REPORT

of the TECHNICAL MEETING on the

“QA/QC IN MANAGEMENT SYSTEMS FOR IRRADIATION FACILITIES”

05-09 August 2019,
Kuala-Lumpur, Malaysia
# TABLE OF CONTENTS

1. INTRODUCTION AND OBJECTIVES OF THE MEETING ............................................. 3  
2. HIGHLIGHTS OF THE MEMBER STATES PRESENTATIONS ..................................... 4  
   ARGENTINA ......................................................................................................................... 4  
   BRAZIL ................................................................................................................................. 4  
   HUNGARY ............................................................................................................................ 5  
   INDIA ..................................................................................................................................... 7  
   INDONESIA ........................................................................................................................... 7  
   JORDAN ................................................................................................................................ 8  
   KOREA, REPUBLIC OF ....................................................................................................... 8  
   MALAYSIA ........................................................................................................................... 9  
   MYANMAR ........................................................................................................................... 9  
   PHILIPPINES ..................................................................................................................... 9  
   POLAND .............................................................................................................................. 10  
   RUSSIAN FEDERATION ................................................................................................... 10  
   SLOVAKIA ............................................................................................................................ 11  
   SRI LANKA ......................................................................................................................... 11  
   TUNISIA .............................................................................................................................. 11  
3. PRESENT STATUS OF QA/QC/QMS IN PARTICIPATING MEMBER STATES .......... 12  
4. CURRENT STATUS OF ISO CERTIFICATION, TRACEABILITY AND DOSIMETRY IN PARTICIPATING MEMBER STATES ................................................ 16  
5. EMERGING CHALLENGES IN DOSIMETRY FOR QA/QC OF NON-Routine PRODUCTS AND NEW APPLICATIONS ........................................................................ 17  
6. INTEGRATED MANAGEMENT SYSTEMS AT IRRADIATION FACILITIES: THE NEW CONCEPT .................................................................................................................. 17  
7. THE NEEDS OF COUNTRIES IN EARLY STAGES OF IMPLEMENTING QMS . 18  
8. REVISION OF QA/QC GUIDELINES ........................................................................ 18  
9. ACHIEVEMENTS OF IAEA REGIONAL TC PROJECTS RELATED TO QA/QC IN RADIATION PROCESSING AND STEPS FOR INITIATING REGIONAL TC PROJECTS ........................................................................................................................... 20  
10. EXPECTATIONS FROM IAEA ............................................................................... 21  
11. CONCLUSIONS ............................................................................................................. 22  
12. THE WAY FORWARD ................................................................................................... 23  
ANNEX I - COUNTRY TECHNICAL REPORTS .............................................................. 24  
ANNEX II ............................................................................................................................. 144  
ANNEX III ......................................................................................................................... 148
1. INTRODUCTION AND OBJECTIVES OF THE MEETING

Radiation processing has become a well-accepted technology for applications such as radiation sterilization of medical devices, polymer crosslinking and curing, food irradiation, with over 250+ gamma radiation facilities and over 1600 electron beam accelerators working throughout the world. QA is vital for implementing these technologies with standardized and harmonized procedures of process validation and process control. Further, the Quality Assurance/Quality Control processes for radiation technologies need to be integrated with quality standards and guidelines being recommended by international and national organizations namely, the International Organization for Standardization (ISO), European Committee on Standardization (CEN), etc.

IAEA has been working with Member States to help introduce quality management system and the relevant procedures at irradiation facilities at different level by providing a set of guidelines for the development, validation and process control in this field. Based on the requests and information from the Member States, IAEA organize the Technical Meeting on ‘Strengthening QA/QC Protocols in Radiation Facilities Through Dosimetry Inter-comparison’ in Vienna from 1 to 5 October 2018 at the IAEA to review the status of present understanding of quality management system of irradiation facilities, and the meeting participants agreed that implementing QA/QC is very important in radiation processing. However, it was found that there are differences concerning the level of implementation QM practices among MS belonging to same region. Based on the presentations of the participants, it was shown that the Regional TC Projects reduced the gap among MS: countries with longer and more advanced practices shared their expertise and gave support to other countries.

Therefore, IAEA organized this technical meeting to share up-to-date information with Member States on the present status of QA/QC practices being followed in radiation facilities and on the systematic strategy for conducting a radiation dosimetry inter-comparison. This event will include the Presentation of country reports and discussions of achievements, Lectures from experts in the area, Exercises for routine management of irradiation facility and irradiation facility excursion at the Malaysian Nuclear Agency and Discussion of future work.
2. HIGHLIGHTS OF THE MEMBER STATES PRESENTATIONS

ARGENTINA

Argentina has a long tradition in radiation processing. Starting at CNEA in the 60’s with applied research irradiations -in a gamma cell 220- for different applications, it was followed by the design and put into operation of the first multipurpose $^{60}$Co irradiation facility in the country (PISI) and a mobile irradiator for SIT application (IMO), with a subsequent technology transfer which gave rise to the construction of IONICS’ first industrial irradiator and another irradiator for SIT applications. There are at least three in-house low energy e-beams for polymer applications. Dosimetry activities started at CNEA in an early stage, with transference standard dosimeters (potassium and silver dichromates and Fricke) and routine dosimeters (potassium nitrate), all made at the CNEA’s High Dose Dosimetry Laboratory (HDDL). When routine dosimetry started being carried out by operators at the irradiation facility in the late 90’s, PMMA routine dosimetry systems were adopted, and IQ/OQ/PQ started being performed at PISI according to the ISO 11137. More recently, dichromates were replaced by alanine dosimetric system, which is traceable to NPL. HDDL participated in several IDAS exercises and coordinated five regional dosimetry inter-lab exercises within the framework of different IAEA regional projects. Both multipurpose irradiation facilities have certified their quality management system based on ISO 9001:2015, and an integrated management system is being implemented at PISI.

Integrated management systems highly contribute to the efficient fulfillment of installations’ objectives by unifying all relevant aspects of irradiation facilities-such as quality, safety, occupational health, good irradiation practices and environment- in a single structure, assuring continuous improvement to achieve the highest levels of compliance with customers and regulatory requirements with strong focus on client’s satisfaction and contributing to the overall results, some of which are intangible aspects directly related to human factors, such as improvement of public perception, motivation and increase in confidence and trust of workers, as well as the enhancement of safety/quality/good irradiation practices/continuous improvement cultures. This motivated the proposal of a regional project with the overall objective of harmonizing integrated management systems and good irradiation practices procedures at irradiation facilities of Latin America and the Caribbean, the RLA1015.

BRAZIL

Until recently, at the end of the 1990s, protection, hygiene, product quality and convenience The Nuclear and Energy Research Institute–IPEN mainly through the Multipurpose Gamma Irradiation Facility and the Electron Accelerator Facility located inside the University of São Paulo campus have developed irradiation technology. These facilities have treated by radiation processing several materials for disinfection, sterilization, crosslinking, etc. Many radiation processing applications developed at IPEN are related to a desired effect in the irradiated material as curing or cross-linking of hydrogels, wire and cables or the consolidation of cultural heritage materials using a resin. Disinfection of cultural heritage objects or sterilization of human tissues needs to be applied between a maximal dose to avoid degradation of the irradiated materials and a minimal dose to ensure the biological effect. In this sense, many policies related to the Quality Assurance and Quality Control have been developed. Processes definition, installation qualification, operation qualification, performance qualification and routine process control procedures have been applied to satisfy the requirements of standards as ISO 11137 and ISO 13004. Industrial dosimetry systems as well PMMA, alanine, FWT, CTA, etc. have been implemented and validated with high efficiency. The Nuclear and Energy
Research Institute also implanted an Integrated Management System under the ISO 9001 to control the mean process including the related to the radiation processing. The IPEN has been actively participating in IAEA regional projects as the RLA 1013 to promote the dosimetry inter-comparison and the RLA 1015 to harmonize integrated management systems and good irradiation practice procedures in irradiation facilities. Additionally, in this work are described the mean Brazilian irradiation facilities and their associated quality assurance and control systems.

**HUNGARY**

In Hungary R&D in radiation chemistry is performed at the Centre for Energy Research of the Hungarian Academy of Sciences. The practical applications, i.e. industrial gamma radiation processing is carried out at the Dispomedicor Co. Ltd and at the Agroster Co. Ltd, while a pilot scale gamma irradiation plant is in operation at the Institute of Isotopes Co. Ltd. Additionally the design and construction of experimental and industrial gamma irradiation facilities, as well as the production of various radioactive isotopes for medical and industrial purposes is performed at the

*Centre for Energy Research, Hungarian Academy of Sciences, Budapest*

The Centre for Energy Research is part of the research network of the Hungarian Academy of Sciences. The Centre for Energy Research was established in January 2012 on the basis of two former independent Institutions, the Atomic Energy Research Institute and the Institute of Isotopes. At 2015 Institute of Technical Physics and Materials Science became part of the Centre for Energy Research.


At the Centre for Energy Research, Hungarian Academy of Sciences (MTA EK) a 4 MeV energy, LPR-4 type linear electron accelerator (Tesla Vuvet, Czech Republic) is in operation for R&D purposes in radiation chemistry (e.g. for waste water treatment). The facility is certified according to ISO 9001:2008 and the process control activities are performed by using low energy polystyrene calorimeters (Danish Technical University, Roskilde, Denmark) and ethanol-monochlorobenzene (ECB, ISO/ASTM 51538) and aqueous alanine solutions.

*Institute of Isotopes Co. Ltd., Budapest*

Radiation processing has been established in the sixties of the 20th century based on the well-developed radiation chemistry R&D in the fields of radiation sterilization, polymer modification and food processing in various research centres. In the former Institute of Isotopes of the Hungarian Academy of Sciences, (now Institute of Isotopes Co. Ltd.) a pilot ⁶⁰Co gamma irradiation facility was built in the late sixties for R&D and pilot scale radiation sterilization of medical devices, for polymer and food processing of 120 kCi nominal activity. The facility is in continuous operation with well-established quality management system.
The company is:
audited according to ISO-9001 standard;
audited according to ISO 14001 standard;
GMP audited according to EU regulations;
audited according to ISO 13485 standard.

The company can use the CE mark for medical devices according to the EU regulations.

The radiation technologies are performed on the basis of ISO 11137 using various liquid and solid state reference and routine dosimetry systems for process control – mainly ethanol-monochlorobenzene solution - based on ISO/ASTM dosimetry standards related quality control procedures having traceability to the Danish Technical University (DTU) (former Risø National Laboratory).

As this irradiation facility is a semi-industrial one, during the last few years the emphasis has been put on special condition irradiations. Thanks to the participation in the previous cooperation the dose measurement procedures and quality of the dosimetry reports have been improved significantly.

The main challenge for the Quality Management System are the special irradiations, (radiation aging) where the customers have special requirements.

To execute the irradiations at the requested level either previous validations are used, or customers’ audits are carried out either before the irradiation, or during the irradiation.

Dispomedicor Co. Ltd., Debrecen

An in-house industrial gamma irradiation facility was established 40 years ago and is still in operation at the Dispomedicor Co. in Debrecen. The JS-6900 (Nordion, Canada) carrier type, continuous mode $^{60}$Co facility is operated according to ISO 9001:2008 sterilizing mainly the medical products produced at this company. The company uses ethanol-monochlorobenzene dosimeter solution (ISO/ASTM 51538) for routine process control having traceability to the Danish Technical University.

The recent $^{60}$Co activity of the facility is quite low, therefore the company is examining the possibility of purchasing additional gamma sources.

AGROSTER Irradiation Company, Budapest

The AGROSTER Irradiation Company was established in 1982 with the ownership of the government. The company has a commercial, multipurpose, pool type, $^{60}$Co gamma service irradiator, where the products are treated in carriers in an amount of about 450 t/year. The largest part of the products are healthcare and laboratory devices, different packaging materials, animal foods, base materials of healthcare and cosmetics, while 30-35% of the products are spices and herbs. The AGROSTER works under control of three certified and continuously operated QMS, i.e. ISO 9001, ISO 13485. The treatment of food makes the application of HACCP system also necessary. At the AGROSTER for process control the ECB chemical dosimeter is used with high frequency conductivity evaluation technique. Besides ECB dosimeter Fricke dosimeter is used as a reference system to calibrate radiation field and calibrate routine dosimeter. The ECB dosimetry system is traceable to the Danish Technical University. The company is also considering to purchase additional $^{60}$Co sources in the near future.
INDIA
Radiation processing is a well-established industry in India with nearly 25 gamma irradiators and 15 electron beam facilities successfully operating in the country for applications such as sterilization of medical products, food irradiation, pet feed irradiation, sewage sludge hygienization, modification of polymeric materials and treatment of gem stones. The radiation processing industry related to sterilization and food industry is a highly regulated industry and most clients require an accredited Quality Management System (QMS) such as ISO 9001, ISO 11137 and specific standards for treatment of their products. Therefore, most of these facilities follow well established International Standards ensuring product quality, meeting necessary regulations thus gaining acceptance by the end users. Radiation Standards and Safety Division (RSSD) at Bhabha Atomic Research Centre (BARC) is the main laboratory entrusted with the responsibility of maintaining appropriate national and international standards, traceability to international standards, conducting dose inter-comparison exercise for standardization of dosimetry in facilities across the country, conduct dose audit program for radiation processing facilities, providing calibrated dose to standard and non-standard geometry samples under standard reference conditions as well as calibration of spectrophotometer and instruments related to dosimetry. The availability of trained human resources in radiation meteorology equipped with state-of-the art measurement facilities ensure that radiation processing applications are implemented in effective and efficient manner for a wide variety of applications.

INDONESIA
In Indonesia, food irradiation technique has been acknowledged as useful treatment for various food products and has been used by food companies, Small to Medium Enterprise (SMEs) and government agencies for various applications. The vastly growing needs of business sector on the use of food irradiation has made Indonesian government enacted regulations related to the application of this beneficial technique since 1980s, following research in food irradiation which was started in the 1960s decade. The Ministry of Health and National Agency for Drugs and Food Control (BPOM) has been playing their important role in adapting international codex on food irradiation and monitoring function to the use of food irradiation technique by various sectors across nation. In cooperation with National Nuclear Energy Agency (BATAN), the Ministry & BPOM continuously develop & strengthen regulatory framework to accommodate vastly growing needs from industrial sectors on this technique, as well as to adapt with new technologies in the field. To ensure safety applications of irradiation technique, BPOM enacted Regulation Number 3 of 2018 as the newest standard for reference. Indonesia now operates 3 gamma irradiators which provide irradiation services to the customers. Two of them are operated by government agency, National Nuclear Energy Agency, BATAN, at Jakarta & South Tangerang city. The only private-owned gamma irradiator is operated by Rel-Ion Co. at Cikarang city (25 km east of Jakarta). There are 5 (fives) Companies operated electron beam machine for their own production process. In year 2016, The National Nuclear Energy Agency of Indonesia (BATAN) and Izotop-Hungary signed the agreement regarding the construction of the gamma irradiation facility. The gamma irradiator facility call as Irradiator Gamma Merah Putih (IGMP), inaugurated on November 15, 2017, was built with the scheme of cooperation in technology transfer and its local content reached 80%. IGMP was designed to be an irradiator prototype on a commercial industrial scale that could be used as an example for the application of similar technology by investors in many potential areas in Indonesia. Complementing with the gamma irradiator BATAN intent to develop high energy electron accelerator will be carried out through technology transfer cooperation with EB Tech Co. Ltd. South Korea. The MoU signed by both parties at Vienna-Austria on May 30, 2017.
Milestone approach for radiation facility project urgent to develop and implemented to ensure self-reliance and sustainability of the radiation technology project. Regulatory aspect and management system were implemented to keep high safety standard and ISO 14470 regarding Food Irradiation and Validation and ISO 11137 regarding Healthcare Products Irradiation and Validation need to be implementing because it has become the demands and requirements of the customer.

**JORDAN**

Jordan is equipped with a gamma irradiation plant that is being used for treatment of medical and food products. The plant is in operation since 2000 and the process control is conducted using ECB dosimetry. The presentation focused on irradiation and dosimetric capabilities in Jordan and the procedures being followed to implement the ISO 11137-1 paragraphs showing the extent of compliance with the following elements: Quality management system elements, Sterilizing agent characterization, Process and equipment characterization, Product definition, Process definition, Validation, Routine monitoring and control as well as product release after sterilization, Maintaining process effectiveness.

**KOREA, REPUBLIC OF**

Korea Association for Radiation Application (KARA) is established to contributes to the use of radiation and radioisotopes, promoting safety and industrial development, and communication of networking among members in Korea. Recently, KARA has established an irradiation facility to provide calibration, testing and irradiation services for radiological equipment. This irradiation facility was built with government support and is located in Jeongup, Jeollabuk-do. This facility consists of a Quality Assurance center for medical radiation, Accredited Testing center for radiation device and has established a standard radiation field as set out in ISO 4037. In addition, KS Q ISO/IEC 17025 was obtained from KOREA Laboratory Accreditation Scheme (KOLAS) for the quality management of the facility, radiation measurement, and dosimetry. In South Korea, the Korea retrospective dosimetry working group formed in 2016 to improve the capability of dosimetry techniques and to offer prompt joint assistance. There are three methodology groups in dosimetry working group: biodosimetry, electron paramagnetic resonance (EPR) dosimetry, and thermoluminescence (TL) – optically stimulated luminescence (OSL) dosimetry. Currently, intercomparison exercises are ongoing in each methodology group. EPR dosimetry is one of the physical dose assessment methods. Alanine-EPR dosimetry systems are used in reference or transfer standard or routine dosimetry systems in radiation applications that include sterilization of medical devices and pharmaceuticals, food irradiation, polymer modifications, medical therapy, and radiation damage studies in materials [1]. In general, the range of absorbed doses for which the alanine dosimeter can be used is between 1 and $1.5 \times 10^5$ Gy for photons and electrons irradiation. This dosimeter is used at relatively high dose compared to TL dosimeter (TLD) or radio-photoluminescence glass dosimeter (RPLGD). It is also suitable for long-term accumulated dose assessment because it has very low fading and repeated measurements are possible. Therefore, the alanine dosimeter, which is well known as the standard dosimeter in EPR dosimetry, was selected as the first intercomparison sample. Five laboratories participated in this alanine-EPR intercomparison. The Korean Association for Radiation Application (KARA), Korea Institute of Radiological and Medical Sciences (KIRAMS), Dongnam Institute of Radiological and Medical Sciences (DIRAMS), and Radiation Health Institute (RHI) participated in the dose assessment of blind samples. A fifth laboratory, the Korea Atomic Energy Research Institute (KAERI) was in charge of irradiation of the intercomparison samples to maintain the neutrality of the blind doses. This intercomparison is considered to be the initial step toward establishing a cooperation system.
among the laboratories using EPR dosimetry methods in South Korea. This also was an opportunity to improve the reliability of the EPR measurement system in each laboratory.


