Standards in Radiation Processing

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Abstract

The evolution of standards pertaining to industrial radiation processing will be presented, including a discussion of the relationships between the International Organization for Standardization (ISO), ASTM International, and national laboratories. RadTech's development of ASTM D-5403, which in turn was adopted by the Environmental Protection Agency as part of its Method 24, will be reviewed. An overview of current activities in the development of dosimetry standards for low-energy electron beam processing will be presented.

Why Standards?

Standards are used so that those engaged in commerce can communicate in meaningful ways pertaining to the properties and use of articles. Standards may involve the means of appraising the properties of an article (Methods of Test), the manner in which certain articles are to be dealt with or used (Practices), and/or a specific set of properties that a given material has been found to have or is required to have (Specifications). Measurements are at the foundation of standards. Measurement is the assignment of numerals to quantify a property.¹ A measurement consists of a numeral and the measureand, the property being measured. In using numerical values, all of the abilities of mathematics can then be applied to summarizing, analyzing and characterizing a measureand.

The earliest use of a form measure was the calendar, going millenniums back into pre-recorded history. Systems of weights and measures were developed between the third and second millennium BC. In medieval times, King Henry I of England standardized a measurement of length by instituting the *ell*, the equivalent to the length of his arm. During the US Civil War, the government worked with railroads and mandated a gauge distance between rails, one of the first US standardized measures. With the industrial revolution, demands for agreed upon measurement became critical to the conduct of commerce. Consensus approaches to measurement and the establishment of measureands have, for the most part, replaced mandated approaches. In the US, Public Law 104-113, Section 12 on "Standards Conformity" and Executive Order OMB Circular 119 lend authority to the consensus approach.^{2,3}

Measureands are one of the basic units of measure or are derived from these. The seven basic units of measure are: time (second, s), length (meter, m), mass (kilogram, kg), thermodynamic temperature (degrees Kelvin, °K), quantity of matter (mole, mol), electric current (ampere, A), and luminous intensity (candela, cd). The measureand and its unit value bring coherence to a measurement system, with the unit value being agreed upon through consensus. Over the years, derived measureands have changed. In polymer chemistry, molecular weight has gone from the use of the Staudinger to the Dalton, the unified atomic mass unit, which is one twelfth of the mass of an unbound atom of carbon-12. In ionizing radiation, the measureand has evolved from the Roentgen, to the Rad and now the Gray (Gy), which is one Joule (J) per kilogram of absorbed energy (Gy = J/kg, where one Joule is the kinetic energy

of a mass of two kilograms moving at a velocity of 1 m/s). The Joule has been described as the universal measure of energy.⁴ Three laboratories maintain the references for the different basic units of measure: the Bureau International des Poids et Mesures (BIPM – www.bipm.org), the National Physical Laboratory (NPL – www.npl.co.uk) and the National Institute of Standards and Technology (NIST – www.nist.gov). For example, NIST maintains an atomic clock that determines the second down to the order of 10^{-15} and collaborates with the BIPM, which assembles data from around 50 laboratories to produce a time scale called International Atomic Time.

Standards Organizations

Within the United States, there are two broadly based standards organizations that deal with topics of interest in electron beam processing:

ASTM International: The American Society for Testing and Materials was founded in 1898 and predates many other standards organizations. ASTM standards development is conducted by individual participating members who work within task groups that are part of sub-committees within ASTM committees. For a standard to become an ASTM document it must pass task group, sub-committee, committee and then full society ballot. Specific objections are dealt with on a one-on-one basis. From its start, ASTM focused on building consensus on measurements and property tests. The ASTM committees and standards of interest to those involved in radiation processing are discussed below. More information on ASTM International can be found on its web site: www.astm.org.

ANSI: The American National Standards Institute was founded in 1918. ANSI is the national standards body in the US, not ASTM. ANSI tends to focus on performance criteria whereas ASTM on the methods to carry out specific tasks. Sometimes the same document can be both an ANSI and an ASTM International standard. More information on ANSI can be found on its web site: www.ansi.org.

