QUALITY AUDIT SERVICE OF THE IAEA FOR RADIATION PROCESSING DOSIMETRY

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ABSTRACT

The mandate of the International Atomic Energy Agency includes assistance to Member States to establish nuclear technologies safely and effectively. In pursuit of this, a quality audit service for dosimetry relevant to radiation processing was initiated as a key element of the High-Dose Standardization Programme of the IAEA. The standardization of dosimetry for radiation processing provides a justification for the regulatory approval of irradiated products and their unrestricted international trade. In recent times, the Agency's Dosimetry Laboratory has placed concentrated effort towards establishing a quality assurance programme based on the ISO 9000 series documents. The need for reliable and accurate dosimetry for radiation processing is increasing in Member States and we can envisage a definite role for the SSDLs in such a programme.

1. INTRODUCTION

Several guidelines and standard practices presently exist that provide recommendations that should be followed for the radiation processes, such as sterilization of health care products and food irradiation. These publications have been developed - and are frequently updated - by the international and regional organizations, such as ISO, WHO, FAO, CEN, ASTM and AAMI[1] [1-5]. One of the principal concerns of all the guidelines is process validation, the objective of which is to establish documentary evidence that the radiation process will reliably achieve the desired results. The key element in process validation is a well characterized, reliable and accurate dosimetry system that is traceable to a Primary Standard Dosimetry Laboratory (PSDL).

To help the developing Member States to establish such a dosimetry system in particular, and the radiation processing technology in general, the IAEA started the High-Dose Dosimetry Programme in 1977 [6]. This program is now firmly established and has created a strong impact on the processing industry. It has helped several laboratories and industrial facilities in the developing countries to install the new technology in a confident fashion. The principal vehicle of the achievement has been the quality audit service called the International Dose Assurance Service (IDAS) which was initiated in 1985 [6].

For the last more than ten years, this service has been operating successfully fulfilling its objectives in the field of radiation processing applications (dose range = 0.1 to 100 kGy). The long-range objective, however, would be to involve the SSDLs in this programme in a fashion similar to their involvement in the radiotherapy dosimetry. The need for reliable and accurate dosimetry for radiation processing is increasing in Member States, and we can envisage a definite role for the SSDLs in such a programme.

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[1] ISO - international Organization for standardization
WHO - World Health Organization
FAO - Food and Agriculture Organization
CEN - European Committee for Standardization
ASTM - American Society for Testing and Materials
AAMI - Association for the Advancement of Medical Instrumentation.

2. OBJECTIVES OF IDAS

The standardization of dosimetry provides a justification for the regulatory approval of irradiated products and the unrestricted international trade of such products. The principal objective of the IDAS is thus to assist Member States in establishing a reliable dosimetry system in their radiation facilities in order to meet stringent requirements for dose measurement, and to achieve quality control in radiation processing. It is expected that the facility has an operating dosimetry system that has been calibrated and hopefully traceable to a PSDL. The IDAS then provides an independent check on all the components of the dosimetry system; for example, dosimeters, analysis equipment, procedure for the use of the dosimeters, any computer software being used, and the skill of the technical staff. This is essential, since having a calibrated dosimetry system is not sufficient for an acceptable QA programme. Thus, participation in the IDAS is the first step, and an important one, towards a comprehensive audit of the dosimetry system in use at a facility. At present, the IDAS is available for cobalt-60 gamma rays only; however, it is anticipated that a similar service for electron beams would be available in near future.