MALAYSIA
Malaysia has ten irradiation facilities with six of them are using gamma radiation and four plants are using electron beam machine. From six gamma irradiation facilities, four of them are private entity and mainly for sterilization of medical devices. Another two facilities belong to the government that provide services to the industries as well as R&D projects. There are three private electron beam irradiation facilities and one owned by government. All facilities are certified with quality management system at least ISO 9001. There are also having certified by functional certified body like ISO 13485, ISO 14001 and OHSAS 18001. In Malaysia, QMS’s are in placed in order to ensure that the QAQC activities are followed and implemented accordingly. All facilities are working align with customer’s requirement based services together with legal requirement that enforced by Malaysian government.

MYANMAR
Currently, only research gamma cell 5000 with dose rate 0.792 kGy/hr is functioning and it is used as versatile tool for research and development activities and sterilization of health care products. Myanmar is implementing to promote radiation processing technology in Ministry of Education and in private sectors. Myanmar is implementing national projects as MYA1015 and MYA1017 for establishing an electron beam irradiation facility, MYA2018001 for capacity building for commercial gamma irradiator and MYA 8033 establishing a national secondary dosimetry laboratory. Human resource program is being developed under the national projects and India-Myanmar joint project. The Ministry of Education conducted national level awareness seminar for radiation processing technologies (electron beam & gamma) with the RCA experts under RCA/UNOSSC program in 2017 and national level executive management awareness seminar for electron beam application technology with IAEA expert under MYA1017 program in 2018. QA/QC is vital for radiation processing technology and human resource for Quality Management System is enhanced under the national projects. The MYA1017 members are doing the experiments with Fricke dosimeter and Ceric-cerous dosimeter for dose calibration of gamma cell. Moreover, dose distribution experiments are done with Fricke dosimeter for low dose and Ceric-cerous dosimeter for high dose. In addition, a study of comparison of dosimeters between Ceric-cerous and alanine dosimeters is also done. The QA/QC methodologies are being practiced with existing gamma cell for implementation in future envisaged irradiators.

PHILIPPINES
In the Philippines, two irradiation facilities were established at the Philippine Nuclear Research Institute. These are the Multipurpose Gamma Irradiation Facility (MGIF) and the Electron Beam Irradiation Facility (EBIF). The MGIF is a semi-commercial, semi-automated, two-pass, batch and tote box-type irradiator, which is used for the decontamination of spices, herbal products, dehydrated vegetables, cosmetic raw materials, sterilization of medical devices and
packaging materials, and irradiation of R&D samples. The Model ELV-8 electron accelerator is supplied by EB Tech Co., Ltd., and can be operated from 1 to 2.5 MeV, with a maximum current of 50 mA and a maximum power of 100 kW. The cart conveyor system is used for the irradiation of solid and small volume of liquid samples while the liquid handling system is used for the irradiation of large volume of liquids/solutions such as carrageenan solution for plant growth promoter. In the MGIF, ethanol chlorobenzene and alanine dosimetry systems are used for routine irradiation while B3 WINdose and alanine dosimetry systems are used in the EBIF. The dosimetry systems are traceable to the National Physical Laboratory. Installation qualification, operational qualification and performance qualification were performed after each installation in the two irradiation facilities. The quality management system of the irradiation facilities is certified to ISO 9001:2015 and ISO 11137 standard is complied for the validation, process control and routine monitoring in the radiation sterilization of health care products. In 2020, the MGIF will be upgraded to a commercial-scale, 4-pass, fully automated batch/continuous tote box type irradiator and there will be source replenishment of about 150 kCi.

**POLAND**

To improve QA/QC procedures in the European Member States in 2017 IAEA started a project titled: “Inter-laboratory Comparison in Technical Dosimetry Conducted to Improve QA/QC Procedures in Radiation Processing in the European Region”. IAEA decided that 15 facilities from 11 countries would take part in the test and it would be carried out by the Institute of Nuclear Research and Technology in Poland. The test would consist of two identical rounds. 10 facilities had gamma irradiators, and 5 EB accelerators. It was expected that the comparison exercise would help to assess the performance quality of the dosimetric systems and the procedures in use at the participating facilities. The exercise would also provide the user’s measurements with the traceability to international standards. The test was carried out using method 1, i.e. the reference laboratory sent the standard transfer dosimeters for irradiation to participating laboratories and read out the doses after dosimeters came back. The doses obtained by the participants were calculated using the calibration curves prepared by the Reference Laboratory. The deviations from the nominal dose were then calculated. The deviations were from -14.4% to +7% for gamma facilities and from -11% to +28% for EB accelerators. Two participants withdraw from the second stage of the test and four new participants declared to take part in the second stage.

**RUSSIAN FEDERATION**

In Russia Federation the Budker Institute of Nuclear Physics develops and delivers ELV accelerators. It is main manufacturer of accelerator for industrial application. These accelerators are the most popular Russian accelerators and well known in the world. ELV accelerators are used for EB for polymer treatment: modifying of cable insulation and production of foamed polyethylene. The most of them (except extra old) have EB power of 100 kW. Typical maximum energy is 1.5 MeV or 2.5 MeV.

We had cooperation in delivering of accelerators with 2 companies: from China and republic Korea. ELV accelerators are operating with technology equipment that was produced in Russia, Austria, China, Republic of Korea and etc. Everywhere it was a good synchronization between accelerator and technologies.
In cooperation with our partners companies we are delivering “turn key” accelerators with the set underbeam, pay off and take up system that allows to treat the cables with very big area of dimensions and purpose to applications.

SLOVAKIA

The first and so far, the only facility for radiation treatment in Slovakia started its operation at the University Centre of Electron Accelerators of the Slovak Medical University in 2012 in Trencin. The facility was designed for research and industrial applications and it is running a 5 MeV 1 kW linear electron accelerator equipped with a beam-scanning system, a conveyor line and an X-ray converter. Although it could be used also for routine radiation processing in an industrial-like mode, its main purpose is focused on research and on revealing potential applications with the main aim to bring the new technology in country into practise.

A routine dosimetric system used at the UCEA accelerator is based on B3 radiochromic films evaluated by a Spectrophotometer Genesys20. The routine dosimetric system can be used in the range of doses of 1 – 100 kGy and it is calibrated by RISO polystyrene calorimeters, traceable to national standards. For dosimetry of lower doses, in the range of Gy, the FARMER ionization chamber is used at the facility.

In 2014 we implemented the ISO 9001 standard for Quality Management System in Radiation processing by beam of accelerated electrons and the EN ISO 13485 in Sterilization of medical devices using the beam of accelerated electrons.

The examples of on-going research activities and the most significant scientific facility achievements in the area of medicine, environment, technology and cultural heritage were presented.

SRI LANKA

Sri Lanka Gamma Centre is the first government owned open access gamma irradiation facility in Sri Lanka which belongs to the Sri Lanka Atomic Energy Board. It is in commercial operation since 2014 January catering mainly healthcare and food processing sectors of the country. It serves as the National Centre for gamma irradiation services and research and development center for gamma radiation processing. Approximately 4070 m$^3$ of medical products especially surgical gloves, surgical aprons and gauze swabs were irradiated in the year 2018 and earned. Also about 60 MT of spices, tea and herbal products were irradiated for the international market so far. Sri Lankan government was able to stop importation of the surgical gloves completely and save billions of foreign exchange within the country with the establishment of the facility. In addition to that it opens the path for the production of many more health care products within the country.

SLGC has been achieved ISO 9001 and 13485 quality management systems in order to provide quality irradiation service to customers. The Dosimetry, Microbiology and Food Technology Laboratories established within the premises are capable to provide better service to customers. The process effectiveness is maintained with the continual improvement in accordance with the quality management systems.

TUNISIA
Tunisia has two irradiation facilities located at the National Center for Nuclear Science and Technology (CNSTN): a Cobalt-60 gamma irradiator and a semi-industrial electron beam accelerator.

Gamma facility was commissioned in 1999 with maximum capacity of 100 kCi and is used until today for food preservation, sterilization of medical products and treatment of cultural heritage products.

EB facility has variable energy (from 5 to 10 MeV) and a maximum power of 5 kW. Since the beginning of warranty period (2010), several defects were encountered and the facility was totally stopped in June 2011 due to breakdown of a part of modulator (PFN : Pulse Forming Network).

It was only in 2017 that the accelerator has become operational again and a part of requalification work (IQ, OQ and PQ) of the facility with the assistance of an IAEA expert has been performed.

It is now planned to work on stabilization of the energy of the electron beam and on the obtaining of a certain reliability of the accelerator by solving the problems related to conveyor, cooling system and vacuum.

### 3. PRESENT STATUS OF QA/QC/QMS IN PARTICIPATING MEMBER STATES

<table>
<thead>
<tr>
<th>S. N</th>
<th>Member State</th>
<th>Institution s/ Facilities</th>
<th>Standard Followed</th>
<th>Dosimetry</th>
<th>Traceability/Intercomparison</th>
<th>Specific Needs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Argentina</td>
<td>CNEA/ PISI (government ) IONICS (private) Both multipurpose gamma cat. IV* *there are 2 gamma irradiators for SIT and at least 3 in-house low energy e-beams for polymer applications</td>
<td>ISO 9001/14001/450 01/11137/14470</td>
<td>PMMA (routine) Alanine (transfer/routine / Fricke)</td>
<td>NPL/ YES</td>
<td>Systematization of interlabs Training on Montecarlo based software for dosimetry</td>
</tr>
<tr>
<td>2.</td>
<td>Brazil</td>
<td>-Nuclear and Energy Research Institute-IPEN/03 gamma and 03 EB</td>
<td>ISO 9001 ISO 11137 ISO 13004 ISO 17025</td>
<td>-PMMA, alanine, FWT-60, CTA</td>
<td>Inside IAEA inter-comparison projects RLA 1013, dose certification by NIST.</td>
<td>-Dose certification e.g. IDAS-IAEA -Dosimetry inter-comparison projects and activities -Training on PLC systems address to irradiation facilities -Recycle training on QA/QC/QMS</td>
</tr>
<tr>
<td>#</td>
<td>Country</td>
<td>Description</td>
<td>Safety Culture Address to Irradiation Facilities</td>
<td>TC in Uncertainty Calculation and Dosimetry</td>
<td></td>
<td></td>
</tr>
<tr>
<td>----</td>
<td>--------------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>---------------------------------------------------</td>
<td>---------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Hungary</td>
<td>1. Centre for Energy Research of HAS</td>
<td>ISO 9001</td>
<td>DTU Risö; Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Institute of Isotopes Co. Ltd.</td>
<td>ISO 9001, ISO 14001, ISO 13485</td>
<td>DTU Risö; Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Agrostar Co. Ltd.</td>
<td>ISO 9001</td>
<td>DTU Risö; Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. Dispomedico Co. Ltd.</td>
<td>ISO 9001</td>
<td>DTU Risö; Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Most facilities are ISO 9001 compliant with ISO 11137 and following other relevant standards</td>
<td>ECB, Fricke, aqueous alanine, B3 film, PS calorimetry ECB, Fricke</td>
<td>TC in uncertainty calculation and dosimetry</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ceric-Cerous is the most widely accepted dosimetry system for gamma irradiation</td>
<td>Fricke ECB</td>
<td>TC in uncertainty calculation and dosimetry</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>National standards laboratory at BARC, traceable to NPL. Dose inter comparison conducted within the country.</td>
<td>DTU Risö; Yes</td>
<td>TC in uncertainty calculation and dosimetry</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>India</td>
<td>Department of Atomic Energy; About 25 gamma irradiators and 15 Electron beam accelerators in the country mostly in private sector</td>
<td>Ceric-Cerous is the most widely accepted dosimetry system for gamma irradiation</td>
<td>Inter comparison with international laboratories.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Indonesia</td>
<td>National Nuclear Energy Agency; two Gamma Irradiator</td>
<td>Certified ISO 9001:2015, OHSAS 1801:2007, ISO 17025</td>
<td>Training in Dosimetry for High dose</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Most facilities are ISO 9001 compliant with ISO 11137 and following other relevant standards</td>
<td>dosimeter Fricke solution as a reference standard dosimeter and for routine dosimeters are used red and amber Perspex dosimeters,</td>
<td>Training in ISO 13347, ISO 11137 and ISO 14470</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Indonesia SSDL/not yet conduct inter comparison</td>
<td>IndRisö</td>
<td>Fellowship in Entrepreneurship on Irradiator Business Services</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Training in Dosimetry for High dose</td>
<td></td>
<td>Fellowship on designed and EPC of High energy accelerator</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Jordan</td>
<td>Jordan Atomic Energy Commission /two irradiators; industrial&amp; research</td>
<td>ISO 9001, ISO 13485, ISO 11137, ISO 14470</td>
<td>Inter comparison with INCT Warsaw- Poland, in two trials</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Republic Of Korea</td>
<td>Korean Application for</td>
<td>ISO/IEC 17025</td>
<td>-KRISS/conduct intercomparison</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Ion chamber</td>
<td></td>
<td>Training in Dosimetry for High dose</td>
<td></td>
<td></td>
</tr>
<tr>
<td>#</td>
<td>Country</td>
<td>Organization/Institute</td>
<td>Standards/Qualifications</td>
<td>Materials/Equipment</td>
<td>Dosimetry/Related Activities</td>
<td></td>
</tr>
<tr>
<td>----</td>
<td>---------------</td>
<td>----------------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td></td>
</tr>
</tbody>
</table>
| 8  | Malaysia      | Malaysian Nuclear Agency                                                               | ISO 9001, ISO 13485, ISO 11137, ISO 17025                                              | Ceric cericous, Fricke CTA                                                        | - Traceable to IAEA through Nuclear Malaysia’s SSDL Secondary Standard  
- Intercomparison - under SSDL for gamma irradiation (Sinagama) this year and followed by EB irradiation (ALURTRON)  
- New dosimetry system  
- ISO 14470 for Food Irradiation  
- Technical support on intercomparison and dosimetry for EB  
- Uncertainty budget for gamma and EB |
| 9  | Myanmar       | Ministry of Education Gamma Cell 5000 (1)                                              | -                                                                                      | Fricke, Ceric-cerous, FWT-60 Film, Gamma chrome YR Perspex                         | SSDL lab is established for  
intercomparison on way with Malaysia (MNA)  
Standard practices/experience for ISO 13347, ISO 11137 and ISO 14470 for near future irradiator |
| 10 | Philippines   | Philippine Nuclear Research Institute                                                  | ISO 9001, ISO 11137                                                                  | Ethanol, chlorobenzene, alanine, B3 WINDose CTA, Gafchromic Fricke                 | Traceable to National Physical Laboratory  
a. Dose intercomparison in the region  
b. Expert mission for the determination of uncertainty of different dosimetry systems  
c. Expert Mission on dosimetry of flow systems e.g. for plant growth promoter  
d. Training course/Workshop on dosimetry in radiation processing  
e. Training on ISO 11137, 13004, 13485, 14470 |
| 11 | Russia        | Budker Institute of Nuclear Physics, SB RAS                                             | Certified - ISO 9001, - National certificates                                         | Film dosimeters, direct measurement of beam current, alumina plates for energy measurements | Russian Institutes: VNIIFTRI, Agriculture, Technical physics and automatic, Biological centre  
Training in Dosimetry for High dose |
| 12 | Slovakia      | University Centre of Electron Accelerators of SMU in Trenchin /EB                      | ISO 9001, ISO 13485, ISO 11137                                                       | B3 films calibrated by RISO, Polystyrene calorimeters, Ionization chamber          | Traceable to NPL indirectly through RISO, Inter comparison with INCT Warsaw- Poland 2017/2019  
TC on uncertainty calculation and dosimetry  
TC on dosimetry in radiation processing |
<table>
<thead>
<tr>
<th>No.</th>
<th>Country</th>
<th>Certification Details</th>
<th>Dosimeter Details</th>
<th>Action Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>13</td>
<td>Sri Lanka</td>
<td>Sri Lanka Gamma Centre of Sri Lanka Atomic Energy Board Certified ISO 9001:2015</td>
<td>Ceric Cerouse Red &amp; Amber PMMA Fricke</td>
<td>The last intercomparison was carried out with RISO High Dose Reference Laboratory in 2017 which is traceable to NPL. 1. A programme to carry out intercomparison studies in regional/inter-regional wise through IAEA. 2. Training/workshop on uncertainty estimation in dosimetry measurements</td>
</tr>
<tr>
<td>14</td>
<td>Tunisia</td>
<td>CNSTN/gamma ISO17025 ISO 11137 ISO/ASTM 51649 (and all other Standards on DOSIMETRY</td>
<td>Genesys 5 UV-Vis Genesys 20 Vis PMMA Fricke</td>
<td>Aerial SSDL / not yet conduct intercomparison - acquisition of Aérial Dosasap dosimetry system for EB - calibration of dosimetry systems - certification ISO 9001 - certification ISO 11137 - establishment of SSDL at CNSTN</td>
</tr>
<tr>
<td></td>
<td></td>
<td>for RADIATION PROCESSING)</td>
<td>Alanine Riso Riso Calorimeter Riso aluminium wedge</td>
<td></td>
</tr>
</tbody>
</table>
4. CURRENT STATUS OF ISO CERTIFICATION, TRACEABILITY AND DOSIMETRY IN PARTICIPATING MEMBER STATES

