International dose assurance service

An IAEA programme for quality control in radiation processing

by J.W. Nam

Radiation processing today offers technological advantages in the fields of sterilization, food preservation, and in processing plastics and a variety of other products widely used in modern society. For food irradiation, in particular, the number of irradiated food items approved for consumption has increased considerably in recent years. In the near future, it is envisaged that food irradiation will become a regular commercial process as more countries come to recognize its safety and economic importance.

Reliable dosimetry is a key requirement for good irradiation practice and quality assurance of irradiated products. Accurate dosimetry, therefore, is a prerequisite for safe and legal plant operations in radiation processing.

Since 1977, the Agency has been implementing a new programme on high-dose dosimetry for the development of quality control measures by standardizing dosimetry for radiation processing. A new component of this programme is the International Dose Assurance Service (IDAS), which is provided for irradiation facilities in the IAEA's Member States. The aim of IDAS will be to meet stringent requirements for standardization of dosimetry, and to achieve concerted international efforts for quality assurance in radiation processing.

As part of initial efforts, dose intercomparisons already have been performed with 19 laboratories in 14 countries and one participating international organization. In parallel, a co-ordinated research programme — with activities concentrated on the study of quantities affecting reliability and accuracy — has been organized for necessary investigations. (Throughout a series of dose intercomparison studies with several candidate dosimeters, the alanine/ESR dosimetry system was found to be the most appropriate one for this particular purpose. It has shown consistent and stable behaviour to cover the entire dose range of gamma radiation for 10 gray to 100 kilogray for radiation processing practices.)*

Pilot project

Before the start of the service on an international scale, a pilot service project with 15 selected commercial radiation processing plants in 14 countries was executed. The result was excellent in general, whereas the mean ratio between nominal dose and estimated dose was 0.98. However, the overall deviation varied between minus 23% and plus 26%. The need for the International Dose Assurance Service was demonstrated, and so far, no organizational problems involved in its operation, or in the behaviour of the alanine/ESR dosimetry system under practical conditions, have been found.

IDAS is being provided on the basis of an agreement between the Member State and the Agency, and commercial and non-commercial irradiation facilities — as well as high-dose applied research institutes dealing with gamma radiation doses from 10 gray to 100 kilogray — are invited to participate. Member States of the Agency are asked to designate the irradiation facilities for participation in the service and to indicate acceptance of the agreement.* For each participating facility, the Agency requests that data relevant to the service's provision is provided with notification of participation. Designated facilities, however, may be screened due to a limited capacity of the service.

Member States party to the IDAS agreement that import irradiated goods will recognize a certain dose assurance as an internationally accepted standard, but they are not obligated to import irradiated goods under the agreement.

Service procedures

Within 3 months of IAEA's receipt of notification of participation, the details of the appropriate service for the participating facility will be determined. The facilities will then be sent the required number of dosimeters in accordance with an agreed schedule. Details will be provided as to conditions of use for dosimeters and as to their return mailing to the evaluation laboratory.

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^{*} See report of the IAEA Advisory Group on High-Dose Pilot Intercomparison, Vienna (9—13 November 1981); and Research in Radiation Processing, IAEA-TECDOC-321 (1984).

^{* &}quot;Agreement Concerning the Provision of a Dose Assurance Service by the IAEA to Irradiation Facilities in its Member States".

Dosimeters returned after irradiation will be read by means of an electron-spin-resonance analysis of radiation-induced free radicals in alanine. Results will be communicated, together with a certification, to respective facilities within a period not exceeding 20 days after receipt of the irradiated dosimeters.

Operation of the alanine/ESR dosimetry laboratory is being provided under a contract with the Gesellschaft für Strahlen und Umweltforschung (GSF) in Munich, Federal Republic of Germany. The Agency, therefore, is subsidizing GSF for the production of dosimeters, ESR readouts, mailing of dosimeters, and related work.

According to the cost-recovery principle for the service, participating facilities will be requested to reimburse part of the immediate expenditure incurred by the Agency for IDAS, which totals US \$20 000 a year. (See box, page 50). Participants will be directly invoiced by the IAEA for a service charge to be paid annually. (Since this service agreement is made between the IAEA and its Member States, the government concerned will be responsible for assuring payment.)

All data the participating facility communicates to the IAEA for provision of the service will be kept in confidence. In particular, the results of the service will be kept confidential and will not be published or otherwise made known to unauthorized persons. In providing its service under the agreement, the Agency will not assume any liability for compensation of damages as a result of the dose assurance given.

Early results, future plans

Over the several months IDAS has been in operation, 44 dose checks have been performed for 20 cobalt-60 and one caesium-137 irradiation facility that are being operated at l9 institutes or plants in 13 countries. Results have been very good in general; however, the overall deviation varied between minus 28.8% and plus 22.7%.

Currently, IDAS only deals with photons. The service for electron beams will be implemented in the near future. Recently completed was a series of intercomparison studies using calorimeters under standardized conditions in 10-MeV electron beams. Two national laboratories would provide standardized 10-MeV electron beams in order to supply two dose ranges (low: 0.01 to 3 kilogray; high: 5 to 100 kilogray) for dose intercomparison.

A series of electron dose checks — using candidate dosimetry systems supported by a co-ordinated research programme — presently is in progress with four participating national dosimetry laboratories. A comprehensive IDAS for both photon and electron irradiation facilities is expected to be carried out beginning in 1988.

Importance of reliable dosimetry

Reliable and accurate dosimetry as a quality control measure has been particularly stressed in the field of food irradiation. In 1981, the Expert Committee for Wholesomeness of Irradiated Food of the Food and Agriculture Organization (FAO), World Health Organization (WHO), and IAEA noted that the operation of irradiation facilities should be subject to supervision by the appropriate national authorities to ensure that proper dose control is exercised. In this regard, the high-dose standardization programme of the Agency was noted for calibration of dosimeter and dose assurance. Moreover, the Codex Alimentarius Commission stated that the control of the food irradiation process within the facility shall include the keeping of adequate records, including quantitative dosimetry using a recognized and calibrated dosimetry system to ensure the correct operation of the process. It was also stressed by the International Association for Industrial Irradiation in its professional regulation for industrial irradiation that the irradiation doses should be kept by the plant operator.*

Applying the appropriate dose is thus the key to the technologically and economically proper application of food irradiation. Proper determination of "average dose" and "maximum overall average absorbed dose (10 kilogray)" can therefore be fulfilled by doing standardized dosimetry.

International effort

Until recently, there was no concerted international effort to achieve measurement standardization of dosimetry and dose assurance for large radiation sources. It is, therefore, the objective of IDAS, which is organized by the IAEA within the framework of its high-dose standardization programme. It is envisaged that IDAS results can be used by national authorities for quality control of radiation processing, as well as for licensing and inspection of the facility. Furthermore, the standardization of radiation processing dosimetry provides a justification for the regulatory approval of irradiated products and the basis of international clearance for free trade.

^{*} See Wholesomeness of Irradiated Food, report of a Joint FAO/IAEA/WHO Expert Committee, Technical Reports Series 659, WHO, Geneva (1981); Codex Alimentarius, Volume XV, Joint FAO/WHO Food Standards Programme; Codex General Standard for Irradiated Foods; and Recommended International Code of Practice for the Operation of Radiation Facilities used for the Treatment of Foods, FAO/WHO (1984); and International Association for Industrial Irradiation Newsletter, No.14, Professional Regulations for Industrial Irradiation (1986).