members have the individual power to cast a negative vote, which can be overridden only by the subcommittee providing a persuasive written explanation. The results of this consensus process are *standard practices* and *standard guides* that represent state-of-the-art thinking, and that have the technical consensus and support from all interested parties. This gives the standards particular credibility for specifying how research or production operations should be done properly, and makes them ideal for use in government regulations. ASTM has a policy where standards may undergo a technical review at any time, but must undergo this review at least every 5 years.

3. DOSIMETRY STANDARDS

Table I lists the 24 standards that have completed the ASTM ballot process with unanimous approval, and that are published in Volume 12.02 of the Annual Book of ASTM Standards [2]. There are plans to publish this set of standards also as a separate handbook.

Four of the standards are specifically for food irradiation or agricultural applications, but the majority apply to all forms of gamma, x-ray, bremsstrahlung and electron-beam radiation processing. Twelve of them are "vertical" standards that provide exact procedures for implementing 12 different dosimetry systems. The remaining twelve "horizontal" standards, which can be used with any of the individual dosimetry systems, include seven standards for characterizing and operating various types of gamma, x-ray, bremsstrahlung and electron beam irradiation facilities. The remaining horizontal standards include Guide E1261, which provides detailed information and criteria for selecting an optimum dosimetry system, and describes the three ways of calibrating dosimetry systems; and Guide E1707, which covers the treatment of uncertainties in absorbed dose measurements using the new ISO Type A and Type B evaluations. The remaining three standards are for specific applications on how to perform dosimetry while irradiating blood products or irradiating insects for sterile release programs, and on how to perform dosimetry during research on food and agricultural products. The latter standard was originally considered to be unnecessary, but the subcommittee, after examining some recent research papers in which there was inadequate dosimetry, and after noting that detailed dosimetry information is often not reported in the literature, decided that such a standard was very much needed.

Table II lists six draft standards that are currently being developed. The first, for the use of a label dosimetry system, has until recently been dormant due to the unavailability of label dosimeters. Some research is being undertaken by Ehlermann [3] to develop a label system, but more work still needs to be done to determine how his "dose meters" can be commercially implemented. Draft standard E10.01-N on dosimetry for small self-contained dry-storage irradiators of the type used widely for blood irradiation and for insect sterilization, is in its final ballot stage. Guide E10.01-S for dose mapping has been worked on for more than five years and is now in its seventh draft. Dose mapping is covered to some extent in some of the other existing dosimetry standards, but this standard is intended to treat the subject much more comprehensively.

TABLE I. COMPLETED DOSIMETRY STANDARDS

E1204 - 97	Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing
E1205 - 93	Practice for Use of a Ceric-Cerous Sulfate Dosimetry System
E1261 - 94	Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing
E1275 - 93	Practice for the Use of a Radiochromic Film Dosimetry System
E1276 - 96	Practice for the Use of a Polymethylmethacrylate Dosimetry System
E1310 - 94	Practice for the Use of a Radiochromic Optical Waveguide Dosimetry System
E1400 - 95a	Practice for Characterization and Performance of a High-Dose Radiation Dosimetry Calibration Laboratory
E1401 - 96	Practice for Use of a Dichromate Dosimetry System
E1431 - 98	Practice for Dosimetry in Electron and Bremsstrahlung Irradiation Facilities for Food Processing
E1538 - 93	Practice for Use of the Ethanol-Chlorobenzene Dosimetry System
E1539 - 93	Guide for Use of Radiation-Sensitive Indicators
E1540 - 98	Practice for Use of a Radiochromic Liquid Dosimetry System
E1607 - 94	Practice for Use of the Alanine-EPR Dosimetry System
E1608 - 94	Practice for Dosimetry in an X-Ray (Bremsstrahlung) Facility for Radiation Processing
E1631 - 96	Practice for Use of Calorimetric Dosimetry Systems for Electron Beam Dose Measurements and Dosimeter Calibrations
E1649 - 94	Practice for Dosimetry in an Electron-Beam Facility for Radiation Processing at Energies between 300 keV and 25 MeV
E1650 - 97	Practice for Use of Cellulose Acetate Dosimetry Systems
E1702 - 95	Practice for Dosimetry in a Gamma Irradiation Facility for Radiation Processing
E1707 - 95	Guide for Estimating Uncertainties in Dosimetry for Radiation Processing
E1818 - 96	Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 80 and 300 keV
E1900 - 97	Guide for Dosimetry in Radiation Research on Food and Agricultural Products
E1939 - 98	Practice for Blood Irradiation Dosimetry
E1940 - 98	Guide for Dosimetry for Irradiation of Insects for Sterile Release Programs
E1956 - 98	Practice for Thermoluminescence Dosimetry (TLD) Systems for Radiation Processing

TABLE II. DOSIMETRY STANDARDS BEING DEVELOPED

E10.01-J	Practice for Use of a Label Dosimetry System
E10.01-N	Practice for Dosimetry for a Self-Contained Dry-Storage Irradiator
E10.01-S	Guide for Dose Mapping Product in Radiation Processing Facilities
E10.01-ß	Practice for Dosimetry in Radiation Processing of Fluidized Beds and Fluid Streams
E10.01-Δ	Guide for Using Mathematical Models for Predicting Absorbed Dose in Radiation Processing
E10.01-ζ	Guide for Performance Testing of Dosimetry Systems

The final three draft standards listed in Table II have not yet reached the ballot stage but are being worked on by their respective task groups. Significant progress on developing the guide for performance testing of dosimetry systems, including a discussion of influence quantities, was made at the ASTM meeting following the present symposium in Vienna.