<table>
<thead>
<tr>
<th>S.N</th>
<th>COUNTRY</th>
<th>ISO STANDARD</th>
<th>ISO 11137</th>
<th>TRACEABILITY</th>
<th>PROFICIENCY IN UNCERTAINTY</th>
<th>AUDIT</th>
<th>DOSIMETRY INTERCOMP</th>
<th>ARISON</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>ARGENTINA</td>
<td>9001, 14001,</td>
<td>45001, 26000</td>
<td>YES</td>
<td>NPL</td>
<td>YES (IRAM)</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>17025, 26000,</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>BRAZIL</td>
<td>9001, 17025,</td>
<td></td>
<td>YES</td>
<td>IRD/NIST</td>
<td>YES</td>
<td>(FUNDACAO VANZOLINI)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>26000, 13004</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>INDONESIA</td>
<td>9001, 18001,</td>
<td></td>
<td>NO</td>
<td>SSDL INDONESIA</td>
<td>NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>17025,</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>HUNGARY</td>
<td>9001, 14001,</td>
<td></td>
<td>YES</td>
<td>DTU, RISO</td>
<td>YES</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>13485,</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>JORDAN</td>
<td>9001 (IN</td>
<td></td>
<td>YES</td>
<td>INCT</td>
<td>NO</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>PROCESS)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>KOREA</td>
<td>9001, 17025,</td>
<td></td>
<td>YES</td>
<td>KRISS</td>
<td>YES</td>
<td>(KOLAS)</td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td></td>
<td>13485</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>MALAYSIA</td>
<td>9001, 17025,</td>
<td></td>
<td>YES</td>
<td>SSDL MALAYSIA</td>
<td>YES</td>
<td>(SIRIM, SGS, LYLODS, STANDARD MALAYSIA)</td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td></td>
<td>13485</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td>INDIA</td>
<td>9001, 17025,</td>
<td></td>
<td>YES</td>
<td>BARC</td>
<td>YES</td>
<td>(SSDL BARC)</td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td></td>
<td>14001, 13485</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>MYANMAR</td>
<td>9001 (IN</td>
<td></td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PROCESS)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td>PHILIPINES</td>
<td>9001</td>
<td></td>
<td>YES</td>
<td>NPL</td>
<td>NO</td>
<td>(SOCOTEC)</td>
<td>NO</td>
</tr>
<tr>
<td>11.</td>
<td>POLAND</td>
<td>9001, 13485,</td>
<td></td>
<td>YES</td>
<td>NPL</td>
<td>YES</td>
<td>(PCPC, GIF)</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td></td>
<td>14001, 13485</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12.</td>
<td>RUSSIA</td>
<td>9001</td>
<td></td>
<td>YES</td>
<td>BINP</td>
<td>YES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13.</td>
<td>SLOVAKIA</td>
<td>9001, 13485</td>
<td></td>
<td>YES</td>
<td>RISO</td>
<td>YES</td>
<td>(3EC)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>13485</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14.</td>
<td>SRI LANKA</td>
<td>9001, 13485</td>
<td></td>
<td>YES</td>
<td>RISO</td>
<td>NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>13485</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15.</td>
<td>TUNISIA</td>
<td>9001 (IN</td>
<td></td>
<td>YES</td>
<td>AERIAL</td>
<td>NO</td>
<td>(TUNAC)</td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PROCESS), 17025</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
5. EMERGING CHALLENGES IN DOSIMETRY FOR QA/QC OF NON-ROUTINE PRODUCTS AND NEW APPLICATIONS

<table>
<thead>
<tr>
<th>S.N.</th>
<th>Non-routine product/process</th>
<th>Issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Cultural heritage</td>
<td>Geometry, density, radiation sensitivity, guidelines in progress</td>
</tr>
<tr>
<td>2.</td>
<td>Pharmaceuticals</td>
<td>Low-temperature, -guidelines not available</td>
</tr>
<tr>
<td>3.</td>
<td>Human tissues</td>
<td>Low temperature, -guidelines not available</td>
</tr>
<tr>
<td>4.</td>
<td>Irregular shape products</td>
<td>Geometry, density, - guidelines not available</td>
</tr>
<tr>
<td>5.</td>
<td>Frozen products</td>
<td>Low temperature, -guidelines not available</td>
</tr>
<tr>
<td>6.</td>
<td>Flow systems (waste water, honey, gas, environment…)</td>
<td>Reproducibility - lack of - appropriate dosimeters, guidelines not available</td>
</tr>
<tr>
<td>7.</td>
<td>Software validation as a part of IQ validation</td>
<td>Guidelines not available for validation of software with impact on dose (e.g. conveyor system, dose measurement system)</td>
</tr>
</tbody>
</table>

6. INTEGRATED MANAGEMENT SYSTEMS AT IRRADIATION FACILITIES: THE NEW CONCEPT

Radiation processing has been used for more than 50 years in order to add value to products, mainly to improve their quality or their functionality, as well as facilitating access to international markets. This can only be achieved as long as best practices are applied at all stages of the process. There are several standards and handbooks which establish requirements or offer guidelines to irradiation facilities in order to obtain products which comply with quality, safety and functionality expectations. Quality management systems have proved to be a fundamental tool to support the fulfilment of these practices. There are other aspects, however, which are not being considered in most irradiation facilities, although they are relevant to general operation and sustainability of radiation processing, such as safety, occupational health and environmental concerns.

In that sense, integrated management systems integrates all the systems, processes and other relevant matters of an organization into a single framework, allowing it to function as a single unit with unified objectives, thus highly contributing to the effective fulfillment of installations’ objectives, providing robustness, reliability and continuity to the application of good practices. In that sense, Quality Management Systems provide irradiation facilities the ability to achieve the highest levels of compliance with customer and applicable legal and regulatory
requirements as well as customer’s satisfaction, whereas Environmental Management Systems and Occupational Health & Safety Management Systems highly contribute to the overall results, some of which are intangible aspects directly related to the human factor: while improvement of public perception due to a good organization’s environmental performance increases radiation processing acceptance and sustainability, on the other hand, the enhancement of workers’ confidence and trust due to the understanding that their health and safety are equally important to the organization’s authorities than quality and productivity, increases their motivation and sense of belonging. Therefore, the implementation of Integrated Management System at irradiation facilities together with training of personnel and the development of cultures for safety, quality, environment preservation and continuous improvement, are relevant steps towards the achievement of such unified objectives, with positive impact on overall performance.

An IAEA regional project was initiated at Latin America and the Caribbean region (RLA 1015) with the overall objective of increasing quality and safety of irradiated products as well as enhancing safety, awareness and preservation of the environment at irradiation facilities, in order to favor sustainable development of radiation processing and a regional balance. In order to achieve these goals, it was considered that the most relevant aspects to cover were to obtain a harmonized structure for integration of management systems and good irradiation practices based on ISO standards and IAEA’s safety requirements together with a gap-analysis check list as a guidance to self-assessment, as well as training of personnel and enhancement of cultures for safety, quality, best practices and continuous improvement.

7. THE NEEDS OF COUNTRIES IN EARLY STAGES OF IMPLEMENTING QMS

In many of the Member States their radiation facility is usually the first or the only one in the country and therefore there is a lack of experiences within the country for implementing QMS in the irradiation facilities. Further no structure learning specifically related to implementing QA/QC practices is available in the industry. Therefore, the Member States in early stages of implementing gain the knowledge and experience through sporadic training courses, workshops, or meetings conducted by the IAEA. In order to give comprehensive picture about implementing QMS appropriate training and hands on experience in a structured manner needs to be provided to the Member States.

8. REVISION OF QA/QC GUIDELINES

The Guidelines for Development, Validation and Routine Control of Industrial Radiation Processes, IAEA Radiation Technology Series No. 4 published by the IAEA in 2013 is focused on sterilization application based on ISO 11137. As discussed above, new applications of radiation technology in areas such as cultural heritage preservation, environmental applications and material modification have emerged in recent years for which appropriate guidelines now needs to be developed. The valuable experience gained in cultural heritage preservation as published in ‘Uses of Ionizing Radiation for Tangible Cultural Heritage Conservation, IAEA Radiation Technology Series No. 6’ could be an excellent starting point to be included in
revised document. Further additional information related to establishing suitable maximal and minimal absorbed doses for irradiated materials as well as description of the methods based on the determination of the effects achieved by radiation treatment (ISO 13004) can be included along with restrictions on irradiating conditions (temperature range, specific environment, etc.). Inclusion of processing parameters related to irradiation in a given facility such as dose rate, ionising radiation penetration depth, treatable volume, beam energy, beam current, etc. in the revised guidelines will facilitate transfer of recommended parameters between facilities and technologies.

It is worth mentioning that a new standard the ISO 13004 Sterilization of health care products — Radiation — Substantiation of selected sterilization dose: Method VDmaxSD which extends the utility of ISO 11137 standard to validation of additional sterilised doses such as 17.5 kGy, 20 kGy, 22.5 kGy, 27.5 kGy, 30 kGy, 32.5 kGy and 35 kGy has been recently published in 2014 should be included as a reference in the IAEA guidelines.

Computational simulations based on MCNP, GEANT4, etc. can provide valuable approximation to the absorbed dose under defined conditions and can be recommended before actual radiation treatment. Limited knowledge is available in this field and therefore personal training in the field of specific computational simulation needs to be organized.
9. ACHIEVEMENTS OF IAEA REGIONAL TC PROJECTS RELATED TO QA/QC IN RADIATION PROCESSING AND STEPS FOR INITIATING REGIONAL TC PROJECTS

The outstanding achievement of the IAEA efforts in enhancing QA/QC in radiation technologies is clearly seen in European Regional (RER) and Regional Latin Americas and the Caribbean (RLA) TC Projects. This required implementation of the necessary QA/QC procedures both for the safe operation of the relevant irradiation facilities and the reliable execution of the process control in radiation technologies. The methodologies followed relied on the standardized use of reference and routine dosimeter systems and the necessary traceable dosimetry calibration procedures validated through dosimetry intercomparison exercises. Quality assurance was also ensured by the introduction and use of the relevant integrated quality management systems and strong effort for adoption of QMS documentation in all relevant Member States involved in these regional projects. These experiences gained so far in two IAEA TC regions (RER and RLA) in radiation processing applications is suggested to be introduced and utilized in other IAEA TC regions like in Asia and the Pacific, Africa and the Middle East.

Based on these favourable experiences the participants from the other IAEA TC regions (Africa and Asia and the Pacific) agreed to propose a regional TC project in both regions, where Malaysia and Tunisia agreed to take the lead in preparing the necessary documentation and in carrying out the required organizational tasks. In order to help these actions a short summarization about the necessary tasks to fulfill the requirements of the project proposal has been prepared by the Member States already experienced in this type of cooperation programmes. The most important tasks of initiating a regional cooperation program and preparing the required documentation are the followings:

I. To appoint the dedicated team member (DTM) of the project.

The DTM, with significant experience in the given field (i.e. in this case radiation processing) shall be appointed from the leading Member State. The DTM is responsible to contact the relevant Member States already performing radiation processing activities in industry and R&D asking about their intention to participate in the planned regional project. Each Member States with interest should select one person with experience in the given field to act as a contact point for the DTM during the project lifetime.

II. Preparation of the pre-project concept (Regional Program Note).

With the leadership of the national contact point Each Member State – based on their actual achievements and requirements - should summarize their basic needs and expectations to be involved in the project proposal. These actions should be carried out by involving all potential stakeholders of the MSs in these discussions.

III. Using the individual MS’s suggestions, the DTM of the project – together with the national contact points – should prepare the harmonized project concept.

IV. Involvement of the NLOs in reviewing the pre-project concept.
V. Finalization of the pre-project concept and its review with the relevant IAEA TO and PMO. Submission of the concept to the IAEA. If accepted:

preparation of the PCMF, LFM and project work plan by the DTM involving all national contact points.

VI. Continuous involvement and discussion with the relevant IAEA TO and PMO. Involvement of the relevant NLOs in the finalization of the project proposal

10. EXPECTATIONS FROM IAEA

(i). Initiating Regional and Inter-regional IAEA TC Programmes: The crucial role of implementing QA/QC in radiation processing to meet the demanding needs of customer in areas such as health care, food processing, producing advanced materials and protecting the environment is evident to the Member States. However, countries which are advanced in radiation technologies having established large scale facilities related to producing specific products in private sector have been implementing such Quality management practices while many of the Member States which are new to these technologies and where most of such facilities are in public sector which are in the process of implementing these practices. Thus, there exists differences concerning the level of implementation QM practices among MS even within the same geographical region. IAEA initiatives over the years have demonstrably led to reduction of the gap among Member States as sharing of experience and expertise from Member States with longer and more advanced practices to other Member States allows easier and faster adaption of the practices to enhance quality management practices. Based on the earlier experience of IAEA TC programmes over the years in this area in Europe region (RER 1015, RER 1017) and in Latin America (RLA 1013, RLA 1015), similar programmes be initiated in Asia-Pacific, Arab Countries and in Africa region.

(ii). Conduct Dosimetry Inter-comparison Exercises: Accurate and reliable dosimetry constitutes the backbone of radiation processing practices. It has been observed many Member States specially in the early years of establishing radiation processing facilities have limited knowledge in dosimetry system calibration and estimation of associated uncertainties in dosimetry measurements. In the absence of availability of any structured learning courses in the industry related to these topics, it takes a long time for radiation technologists to gain expertise. As a first and immediate step to focus the attention of MS who are new to this technology, IAEA is requested to implement regular dosimetry inter-comparison exercises which will provide the necessary confidence to the facility operators in their process as it will be duly supported by an external agency. Further, IAEA should organize workshop/meeting to discuss the results of this exercise so that any inaccuracies that occur advertently or inadvertently could be minimized. Sharing the knowledge through Interregional Cooperation will result in better use of existing resources. The inter-comparison exercise has been discussed and all members have agreed to participate in the proposed interregional exercise. IAEA has the necessary experience and strategies to implement such a programme.

(iii). Developing guidelines for new emerging applications and revising the existing guidelines to include the recent developments:
The Guidelines for Development, Validation and Routine Control of Industrial Radiation Processes, IAEA Radiation Technology Series No. 4 published by the IAEA in 2013 is focused on sterilization application based on ISO 11137 should be revised.

(iv). Planning to Integrated Management System in Radiation Processing Facilities

- The application of the High Level Structure (Annex SL) for the integration of, at least, quality (ISO 9001 or ISO 17025); environmental (ISO 14001) and occupational health and safety (ISO 45001) management systems at irradiation facilities, with further verification of compliance with IAEA GSR pt. 2, and their articulation with good irradiation practices standards (e.g. ISO 11137, ISO 14470 and other reference standards) is highly recommended.
- The implementation of RLA 1015 has contributed significantly towards a harmonized integration of management systems in Latin America and the Caribbean. The establishment of similar regional projects in other regions, together with interregional meetings, will contribute to a major harmonization of integrated management systems and best practices at all irradiation facilities.
- Peer-review audits can help in this implementation.

11. CONCLUSIONS

i. The Member States attending the meeting either have the necessary quality management systems or are in the way of establishing it in their own irradiation facilities although there exists a distinct difference in the level of implementation among the Member States.

ii. The discussions at the meeting clearly reflected that the Member States that have participated either in the IAEA regional TC programmes or in dose intercomparison exercises have made considerable progress and achievements in implementing QA/QC protocols in radiation processing.

iii. The Member States from Asia-Pacific and Africa regions have decided to establish IAEA TC regional projects in radiation processing. The experiences from Latin American and European TC regional projects could be utilized in this process. The participants of the technical meeting recognized the necessity of interregional cooperation utilizing the existing knowledge and experience in the present and planned regional cooperation projects.

iv. The Member States from Asia-Pacific and Africa regions realized the necessity of participating in dosimetry intercomparison exercises based on the experiences of the one in progress in the European and Latin American TC regions.

v. The Member States attending the meeting realized the need for revising the QA/QC guidelines for non-routine and emerging applications.

vi. Implementation of Integrated Management System at irradiation facilities together with training of personnel and the enhancement of cultures for safety, quality, environment preservation, among others, are relevant steps towards continuous improvement of their overall performance.
12. THE WAY FORWARD

i. The experience gained during the implementation of RLA 1015 integrating various management systems related to the facility processes and the environment should be shared with the Member States in the other regions and IAEA will be requested to initiate an interregional project. This will lead to a major harmonization of integrated management systems and best practices at all irradiation facilities.

ii. The Member States from Asia-Pacific and Africa regions will initiate the discussions to establish regional TC projects in QA/QC and dosimetry intercomparison to be submitted to IAEA in March 2020 in which Malaysia and Tunisia will take the leaderships. In the Asia-Pacific region the pre-project concept will be discussed at the 48th RCA GCM NRs on 13th September 2019. The necessary guidance will be sought from the dedicated team members of Europe as well as Latin America and the Caribbean regions.

iii. Keeping in view that the regional projects or the interregional projects of the IAEA can only be initiated from the year 2021, IAEA will be requested to conduct intercomparison dosimetry exercises as soon as possible. It will be communicated to the relevant technical staff. The participants from these Member States should explore the possibility of participating in the QA/QC programmes being conducted in other regions.

iv. The implementation of the new standard ISO 13004 needs to be disseminated among the Member States to enhance the applicability of ISO 11137.

v. The IAEA should support technical meetings with several experts in relevant areas to revise the QA/QC guidelines.

vi. Taking into consideration the need of sustainability and increasing of human capacity at irradiation facilities, the IAEA should be approached to support MS by utilizing all available resources, not to be reduced to those included in the same field of activity (e.g. IAEA’s Safety Culture Continuous Improvement Process (SCCIP), specific computational simulation based on MCNP, GEANT4, for approximation to absorbed dose).
ANNEX I - COUNTRY TECHNICAL REPORTS

ARGENTINA

INTEGRATED MANAGEMENT SYSTEMS AND BEST PRACTICES AT IRRADIATION FACILITIES

DOCTERS, A.

Atomic Energy National Commission

Buenos Aires, Argentina

Abstract

Radiation processing has been used for more than 50 years in order to add value to products, mainly to improve their quality or their functionality, as well as facilitating access to international markets. This can only be achieved as long as best practices are applied at all stages of the process. There are several standards and handbooks which establish requirements or offer guidelines to irradiation facilities in order to obtain products which comply with quality, safety and functionality expectations. Quality management systems have proved to be a fundamental tool to support the fulfilment of these practices. There are other aspects, however, which are relevant to general operation and sustainability of facilities, such as safety, occupational health and environment concerns. Integrated management systems unify all relevant aspects in a single structure, with a strong focus on the processes and "risk-based" thinking, the evaluation of overall system performance and the search for continuous improvement, and therefore highly contribute to the efficient fulfillment of installations’ objectives, providing robustness, reliability and continuity to the application of good practices.