There are also more focused and industry targeted organizations that develop standards. These concentrate on specific areas of market and technical interest. Amongst the number of industry focused organizations that develop standards, several are of interest to those engaged in radiation processing:

PSTC: The Pressure Sensitive Tape Council, founded in 1953, is a trade association of companies involved in the manufacture of pressure sensitive tapes. The PSTC publishes its own Test Methods manual, but the organization and its members also work closely within ASTM International committees, such as the committee on Adhesives, ASTM D-14. The PSTC web site is: www.pstc.org.

SPE: The Society of Plastics Engineers, formed in 1942, enables technologists involved with all types of plastics and plastic processing to network through publications and conferences. Although SPE itself does not publish standards, its members are involved in different standards organizations. In 2005, SPE formed a Special Interest Group (SIG019) devoted to the Radiation Processing of Polymers. This group has held sessions within SPE's major annual technical meetings and has affiliation in Europe. The SPE web site is: www.4spe.org and one can link into information on SIG019.

TAPPI: The Technical Association of the Pulp and Paper Industry was founded in 1915. Many TAPPI Standards can be cross-referenced to ASTM standards. ASTM Committee D-06 on Paper and Paper Products deals with paper properties. The TAPPI web site is: www.tappi.org.

TLMI: The Tag and Label Manufacturers Institute was founded in 1933 as a trade association for label producers and their suppliers. Many TLMI standards correspond to ASTM standards and ones related to adhesives are also standards of ASTM committee D-14. TMLI's web site is: www.tlmi.com.

Other professional and trade associations also produce standards relevant to their commercial interests that pertain to the diverse uses of radiation processing, such as the Institute of Electrical and Electronics Engineers (IEEE – www.ieee.org) and Underwriters Laboratories (UL – www.ul.com).

ISO: On the international level, the International Organization for Standardization (ISO – www.iso.org) covers a broad spectrum of interests, producing standards, reports, specifications and directives for "business, government and society." ISO is relatively new as a standards organization, formed in 1947 in Europe. ISO (derived from the Greek word looc which means equal) differs significantly from the standards organizations in the United States. US standards organizations are based on the principle of "one man, one vote," that is individual joining members, be they companies, institutions, or individuals, have an equal vote. ISO is predicated on the participation of nation-states. Delegates represent their countries and member states do the voting as member bodies. Thus, for example, the US (population of >300,000,000 and a Gross Domestic Product, GDP, of nearly \$14 trillion) has an equal vote in ISO as, say, Sri Lanka (population ~19,000,000 and GDP of ~\$27 billion) or Iceland (population ~300,000 and GDP of ~\$12 billion). There are efforts within the US based standards organizations, such as ASTM International and ANSI, to harmonize standards with ISO. Within the "Referenced Documents" section of some ASTM standards, there will be reference to ISO equivalent documents. In the field of ionizing radiation, ASTM and ISO have an accord such that standards published by the ASTM subcommittee on dosimetry, ASTM E-10.01, are at once both ASTM and ISO documents. Differences in balloting processes can delay and complicate the resolution of different comments made within these two organizations, ASTM and ISO.

The Electron Beam Processing Industry

It has been estimated that there are >1400 high current electron beam (EB) accelerators being used in industry. This does not include research accelerators, such as low current linear accelerators (linacs), or electrostatic accelerators, such as Van de Graaff generators. The pie chart in Figure 1 illustrates the market end-use distribution of these accelerators. Accelerator energy tends to dictate the preference in specific end-use applications, as shown in Table I.⁵ RadTech International North America has been involved with the low-energy, self-shielded electron beams that are used in the curing of inks, coatings and adhesives, and not with the more dominant higher-energy electron beam applications. However, the low-energy segment of the market has been the fastest growing.