4. COORDINATION WITH OTHER INTERNATIONAL ORGANIZATIONS

Over the past few years, there have been significant international movements to coordinate various national regulations and procedures. Accordingly, concurrent with the development of new

dosimetry standards, and to minimize overlapping or conflicting efforts, Subcommittee E10.01 has been coordinating its standards development activities with other international groups having similar or complementary interests. As a result of this effort, many of the 24 standards that have been completed and published are presently being used by a number of national and international groups and regulatory bodies. For example, some of the standards are regularly referred to (and have methodology that is consistent with) documents issued by AAMI. Others are referenced in documents issued by the International Consultative Group on Food Irradiation (ICGFI), a group established under the ægis of the United Nations' FAO, IAEA, and WHO to evaluate global developments in the field of food irradiation. Several of these dosimetry standards are quoted in US government regulations on food irradiation, and are being considered for inclusion or are already included in regulations issued by other countries. Also, several are relied upon and referred to extensively in international standards being developed for the radiation sterilization of health care products by ISO's Technical Committee 198 (ISO/TC198), or are utilized as the basis for dosimetry equipment Recommendations being developed by the International Organization of Legal Metrology (OIML).

Two other ASTM groups are responsible for closely related standards. Subcommittee F02.40 on "*Food Processing and Packaging*" is developing standard guides on good irradiation practice for food commodities as well as standards for the selection and use of packaging materials. Subcommittee E10.07 on "*Radiation Dosimetry for Radiation Effects on Materials and Devices*" is developing a number of standards on dosimetry for "radiation hardness" testing, and is responsible for Standard E1026 "*Practice for Using the Fricke Reference Standard Dosimetry System*", which is not included in Table I. Finally, ASTM Subcommittee E10.01 will cooperate with the International Commission on Radiation Units and Measurements (ICRU) should that organization decide to develop a report on dosimetry for radiation processing. All these coordination efforts are being helped by the fact that the experts writing the standards come from many different countries, and many are active in more than one of these organizations. The goals of these various organizations are all similar: to develop consensus standards that have the solid technical support of the worldwide radiation processing community.

5. ADOPTION BY ISO USING THE "FAST TRACK" PROCESS

An effort started in 1995 to transform 20 of the completed ASTM standards into ISO standards using the "fast track" process completed its final ballot stage in 1998. In 1996, ISO Technical Committee TC85 (Nuclear Energy) took responsibility for making this happen, and a new Working Group-3 (WG3) "*High-Level Dosimetry for Radiation Processing*" was formed. In a subsequent 1997 ISO ballot, all 20 dosimetry standards (then classified as Draft International Standards) were approved, but WG3 nevertheless decided to accommodate negative votes on three of the draft standards. The negative votes were made because the three standards contained technical information that overlapped with requirements in the existing Standard ISO 11137 "*Sterilization of health care products - Requirements for validation and routine control - Radiation sterilization.*" Although the overlapping requirements are technically consistent at the present time, there was concern that this might not always be the case in the future. As a result, compromise wording in the scopes of the three draft standards was worked out to everyone's satisfaction, including the membership of ISO/TC198/WG2, which is responsible for ISO 11137. Specifically, to satisfy the overlap problem, the scopes of the three Standards E1608, E1649, and E1702 were modified in the ISO versions to include the words "*In those areas covered by ISO 11137, that standard takes precedence.*" Except for the scope changes to these three standards, the contents of the 20 new ISO standards are identical to the ASTM versions that were submitted for ISO consideration in 1995. The first 20 standards listed in Table I have ISO designations starting with ISO 15554 (for E1204) and continuing consecutively to ISO 15573 (for E1818).

The main problem with this adoption by ISO of the first 20 dosimetry standards listed in Table I is that 9 have since been revised, and the ISO versions that have just been balloted are therefore already out of date! Working Group 3 of ISO/TC85 is aware of this issue, and has devised a strategy to minimize this problem in the future. The working group also knows that there are four new dosimetry standards that have not yet been considered for ISO adoption. The decision

was made at the biennial ISO/TC85 meeting in Paris in March 1998 to take one step at a time, and first get the 20 fast-tracked standards established. Now that this has been done, the working group is expected to request permission from ISO to update the standards, but not using the "fast track" process. For this effort, the working group will require additional technical manpower, and so an effort will be made to encourage more people from additional ISO member countries to join.

6. FINAL OBSERVATIONS

An enormous amount of work has been expended by many experts from around the world to generate this set of consensus standards that cover essentially all aspects of dosimetry for radiation processing. These *standard practices* and *standard guides* represent the state-of-the-art thinking and have the technical consensus and support from all who helped put them together. They are now published and available for use by the radiation processing community and national authorities for incorporation into harmonized regulations to avoid trade barriers and to facilitate international trade.

REFERENCES

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[2] ANNUAL BOOK OF ASTM STANDARDS, Vol. 12.02, The American Society for Testing and Materials, West Conshohocken, Pennsylvania (1998).

[3] EHLERMANN, D.A.E., "Validation of a label dose meter with regard to dose assurance in critical applications as quarantine control", these Proceedings, paper number: IAEA-SM-356/38.