1. BACKGROUND

1.1. EVOLUTION OF MANAGEMENT SYSTEMS (MS)

Management systems are defined as a “set of interrelated or interacting elements of an organization to establish policies and objectives and processes to achieve those objectives” [1]. The most frequently used worldwide are those developed by the INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO). There are different types according to their specific subject, and each of them arose due to different prevailing situations: while quality management systems have been developed in order to improve organizations ‘competitiveness, environmental MS emerged to satisfy legislation and society expectations whereas Occupational Health and Safety MS came into effect mainly due to pressure of interested parties. This is why in many organizations the three matters are dealt with by different areas, and therefore, they are managed separately.

The INTERNATIONAL ATOMIC ENERGY AGENCY (IAEA) has developed management systems with main focus on safety of nuclear power plants, but usable in other Class I facilities, such as irradiation plants. Their use is therefore limited. For more than a decade they have been fostering the implementation of integrated management systems.
1.2. EVOLUTION OF QUALITY MANAGEMENT SYSTEMS (QMS)

During First World War, production process chains became more complex and quality control techniques (QC) emerged as a helpful tool to control products and services compliance with specifications, in order to achieve higher levels of quality. With time, QC inspections gradually moved forward to a more global approach through statistic evaluations until the first quality systems were adopted. Quality was prioritized over quantity, and root cause analysis was implemented, being an antecedent of corrective actions. It was not until the 80’s when quality started being considered a strategic process, and Quality Assurance systems (QA) were “focused on providing confidence that quality requirements would be fulfilled” [1]. QMS have been used since 1990 until present time: systems are now analyzed as a whole. With customer focus and process approach, applying the Deming (PDCA) cycle for continuous quality improvement and risk-based thinking, among others, the implementation of QMS based on ISO 9001:2015 provides irradiation facilities with a solid structure to support the good irradiation practices, and thus strengthening their “ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements” as well as “facilitating opportunities to enhance customer satisfaction” [2].

1.3. EVOLUTION OF ENVIRONMENTAL MANAGEMENT SYSTEMS (EMS)

An EMS “is part of the management system used to manage environmental aspects, fulfil compliance obligations and address risks and opportunities” [3].

EMS started as an informal approach to comply with regulations. Based on QMS, BSI 7750:1992 was the starting point of current EMS, which some years later lead to ISO 14000 series.

The purpose of ISO 14001:2015 is “to provide organizations with a framework to protect the environment and respond to changing environmental conditions in balance with socio-economic needs” [3]. The implementation of EMS highly contributes to improve public perception of radiation-related activities, such as radiation processing, by showing a social responsible behavior towards environmental matters. It also helps irradiation facilities to improve their environmental performance as well as compliance with regulations and other obligations, among others. Similarly, to QMS, EMS applies a process approach, the Deming (PDCA) cycle for continuous improvement of environmental performance and risk-based thinking [3].

1.4. EVOLUTION OF OCCUPATIONAL HEALTH AND SAFETY MANAGEMENT SYSTEMS (OH&S MS)

An OH&S MS “is part of a management system used to achieve the OH&S policy” [4].

OH&S first approaches were carried out as individual self-protection actions. This was followed by efforts of World Health Organization (WHO) and International Labor Organization (ILO) to persuade governments to reinforce public policies. Based on QMS and EMS, it was in the 90’s that the first OH&S MS standards were delivered (BS 8800:1996, OHSAS: 1999). Finally, in 2018, the first OH&S MS ISO standard took effect: ISO 45001:2018 [4].

As it is described in Ref. [4], “the purpose of an OH&S management system is to provide a framework for managing OH&S risks and opportunities. The aim and intended outcomes of the OH&S management system are to prevent work-related injury and ill health to workers and to
provide safe and healthy workplaces; consequently, it is critically important for the organization to eliminate hazards and minimize OH&S risks by taking effective preventive and protective measures”. Similarly, to QMS and EMS, this standard applies a process approach, the Deming (PDCA) cycle for continuous improvement of OH&S performance and risk-based thinking [4].

The implementation of OH&S MS makes a positive contribution to irradiation facilities by providing confidence to workers, regulators and other interested parties; systematizing risk analysis; favoring safety control as well as continuously improvement of their safety performance, thus enhancing safety culture.

1.5. EVOLUTION OF IAEA’S SAFETY SERIES AND REQUIREMENTS RELATED TO QA/IMS TO FOSTER RADIOLOGICAL SAFETY

The Safety Series no.50-C-QA Quality Assurance for Safety in Nuclear Power Plants

A Code of Practice, published in 1978, was one of the five codes of practices, which although it was intended for nuclear power plants in order to set minimum requirements for their safe operation, it was adopted by other nuclear or radioactive facilities with the intention of implementing a QMS consistent with regulatory requirements. In 1996 it was superseded by the Safety Series no.50-C/SG-Q Quality assurance for Safety in Nuclear Power Plants and other Nuclear Installations Code and Safety Guides Q1-Q14 whose scope was extended to other facilities. The Safety Requirements no.GS-R-3 The management for facilities and activities (2006) superseded Safety Series no.50-C/SG-Q [5], and extended its scope to Integrated Management Systems (safety, health, environmental, security, quality, economic elements), taking into consideration ISO’s QMS and EMS, with focus to statements made by the International Nuclear Safety Group related to safety culture (INSAG -4)[ 6]. As it is specified in [5, 1.3] the document reflects what INSAG-4 determined as the two aims of an integrated management system: “To improve the safety performance of the organization through the planning, control and supervision of safety related activities in normal, transient and emergency situations” and “To foster and support a strong safety culture through the development and reinforcement of good safety attitudes and behavior in individuals and teams so as to allow them to carry out their tasks safely”. Safety Standards No. GSR Part 2 Leadership and Management for Safety “establishes requirements for establishing, assessing, sustaining and continuously improving effective leadership and management for safety in organizations concerned with, and facilities and activities that give rise to, radiation risks. This includes the regulatory body and other competent authorities, and the organization responsible for the facility or for the activity” [7, 1.1]. It is important to stand out that when a new standard is published, it develops concepts of superseded document and introduces considerations of lessons learned from accidents or events.

1.6. GOOD IRRADIATION PRACTICES

There are two main standards related to good irradiation practices. The first is ISO 11137 Sterilization of health care products — Radiation which was first made effective in 1995. It consists of three parts, establishing Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices (part 1), methods for Establishing the Sterilization Dose (part 2) and Guidance on Dosimetric Aspects of Development, Validation and Routine Control (part 3) [8]. The second, ISO 14470 Food Irradiation — Requirements for the Development, Validation and Routine Control of the Process of Irradiation Using Ionizing
Radiation for the Treatment of Food [9] was first published in 2011. In addition, there are several ISO/ASTM standards and guides covering different practices related to dosimetry or specific practices as well as handbooks which offer guidelines of how to proceed in order to comply with standards, among others.

1.7. STATUS OF IRRADIATION FACILITIES OF LATINAMERICA AND CARIBBEAN REGION IN RELATION TO IMPLEMENTATION OF MANAGEMENT SYSTEMS (MS) AND GOOD IRRADIATION PRACTICES (GIP)

The status of the irradiation facilities regarding MS and GIP was extracted from the RLA / 1/015 Report of the First Project Coordination Meeting [10] and from the results of a survey completed by participants who could not attend to this event. It should be noted that at the moment of determining the baseline (2017), of the twelve countries participating in the project, four counted with facilities on an industrial scale, seven on a pilot or semi-industrial scale, two had Gammacell equipment at experimental scale, and one was in the stage of construction.

The irradiation facilities had different levels in terms of the implementation of management systems. Requirements of the regulatory authorities of the respective countries and the characteristics of the services that are required of them have led to the generation of procedures related to operation, radiological protection programs and security, not necessarily linked together as part of a management system.

In relation to specific standards, 54% of the countries had high level of implementation of QMS-ISO 9001 (among which, two had certified their MS), 31% were in the process of structuring, organizing and implementing the system using this standard as a reference, and 15% had not started. As for EMS-ISO14001, 46% have a high or medium level of implementation whereas regarding OH&SMS-OHSAS 18001, this value increases to 77%.

In relation to GIP, no country had certification. It was observed that both in ISO11137-1-2-3 and ISO14470, the percentage of countries with low level of implementation (62% and 54% respectively) exceeded those with high and medium level (38% and 46% respectively). Nonetheless, 42 % apply IQ/OQ/PQ. Regarding dosimetry, 42% were traceable to a Primary Laboratory, and 58% had participated in previous interlab dosimetry exercises or were in process of taking part in the RLA1013 project’s.

1.8. INTEGRATED MANAGEMENT SYSTEMS

Integrated management systems unify all relevant aspects in a single structure, with a strong focus on the processes and "risk-based" thinking, the evaluation of overall system performance and the search for continuous improvement, and therefore highly contribute to the efficient fulfillment of installations’ objectives, providing robustness, reliability and continuity to the application of good practices. Although there is no doubt about the benefits a QMS provides to radiation processing as for the continuous improvement to achieve the highest levels of compliance with customer requirements and applicable legal and regulatory as well as client’s satisfaction, EMS and OH&SMS highly contribute to the overall results, some of which are intangible aspects directly related to the human factor. The improvement of public perception due to a good environmental performance increases radiation processing sustainability whereas the perception that quality, environment, health and safety are equally important for the organization’s authorities, increases confidence and trust of workers and other interested parties.
1.9. HARMONIZING IMS AND GIP AT IRRADIATION FACILITIES OF LATINAMERICA AND CARIBBEAN- OUTCOMES OF THE RLA1015 PROJECT

The overall objective of the project was to increase quality and safety of irradiated products as well as enhancing safety, awareness and preservation of the environment at irradiation facilities, in order to favor sustainable development and regional balance, and contribute favorably to the perception that the general public has about radiation processing. In order to achieve these goals, it was considered that the most relevant aspects to cover were the harmonization of integrated management systems and good irradiation practices (both based on the standards previously mentioned), as well as training of personnel.

In the case of IMS, countries were classified according to their level of implementation. Those with medium and high level participated at a workshop were IMS harmonization activities were done. The main products obtained were a harmonized structure of such IMS, a gap analysis and self-assessment check list in order to facilitate self-monitoring grade of advance. Other harmonized products were the identification and classification of main, strategic and support processes at irradiation facilities; internal and external context analysis with potential impact on facilities’ performance; identification of interested parties; and a risk analysis. Countries with low level of implementation participated at a regional course on fundamentals on IMS (which included harmonized products) and national courses were organized. Similarly, national courses were organized for countries with low level of implementation of GIP.

There were several courses targeted to operators, dosimetrists (basic and advanced), heads of irradiation facilities.

It is expected that these training activities, in combination with the interlab dosimetry exercise should have a positive impact on irradiation facilities performance related to good irradiation practices.

2. CONCLUSIONS

It is considered that the implementation of Integrated Management System at irradiation facilities together with training of personnel and the development of cultures for safety, quality, environment preservation and continuous improvement are relevant steps towards continuous improvement of overall performance.

In Latin America and Caribbean Region, it is observed that in terms of implementation of GIP reference standards, results are not as expected. Generational renewal is taking place at irradiation facilities, and in some cases flaws in knowledge transfer have taken place. On the other hand, new countries are now participating in IAEA’s projects, some of which are in process of adopting radiation processing technology. It is challenge to revert the current situation in a short-mid term, and technical support from experts of the region together with IAEA should be an important step in this direction.

REFERENCES


Abstract

The Nuclear and Energy Research Institute–IPEN mainly through the Multipurpose Gamma Irradiation Facility and the Electron Accelerator Facility located inside the University of São Paulo campus have developed irradiation technology in Brazil. These facilities have treated by radiation processing several materials for disinfection, sterilization, polymerization, crosslinking, etc. In this sense, many radiation processing applications aim a desired effect in the irradiated material as curing or cross-linking of hydrogels, wire and cables or the consolidation of cultural heritage materials using a resin. Disinfection of cultural heritage objects or sterilization of human tissues needs to be applied between a maximal dose to avoid degradation of the irradiated materials and a minimal dose to ensure the biological effect. In this sense, many policies related to the Quality Assurance and Quality Control have been developed. Processes definition, installation qualification, operation qualification, performance qualification and routine process control procedures have been applied to satisfy the requirements of standards as ISO 11137 and ISO 13004. Industrial dosimetry systems as well PMMA, alanine, FWT, CTA, etc. have been implemented and
validated with high efficiency. The Nuclear and Energy Research Institute also implanted an Integrated Management System under the ISO 9001 to control the mean process including the related to the radiation processing. The IPEN has been actively participating in IAEA regional projects as the RLA 1013 to promote the dosimetry inter-comparison and the RLA 1015 to harmonize integrated management systems and good irradiation practice procedures in irradiation facilities. Additionally, in this work are described the mean Brazilian irradiation facilities and their currently associated quality assurance and control systems.

1. INTRODUCTION

Brazil has been investing in irradiation technology since the 1970s. The activities of private companies were developed in partnership with the Nuclear and Energy Research Institute – IPEN/, from technology transfer to process monitoring in relation to dosimetry and control. Over the last years, the Nuclear and Energy Research Institute – IPEN/CNEN located inside the São Paulo University campus has been providing services on radiation processing, especially for sterilization of health care and disposable medical products as well as support to research studies on modification of physical, chemical and biological properties of several materials. These activities have been developed mainly in the Multipurpose Gamma Irradiation Facility and in the Electron Beam Accelerator Facility at the Radiation Technology Center – CETER-IPEN. Placed at the same campus operates an extremely important radiopharmaceutical production facility when almost all disposable supplies used to produce medicinal products as the technetium-99m are continuously sterilized by gamma radiation. Many university biomedical research laboratories specially those working with equipment for cell cultures and vaccine production also make use of the gamma sterilization. Animal feed and shavings used by certified bioteries are routinely disinfected. Alternative underwater irradiation methods were developed to meet the demand of gemstone color enhancement. Human tissues including bone, skin, amniotic membranes, tendons, and cartilage belonging to National Banks are usually irradiated too. Different kind of polymers, hydrogels, foods as well native fruits, have been irradiated in this facility. Cultural heritage objects as books, paintings and furniture are disinfected routinely by gamma radiation. The success of the implementation of radiation processing in these facilities is due to research and development of irradiation and dosimetry methods suitable for each condition according to specific standards as well ISO 9001, ISO 11137 and ISO 13004. Similarly, IPEN has been participating in IAEA-sponsored regional projects focusing on dosimetry, quality assurance and quality control in irradiation facilities.

2. IRRADIATION FACILITIES IN BRAZIL

Brazil has more than seven gamma irradiators with installed activities between 10 kCi to 100 MCi and more than twenty electron beam accelerators with energies between 100 keV to 10 MeV. Table 01 shows the means facilities inside the country (Table 1).
TABLE 1: IRRADIATION FACILITIES IN BRAZIL

<table>
<thead>
<tr>
<th>Facility</th>
<th>Start date</th>
<th>Operation mode</th>
<th>City</th>
<th>Technology</th>
</tr>
</thead>
<tbody>
<tr>
<td>JOHNSON &amp; JOHNSON</td>
<td>1978</td>
<td>Private</td>
<td>São José dos Campos/SP</td>
<td>-01 Gamma</td>
</tr>
<tr>
<td>STERIGENICS INTERNATIONAL</td>
<td>2017</td>
<td>Private</td>
<td>Jarinu/SP and Cotia/SP</td>
<td>-03 Gamma (2000 / 5000kCi) -01 electron beam (10MeV) Rhodotron</td>
</tr>
<tr>
<td>CDTN/CNEN</td>
<td></td>
<td>Governmental</td>
<td>Belo Horizonte/MG</td>
<td>-01 Gamma Irradiation Laboratory (60kCi)</td>
</tr>
<tr>
<td>CENA/USP</td>
<td></td>
<td>Governmental</td>
<td>Piracicaba/SP</td>
<td>-under construction 100kCi -01 Gammacell</td>
</tr>
<tr>
<td>IPEN/CNEN</td>
<td>2004</td>
<td>Governmental</td>
<td>São Paulo /SP</td>
<td>-01 Multipurpose Gamma Irradiation Facility (400kCi) -01 Gammacell -01 Panoramic -02 Electron Beam Accelerators 1.5 MeV – 37kW/ 97kW -01 Mobile Electron Beam unit (under construction) 0.7MeV-20kW</td>
</tr>
<tr>
<td>Brazil</td>
<td></td>
<td>Private</td>
<td></td>
<td>-20 Electron Beam Accelerators (0.1 – 10 MeV)</td>
</tr>
</tbody>
</table>

TABLE 2 shows the general situation of the main irradiation facilities in Brazil in relation to the ISO standards, dosimetry, safety and security and Installation qualification (IQ), Operation Qualification (OQ) and Performance qualification (PQ)
TABLE 2: GENERAL SITUATION MAIN IRRADIATION FACILITIES IN BRAZIL

<table>
<thead>
<tr>
<th>Facility</th>
<th>Type</th>
<th>ISO 9001</th>
<th>ISO 11137</th>
<th>ISO 26000</th>
<th>OQ/PQ/IQ</th>
<th>Dosimetry Traceability</th>
<th>Safety &amp; Security</th>
<th>Dosimetry Inter-comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td>J&amp;J</td>
<td>01 gamma</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Sterigenics</td>
<td>03 gamma</td>
<td>yes</td>
<td>yes</td>
<td>no</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>CDTN-CNEN</td>
<td>01 gamma</td>
<td>yes</td>
<td>In process</td>
<td>no</td>
<td>In process</td>
<td>yes</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>Multipurpose Gamma Irradiation Facility-IPEN</td>
<td>01 gamma</td>
<td>yes</td>
<td>yes</td>
<td>13004</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Electron Beam Accelerator-IPEN</td>
<td>02 EB</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
</tbody>
</table>

3. NUCLEAR AND ENERGY RESEARCH INSTITUTE – IPEN

The Nuclear and Energy Research Institute [1] founded in 1955 is a State of São Paulo autarchy, associated for academic purposes to the University of São Paulo – USP and supported and operated technically and administratively by the National Nuclear Energy Commission – CNEN, a federal agency of the Ministry of Science and Technology (FIG.1).

