HIGH-DOSE SECONDARY CALIBRATION LABORATORY ACCREDITATION PROGRAM

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Abstract - There is a need for high-dose secondary calibration laboratories to serve the multi-billion dollar radiation processing industry. This need is driven by the desires of industry for less costly calibrations and faster calibration-cycle response time. Services needed include calibration irradiations of routine processing dosimeters and the supply of reference standard transfer dosimeters for irradiation in the production processing facility. In order to provide measurement quality assurance and to demonstrate consistency with national standards, the high-dose secondary laboratories would be accredited by means of an expansion of an existing National Voluntary Laboratory Accreditation Program. A laboratory performance criteria document is under development to implement the new program.

INTRODUCTION

The multi-billion dollar radiation processing industry uses high doses of ionizing radiation to produce a variety of products and services, including sterilization of medical devices and supplies (such as disposable syringes, operating room drapes and gowns); modification of polymers (wire and cable insulation, rubber tires, and auto parts); and treatment of foods (extension of shelf life for fruits, control of salmonella in chicken). Dosimetry is the principal means of measurement quality assurance (MQA) for processors to assure that the product received the appropriate radiation dose, i.e., a dose adequate to produce the desired effect without causing product degradation. Proper calibration of the dosimetry systems is essential to the MQA programs of the processors.

NEED FOR ACCREDITATION PROGRAM

Most current dosimeter calibrations for the radiation processing industry are performed by the National Institute of Standards and Technology (NIST). Some calibrations are performed by the University of Maryland Dosimetry Laboratory; however, they are not recognized as an official secondary calibration laboratory since an accreditation program for high-dose applications does not presently exist. Due to the cost and occasionally long turn around time for these services, a number

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of facilities in the industry have expressed interest in becoming accredited high-dose secondary calibration laboratories.

TYPES OF PROCESSING FACILITIES

The radiation processing industry uses a variety of ionizing radiation sources for their material processing facilities. The majority of facilities use ^{60}Co gamma ray sources in large plaque arrays containing millions of curies. Dosimetry is performed by placing routine passive dosimeters on or within the product units that are cycled through the shielded irradiation vault. The process usually requires several hours to complete.

Electron beams are becoming increasingly popular as radiation sources for processing. The very high dose rates available provide very short irradiation times (seconds instead of hours) and, thus, higher throughput of product. The energies of the electrons utilized range from about 200 keV for the curing of surface coatings to about 10 MeV for bulk products. The routine dosimeters are usually placed on the surface of the product.

High-energy x-rays (bremsstrahlung), generated by new high-power electron accelerators, are starting to be used for radiation processing. The energies of the x-rays are limited to a maximum of 5 MeV to avoid any possible activation of the product. These x-rays combine the penetration characteristics of ^{60}Co gamma rays with the convenience of a machine source that can be turned on and off when desired. Dosimeters are used in a manner similar to that for gamma facilities.

CALIBRATION SERVICES REQUIRED

The calibration services that should be available from the secondary calibration laboratory include the irradiation of customer dosimeters to absorbed doses of about 100 Gy to 1 MGy (10 krad to 100 Mrad) in a reasonable time. Generally, this would be done with a well-characterized, calibrated ^{60}Co facility that provides a minimum dose rate of about 4 kGy/h. The laboratory should be able to supply high-quality, reference-class transfer dosimeters to customers for irradiation at the customer's facility. These reference dosimeters would be used either to go through the production irradiator side-by-side with routine dosimeters, or to calibrate the dose rate of the customer's in-house calibration source. If the secondary laboratory has an electron accelerator, it could also be used as a calibration source after appropriate calibration. All the radiation facilities employed by the secondary laboratory for calibrations must be shown to be consistent with and traceable to national standards by means of proficiency tests and appropriate measurement intercomparisons.

ACCREDITATION PROGRAM DOCUMENT REQUIREMENTS

There is currently an accreditation program called Secondary Calibration Laboratories for Ionizing Radiation (SCLIR), administered by the National Voluntary Laboratory Accreditation Program (NVLAP) at NIST (Eisenhower 1991). This program is concerned with MQA procedures at dose levels appropriate to personnel dosimetry and radiation therapy. NVLAP has expressed willingness to expand that program to include high-dose secondary calibration laboratories. As part of that expansion process, it was recognized that a laboratory performance criteria document appropriate to those high-dose areas is required. Additionally, an associated accreditation checklist for the assessors will be needed.