Table 1. Electron penetration by industrial market segment

Market Segment	Typical <u>Energy</u>	Electron <u>Penetration</u>
Surface Curing	80 – 300 keV	0.4 mm
Shrink Film	300 – 800 keV	2 mm
Wire & Cable	0.4 - 3 MeV	8 mm
Sterilization	4 –10 MeV	38 mm



Figure 1. Major industrial electron beam accelerator end-use markets

RadTech Involvement in Standards

Shortly after its inception in 1986, RadTech International North America was compelled to address market issues concerning the environmental effects of radiation processed materials. Whether paper on which inks were cured with either EB or ultraviolet radiation (UV) could be recycled was addressed through a study conducted by the then (1990-1992) RadTech Environmental Committee. The potential emissions from coatings that were to be cured with EB or UV were also addressed. The method used by the US Environmental Protection Agency, its then Method 24 (based on ASTM D-2369, "Standard Method of Test for Volatile Content of Coatings") called for a weighing of materials before and after a bake cycle to determine volatile organic compounds (VOCs). With this method of just baking and weighing, some monomers used in radiation curable coatings could volatilize. The test would not reflect a production benefit of radiation curable materials, the elimination of organic volatiles.

In 1990, RadTech's Technical Committee chairman, Lee Carlblom attended an ASTM D-01 committee meeting and recognized the need for a new method for testing the volatiles as related to radiation curable materials. A task group was formed within ASTM D-01 to address this, draft test methods were developed and inter-laboratory tests conducted. Representatives from fourteen companies then involved in RadTech participated in a series of round-robin inter-laboratory tests. Two categories of materials were evaluated: one with <3% volatiles and the other with >3% volatile (i.e. the use of some volatile solvent to reduce viscosity). The inter-laboratory studies were conducted in accord with ASTM E-691 "Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method." Three test materials at <3% potential volatiles (Method A) were evaluated for weight loss after curing by nine laboratories. Three other materials with >3% potential volatiles (Method B) were evaluated by eleven different laboratories. The fundamental change was to cure the radiation curable material before subjecting it to the oven bake cycle as prescribed in D-2369 and Method 24.

By January 1993, challenges to the test method resulting from committee ballot were resolved and the method for evaluating volatiles in UV/EB cured coatings was submitted to society ballot.⁶ This passed and is now ASTM D-5403, "Standard Test Methods for Volatile Content of Radiation Curable Materials." D-5403 has been reapproved and seen only slight editorial changes since its adoption. A presentation on this work and other RadTech environmental activities was given at EPA's Washington headquarters in October 1992. Through RadTech's efforts, including those of Alex Ross, the then Director of Regulatory Affairs, EPA Method 24 has been modified to include the D-5403 procedures. D-5403, Method A, calls for a minimum of 0.2 grams of test material; in Method B a wet film thickness of 50 m μ to 75 m μ is suggested. The wet film thicknesses of printing inks are considerably lower, <10 m μ and weigh <0.2 g even when applied on a wide area. Studies are being conducted to see how to properly determine the VOCs when these lower film thickness and weights are used. There are two difficulties: first, since radiation curable materials have near-zero VOCs, one is looking for practically no change when subjecting a radiation curable material to a VOC test; second, if gravimetric methods are to be used, one approaches the limits of any practical or commonly used laboratory balance.

The other major activity in RadTech pertaining to standards was the compilation of ASTM standards related to radiation curable materials, including tests relevant to the performance of the cured materials themselves. In 1988, Camille Kallendorf-Rechel authored RadTech's publication "Radiation Curing Test Methods." This 433 page volume was put together under a license agreement with ASTM.⁷ Since then, RadTech has cooperated with ASTM International and ASTM itself published "ASTM Standards Related to Testing of Radiation-Cured Coatings" in 2002.⁸ This more current edition is also available on compact disk (CD), which facilitates searching.