FIG.1: Nuclear and Energy Research Institute – IPEN /Brazil
Several research nuclear technology centers operate inside IPEN (FIG.2):

a. CAC  – Cyclotron Accelerators  
b. CCN  – Nuclear Fuel  
c. CCTM – Science and Materials Technology  
d. CEN  – Nuclear Engineering  
e. CFC  – Fuel Cell  
f. CLA  – Lasers and Applications  
g. CMR  – Radiation Metrology  
h. CQMA – Chemistry and Environmental  
i. CR  – Radiopharmacy  
j. CBM  – Molecular Biology  
k. CRPq  – Research Reactor (02 Reactors)  
l. LRR  – Radioactive Waste Laboratory  
m. CETER – Radiation Technology Center

**FIG.2: Research on Nuclear Technology at IPEN /Brazil**

In the Radiation Technology Center –CETER/IPEN are located the most important irradiation facilities where are practiced activities for research and application on different kind of materials for several purposes.
3.1 Radiation technology center – CETER

The mission of the CETER is the Application of the radiation and radioisotope technologies in Industry, Health, Agriculture and Environmental Protection, increasing scientific knowledge, improving human power resources, transferring technology, generating products and offering services for the Brazilian society (FIG.3).

FIG.3: Radiation Technology Center – CETER

3.2 Irradiation facilities at the CETER/IPEN

The CETER has the Multipurpose Gamma Irradiation Facility and the Electron Beam Accelerator Facilities as the most representatives. In addition, CETER has a Gammacell and a Panoramic Irradiator with low activities. A mobile Electron Beam unit for environmental applications is already under construction.

a. Multipurpose Gamma Irradiation Facility

This is Brazilian technology facility started in 2004 [2] [3] [7] [8] [9] [10] [13]. This facility is a panoramic wet source storage compact irradiator (IAEA - Category IV); the radioactive sources are stored and fully shielded in a pool of 7m. depth deionized water. The facility uses standard cobalt-60 source pencils. The source pencils are distributed into 16 source modules and these modules are distributed over two source racks. The installed activity is 400kCi (2019) related to 64 pencils (total capacity 500 pencils). The Multipurpose Gamma Irradiation Facility can be operated in dynamic or stationary modes. In the dynamic mode a container overlap system is used to transport the products around the radioactive sources. Nevertheless, research materials or very delicate objects (e.g. cultural heritage or human tissues) need to be loaded by hand and the stationary method is the more suitable to take care mainly parameters related to the distribution dose (DUR). Then the stationary operations can be described in the following methods in function of the DUR (FIG.4).
b. Electron Beam Accelerator Facility

This facility has 02 electron beam accelerators under the same building/shielding. Each accelerator has an independent control system. One accelerator is dedicated to research applications and the other one works with cable and wire cross-linking applications [11][10](FIG.5).
c. Mobile e-beam Unit

Under construction mobile electron beam unit to process waste water, potable water and sludge treatment (FIG.6). Beam conditions: 0.7 MeV and 20 kW.

FIG.5: Multipurpose Gamma Irradiation Facility, IPEN -Brazil

FIG.6: Mobile e-beam unit, IPEN -Brazil
d. High Doses Dosimetry Laboratory

This laboratory performs tasks related to calibration on different types of dosimeters using a gammacell unit or in-plant conditions (FIG.7)[7][9]. Calibration conditions can include irradiations carried out at room temperature or at low temperatures (e.g. 0°C, -70°C). This laboratory works inside ISO 17025 and applies traceability related conditions. Inter-comparison dosimetry exercises have been performed inside ARCAL Projects (e.g. RLA 1013). Absorbed doses can be validated by NIST. Many types of dosimetry are available:

- PMMA Harwell Dosimetry: Gammachrome (0.1 – 0.3 kGy), Amber (1-30 kGy) and Red Perpex (5-50 kGy)
- Alanine Dosimetry
- FWT-60: Radiochromic thin film (0.5-200 kGy, 605 nm) – EB applications
- CTA: Cellulose Triacetate Film (10-300 kGy) – EB applications

![FIG.7: High Doses Dosimetry Laboratory, IPEN -Brazil](image-url)

### 3.3. Radiation processing at CETER -research and applications

Several applications have developed at the CETER facilities together with the High Doses Dosimetry Laboratory according to policies related to the Quality Assurance and Quality Control.

a. Preservation/ disinfestation of food and agricultural products.
Mean activities: modification of physical, chemical and biological properties. Rheology studies, nutritional properties, increase in shelf life, new formulas, aging, mechanical tests, etc. Animal feed and shavings used by certified bioteries are routinely disinfected.

b. Radiosterilization of Human tissues.

Mean activities: Sterilization of human tissues including bone, skin, amniotic membranes, tendons, and cartilage belonging to National Banks. Low temperature gamma irradiations (0°C, -70°C). New applications on tilapia skin to treat human burns (FIG.9).
c. Cultural Heritage artefacts and archived materials disinfection and consolidation

*Mean activities:* Disinfestation and disinfection of cultural heritage objects and archived materials [15][16][17][12]. Consolidation of resins using gamma radiation (FIG.10).

![FIG.10: Cultural Heritage Preservation using gamma radiation](image)

**d.** Polymerization – cross-linking of foams, semiconductors, wire - electric cables, heat shrinkable tubes, etc.[15]

![FIG.11: Cable/wire cross-linking](image)

**e.** Polymeric materials development and processing / radiosterilization of medical, surgical and biological products /cosmetics

*Mean activities:* Biomaterials development, curing/crosslink of hydrogel polymers, sterilization of hydroxyapatite, animal origin surgical suture, etc. (FIG.12)
3.4. Integrated management system (SGI) at IPEN

The Nuclear and Energy Research Institute has and Integrated Management System (SGI) to control several processes under the ISO 9001 certification. Processes are classified as Management Responsibility Processes; Resource Management Processes; Product Realization Processes and Processes for Measurement, Analysis, and Improvement. Most of the centers cited in item 3 are included in this system [14].
a. Management responsibility process

Includes the following information:
- Management manual (MG)
- Information – documentation
- Organization
- Critical analysis
- Planning
- Regulatory requirement
- Commercial
- Customer service

b. Resource management processes

Includes the following information:
- Infrastructure
- Training and development
- Radioprotection

c. Processes for product realization

Includes the following information:
- Project management
- Acquisition
- Storage and packing
- Commercial

d. Processes for measurement, analysis and improvement

Includes the following information:
- Audits
- Continuous improvement
- Customer service

3.5. Irradiation process at IPEN

Next flowchart shows the radiation processing process at IPEN[3] (FIG.14).
3.6. Installation qualification (IQ), Operation Qualification (OQ) and Performance qualification (PQ) validation at IPEN[13][7].

In order to guarantee controlled sterilization, the sterilization processes shall be IQ, OQ and PQ validated.

3.6.1. Installation Qualification (IQ)
Tests and checks are performed on the sterilization equipment to verify that their characteristics meet previously established specifications. Installation qualification (IQ) is responsibility of the sterilization operator.

3.6.2. Operational Qualification (OQ)
After setting the standard adjustment parameters for obtaining a sample result meeting the specifications, the OQ enables validation of these standard parameters, even when the process is carried out under imperfect conditions (adjustment validations and critical cases). Operational
qualification (OQ) falls under the responsibility of the sterilization operator. Dose mapping shall be performed based on the distribution and variability of the dose (FIG.15)[5][6][3].

3.6.3. Performance Qualification (PQ)
This process demonstrates that the gamma sterilization system yields a reproducible, correct result on the product. Product PQ: carried out under the supervision of the product manufacturer. This determines compliance of the sterilization process on the product.

a. Dose Mapping:
The first step of the validation is to verify that every product in the sterilization container receives a dose complying with the specifications (for example 25-40 kGy). As the dose received by the products can depend on the density of the products and their position in the sterilization container, before performing the dose mapping validation, the product loaded pattern shall be established. With this product loaded pattern, dosimeters will be placed to measure the dose received by the products at different points of the sterilization container.

b. Validation of the sterilizing dose:
This part of the product PQ makes it possible to validate the minimum irradiation dose required to sterilize the product (i.e. to guarantee a sterility assurance level -SAL of 10-6).

c. Validation of the maximum dose:
This part of the validation procedure verifies by means of various kinds of tests that product characteristics are not degraded by irradiation, even at the maximum dose.

3.7. Validation of the sterilization dose under ISO-11137 and ISO 13004 at IPEN
Establishment of the sterilizing dose according ISO 11137 and ISO 13004 can be determined following specific methods (microbiological methods must be validated before the analyzes are performed). ISO 11137 includes Method 1, method 2A, method 2B and VDmax method for 15 and 25 kGy. ISO 13004 includes VDmax method for 17.5, 20, 22.5, 27.5, 30, 32.5 and 35 kGy. The most widely used method is VDmax.

3.7.1. Method 1: Determining the dose using bioburden information under ISO 11137
   a. Selection of the sterility assurance level (SAL) and 10 product samples from three independent production batches (e.g. 30 samples). Samples must be representative of routinely sterilized products.
   b. Determination the average microbial load of the 3 batches of 10 items (method based on ISO 11737-1)
   c. Obtaining of the verification dose (referring to table 5 of ISO11137-2)
   d. Conduction of verification dose experiments on 100 irradiated pieces (method based on ISO 11737-2)
   e. Interpretation of the results
   f. Establishing the sterilization dose based on the results (maximum of 2 positives out of 100 pieces)

Remarks: 130 products are therefore required for this method. The advantage of this method is that it enables any sterilizing dose to be validated.

3.7.2. Method 2A: Determining the dose using information about the proportion of positives from the incremental dosage in order to determine an extrapolation factor under ISO 11137.
   a. Selection the sterility assurance level (SAL) and obtaining samples of the product (280 samples for 2 independent production batches). The product samples must be representative of the products routinely sterilized.
   b. Conduction of the incremental dose experiments; irradiation of 20 pieces at incremental doses of 2 kGy beginning with the 2 kGy dose and using at least 9 values. This needs to be done for each of the 3 batches involved. Performing a sterility test on each of the products.
   c. Conduction of verification dose experiments; irradiation of 100 pieces at the verification dose and performing of the sterility test on each of the products
   d. Examination the results
   e. Establishing the sterilizing dose based on the results

Remarks: This method is rarely used due to the large number of products and tests required to validate a sterilization dose.

3.7.3. Method 2B: Determining the dose using information about the proportion of positives from the incremental dosage in order to determine an extrapolation factor under ISO 11137

Applicable if the entire product is tested (SIP = 1); and after irradiation at any incremental dose, the number of positive sterility tests observed does not exceed 14; FNP (first non-positive) shall not exceed 5.5 kGy.
a. Selection of the sterility assurance level (SAL) and obtaining of samples of the product (260 samples for 3 independent production batches). The product samples must be representative of the products routinely sterilized.

b. Conduction of the incremental dose experiments; irradiation of 20 pieces at incremental doses of 1 kGy beginning with the 1 kGy dose and using at least 8 values. This needs to be done for each of the 3 related batches. Performing of a sterility test on each of the products.

c. Conduction of the verification dose experiments; irradiation of 100 pieces at the verification dose and performing of a sterility test on each of the products.

d. Examination of the results

e. Establishing of the sterilizing dose based on the results

Remarks: This method is rarely used due to the large number of products and tests required to validate a sterilization dose.

3.7.4. VDmax Method: justification for a sterilizing dose of 15, 17.5, 20, 22.5, 25, 27.5, 30, 32.5 and 35 kGy under ISO 11137 and ISO 13004 (TABLE 3)

Regardless of the desired dose, this method follows the same steps only by changing the ISO reference tables. For VDmax15 is only possible to apply for SIP=1.

a. Obtaining of product samples (30 samples for 3 independent production batches). The product samples must be representative of routinely sterilized products.

b. Determination of the average bioburden of 3 batches of 10 pieces

c. Determination of the verification dose according to the reference tables in ISO11137 or ISO 13004.

d. Conduction of the verification dose experiments; irradiation of 10 products at the verification dose and performing the sterility test on each of the products

e. Interpretation of the results: accept the related sterilization dose if 0 or 1 of the 10 pieces is positive. Conduction of the verification dose confirmation experiments if 2 are positive. Do not accept the verification if there are more than 2 positives

Remarks: Between 20 and 40 products are required for this method.
### TABLE 3: VDMAX METHOD SPECIFICATION

<table>
<thead>
<tr>
<th>Maximal bioburden value</th>
<th>VDmax Method</th>
<th>ISO</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.5</td>
<td>15</td>
<td>11137</td>
</tr>
<tr>
<td>9.0</td>
<td>17.5</td>
<td>13004</td>
</tr>
<tr>
<td>45</td>
<td>20.0</td>
<td>13004</td>
</tr>
<tr>
<td>220</td>
<td>22.5</td>
<td>13004</td>
</tr>
<tr>
<td>1000</td>
<td>25.0</td>
<td>11137</td>
</tr>
<tr>
<td>5000</td>
<td>27.5</td>
<td>13004</td>
</tr>
<tr>
<td>23000</td>
<td>30.0</td>
<td>13004</td>
</tr>
<tr>
<td>100000</td>
<td>32.5</td>
<td>13004</td>
</tr>
<tr>
<td>440000</td>
<td>35.0</td>
<td>13004</td>
</tr>
</tbody>
</table>

### 4. REGIONAL IAEA LATIN AMERICAN RELATED PROJECTS

The RLA 1013 (2016-2019) “Creating Expertise in the Use of Radiation Technology for Improving Industrial Performance, Developing New Materials and Products, and Reducing the Environmental Impact of the Industry” has been provided conditions to realize dosimetry inter-comparison exercises between the LA countries.

The RLA 1015 (2018 – 2019) “Harmonizing Integrated Management Systems and Good Irradiation Practice Procedures in Irradiation Facilities” has been helping the LA governmental facilities to train the personnel in specific areas as dosimetry and ISO standards.

### 5. CONCLUSIONS AND RECOMMENDATIONS

Several radiation processing applications developed at IPEN are related to a desired effect in the irradiated material (e.g. curing, cross-linking) as well hydrogels, wire and cables or the consolidation of cultural heritage materials using a resin. Disinfection of cultural heritage objects needs to be applied between a maximal and a minimal dose to avoid degradation of the material (e.g. cellulose based materials or human tissues) and to ensure the biological effect (insects or fungi). References available (IAEA Tec Docs, Series etc.) need to be updated specifically the Guidelines for Development, Validation and Routine Control of Industrial Radiation Processes. IAEA Radiation Technology Series No. 4.
ACKNOWLEDGMENTS

The authors would like to thank the financial support provided by the IAEA.

REFERENCES

[1] https://www.ipen.br/
HUNGARY

THE ROLE OF THE INTERNATIONAL ATOMIC ENERGY AGENCY EUROPEAN REGIONAL TC PROJECTS IN QA/QC DEVELOPMENT AND SUSTAINABILITY IN RADIATION PROCESSING

A. KOVÁCS¹, B. HAN²

¹Centre for Energy Research, Hungarian Academy of Sciences
Budapest, Hungary

²International Atomic Energy Agency
Vienna, Austria

Abstract

The introduction and daily use of radiation processing in various fields of applications is of key importance for public health safety, new materials and cleaner environment. The IAEA has got key role in supporting Member States to introduce and maintain sustainable radiation technologies. QA/QC is of basic importance in performing high standard irradiation technologies. The role of dosimetry is inevitable in carrying out standardized irradiation process control both at gamma and electron irradiation facilities. Suitable calibration of reference and routine dosimeter systems is the basis for traceable use of such dosimeter systems. The experiences gained during the Regional European IAEA TC projects during the past decade could strongly help the IAEA efforts to initiate regional projects in radiation processing in other TC regions to improve the standardized performance of these technologies worldwide.

1. THE SIGNIFICANCE OF THE INTERNATIONAL ATOMIC ENERGY AGENCY’S EUROPEAN REGIONAL PROJECTS IN ASSURING SUSTAINABILITY IN RADIATION PROCESSING

Radiation processing is still an emerging application worldwide. The radiation sterilization of medical products, the radiation crosslinking of advanced materials and the radiation decontamination of food products are well established technologies in developed countries for many decades. In some European developing countries (e.g. Bulgaria, the former Czechoslovakia, Hungary, Poland, the former Sovietunion, the former Yugoslavla) the introduction and routine use of these technologies have reached a significant level by the last decades of the previous century (Fig. 1). The economic crisis, however, at the turn of the century resulted in the weakening of the operating conditions of radiation processing due to lack of financial and human resources and expertise. In some cases the consequence was even the disappearance of these technologies in some of these countries. In order to avoid these consequences the strengthening of this industry has been achieved (1) through the partnership of developed and developing countries and (2) with the help, support and coordinating role of the International Atomic Energy Agency through the initiation of the IAEA European Regional Technical Cooperation Program (RER projects). The outstanding role of the IAEA has been clearly seen in these TC Projects, which have been carried out since 2005 to promote and enhance radiation processing in European Member States (Albania, Azerbaijan, Belarus, Bulgaria, Croatia, Estonia, Hungary, Kazakhstan, Latvia, Lithuania, Portugal, Poland,
Romania, Russian Federation, Serbia, Slovakia, Turkey, Ukraine) (Fig. 2). These projects were the followings: RER 8010 (Quality Control Methods and Procedures for Radiation Technology, 2005-2008); RER 8017 (Enhancing Quality Control Methods and Procedures for Radiation Technology, 2009-2011); RER 1011 (2012-2013) and RER 1014 (2014-2015), (Introducing and Harmonizing Standardized Quality Control Procedures for Radiation Technologies); RER 1017 (Using Advanced Radiation Technologies for Materials Processing, 2016-2017).

The main tasks and topics of these regional (RER) projects were the followings:

- Survey of the MSs’ capabilities, difficulties and plans in 2008 & 2017:
  (irradiation facilities, technologies, QA/QC - dosimetry; QMS – audits;
- Establishment, upgrading and safe operation of irradiation facilities;
- QA/QC in the validation and routine process control procedures;
- Introduction/upgrading of QMSs, ISO and ISO/ASTM standards;
- Initiation and introduction of new irradiation technologies;
- Assuring traceability in dosimetry procedures;
- Initiation of bi/trilateral /interregional cooperation programmes;
- Introduction of voluntary audits;

In order to have a clear view on the actual situation on radiation processing a survey was prepared in 2008 in the following 11 IAEA European Regional Developing Member States:
Albania, Bulgaria, Croatia, Hungary, Portugal, Poland, Romania, Serbia, Slovakia, Turkey and Ukraine. In 2017 a new survey was prepared involving more Member States from the region: Azerbaijan, Belarus, Estonia, Kazakhstan, Latvia, Lithuania. The survey involved the name, head, type, postal address, website of the irradiation organization, the type, manufacturer, commissioning date, nominal and present activity and/or the electron energy of the irradiation facility, dosimetry systems used, calibration methods and dosimetry standards applied, traceability achieved and potential participation in dosimetry intercomparison exercises, processed products, quality management systems applied and standards used. Based on the survey, as well as on the requests of the Member States the programs were established and realized by using workshops, training courses, expert missions, scientific visits, voluntary audits and dosimetry intercomparison exercises.