3. PROCEDURE

The IDAS fulfills its objective by providing the transfer standard dosimeters to the participating laboratories and radiation processing facilities. This service is similar to the IAEA/WHO quality audit service for the radiotherapy centres using TL dosimetry. A dosimeter set, used for one dose point, consists of three dosimeters for irradiation and one as a control, where each dosimeter is within its own capsule. The three dosimeters are then irradiated together as a set by the facility operator along with their routine or reference dosimeters under similar irradiation conditions. The irradiated dosimeters and the control dosimeter are then returned to the Agency's Dosimetry Laboratory for evaluation, along with the information on the irradiation conditions, such as the temperature of the dosimeters during irradiation. The dosimeter response is then analyzed, the relative deviation of the participant's dosimetry calculated, and the results conveyed to the participant. The action level is 5%; thus, a follow-up action is initiated if the relative deviation is outside this limit. This would generally involve advice and discussion through letters and a repeat measurement. If the discrepancy persists, an expert from the region may be requested to visit this facility to help correct the situation.

4. TRANSFER DOSIMETER

The transfer dosimeter used for the IDAS is alanine-ESR. The selection of the dosimeter was based on several intercomparisons that were conducted by the IAEA in early 1980s for this specific purpose [6]. Other candidate dosimeters were: radiochromic dye film, ceric-cerous sulphate and ethanol chlorobenzene. Overall, the alanine-ESR was judged to be the most suitable dosimeter for the IDAS for several reasons, for example: near-tissue equivalency, insensitivity to ambient environment, broad useful dose range, non-destructive analysis, and little fading of the response with time.

There were two negative factors against the choice of the alanine-ESR system then: (a) there was not much experience with this system; no PSDL or SSDL was using it on a regular basis, and (b) the analysis equipment, namely the ESR spectrometer was significantly costly. However, a quick review of the field of dosimetry today reveals that both these negative factors have almost disappeared and thus the selection of alanine-ESR as a transfer dosimeter seems to be vindicated:

- almost every PSDL and SSDL is now using alanine-ESR as a reference or a transfer system, and

- the price of the ESR spectrometer has decreased substantially. Today, a dedicated ESR spectrometer for alanine can be purchased for about $50 000 with an on-line computer system.

The alanine dosimeters presently in use at the Agency's Dosimetry Laboratory are the commercially available Aminogray dosimeters which are rod type: 30mm long and 3mm in diameter. The dosimeter consists of polystyrene (30 wt%) as the binder material and DL-α-alanine (70 wt%). The dosimeter is placed inside a polystyrene capsule which provides the required buildup material to achieve secondary electron equilibrium for the cobalt-60 gamma rays and also provides a controlled environment for the dosimeter.

The response of the alanine dosimeter depends slightly on the irradiation temperature; the value reported by several users for the temperature coefficient varies between 0.15% and 0.30%/°C. We have measured this parameter for our dosimeters for 15 and 45 kGy; and its value for our experimental conditions is 0.23%/°C over this dose range as seen in Fig. 1.

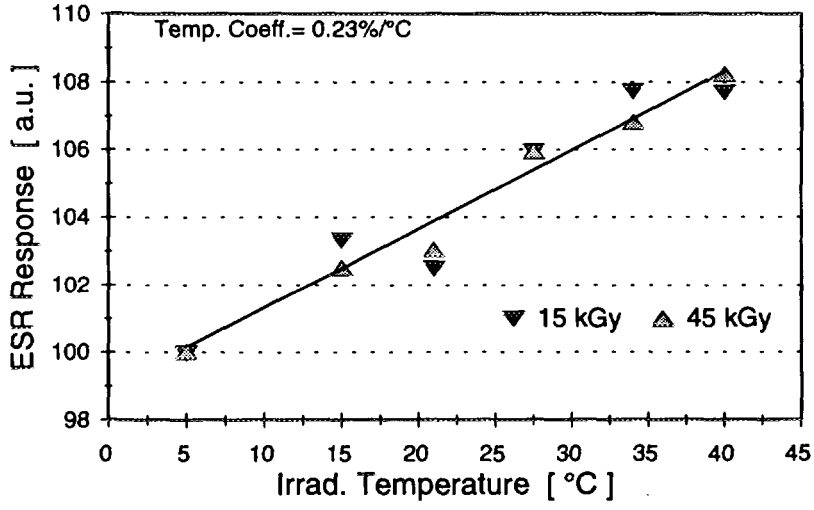

Fig. 1. The effect of the irradiation temperature on the ESR response for the Aminogray alanine dosimeters (▼ 15 kGy and Δ 45 kGy). The two sets of responses are normalised at 27.5°C. Based on these data, the irradiation temperature coefficient is +0.23%/°C.