ASTM International Areas of Interest to Radiation Processing

To become engaged in standards development within a broad based organization as ASTM International, one must understand some basic definitions of terms that are used and accepted by the society for use with standards. These can be found in what ASTM calls its "Blue Book" – the "Form and Style for ASTM Standards."⁹ Some basic ASTM definitions and concepts are:

Test Method, n — a definitive procedure that produces a test result. Discussion: Examples of test methods include, but are not limited to: identification, measurement, and evaluation of one or more qualities, characteristics, or properties. A precision and bias statement shall be reported at the end of a test method.

Practice, n — a definitive set of instructions for performing one or more specific operations that does not produce a test result.

Discussion: Examples of practices include, but are not limited to: application, assessment, cleaning, collection, decontamination, inspection, installation, preparation, sampling, screening, and training.

Guide, n — a compendium of information or series of options that does not recommend a specific course of action.

Discussion: A guide increases the awareness of information and approaches in a given subject area.

Every test method shall contain a statement (1) regarding the precision of test results obtained in the same laboratory under specifically defined conditions of within-laboratory variability (repeatability conditions), and (2) regarding the precision of test results obtained in different laboratories (reproducibility conditions).

Repeatability conditions, n — conditions where independent test results are obtained with the same method on identical test items in the same laboratory by the same operator using the same equipment within short intervals of time.

Reproducibility conditions, n — conditions where test results are obtained with the same method on identical test items in different laboratories with different operators using different equipment.

In its development of D-5403, RadTech adhered to these definitions and developed a precision statement for the two methods in this "Standard Method of Test." This test and others that are related to the properties of radiation cured inks and coatings fall under the auspices of ASTM Committee D-01 on Paint and Related Coatings, Materials, and Applications. Several other ASTM committees engage in standards development of interest to the entire radiation processing industry:

D-01: Paint and Related Coatings, Materials, and Applications
D-07: Wood
D-09: Electrical and Electronic Insulating Materials
D-10: Packaging
D-11: Rubber
D-14: Adhesives
D-20: Plastic
D-30: Composite Materials
E-10: Nuclear Technology and Application
F-02: Flexible Barrier Packaging
F-04: Medical and Surgical Materials and Devices
F-25: Ships and Marine Technology

Within each committee, subcommittees have published standards that are relevant to the radiation processing industry. A few ASTM standards of interest are:

Committee D-01 on Paint and Related Coatings, Materials, and Applications:

- D-5403 Standard Test Methods for Volatile Content of Radiation Curable Materials
- D-7244 Standard Test Method for Relative Cure of Energy-Cured Inks and Coatings
- ASTM Standards Related to Testing of Radiation-Cured Coatings (Book and CD)
- Radiation Curing of Coatings by Joseph Koleske, MNL 45 Book: 240 pages

Committee D-14 on Adhesives:

D-1879 – Standard Practice for Exposure of Adhesive Specimens to Ionizing Radiation

This spells out dose-rates for different radiation sources:

Radioactive sources:

Electrical sources:

Gamma radiation Radioisotones	10^{3} to 10^{4} Gy/h 10^{3} to 10^{5} Gy/h	X-radiation Research accelerators	10^4 to 10^7 Gy/h 10^4 to 10^5 Gy/h
Reactor radiation	10^{3} to 10^{5} Gy/h	Industrial accelerators	10^{8} to 10^{9} Gy/h
(neutrons and gamma	ı)		

These distinctions have industrial consequence since dose-rate can have an effect on material response.¹⁰

Committee D-20 on Plastics:

- D-638 Standard Test Method for Tensile Properties of Plastics
- D-882 Standard Test Method for Tensile Properties of Thin Plastic Sheeting
- D-2838 Standard Test Method for Shrink Tension and Orientation Release Stress of Plastic Film and Thin Sheeting
- D-6248 Standard Test Method for Vinyl and Trans Unsaturation in Polyethylene by Infrared Spectrophotometry

Polyethylene (PE) is the most commonly used material in the major market segments (Figure 1) of wire and cable and of heat shrinkable films and tubing. The PE response to irradiation can be characterized using infrared spectroscopy and determining the changes in transvinylene content.¹¹ Arthur Charlesby, one of the pioneers of radiation chemistry, observed this in the late 1950s.^{12,13}

Committee D-09 on Electrical and Electronic Insulating Materials:

D-2671 – Standard Test Methods for Heat-Shrinkable Tubing for Electrical Use

Committee F-25 on Ships and Marine Technology:

• F-1837M – Standard Specification for Heat-Shrink Cable Entry Seals (Metric)

Heat shrinkable tubing is a major end-use for higher energy accelerators.