![Map of Member States participating in the IAEA European Regional TC Projects (2017)](image)

FIG. 2. Member States participating at the IAEA European Regional TC Projects (2017)

The RER 1017 project has been a significant milestone in maintaining sustainability as well as introducing new technologies in the above Member States. Followed by the successful execution of this project elements and procedures RER1017 was selected as a success story:

- RTC on the implementation and maintaining of QMS in radiation processing facilities (Bucharest, Romania)
- RTC on „Hands-on” dosimetry procedures in gamma (Budapest, Hungary) and in EB irradiation processing technologies (Ekaterinburg, Russian Federation)
- Regional Meeting to complete the „Harmonized Guidance Material and Protocols for Quality Control/Quality Assurance in Radiation Processing Management at Regional Level” (Babadela, Portugal)
– RTC on safe operation of gamma and EB facilities for radiation processing (Belgrade, Serbia)

– Technical Meeting on the evaluation of the first phase of the „Dosimetry Intercomparison Exercise (Vienna, Austria)

– Regional Meeting on Feasibility of Radiation Processing Technologies for Decision Makers (Zagreb, Croatia)

– Workshop on Techno-Commercial Aspects for Setting New Radiation Facilities (Trencin, Slovakia)

These RER projects have also helped the spreading of such emerging radiation applications like environmental protection technologies, development of biomedical products and preservation of cultural heritage artifacts.

2. THE ROLE OF DOSIMETRY IN QA/QC DEVELOPMENT IN RADIATION PROCESSING

The successful implementation of radiation technologies depends very much on reliable quality assurance, i.e. the measurement of absorbed dose during process validation and control, as well as the continuous control of irradiation facility parameters and the use of mathematical modelling in installation, operational and performance qualification. Irradiation process validation and control is achieved by using harmonized and standardized dosimetry procedures and methods. Dosimetry, as part of the total quality system provides quality assurance and documentation that the irradiation process was performed according to the pre-set specifications. Accurate and traceable dosimetry measurements, based on suitable calibration procedures, provide independent means for quality control in radiation processing. In all validation steps (as described in ISO Standard 11137-3) [1], i.e. during process definition, installation-, operational- and performance qualification, as well as in routine process control, various reference standard and routine dosimetry systems are applied for quality control, shown on Fig. 3. and in Table 1. [2].

FIG. 3. Low energy polystyrene calorimeters and GEX, FWT-60, GafChromic film dosimeters

Based on the survey mentioned above, the most frequently used dosimetry systems in the RER Member States are ethanol-monochlorobenzene, Fricke, GEX dosestick, Perspex and alanine in gamma facilities, while polystyrene process calorimeters, radiochromic films (GEX, FWT-60), PVC and alanine for electron irradiation facilities.
The calibration of the reference and routine dosimeter systems is of basic importance with respect to performing accurate and traceable dosimetry measurements. Reference and routine dosimeters are suggested to be calibrated either in accredited calibration dosimetry laboratories or in the actual irradiation facility, where the routine dosimeters are planned to be used (Fig. 4. and 5.).

In the course of the RER 1017 and RER 1019 projects the laboratories participating at the dosimetry intercomparison exercises could achieve traceability through the accredited dosimetry laboratory of the Institute of Nuclear Chemistry and Technology, in Warsaw.

<table>
<thead>
<tr>
<th>DOSIMETER SYSTEM</th>
<th>METHOD OF ANALYSIS</th>
<th>USEFUL DOSE RANGE, GY</th>
<th>NOMINAL PRECISION LIMITS</th>
<th>REFERENCES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fricke solution</td>
<td>UV – spectrophotometry</td>
<td>3 x 10^2 - 4 x 10^3</td>
<td>1%</td>
<td>ASTM E 1026 - 04</td>
</tr>
</tbody>
</table>
### Technical Meeting, Malaysia, 05-09 August 2019

<table>
<thead>
<tr>
<th>Material</th>
<th>Methodology</th>
<th>Concentration</th>
<th>Precision</th>
<th>Standard</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceric – cerous sulphate</td>
<td>UV – spectrophotometry</td>
<td>$10^3 - 10^6$</td>
<td>3%</td>
<td>ISO/ASTM 51205</td>
<td></td>
</tr>
<tr>
<td>Potassium dichromate</td>
<td>UV-VIS spectrophotometry</td>
<td>$5 \times 10^3 - 4 \times 10^4$</td>
<td>1%</td>
<td>ISO/ASTM 51401</td>
<td></td>
</tr>
<tr>
<td>Ethanol-mono-chlorobenzene</td>
<td>Titration, or HF oscillometry</td>
<td>$4 \times 10^2 - 3 \times 10^5$</td>
<td>3%</td>
<td>ISO/ASTM 51538</td>
<td></td>
</tr>
<tr>
<td>L - alanine</td>
<td>EPR</td>
<td>$1 - 10^5$</td>
<td>0.5%</td>
<td>ISO/ASTM 51607</td>
<td></td>
</tr>
<tr>
<td>Perspex systems</td>
<td>VIS - spectrophotometry</td>
<td>$10^3 - 5 \times 10^4$</td>
<td>4%</td>
<td>ISO/ASTM 51276</td>
<td></td>
</tr>
<tr>
<td>FWT – 60 film</td>
<td>VIS - spectrophotometry</td>
<td>$10^3 - 10^5$</td>
<td>3%</td>
<td>ISO/ASTM 51275</td>
<td></td>
</tr>
<tr>
<td>B 3 film</td>
<td>VIS - spectrophotometry</td>
<td>$10^3 - 10^5$</td>
<td>3%</td>
<td>ISO/ASTM 51275</td>
<td></td>
</tr>
<tr>
<td>Cellulose triacetate</td>
<td>UV – spectrophotometry</td>
<td>$10^4 - 10^6$</td>
<td>3%</td>
<td>ISO/ASTM 51650</td>
<td></td>
</tr>
<tr>
<td>Calorimetry</td>
<td>Resistance/temperature</td>
<td>$1.5 \times 10^3 - 5 \times 10^4$</td>
<td>2%</td>
<td>ISO/ASTM 51631</td>
<td></td>
</tr>
</tbody>
</table>

3. **CONCLUSIONS**

Taking into account the differences with respect to the level of applied radiation processing technologies, available irradiation facilities, applied quality management systems and process control methods used in various Member States, the role and support of the IAEA is inevitable. The most important conclusions gained so far from the European Regional TC projects are the followings:

- Reliable QA/QC, standardized dosimetry and detailed QMS in radiation processing is inevitable for the benefit of mankind

- The IAEA TC Regional Projects have great significance to establish and maintain sustainability in performing high quality radiation processing
Cooperation with educational institutions, universities (capacity building) are of great importance

The IAEA Regional TC projects can support accreditation of laboratories in dosimetry, microbiology, material testing, as well as dosimetry intercomparison exercises

Dosimetry intercomparison exercises are key activities to perform traceable and accurate dosimetry measurements

Initiation of such regional projects in other IAEA TC regions is important and the utilization of the experiences gained in the Latin American and European regions is strongly suggested

Establishment of interregional cooperation could help the wider range applications of radiation processing technologies worldwide.

4. REFERENCES


INDIA

QUALITY MANAGEMENT PRACTICES IN RADIATION PROCESSING FACILITIES: CURRENT STATUS AND EMERGING NEEDS

SUNIL SABHARWAL

Tharwani Heritage, Sector 7, Plot No. 24
Kharghar. Navi Mumbai-410210, India
E.mail: sunsab57@gmail.com

Summary
The use of radiation processing in areas such as health care and food for applications such as sterilization of medical products or food irradiation demands implementing rigorous quality management practices to ensure acceptance in these industries. Since radiation processing quality assurance programmes are based primarily on radiation dose absorbed by the product, radiation dosimetry plays a crucial part in ensuring proper control of the irradiation process and final product. In India, radiation processing is being used on a large scale across the country for a variety of applications using gamma as well as electron beam facilities. The present status of quality management practices being followed in such facilities, implanting national facilities and emerging needs of industry are identified and reported in this paper.
1. INTRODUCTION

Radiation processing has been established as a well-accepted technology particularly for applications such as radiation sterilization of medical devices, polymer crosslinking and curing, food irradiation, with over 250+ gamma radiation facilities and over 1600 electron beam accelerators working throughout the world. In India, the era of radiation processing started with establishment of ISOMED plant that was set up in 1974 by the Department of Atomic Energy, India to provide gamma sterilization services for radiation sterilisation of medical and healthcare products in India. Establishing the advantages of radiation sterilization over conventional methods and bringing in a new technology in the country required a tremendous effort over many years by the radiation technologists [1]. The eventual technical superiority of the technology and the commercial success of the plant subsequently prompted a large number of manufacturers to use this technology. The operational experience of operating this plant together with emerging needs of food hygienisation prompted establishment of another gamma radiation facility namely, Radiation Processing Plant (RPP) at Vashi, Navi Mumbai designed for a maximum of one million Ci of Co-60 and capable of processing wide varieties of food products with an approximate throughput of 12,000 T/ year at an average dose of 10 kGy. Currently, eighteen radiation processing plants (RPP) having various capacities are operating in India for irradiation of food, agricultural and medical products and few more plants are under construction. The use of electron beam machines for radiation processing was initiated with commissioning of a 2-MeV, 20 kW ILU-6 electron beam accelerator at Bhabha Atomic Research Centre in 1988 which formed the basis of initiating R&D in collaboration with industry for crosslinking of wire & cables, heat-shrink materials and many more applications for value addition to materials. Today,10 such machines are in operation in the country for industrial applications.

Production of a high-quality product necessitates having an established QMSs that can be followed consistently and with established quality standards and regulations ensuring harmonized protocols across regions in the world leading to enhanced international trade. The fact that quality assurance is vital for implementing radiation processing technologies with standardized and harmonized procedures of process validation and process control was evident since the beginning of radiation processing programmes in India. Therefore, a conscious effort was made to ensure that the QA/QC processes needed for radiation technologies are integrated with quality standards and guidelines being recommended by international and national organizations namely, the International Organization for Standardization (ISO), European Committee on Standardization (CEN), World Health Organization (WHO), American Society for Testing and Materials (ASTM), Food and Agriculture Organization (FAO), etc in the operational radiation facilities. To meet these objectives, appropriate facilities have been established for ionizing radiation metrology in India in designated centres that maintains number of national standards for ionizing radiation and continuously updates them to achieve better accuracy.

This report briefly presents the current status of quality management practices and related activities currently implemented in these facilities.

2. NATIONAL STANDARDS AND RADIATION METROLOGY

Radiation Safety Systems Division, BARC is the designated institute for ionizing radiation metrology in India. It maintains number of national standards for ionizing radiation and
continuously updates them to achieve better accuracy. These standards include primary standards, secondary standards and working standards for radiological quantities, radioactivity, neutron, and chemical dosimetry. BARC has also been recognized as a Secondary Standard Dosimetry Laboratory (SSDL-BARC) by IAEA/WHO. Under this aegis, quality audits are being conducted since 1976 for assessing the dosimetry status of radiotherapy centres, nuclear medicine centres and radiation processing facilities in India. Standards for high dose are established and maintained in the laboratory. Fricke dosimeter is maintained as a reference standard using ASTM practice E 1026 (95). Alanine and glutamine free radical dosimeters (spectrometric readout method) are used as transfer standard dosimeters in radiation processing. The alanine EPR dosimeters are traceable to NIST(USA) and NPL(UK) through calibration exercises inbuilt in the EPR spectrometer.

The centre regularly carries out dose inter-comparison exercise for the radiation processing facilities in India including standardization / calibration of high dose dosimeters. Dosimeters belonging to the radiation facilities (like alanine-EPR, ceric-cerous, dichromate, radiochromic film, radiochromic waveguide etc.) are calibrated against Fricke dosimeters which is maintained as primary reference standard in the laboratory. The dose values are required to be within 3.5% for the exercise to be successful. Upon successful completion of the inter-comparison exercise, transfer standard dosimeters are sent to the radiation processing facility to perform dose verification exercise with the actual food products to be radiation processed. While the first step tests the ability of facility to measure and maintain working dosimeter, in the second step ability of the facility to irradiate the food products within the stipulated dose limits is verified. These procedures ensure that the quality assurance is carried out for high dose applications of radiation processing plants in an appropriate manner. In the earlier years, the laboratory at BARC also participated in the international dose assurance program of the IAEA. The laboratory also has the facilities for providing calibrated high dose rate gamma fields to users.

3. CURRENT STATUS OF QA/QC IN GAMMA RADIATION FACILITIES

3.1 ISOMED RADIATION STERILIZATION PLANT

The ISOMED plant for radiation sterilization of medical products has a maximum capacity of 1 million curies cobalt-60 presently is loaded with about 0.500 M Ci. The dosimetry at the plant is carried out using ceric-cerous dosimetry where change in concentration of ceric ions is measured using electrochemical readout system and an indigenously developed software is used for conversion of mV to absorbed dose. ISOMED has acquired compliance to ISO 9001:2008, ISO 13485:2003, ISO 11137:2006, ISO 22000:2005 - HACCP and also features on the list of approved facilities of the European Union.

3.2 RADIATION PROCESSING PLANT, FOOD IRRADIATION

Radiation processing plant at Vashi which emerged as the focal facility for irradiation of food products also is designed for housing a 1-million curie Cobalt-60 source. This plant is located in the vicinity of agricultural produce market, traders and exporters so as to derive maximum benefit from radiation processing technology with increasing acceptance of their product in the international market. The products are processed under strict adherence to ‘Good Radiation Practices’ and in-house quality assurance programme. The facility like ISOMED uses ceric-cerous dosimetry with potentiometric read-out for routine dosimetry operation. The facility has

3.3 RADIATION PROCESSING PLANTS IN PRIVATE SECTOR

Currently, eighteen radiation processing plants (RPP) having various capacities are operating for irradiation of food, agricultural and medical products and few more plants are under construction. These plants are designed and built indigenously wherein cobalt-60 produced within the country is used as a source. Board of Research in Isotope Technology (BRIT), Department of Atomic Energy is actively engaged in facilitating setting up of these facilities and it conducts the initial dosimetry of the facilities mainly using ceric-cerous dosimetry to ensure OQ/PQ. The subsequent dosimetry validation at these facilities is ensured through dosimetry inter-comparison exercises conducted regularly by RSSD. Further, as many of these facilities are involved in irradiating products that are exported to other countries, these facilities are being operated with appropriate ISO and other required international certifications.

4. CURRENT STATUS OF QA/QC IN ELECTRON BEAM FACILITIES

Electron beams are widely utilized in the radiation processing of large varieties of industrial products in many countries. In India, an industrial electron beam accelerator ILU-6 (2 MeV, 20 kW) at Bhabha Atomic Research Centre (BARC) was the first such facility installed in 1988 which was utilized as demonstration and research facility for developing radiation processing applications in the country for applications such as cross linking of wire & cables, crosslinking of polyethylene “O” rings, heat-shrink materials, Teflon degradation and colouration of gem stones. At this facility, considerable work has been carried out to use calorimeters for electron beam dosimetry of 2-MeV accelerator. The use of polystyrene calorimeters as routine dosimeters for the accelerators operating in the energy range of 1.5 MeV to 4 MeV has been demonstrated by Miller et.al. [2]. As the energy of the beam at ILU-6 accelerator is only up to 2 MeV, a new approach was adopted by using graphite calorimeters of different thickness for the estimating various irradiation parameters of the beam. For this, graphite calorimeters of different thicknesses in the range of 0.6 to 10 mm were designed and fabricated. Using these calorimeters, various parameters such as energy fluence, average absorbed dose, absorbed dose at any depth in the medium and practical range (Rp) were calculated, and reported by Benny et al. [3]. The routine dosimetry at this electron beam facility is conducted using FWT films. The facility now has been upgraded to a 5-Mev, 15-kW ILU-8 electron beam facility. Today nearly 10 electron beam accelerators are operating in the country mainly in private sector for crosslinking of cables, heat-shrink materials, teflon degradation and curing of tire. For most of these applications, meeting the performance characteristics of the end-products constitutes acceptance of the product and routine dosimetry studies are seldom reported.

5. EMERGING NEEDS

The necessity of radiation technologists to keep pace with the emerging needs of the end user requirements in crucial areas such as health care and food requires radiation processing plants to periodically update their skills and facilities so as to become an integrated part of the product safety. Since ensuring QA/QC in radiation processing is principally based on radiation dosimetry, effective implementation of dosimetry protocols including advanced concepts such as uncertainty measurements and budgeting in dosimetry is essential. This requires adequate
providing training and guidance to the dosimetry professionals at the plant level in a structured manner.

Further, a variety of new products, both for sterilization of medical products and food irradiation, need irradiation under non-standard irradiation conditions for which harmonized dosimetry protocols are as yet not available. For example, some of the food materials need to be irradiated at low temperatures under frozen conditions. Under such conditions, harmonized dosimetry protocols to ensure implementation of quality management practices is essential and need to be developed. Such protocols can be developed in an efficient manner through appropriate international collaborations.

6. CONCLUSIONS

India has a well-established radiation processing programme using gamma as well as electron beam irradiation with a large number of facilities operating across the country. Accurate and reliable dosimetry constitutes the backbone of radiation processing practices in these facilities specially gamma radiation facilities engaged in medical sterilization and/or food irradiation. BRIT provides the necessary expertise for establishing initial OQ/PQ at the facilities during commissioning while the subsequent dosimetry inter-comparison exercises conducted indigenously by Radiation Standards Section, Radiation Safety Systems Division, BARC ensures validation and process control in these facilities. The radiation processing facilities across the country have further been certified by external agencies such as ISO certifications as needed by the end users. Implementation of advanced protocols such as uncertainty measurements will further strengthen quality assurance programmes. In view of the new developments taking place world over in radiation processing of materials used in healthcare or food processing that require non-standard irradiation conditions, harmonized protocols need to be developed through international cooperation.