We have also studied the fading characteristics of the ESR signal with time after irradiation over about 5 months for two dose values and three irradiation temperatures. In all cases, the dosimeters were exposed to about 50% relative humidity for 2 to 3 months before irradiation, and the temperature of storage before and after irradiation was 20-25°C [7]. The observed fading for all the cases investigated is about 1% over this time period (see Fig. 2).

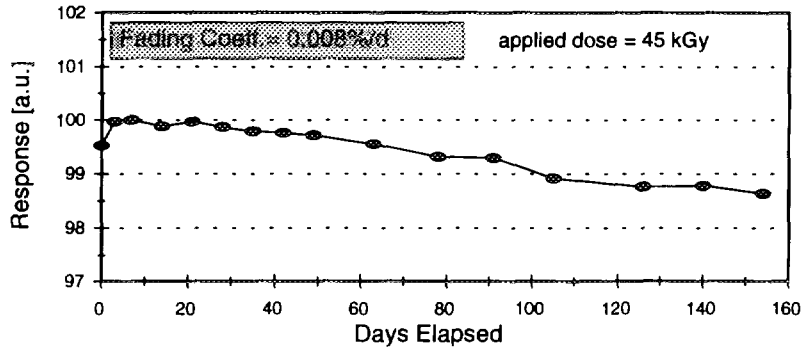

Fig. 2. The slow decrease of the ESR response (fading) for the Aminogray alanine dosimeters over several months after irradiation. The observed degree of fading is similar for the two dose values (15 and 45 kGy) and the three irradiation temperatures (15, 27.5 and 40°C) used for this study.

5. QUALITY ASSURANCE PROGRAMME

It is the policy of the IAEA to operate the IDAS at the highest possible quality standard. To achieve this, we have placed concentrated effort in recent times towards establishing a quality assurance programme for the Agency's Dosimetry Laboratory. To the extent that is relevant, the technical requirements of the QA programme are based on the guidelines described in the ISO 9000 series documents, specifically GUIDE 25: General Requirements for the Competence of Calibration and Testing Laboratories [8]. The QA programme for the laboratory includes the QA Manual and several Standard Operating Procedures (SOPs) describing the various dosimetry systems in use at the Agency's Dosimetry Laboratory and the services afforded by the laboratory. The two SOPs relevant to radiation processing are:

a) *Maintenance of the Transfer Standard Dosimetry System for Radiation Processing (SOP-3).* This SOP describes the procedures for the use of the alanine-ESR reference dosimetry system relevant to radiation processing. Such procedures include acceptance criteria, and handling and storage conditions for the dosimeters; analysis methods and calibration procedure; and operation and maintenance of the necessary equipment.

b) *Dose Quality Audit Service for Radiation Processing (SOP-9).* This SOP describes several aspects of the service, including the objectives of the service, the criteria and procedure for participation, the detailed operating procedures, responsibility for the service, and the nature of the response in case of deviations outside the acceptance limits.

Since the reference dosimetry system is the key to the quality audit service, the quality assurance programme in place at the Agency's Dosimetry Laboratory to maintain this dosimetry system is elaborated in details here. The purpose of the SOP-3 is to help ensure the quality of the reference dosimetry system through documented policies and procedures. It thus creates an element of trust in the quality of the dosimetry system and the service. The SOP also addresses the four key elements of a quality assurance programme: calibration and traceability, a comprehensive statement of uncertainty in the measurement system, audit checks, and documentation.