Sub-committee E-10.07 on Radiation Dosimetry for Radiation Effects on Materials and Devices:

- E-666 Standard Practice for Calculating Absorbed Dose From Gamma or X-Radiation
- E-1250 Standard Test Method for Application of Ionization Chambers to Assess the Low Energy Gamma Component of Cobalt-60 Irradiators Used in Radiation-Hardness Testing of Silicon Electronic Devices

Committee F-04 on Medical and Surgical Materials and Devices:

- F-2381 Standard Test Method for Evaluating Trans-Vinylene Yield in Irradiated Ultra-High-Molecular-Weight Polyethylene Fabricated Forms Intended for Surgical Implants by Infrared Spectroscopy
- F-2565 Standard Guide for Extensively Irradiation-Crosslinked Ultra-High Molecular Weight Polyethylene Fabricated Forms for Surgical Implant Applications

Medical device sterilization with electron beams and X-radiation derived from electron beams is a growing area. The ASTM committee dealing with medical devices relies upon the infrared analysis of the transvinylene in polyethylene to indicate the response to irradiation.

Sub-committee E-10.01 on Radiation Processing: Dosimetry and Applications:

 ISO/ASTM 51818 – Standard Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 80 and 300 keV

E-10.01 has thirty-six standards under its jurisdiction and five more in development. The paradigm for dosimetry is low dose-rate, high penetrating gamma irradiation. National standards laboratories use gamma sources for their referenced calibrations. Given the low dose-rate of gamma (10 kGy per hour), primary indications of "dose" or absorbed energy can be made using calorimetry. Benchmarking with transfer dosimeters has to be done to see if gamma calibrated dosimeters will relate to high dose-rate (100 kGy per second) EB process conditions. World-wide, there are ~160 commercial gamma irradiators, only ~10% of the total number of industrial radiation processing facilites.¹⁴

Low-energy Electron Beam Issues

Two of the national calibration laboratories (NPL in the United Kingdom and Riso, the Danish National Laboratory) have stated that: "calibration doses should, whenever possible, be delivered using the same accelerator, and the same operating conditions, that would be experienced during actual use."¹⁵ It has been shown that calorimetry techniques that can be used with the gamma sources for calibration of "dose" in terms of absorbed energy, heat rise in water or graphite, cannot be used with low-energy electron beam under operating conditions, that is while items pass under the beam. Static conditions had to be used with a laboratory beam.¹⁶ In the low-energy area, dosimeters that are often used for both gamma and higher energy electron beam irradiation are too thick for the limited beam penetration at low energies. A depth-dose profile develops within the dosimeter. It seems that if "dose" must be inferred or ascribed, use of energy deposition calculations via Monte Carlo codes combined with area throughput equations may have to be used. Many common dosimeters have some inherent issues involving consistency of materials and are sensitive to environmental factors, such as light, temperature and humidity. These are exacerbated at low energies. In many areas of industrial irradiation processing, more pragmatic tests, such as solvent rub tests for inks and coatings (ASTM D-7244 "Standard Test Method for Relative Cure of Energy-Cured Inks and Coatings") may be more useful. In using irradiation with plastics and rubber, the tensile modulus, for plastics above their melt transitions, can best be used to guide commercial operations.¹⁷ Many of the ASTM standards noted above are "Standard Methods of Test," and empirical, inter-laboratory tests were used to develop precision statements. This was what RadTech had done in developing ASTM D-5403, the VOC test method. Many of the documents pertaining to dosimetry, as those developed by ASTM subcommittee E10.01, are "Practices" and have not been subjected to inter-laboratory testing and comparison.