REFERENCES

2. A. Miller, A. Kovacs, F. Kuntz, Development of polystyrene calorimeter for application at electron energies down to 1.5MeV, Radiation Physics and Chemistry 63 (2002) 739–744.
INDONESIA

PROJECT DEVELOPMENT PROGRAM ON IRRADIATION FACILITY IN INDONESIA AND URGENCY TO DEVELOP AND APPLIED MILESTONE APPROACH ON RADIATION FACILITY PROJECT

FATMUANIS BASUKI MOHAMMAD¹, DHANDHANG PURWADI², MUJIONO³

¹Center for Education and Training, National Nuclear Energy Agency, Indonesia,
²Center for Engineering of Nuclear Facility, National Nuclear Energy Agency, Indonesia
³Center for Application Isotope and Radiation, National Nuclear Energy Agency, Indonesia

Jl. Kuningan Barat, Mampang Prapatan, Jakarta, 12710

Abstract
Indonesia now operates 3 gamma irradiators which provide irradiation services to the customers. Two of them are operated by government agency, National Nuclear Energy Agency, BATAN, at Jakarta & South Tangerang city. The only private-owned gamma irradiator is operated by Rel-Ion Co. at Cikarang city (25 km east of Jakarta). There are 5 (fives) Companies operated electron beam machine for their own production process. In year 2016, The National Nuclear Energy Agency of Indonesia (BATAN) and Izotop-Hungary signed the agreement regarding the construction of the gamma irradiation facility. The gamma irradiator facility calls as Irradiator Gamma Merah Putih (IGMP), inaugurated on November 15, 2017, was built with the scheme of cooperation in technology transfer and its local content reached 80%. IGMP was designed to be an irradiator prototype on a commercial industrial scale that could be used as an example for the application of similar technology by investors in many potential areas in Indonesia. Complementing with the gamma irradiator BATAN intent to develop high energy electron accelerator will be carried out through technology transfer cooperation with EB Tech Co. Ltd. South Korea. The MoU signed by both parties at Vienna-Austria on May 30, 2017. Milestone approach for radiation facility project urgent to develop and implemented to ensure self-reliance and sustainability of the radiation technology project. Regulatory aspect and management system were implemented to keep high safety standard and

1. INTRODUCTION

In Indonesia, food irradiation technique has been acknowledged as useful treatment for various food products and has been used by food companies, Small to Medium Enterprise (SMEs) and government agencies for various applications. The vastly growing needs of business sector on the use of food irradiation has made Indonesian government enacted regulations related to the application of this beneficial technique since 1980s, following research in food irradiation which was started in the 1960s decade. The Ministry of Health and National Agency for Drugs and Food Control (BPOM) has been playing their important role in adapting international codex on food irradiation and monitoring function to the use of food irradiation technique by various sectors across nation. In cooperation with National Nuclear Energy Agency (BATAN), the Ministry & BPOM continuously develop & strengthen regulatory framework to accommodate vastly growing needs from industrial sectors on this technique, as well as to adapt with new technologies in the field. To ensure safety applications of irradiation technique, BPOM enacted Regulation Number 3 of 2018 as the newest standard for reference.

Indonesia now operates 3 gamma irradiators which provide irradiation services to the customers. Two of them are operated by government agency, BATAN at Jakarta & South Tangerang city. The only private-owned gamma irradiator is operated by Rel-Ion Co. at Cikarang city (25 km east of Jakarta). The location of three operating irradiators which are concentrated around Jakarta region creates challenges for customer who have production facilities outside Jakarta, especially on the additional transportation cost on their food products processing. The condition encourages Indonesian government in promoting construction and operate of new irradiation facilities by private sector in potential areas where food commodities
are produced and at areas where internationally-connected ports are located to cut additional commodities transportation cost.

Besides gamma irradiators, 4 (four) companies have operated electron beam machines, namely Sumi Rubber Indonesia Co., Multistrada Arah Sarana Tbk., Bridgestone Tire Indonesia Co., NIPRO Indonesia Jaya Co., and Indowire Prima Industrindo Co. for the needs of their production processes for the production of tires, cables and sterilization medical.

2. THE GAMMA IRRADIATOR FACILITY ENGINEERING PROJECT IN INDONESIA

The National Nuclear Energy Agency of Indonesia (BATAN) developed a reliable and effective gamma irradiator design by reverse engineering strategy of technology transfer. BATAN and The Institute of Isotopes Co. Ltd. Hungary (Izotop-Hungary) signed the agreement in September 2014 regarding the construction of the irradiation facility. The gamma irradiator was also considered a priority project by the Hungarian–Indonesian Joint Commission on Bilateral Economic Cooperation (JCEC). The schedule and output target to build IGMP shows in Figure 1.

The gamma irradiator designed for capacity of two million curies of cobalt-60, tote dimension 486 x 486 x 915 mm, maximum product weight 120 kg and range density product between 0.1-0.6 g/cc. Gamma Irradiator call as Irradiator Gamma Merah Putih (IGMP) constructed by the major construction company PT. Adhi Karya (Persero) Tbk, was completed in the second half of 2017 and inaugurated On November 15, 2017 the Gamma Irradiator call as IGMP with the main milestone as follow as,

- MoU between BATAN and Institute of Isotopes Co LTD , on September 24, 2014 at Vienna, Austria
- Institute of Isotopes Co. Ltd. Hungary issued letter of appointment for PT. Gamma Mitra Lestari (GML) on April 2015 as a local partner
- IGMP Construction offers 2015-2016
- Institute of Isotopes Co. Ltd. Hungary release of basic design documents of the building.
- Purchase Order of PT. GML on March 2016
- Release of documents non safety related equipment between April-May 2016
- Start of building the facility and production – March-April-May 2016
- Loading of the sources, hand over – June 2017
- Inauguration – Aug 2017

The scope of work between Izotop-Hungary and National Nuclear Energy Agency – Indonesia during the project as well as safety related and non-safety related equipment shows in Table 1.

### TABLE 1. SCOPE OF WORK BETWEEN INSTITUTE OF ISOTOPES CO. LTD. AND BATAN

<table>
<thead>
<tr>
<th>SCOPE OF WORK (HUNGARY)</th>
<th>SCOPE OF WORK (INDONESIA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Institute Of Isotopes Co. Ltd (Izotop)</td>
<td>National Nuclear Energy Agency (BATAN)</td>
</tr>
<tr>
<td>Provides basic design documentation of the building</td>
<td>Constructs the building</td>
</tr>
<tr>
<td>Provides drawings of non safety related equipment</td>
<td>Produces nsre (using the drawings and under the supervision of Institute Of Isotopes)</td>
</tr>
<tr>
<td>Provides supervision for production and installation of non safety related equipment (nsre)</td>
<td>Installs nsre under the supervision of Institute Of Isotopes</td>
</tr>
<tr>
<td>Produces and installs safety related equipment</td>
<td>In charge of all local licences required</td>
</tr>
<tr>
<td>Provides training on operation</td>
<td></td>
</tr>
<tr>
<td>Loads Co-60 radioactive sources</td>
<td></td>
</tr>
</tbody>
</table>

#### Safety-related Systems and Controls
- Co-60 Radioactive sealed sources
- Warning signs and signals
- Main safety and security control system and specific subsystems:
  - Center of Irradiator control system
  - Source hoist system
  - Control of transport system (electronic parts)
  - Radiation measuring system
  - Water level control system
  - Personnel’s access control, the interlock systems
  - PLC independent interlock system
  - Goods maze door security and safety system
  - Personal maze door security and safety system
  - Detection system of Pressurized Air Supply System
  - Electrical power failure detection system with UPS
  - Environmental danger detecting system excluding fire distinguish system
  - Security System

#### Non Safety-related Systems and Controls
- Goods maze door
- Personnel maze door
- Transport system (mechanical part’s)
- Water pool lining with stainless steel sheets
- Water treatment system
- Water cooling system (if activity is higher than 500,000 Ci)
- Electrical network in the building
- Lightning in the building
- Telecommunication network in the building
- Main electrical terminal board (PS)
- Crane (electrical or pneumatic, 6 tons capacity)
- Pressured Air Supply System (air compressor, buffer tank, etc.)
- Ventilation system
- 14. Fire extinguisher system
IGMP facility was built with the scheme of cooperation in technology transfer and its local content reached 80%. IGMP was designed to be an prototype irradiator on a commercial industrial scale that could be used as an example for the application of similar technology, by investors in many potential areas in Indonesia. The construction of similar irradiators such as IGMP will increasingly provide opportunities for the development of the food product industry with optimal competitiveness.

3. PROJECT PLANNING ON DEVELOPMENT OF HIGH ENERGY ELECTRON ACCELERATOR (HEEA)

BATAN, in its planning for the next five years, intends to develop a prototype electron accelerator, complementing the gamma irradiator that has been completed in construction and built in 2017. In general, the development of prototypes of high-energy electron accelerators has two objectives: increasing technological capacity in the nuclear field, especially particle accelerators and improving people's welfare through increasing the capacity of the health medical industry, pharmaceuticals and pharmaceutical packaging industries. In the health industry, the sterilization process is a standard procedure and is very important. All health equipment must be sterile. The most common method or technique for sterilizing a product is by heating or by using chemicals. This technique has disadvantages such as requiring high heat energy and less practical for large scale. The use of chemicals can be done by immersion in chemical media or by gasification. This method is commonly applied on an industrial scale, but this method leaves relatively dangerous chemical residues.

Utilization of nuclear techniques through irradiation of high-energy electron beams in appropriate doses can be used for safe and reliable sterilization, without leaving residual radiation or hazardous chemical residues. This technology is far more efficient than using heating techniques. This technology can also be applied to industrial scale and is more innovative compared to sterilization techniques using chemicals because it does not produce any harmful residues.

In contrast to gamma irradiator facilities, high-energy electron accelerators in operation do not require radioactive or radioactive sources. Electron accelerators only need electrical power and can be switched off during not operation. The availability of gamma irradiators and high-energy electron accelerators will be a combination of complementary irradiation facilities, because each has advantages that can cross each other to fill their weaknesses.

To anticipate the need for electron accelerators in Indonesia, BATAN proposes the existence of innovative research on high-energy electron accelerators developed from a type of electron accelerator that has been proven to operate well and efficiently and has proven its reliability.

In R & D and engineering and innovation, a technology transfer from the vendor country is needed with a reverse engineering strategy. The reverse engineering strategy will cut the maturation time of electron accelerator technology to be adopted. The success of technology transfer will be measured by the mastery of technology and the ability of the national industry to provide electron accelerator components. The level of domestic component content is the main indicator of the success of this technology transfer activity.

The output of the activity was a prototype for the demonstration of technical and economic performance of the 10 MeV High Energy Electron Accelerator which was planned to be built in the Puspiptek area of the Serpong Industrial Zone. This facility is intended as a demonstration of technical and economic performance demonstrations that will test safety, reliability,
efficiency, ease of mastery of component technology and economic performance. From this engineering experience and operation of the High Energy Electron Accelerator, it is hoped that the next accelerators will be built which are ideal for meeting the needs of irradiation facilities in Indonesia.

**Technical specifications of HEEA 10 MeV**

Electron accelerators with a 10 MeV beam energy are ideal for use in industries in Indonesia. The structure of the HEEA design that is able to illuminate products with a more directional beam, electron accelerators that have power, will make the product's irradiation process efficient. The main design parameters of AEET 10 MeV are shown in the following Table.

<table>
<thead>
<tr>
<th>Design parameters</th>
<th>Energy and Power</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>Energy of the electron particle beam</td>
<td>7~10 MeV</td>
<td>adjusted</td>
</tr>
<tr>
<td>Energy instability of electron particle beam</td>
<td>&lt; ± 2.5%</td>
<td></td>
</tr>
<tr>
<td>Electron current</td>
<td>0.1 ~ 4 mA</td>
<td>adjusted</td>
</tr>
<tr>
<td>Instability of electron currents</td>
<td>&lt; ± 2.5%</td>
<td></td>
</tr>
<tr>
<td>Maximum output power of electron particle beam</td>
<td>50 kW</td>
<td></td>
</tr>
<tr>
<td>Window size of electron beam (width of irradiation)</td>
<td>120 cm (80 cm)</td>
<td></td>
</tr>
<tr>
<td>Energy uniformity in the electron beam window</td>
<td>&lt; ± 10%</td>
<td>At 50 mm</td>
</tr>
<tr>
<td>Electric power requirements (including blowers, fans, etc.)</td>
<td>750 kVA</td>
<td>3ф380~460V</td>
</tr>
<tr>
<td>Production capacity (tons / year) with operations for 8000 hours per year</td>
<td>172,800 51,840 20,736</td>
<td>3 kGy 10 kGy 25 kGy</td>
</tr>
</tbody>
</table>

**Schedule of Stage the HEEA 10 MeV Development Project**

Mastery of HEEA 10 MeV technology until the down streaming of technology for medical sterilization takes five years. The construction of HEEA 10 MeV will take three years. Activities will begin with Feasibility Study, Engineering, Development/Manufacturing, Installation (Installation) of Device Components and Function Testing and Validation (Commissioning). After being well tested through the commissioning process, HEEA can be operated to demonstrate its technical performance and economic performance.

<table>
<thead>
<tr>
<th>No</th>
<th>Activities</th>
<th>Tahun</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>2018</td>
</tr>
<tr>
<td>1</td>
<td>Feasibility study</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Procurement of Reference Plant</td>
<td></td>
</tr>
</tbody>
</table>
The development and constructions of HEEA in BATAN will be carried out through technology transfer cooperation with EB Tech Co. Ltd. South Korea, in accordance with the MoU signed by both parties at Vienna-Austria on May 30, 2017. Until now there has been no decision regarding the schedule for implementing the project depending on the funding approval from the government.

4. REGULATORY ASPECT AND MANAGEMENT SYSTEM IMPLEMENTATION

Regulation and standard related construction and utilization of Irradiator are published by The Nuclear Energy Regulatory Agency, BAPETEN and other related Ministry and Agency such as Ministry of Health, National Agency for Drugs and Food Control and National Nuclear Energy Agency. The Regulation and Standard as follows:

b. Government Regulation Number 29/2008 concerning Licensing on the utilization of Ionizing Radiation and Nuclear Materials
c. Government Regulation Number No. 61/2013 concerning the Radioactive Waste Management
d. Government Regulation No. 58/2015 concerning the Safe Transportation of Radioactive Material
e. Ministry of Health Regulation number 701/2009 concerning Food Irradiation
f. National Agency for Drugs and Food Control Regulation Number 3/2018 concerning Food Irradiation
g. BAPETEN Chairman Decree Number 6/2015 concerning the Security of Radioactive Sources
h. BAPETEN Chairman Decree Number 16/2014 concerning the Requirements for obtaining a Working Permit for Certain Officers (personnel certification) at the Installation that utilize Ionizing Radiation Sources;
i. BAPETEN Chairmen Decree Number 11/1999 concerning licensing on Irradiator construction and Operation
j. BAPETEN Chairmen Decree Number 4/2010 concerning Management System on Facility and Nuclear Energy Utilization Activities  
k. National Nuclear Energy Agency Standard number 02/2016 concerning Qualifications and Certifications of irradiator Personnel and supervisors

BAPETEN Chairmen Decree Number 11 of 1999 concerning the licensing on Irradiator construction and operation which contains general requirements; requirement and type of licensing: technical description of irradiator construction, safety analysis reports; obligations of licensee; Inspection. The document must be submitted as attachment are safety, analysis report, irradiator building requirement, electrical, mechanical and water equipment, qualification of irradiator personnel, and safety and security equipment.

The safety analysis report covered the topic such as introduction and brief description of facilities; environmental activities and radiation Monitoring programs; quality assurance guarantee programs during design, construction, commissioning and facility operations; personnel training program; description of the irradiator installation design and design implementation; description of the research program and utilization of irradiator, description of organizational structures, authority and responsibility in radiation protection, Personnel qualification requirements, short operations and normal operations plan including maintenance, inspection and scheduled all component testing, environmental impact analysis, and emergency response planning. The results of the inspections carried out by BAPETEN, the gamma irradiator facilities have met safety and security requirements as indicated by the mark in Figure 3

![The Sticker that (a) facility met the safety and security requirement](a) 
![Certificate on QA and OHSAS Management System](b)

**FIG. 2.** The Sticker that (a) facility met the safety and security requirement  
(b) Certificate on QA and OHSAS Management System

The management system implemented on Irradiator Facility, i.e. at National Nuclear Energy Agency, Implement BATAN integrated management system which cover Quality Management system based on ISO 9001:2015, OHSAS 18001, Environmental Management System 14001:2015 and also management system for the facility and nuclear energy utilization activities based on BAPETEN chairman decree number 4/2010, which adopted from IAEA document GS-R-3 on the Management system on Facilities and Activities.
Dosimeter System, BATAN uses dosimeter Fricke solution as a reference standard Dosimeter and for Routine dosimeters are used red Perspex dosimeters and also used dosimeter markers which are used to differentiate sample boxes that have been and have not been irradiated. For PT Rel-ion the dosimetry system that uses the Radio chromic Dye dosimeter film is used to measure and determine the absorption dose for the product. This dosimetry system is calibrated by the National Atomic Energy Agency (BATAN) and is traceable. As a dosimeter film reader, Genesys 20 spectrophotometers are also used which are also calibrated and confirmed every time period.

5. URGENCY TO DEVELOP AND APPLIED MILESTONES APPROACH FOR THE RADIATION TECHNOLOGY FACILITY PROJECT

National Nuclear Institutions (NNIs) in the Member State are struggling to build institutional capacity toward self-reliance and sustainability. It is becoming evident that a different management outlook and practice are required in order to transform the NNIs’ management, programs and approaches and to reshape and integrate the nuclear science and technology R&D programs sustainably into the national developmental efforts. The R&D programs of mature and potentially productive NNIs need to be adjusted for optimum sustainability and for the benefit of all parties concerned, since complete reliance on government funding cannot go on indefinitely.

This goal can be achieved by designing into the NNIs’ R&D programs (appropriately and in a timely manner) the requisite self-reliance elements and relevant interfaces with collaborating national stakeholders, including the industrial sector. Such an approach will eventually relieve the NNIs from total dependence on government funding and gradually transform the NNIs’ innovative potential into a viable input and contribution to the national socioeconomic development as well as the safe, secure, sustainable construction and operation of a NNI.

The development and assessment the maturity of the Infrastructure radiation technology facility of the NNIs toward self-reliance and sustainability could be use the same approach used for the development of new Research Reactor, by using milestone approach, which provides a comprehensive means to determine the status of the infrastructure conditions covering all the 19 issues. This approach can be used by any interested Member State for self-assessment to identify weaknesses and to determine the additional work needed to develop its national Nuclear Institution infrastructure to an appropriate level.