Calibration: The alanine-ESR dosimetry system is calibrated over the full useful range of the IDAS, namely from 0.1 to 100 kGy of the absorbed dose to water. The dosimeters are irradiated in the two in-house self-shielded cobalt-60 facilities (Gammacell 220 of AECL) to cover the entire dose range. They are irradiated in a specially designed PMMA phantom such that three dosimeters can be irradiated simultaneous. The temperature of the dosimeters is controlled for all irradiations. A fourth-order polynomial expression provides the best fit to the 18 calibration points.

Traceability: The dose rate at a reference point in the gamma field of the high dose-rate Gammacell is traceable to the National Physical Laboratory (PSDL of UK) through dichromate transfer dosimeters. Also, this value of the dose rate was compared with several other PSDLs, namely Bureau International des Poids et Mesures (BIPM), Physikalisch-Technische Bundesanstalt (PTB, German PSDL) and Bundesamt fur Eich- und Vermessungswesen (BEV, Austrian PSDL). Fig. 3 shows the network of calibrations and comparisons for the dose rate measurements of the three irradiators of the Agency's Laboratories in Seibersdorf:

i. teletherapy unit (dose rate ~0.50 Gy/min at 100 cm from the source) is used for calibrating TL dosimeters and ionization chambers,

ii. Gammacell 1 (dose rate ~2.2 Gy/min in the center of the irradiation chamber) is used for the alanine dosimeters for the IDAS, and

iii. Gammacell 2 (dose rate ~47 Gy/min in the center of the irradiation chamber) also used for the alanine dosimeters for the IDAS.

These dose rate values are valid for January 1997. The teletherapy unit was calibrated using an ionization chamber that was calibrated at the BIPM. The Gammacell 1 was calibrated using the Fricke dosimetry system from the PTB. This Fricke dosimetry was then compared with the secondary standard ionization chambers (traceable to BIPM) in the teletherapy unit beam; the agreement was within the uncertainty of the dosimetry systems. Recently, the dose rate in both the Gammacells was measured with a small ionization chamber in collaboration with the BEV. Again, the agreement between the values was within the uncertainty of the dosimetry systems.

The QA programme requires that the dose rate measurements in the Gammacell be undertaken by a PSDL at least once in three years. In addition, measurement intercomparisons are also performed between the Agency's Dosimetry Laboratory and other calibration laboratories. For example, in collaboration with BIPM, the IAEA recently carried out a 'double-blind' intercomparison amongst nine high-dose calibration laboratories using its transfer dosimetry system; this was restricted to cobalt-60 gamma rays only. The agreement amongst all the participants was within 2.1% (1σ) at 15 kGy, and 2.4% (1σ) at 45 kGy. Also, the mean of the dose values measured by the Agency's Dosimetry Laboratory was within 1% of the mean of the dose values stated by the participants for both dose levels.

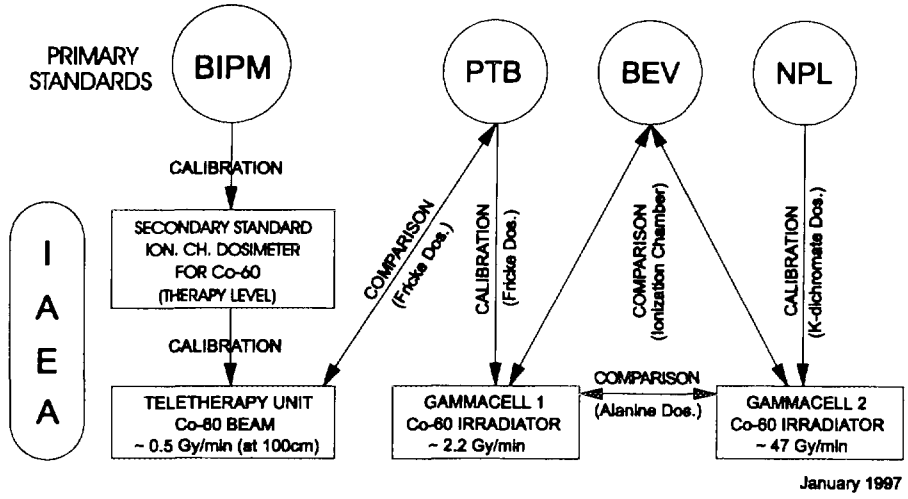

Fig. 3. The network of calibrations and comparisons for the dose rate measurements of the three irradiators of the Agency's Laboratories in Seibersdorf.