LABORATORY PERFORMANCE CRITERIA DOCUMENT

The performance criteria document is being developed as an American Society for Testing and Materials (ASTM) standard within Subcommittee E10.01 on *Dosimetry for Radiation Processing.*

The criteria are based generally on ISO/IEC Guide 25, *General Requirements for the Competence of Calibration and Testing Laboratories* (ISO/IEC Guide 25 1990).

The criteria document will include:

Part A. Section on general criteria that is very close to ISO/IEC Guide 25, retaining that text pertaining to calibration activities while deleting that material pertaining to testing laboratories

Part B. Section making the material of Part A specific to ionizing radiation applications

Part C. Section on specific performance requirements for a secondary calibration laboratory for dose levels appropriate to radiation processing.

Part A will contain general criteria sections, including scope; references; definitions; organization and management; quality system, audit, and review; personnel; accommodation and environment; equipment and reference materials; measurement traceability and calibration; calibration methods; handling of calibration items; records; certificates and reports; sub-contracting of calibration; outside support services and supplies; and complaints.

Part B will set out the specific requirements for a laboratory dealing with ionizing radiation. It will amplify and interpret the general requirements of Part A. It can also be used as a guide for radiation calibration laboratories in developing and implementing their quality systems.

Part C will provide the specific performance requirements for the secondary calibration laboratory, such as level of agreement with national standards of the dose rates in their calibrated radiation fields; types of radiation sources available; types of radiation measurement instruments available; types of associated electronic measurement and test equipment available; and physical arrangements in radiation areas to minimize scattering effects and changes in energy spectra.

ACCREDITATION PROCESS

Accreditation of a secondary calibration laboratory under NVLAP consists initially of the laboratory submitting its Quality Manual (including all quality control [QC] and MQA procedures) to the assessors for evaluation. If the Manual is found to have significant deficiencies, the laboratory is asked to make appropriate modifications. If the Manual is found to be satisfactory, the next step is for proficiency tests to be performed for all types of radiation calibration categories for which the laboratory requested accreditation. This may involve the use of new transfer instruments such as calorimeters for high-power electron and x-ray beams. Once these tests are successfully completed, an onsite assessment is performed by a team of NVLAP selected and trained Technical Experts. The assessors observe the laboratory personnel performing routine calibrations and examine equipment performance and all aspects of the laboratory operations. Any deficiencies observed are pointed out and discussed with the laboratory staff. After completion of the onsite visit, a report of the

assessment results is written. Any deficiencies must be corrected to the satisfaction of the Technical Expert team. After all aspects of the laboratory performance are found to be satisfactory, the laboratory is granted official NVLAP accreditation.

After being accredited by NVLAP, the laboratory can show that a strong MQA program is in place and prove traceability of their dosimetry systems to federal regulatory agencies (such as the U.S. Food and Drug Administration) and to any potential customers of their services. An accredited laboratory that is part of a large company can provide calibration services to its own internal company facilities. This can save them money and provide faster turnaround.

CONCLUSIONS

The ASTM draft laboratory performance criteria should be ready for ballot by the end of 1993 and should gain final approval within a year after that. The assessor check list will be developed within NVLAP in parallel with the ASTM document. NVLAP should be able to offer accreditation of laboratories in the program as soon as the performance criteria standard receives final approval.

Benefits to the radiation processing community (Inn et al. 1993) for the operation of the high-dose secondary calibration laboratory program include:

- Assurance of product quality
- Demonstrated integrity of calibration services
- Satisfaction of regulatory requirements
- Defense of litigation
- Public assurance
- Cost effectiveness and competitive operations
- Consistent technical assessments
- Reduced number of audits.

In addition, the processing community has the opportunity to provide real and substantial input into the development of the ASTM performance criteria document. This is valuable in that the document is a consensus of the views of the entire community as well as helping in the development of internal MQA programs for the processors.

REFERENCES

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