

International Atomic Energy Agency

Regional Training Course on IAEA Validation and Process Control for Gamma Radiation Processing

PROSPECTUS

- Project Number & Title:** RER/1/014 – ‘Introducing and Harmonizing Standardized Quality Control Procedures for Radiation Technologies’
- Place (City, Country):** Budapest, Hungary
- Dates:** **23-27 June 2014**
- Deadline for Nominations:** 25 April 2014
- Organizers:** The International Atomic Energy Agency (IAEA) in collaboration with the Government of Hungary through the Centre for Energy Research of the Hungarian Academy of Sciences
- Host Country Organizer:** Mr Andras Vilmos Kovacs
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- Language:** English
- Purpose:** The purpose of the training course is to provide theoretical and practical training in the field of validation and control for gamma radiation processing, while the requirements of the sterilization standard with focus on the dosimetric aspects in Installation Qualification, Operational Qualification, Process Qualification and routine Process Control.
- Expected Output(s):** The expected outputs of the training course are:
- Knowledge of participants enhanced as per Quality Assurance/Quality Control (QA/QC) requirements for gamma radiation facility operation as well as dosimetry for process control;
 - Participants capable of conducting national training courses on the subject with the technical support of an experienced expert.

Scope and Nature:

The course will provide lectures and practical training in radiation processing dosimetry, and in international standards for radiation sterilization.

The programme will cover the calibration of routine dosimeters to be used in operational qualification measurements at a ⁶⁰Co gamma irradiation facility. Performance qualification experiments will involve dose mapping of medical products to be sterilized by gamma radiation. Different type of routine dosimeters – calibrated earlier – will be used in routine gamma sterilization process control and measured afterwards. Lectures will be given on product testing, material selection for radiation sterilization, and the role of dosimetry in installation-,operational-,and performance qualification.

Background Information:

Radiation processing exists in many European countries mainly for the sterilization of medical products and for the production of advanced polymer materials. The planned further expansion of the European Union will result in increased trade, requiring strictly controlled radiation technologies through standardized quality control methods and procedures. EU and national authorities introduced new standards and regulations related to health care products, pharmaceuticals, food treatment and further development in radiation processing. Regional activities were initiated and carried out to help the establishment of radiation processing technologies and to check the existing quality control procedures in the region in industrial gamma and electron beam facilities.

Building on the achievement of previous TC regional project, such as RER/8/017 “Enhancing Quality Control Methods and Procedures for Radiation Technology” (2009-2011) and RER/1/011 “Introducing and Harmonizing Standardized Quality Control Procedures for Radiation Technologies” (2012-2013), project RER/1/014 aims at facilitating the harmonization of selected national standards with the international standard ISO11137. In particular, through regular dosimetry intercomparison exercises for improved quality assurance and advanced training, the project will facilitate the implementation of product and process control measures, enforced by the EU and national laws and regulations, which in turn is essential for the successful and safe operation of installations.

To this end, this course represents a valuable opportunity to provide regional specialists with advanced training in the field of gamma radiation processing validation and control for the safe operation of irradiation facilities, towards further harmonization of national standards with ISO11137.

Participation:

The training course is open to 12 participants from Member States in the TC Europe Region involved in the regional TC project RER/1/014. For this event, the target countries are those where gamma radiation processing technologies are established or soon to be introduced, namely: Albania, Azerbaijan, Bulgaria, Croatia, Czech Republic, Hungary, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Malta, Montenegro, Moldova, Poland, Romania, Portugal, Russian Federation, Slovenia, Serbia, Tajikistan, The former Yugoslav Republic of Macedonia, Turkey, Ukraine and Uzbekistan.

Participants' Qualifications: The participants should be technical specialists (e.g., physicists/ engineers) with hands-on experience in gamma radiation process control. First priority shall be given to those candidates who are working directly in the field of gamma radiation processing technologies or are planning the introduction of this technology in the country.

Nomination Procedure: Nominations should be submitted to the IAEA online through the Technical Cooperation Department's InTouch system (<http://intouch.iaea.org>). Should this not be possible, nominations may be submitted on the standard IAEA Application Form for Training Courses (available on the IAEA website: <http://www.iaea.org/>). Completed forms should be endorsed by relevant national authorities and returned to the Agency through the official channels, i.e. the designated National Liaison Office for IAEA Matters.

The completed nomination forms should be sent to the Programme Management Officer for this project, Ms Alessia Rodriguez y Baena, through IAEA Official Fax (+43-1-26007) or E-Mail (Official.Mail@iaea.org), not later than 25 April 2014. Nominations received after this date or which have not been routed through the established official channels cannot be considered.

Administrative and Financial Arrangements: Nominating Governments will be informed in due course of the names of the candidates who have been selected and will, at that time, be given full details of the procedures to be followed with regard to administrative and financial matters.

Selected participants from countries eligible to receive technical assistance will be provided with a round trip economy class air ticket from their home countries to Budapest, Hungary, and a stipend sufficient to cover the cost of their accommodation, food, and minor incidentals. Shipment of accumulated training course materials to the participants' home countries is not the responsibility of the IAEA.

The organizers of the training course do not accept liability for the payment of any cost or compensation that may arise from damage to or loss of personal property, or from illness, injury, disability or death of a participant while he/she is travelling to and from or attending the training course, and it is clearly understood that each Government, in nominating participants, undertakes responsibility for such coverage. Governments would be well advised to take out insurance against these risks.