In using ionizing radiation, the term "dose" itself was derived from the medical community's interests in this form of energy for treatment or diagnosis. In 1925, the International Commission on Radiological Units (ICRU) was formed and by 1928 the Roentgen was defined as a quantity of energy as produced by irradiation as measured in a free air chamber.¹⁸ Early experiments, as those done by William Coolidge in the 1920's on the effects of irradiation on materials, quantified beam parameters, as voltage, distance from and time under the beam and their relation to material effects, with no mention of "dose."¹⁹ In the US, protocols or "standards" for using "dose" in regulated areas such as medical device sterilization have been developed by the industrial association, the Association for the Advancement of Medical Instrumentation, which was founded in 1967 (AAMI – www.aami.org). AAMI standards have been adopted by ISO. While the US Food and Drug Administration (US F&DA) prescribes upper "dose" limits for food irradiation, it does not specify "dose" requirements in other areas.²⁰ In

sterilization, the US F&DA inspectors defer to AAMI and ISO documents. Alternative indicators, other than the inference of "dose" for assessing sterility assurance, may be acceptable. The ISO referenced studies of bioburden kill are based on low dose-rate gamma irradiation.²¹ However, besides affecting material properties, differences in dose-rates have also been found in the ability of ionizing radiation from EB sources to cause cell death, with higher dose-rates being more effective.²² There is not as extensive a body of referenced information based on high current, high dose-rate EB effects on bioburdens as there is on studies based on low dose-rate gamma irradiation.

Opportunities for Standardization in Low-energy EB

Most of the standards involving ionizing radiation have been developed to accommodate the low dose-rate gamma processing industry. The paradigm for standards in radiation processing is gamma irradiation; the reference sources used by national laboratories are gamma sources. Yet there are five orders of magnitude difference in dose rate between gamma sources and high current electron beams. There are many factors encountered in the use of high current industrial accelerators that do not exist with gamma processing, notably high product through-put rates. EB systems are used because of their high production rates. The time to make a measurement becomes important when operating printing presses or coating lines in the order of hundreds of meters per minute, as does its reliability. Being off from an optimum process rate one way or another by ~10% can mean under-utilized production capacity or the accumulation of a large amount of scrap within a very few minutes.

The low-energy EB processing area offers opportunities for cooperative effort in three areas:

- As RadTech members pulled together to develop the Standard Method of Test for VOCs, D-5403, they can pull together to develop a "Standard Method of Test" to be used with low-energy electron beams. This means agreeing upon a method by consensus and subjecting that method to inter-laboratory round-robin testing. This is needed since endusers may have accelerators from several different low-energy EB equipment suppliers.
- In terms of bioburden testing, more recently developed techniques in molecular biology can help determine whether there have been sufficient chain breaks in the double-helix of DNA and consequent cell death.^{23,24} Deliberate contamination with a known bioburden can be assessed for survival following exposure to ionizing radiation using the polymerase chain reaction, PCR. PCR can multiply any survivor's DNA by six orders of magnitude. If there is no detectable bioburden DNA, the bioburden has been eliminated. This is a technique is used in forensics, such as in determining the decontamination of facilities that were affected by the deadly anthrax strain.²⁵ Thin test smears of bioburden, on the order of microns of thickness, could be used. Spore strips, commonly used with gamma and high-energy EB sterilization, are too thick for low-energy EB penetration.
- A common ground and means of evaluating the exposure of materials to ionizing radiation from high current accelerators must be sought within the entire electron beam processing industry. Materials development work can be done using low-energy electron beams and then scaled up for use with higher energy equipment or even X-radiation. This has been done in scaling up EB curable matrix materials for use in producing fiber reinforced composites.²⁶

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