Uncertainty: The result of a measurement is only an approximation or an estimate of the value of the measurand and thus is complete only when accompanied by a statement of uncertainty in that estimate. Following the ASTM Standard Guide for Estimating Uncertainties in Dosimetry for Radiation Processing [9], the entire dose measurement system was divided into various components, sub-components and activities. The contribution to the uncertainty in the measured dose value from each of these activities was identified and the values assigned to Type A and Type B categories [10]. These contributions are then combined to yield the overall estimate of the uncertainty value. The three components and the associated uncertainties (1σ) are:

1. determination of the dose rate at the reference point in the Gammacell (1.05%);
2. calibration of the alanine-ESR dosimetry system (1.11%); and
3. dose measurement at an unknown location using the calibrated dosimetry system (0.35%, for a 3-dosimeter set, and assuming no contribution due to irradiation-temperature or fading correction).

The uncertainty in the first component is largely transferred from the calibration laboratory that measured the dose rate for our reference field. The second component, namely the calibration of our dosimetry system using the in-house reference field, consists of four sub-components: irradiation of the dosimeters, ESR analyses of the irradiated dosimeters, intra-batch variability and polynomial fit of the calibration data. The last component includes: ESR analyses and the intra-batch variability. It assumes here that the effects of the irradiation temperature and fading have been compensated perfectly. Thus, adding the three components in quadrature, the combined uncertainty in the measured dose value is 1.7% (1σ).

Audit Check: To assure and verify that the reference dosimetry system is performing at the highest quality level, the SOP-3 requires that a comprehensive audit be performed at regular intervals. Two different levels of audits are in place:

- Compliance with Procedures: the objective is to review the procedures followed in the laboratory and to ensure that there are no discrepancies between these and the requirements laid out in the QA programme. This audit is conducted by the Internal Audit Group of the Agency's Laboratories in Seibersdorf (RIAL).
- Dosimetry Audit: the objective is to provide the check on the quality of the transfer standard dosimetry system and also on the entire procedure used in the IDAS. The protocol developed and used for this audit is such that the exercise includes checks on all the relevant activities, for example, data transfer, retrieval of the calibration data, data manipulation using computer software and the skill of the technical staff. It is conducted by a Primary Standard Dosimetry Laboratory.

If the audit findings are at a variance with the QA programme requirements, immediate actions are needed as stated in the QA Manual to correct the situation. All audits and the review findings, and any corrective actions that arise from that are documented.

Documentation: A safe and secure recording system is set up to retain all original observations, calculations and derived data, calibration and maintenance records, audit reports and calibration certificates. These records contain sufficient information to permit their revalidation or repetition.

6. CONCLUSION

The International Dose Assurance Service is now well established for the cobalt-60 gamma rays. The quality assurance programme for the reference dosimetry system is nearly established and we are confident that the service provided to the Member States is of high quality. However, we are well aware that it is important to maintain and improve such a programme through constant vigil.

We are addressing this in several ways:

- periodic review of the quality assurance programme for its currency and relevance,
- organizing intercomparisons with calibration laboratories,
- continuously reviewing the uncertainty estimates for various components of the dose measurement system, and
- periodic audit checks as required by the QA programme.

7. FUTURE

It is conceivable that in a near future several members of the present IAEA/WHO SSDL Network would have established the capability for dosimetry for radiation processing. At that time, the Agency's Dosimetry Laboratory would be interested in organising an intercomparison involving interested SSDLs. Also, similar to the radiotherapy dosimetry, some of these SSDLs will be able to assist the IAEA in the quality audit service by helping the IDAS participants in their countries or regions for resolving critical situations. We would like to hear from any laboratory that is planning to expand in this field.

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