In the areas of safety, security, and safeguards, the framework for the required infrastructure development is well established by the IAEA and is mainly based on the fulfillment by Member State of its obligations under international instruments applicable to the corresponding conventions. Furthermore, this publication assumes that a program to establish Radiation Facility at the NNI infrastructure toward self-reliance and sustainability is being undertaken by a single Member State in specific nuclear – radiation facility such us:

- Radioisotope and Radiopharmaceutical
- Irradiator/Cyclotron for Industry and medical purposes
- Non Destructive Testing Facility including Production Gamma projector
- Other Radiation Technology Application etc.

The Project could be the new project on specific nuclear application or enhancement or optimization from the existing project on nuclear application of the NNI.
During the development and assessment process, it is necessary to address and review progress across all 19 infrastructure issues with graded approach because each of them is essential, and because there are significant relationships between them. Member States wishing to use this publication need to ensure that all 19 issues are reviewed in depth and the results brought together in a final report to provide an integrated view of infrastructure status and any gaps, thereby allowing the country to decide on its readiness to move to the next phase.

The milestone approach on for the radiation facility (RF) was refer and adapted from the Research Reactor Milestones publication provides an overview of the overall efforts to develop the national infrastructure to support a new research reactor programme. Figure 2 shows the various phases of such a programme, also listed in Table 4. The activities are split into three progressive phases of development. The completion of the work of each of these phases is marked by a specific milestone at which the progress and success of the development effort can be evaluated and a decision made to move on to the next phase. The milestones do not have a specific time frame; the duration of each phase will depend upon the degree of commitment and resources applied by the Member State, as well as the size and scale of the programme, its complexity (e.g. planned experimental facilities, radioisotope production facility, etc.) and the associated potential hazard.

### Table 4. Infrastructure Development Phases and Milestones [reproduced from ref 9]

<table>
<thead>
<tr>
<th>Phase</th>
<th>Description</th>
<th>Milestone</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Pre-project</td>
<td>Justification of the RF and considerations before a decision to launch a RF is taken</td>
<td>Ready to make a knowledgeable commitment to a RF project.</td>
</tr>
<tr>
<td>(2) Project formulation</td>
<td>Preparatory work for the construction of a RF after a policy decision has been taken</td>
<td>Ready to invite bids for the RF.</td>
</tr>
<tr>
<td>(3) Implementation</td>
<td>Activities to design and construct a RF</td>
<td>Ready to commission and operate the RF.</td>
</tr>
</tbody>
</table>

**Milestone 1**

During phase 1, a preliminary strategic plan [10], based on quantitative determination of the stakeholders’ needs, is completed to justify the construction and future operation and effective utilization of the radiation facility programme. However, to make an informed decision on whether to proceed with the RF programme or not, the Member State also needs to develop a comprehensive understanding of the obligations and commitments involved, and ensure that there is a long-term national strategy and resources available to meet them. This work will culminate in the attainment of milestone 1 and the production and development the document such as:

- Pre Project assessment report
- Preliminary strategic planning
- Market study and analysis
- Technical study and analysis
- Comprehensive analysis on 19 infrastructure issue (on phases 1)
- Financial analysis
- Economic or cost benefit analysis

The Feasibility document will incorporate the results of a detailed and comprehensive assessment of the 19 issues of the national infrastructure, including identification of future development needs and means to address these needs, the results of the Preliminary Strategic Plan as well as cost-benefit analysis of the programme.

**FIG. 3. Milestones for a Radiation Facility (RF) Programme (Reproduced from Ref. [9]).**

**Milestone 2**

Following the decision to proceed with a new Radiation Facility (RF), substantial work for achieving the necessary level of technical and institutional competence and of development of the national infrastructure needs to be undertaken. This second phase requires a significant and continuing commitment from the government and from the future Radiation Facility (RF) operating organization. In fact, during this phase, the Member State will carry out the work required to prepare for the establishment a RF. The document should be addressed are related to:

- Project management organization and operating organization
- Strategic Planning
- Project Management
- Comprehensive analysis on 19 infrastructure issue (on phases 2)
- Conceptual and Basic design
- Functional specification

At the end of phase 2, the necessary infrastructure needs to be established to the point of complete readiness to enter the bidding process for the procurement of the RF or direct negotiations with a vendor [9].
Milestone 3

After the vendor country has been chosen, the third phase of the programme development consists of all the activities necessary to build the new Radiation Facility (RF) and complete most of the infrastructure development. During this phase, the greatest capital expenditures will occur. Attention by all involved organizations and stakeholders, who all have important roles to play, is crucial to the successful outcome. At the end of this phase, the RF operating organization will have developed from an organization capable of ordering a RF to an organization capable of accepting responsibility for commissioning and having capability for future operation.

Procedures and arrangements to ensure safe operation and control of radiation facility (RF) under both normal and accidental operation conditions will have been developed as well as the required professional development and training for all levels of staff. While achieving the third milestone is a major accomplishment, it has to be remembered that it is only the beginning of a long-lasting commitment to the safe, secure and effective utilization or commercialization of the Radiation Facility for its entire life time.

6. CHALLENGES

Some challenges in the use of irradiators are as follows:

- The number and utilization of irradiator is still very limited, so BATAN needs to encourage its use by the industrial sector.
- BATAN as an research and development institution needs to accelerate the mastery of technology and construction of irradiator through technology transfer schema
- The optimal utilization of irradiators that have been built is the key to success that drives the sustainability of the project, so the milestone approach needs to be implemented including making strategic planning from the beginning of the project.
- Compliance with regulations, and implementing management systems, are needed for safe, secure and reliable operations

REFERENCE

1. BATAN, Irradiator Feasibility study, 2014
2. BATAN, Report on Construction Management of Irradiator Construction, 2017
3. BATAN, Development of High Energy Electron Accelerator rev 12, 2017
4. Ferly Hermana, Presentation on Engineering Development And Construction Of Gamma Irradiator In Indonesia, 2018
5. Imre Madar, Gamma Irradiation Facility Within Two Years Common Effort Of Two Nations, Institute of Isotopes Co Ltd., 2018
6. BAPETEN, BCD number 11 YEAR 1999 concerning licensing on Irradiator construction and Operation, 1999
7. BAPETEN, BCD number 4 YEAR 2010 concerning Management System on Facility and Nuclear Energy Utilization Activities, 2010
11. IAEA Nuclear Energy Series No. NG-T-3.18, Preparation of a Feasibility Study for a New Research Reactor Programme
12. IAEA Safety Series No 107, Radiation Safety of gamma and electron irradiation facilities
14. www.rel-ion.com

JORDAN

MOHAMMED ETOOM
Gamma Irradiation Facility (GIF), Jordan Atomic Energy Commission
Amman, Jordan

Abstract
Gamma Irradiation Facility starts development Quality Management system in 2018 and still working as a team with the Quality Department in Jordan Atomic Energy Commission. Before that year GIF had a non-systematic QMS to arrange the work, as example there was Company Operations List Form, Daily Operations, logbook for operation, SOP's for dosimetry, Maintenance checklist, and dose mapping report.

Gamma Irradiation Facility and QMS Department start to develop QMS requirements under the ISO Standards related to irradiation processes like ISO 9001, ISO 13485 and ISO 11137.

1. INTRODUCTION
The management system is a set of interrelated or interacting elements (system) for establishing policies and objectives and enabling the objectives to be achieved in an efficient and effective manner [1].

The quality management system integrates its elements, including safety, health, environmental, security, quality, human-and-organizational-factor, societal and economic elements, so that safety is not compromised [2].

The potential benefits to an organization of implementing a quality management system are:

a) The ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements;

b) Facilitating opportunities to enhance customer satisfaction;

c) Addressing risks and opportunities associated with its context and objectives;
The ability to demonstrate conformity to specified quality management system requirements [3].

The irradiation plant does not need to have a complete QMS as described in ISO 9001, but only those elements that are required to control the radiation process [4].

The Gamma Irradiation Facility (GIF) is a facility based in Jordan Atomic Energy Commission (JAEC). GIF provides services in irradiation of disposable medical devices, Pharmaceutical raw materials, veterinary, species, herbs, nuts, cosmetics, and various other products using gamma ray from Co-60 sources.

GIF is committed to controlled growth by providing consistent processes, safe services and meeting the customers’ requirements through the implementation of JAEC quality policy.

GIF established a Quality System Manual (QSM) according to ISO 9001:2015 and ISO 13485:2016 standards to ensure the competence of its services, and achieve the international accreditation for the services specified in its scope of accreditation.

GIF standard operation procedures (SOPs), Work Instructions (WIs) and Quality Procedures (PRCs) describe the requirements of technical and managerial processes in the GIF and form a complementary part of the QSM. The QSM, WIs, SOPs and PRCs are the main documents of the quality management system, and they take into consideration policies, regulations, and management systems governing Gamma Irradiation processes.

This manuscript summarizes the most important requirements of QMS manual in GIF.

2. QUALITY MANUAL CLAUSES

2.1. ORGANIZATION

The GIF team is responsible and committed to the full implementation of a quality system and continuous improvement for achieving customer satisfaction and safety.

GIF Quality Policy clearly defines the GIF staff responsibility and commitment to quality products and customer satisfaction.

The GIF requires technical director to also serve as GIF Director. His responsibilities include: providing the facilities with the necessary resources and qualified personnel to consistently maintain an effective QSM to produce defect-free products.

2.2. LEADERSHIP

The JAEC Top Management takes a visible and leading role in creating and sustaining core values, policies, strategies, directions, performance expectations and customer focus.

Leadership from all levels of JAEC provides evidence of its commitment to the development and implementation of the quality management system and maintenance of its effectiveness.
The JAEC top management ensures that not only are customer requirements and applicable regulatory requirements understood, but they are determined and met with the aim of enhancing customer satisfaction.

The JAEC top management ensures that responsibilities are defined, documented and communicated within GIF.

2.3. PLANNING

Quality objectives are established to support GIF commitment and efforts in achieving our quality policy and reviewed for suitability.

Quality objectives are reviewed by semi-annually for suitability. The quality objectives are measurable and consistent with the quality policy. They are reviewed against performance goals at each management review meeting and communicated throughout the organization.

GIF has an integrated planning process that evaluates past and current performances; identifies key action plans to achieve desired results, meet the planned objective and a way to measure results and resources needed as tabled at the annual strategic business planning at JAEC level.

The quality plan employed by the GIF starts with customer inquiries followed by the process; all the various activities are carried out in a coordinated manner for a smooth flow. The next in the flow of event is the receipt of products whereby the receiving /inspection is carried out. When both customer and internal requirements are met, the next step is the actual process of irradiation. If it is a new product, product dose mapping shall be performed.

After processing the product, evaluation of the absorbed dose shall be done according to GIF SOPs based on Dosimetry Standards. In the event that the product has not met the minimum acceptable dose, then re-irradiate or report to customer. When all specifications for processing are met; Dosimetric release, the product can be released.

2.4. SUPPORT

The Management shall identify and provide sufficient resources that are essential to the implementation and maintenance of QMS, Quality Policy, and to continually improve its effectiveness and enhance customer satisfaction by meeting customer requirements and regulatory requirements. These resources include:

a) Machinery / equipment for irradiation services, inspection or testing
b) Human resources and specialized skills. All employees, new or existing are to be trained to perform their respective job functions.
c) Financial resources for new projects.

The management shall determine, provide and maintain the infrastructure including:

a) Product receiving area.
b) Loading station — non-irradiated product area.
c) Unloading station — irradiated product area.
d) Irradiator facility system.
e) Inspection and testing equipment.
f) Sufficient labor and electricity supply.
g) A back-up system for any of the water or electricity supply failure.
h) Sufficient amenities for employees.
i) Relevant supporting services/equipment such as administration equipment, forklifts, weighing scale, pallets and outside supporting services such as microbiological services and calibration services.

Processes, which directly affect quality, shall be planned and identified in order to ensure that they are executed under controlled work environment.

The monitoring and control of suitable process parameters and product characteristics Record on all process controls shall be maintained.

GIF shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This knowledge shall be maintained and made available as necessary.

The methods for competency appraisal, quality awareness development, training provision, and evaluation are defined. Records of employee education, skills, training, and experience are maintained.

GIF shall ensure that employees are aware of the Quality Policy, Quality Objectives, their contribution to the effectiveness of the QMS (including benefits of improved performance), and implications of not conforming to the QMS requirements.

Effective and appropriate communications between functions and levels regarding effectiveness are promoted by GIF management. Communication may be initiated by any employee or external provider. Communication may include:

a) Corrective or Preventive Action.
b) Meetings.
c) Internal audit results.
d) Data analysis.
e) Internal email.
f) Memos.
2.5. DOCUMENTED INFORMATION

The QMS documentation has been established, effectively implemented and maintained in order to ensure that the operation consistently conformed to the specified requirements.

And when necessary, the documentation and activities relevant to the quality management system shall be reviewed and updated.

All documentation required to ensure GIF products and processes meet internal and regulatory requirements is controlled and available at the point of use either in hard copy or electronically. All controlled documents are clearly identified by a unique control number.

The distribution and obsoleting of all controlled documentation is accomplished as necessary through on-going database and hard copy management. Approval, storage, distribution, updating, purging and obsoleting of all controlled documents are the responsibility of document control officer which he is generated. Documents of external origin are also controlled within the document control system.

2.6. OPERATION

GIF has procedure for verifying the performance of the facility set-up through product dose mapping, receiving inspection and final inspection. Finally, a set of evidence shall be demonstrated that full conformance to the process specification are met.

GIF and each customer shall have an agreement designate specific service specifications, terms and conditions agreeable to both parties. GIF shall observe that the requirements are met and necessary review is taken place to ensure full compliance. Relevant procedure shall cover the following:

a) Responsibility of both parties.
b) Contractual requirements.
c) Contract review.

The customer is required to bring official letter for Gamma Irradiation Services with regards to the irradiation requirement / specification.

GIF reviews requirements related to product. In order to establish and maintain customer satisfaction, a formal system is in place and maintained to ensure that each commitment to supply a product is reviewed and controlled.

When a customer does not provide a documented statement of requirement, the customer requirements shall be confirmed before acceptance (or refer to internal specifications).

Where product requirements are changed, GIF ensures that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

GIF have provided sufficient control to the proper flow of irradiation process which include step-by-step verification that specific task has been executed successfully and to comply with
the relevant procedure prepared for that particular task. The control shall cover both the normal or routine process as well as for the purpose of disposition of non-conformity.

GIF have established and maintain documented procedure to provide means for preventive maintenance to equipment’s, which are the mainline of the sterilization process. The relevant procedure has covered the fortnightly, monthly, semi-annual and annually checklists.

GIF have procedure to ensure that the status of a product (has not been processed, has been processed, acceptable, hold or rejected), Product status is identified through Certificate of Irradiation.

GIF have procedure to provide proper identification of products to be subjected to the irradiation process.

All customers’ products shall be identified handled carefully to avoid damage and kept in proper storage area to avoid deterioration and prevent from possible losses.

GIF meet post-delivery requirements associated with products and services by:

a) Statutory and regulatory requirements.
b) The potential undesired consequences associated with products and services.
c) The nature, use, and intended lifetime of products and services.
d) Customer requirements.
e) Customer feedback.

The release of products or services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by the relevant authority and, where applicable, by the customer.

Nonconforming products are identified and placed into a designated quarantine location, until a final disposition is determined. A nonconforming materials report is prepared and tracks the status of the product. A disposition to 'return to supplier' or 'destroy' will be prepared and approved by the appropriate personnel. Nonconforming material which is reworked, according to written procedures, is subject to the same level of inspection and testing as the original process. Records of all non-conforming materials/finished devices are kept for trend analysis and for verification that the materials or device were not used or released for use.

2.7.PERFORMANCE EVALUATION

GIF plan and implement the monitoring, measurement, and analysis processes needed:

a) To demonstrate conformity of the product.
b) To ensure conformity of the quality management system.
c) To continually improve the effectiveness of the quality management system.
GIF process and related documents improvement is affected through the regular collection and analysis of data relating to customer satisfaction, product and service conformity, process performance, and external provider performance. Improvement measures are instituted during management review meetings and through corrective and preventive actions effectiveness of actions taken to address risks and opportunities are evaluated.

Internal audit shall be performed at least once a year or whenever deemed necessary and shall cover all quality aspects throughout the year. The internal audit will be carried out by Quality Department in Jordan Atomic Energy Commission; appropriately trained personnel, not directly responsible for the area being audited. Follow-up action to correct deficiencies is re-audited to verify compliance and a report issued.

Management Reviews of the quality system of GIF are conducted annually to ensure continued system adequacy and effectiveness in achieving quality objectives. Reviews are planned by the Quality Department in Jordan Atomic Energy Commission, and attended by Senior Managers, and other relevant management or staff members.

2.8.IMPROVEMENT

GIF determined and select opportunities for improvement, and implement necessary measures to meet customer requirements and enhance customer satisfaction, including:

a) Improving products and services to meet requirements as well as to address future needs and expectations.

b) Correcting, preventing, and reducing undesired effects.

c) Improving performance and effectiveness of the Quality Management System.

Appropriate Corrective Action is taken to identify the cause of nonconformity and prevent its recurrence, including those involving service non-conformances and customer complaints. Preventive Action is taken to eliminate the causes of potential nonconformity and its occurrence.

GIF continually strives to improve their operations through rigorous application of its Quality Policy and objectives, internal audits, analysis of data, corrective and preventive actions, and Management Reviews.

CONCLUSION

The objective of this effort is to support the development of the Jordan nuclear energy program while considering the protection of public health and the environment.
By gotten the ISO Certificate, GIF will gain of the following objectives:

- Get the License from Energy and Menial Regulatory Commission.
- Continuing technical development of capabilities and capacity.
- Training and competency of facility staff to properly perform the services.
- Development and improvement for achieving customer satisfaction and safety.
- Sustainability work under the good practice.

REFERENCES


KOREA, REPUBLIC OF

INTERCOMPARISON EXERCISE USING ALANINE PELLET IN SOUTH KOREA

HAN-KI JANG, KI-TEK HAN, JEHO MIN, BYEONG RYONG PARK, JAE SEOK KIM, JAERYONG YOO, WI-HO HA, SEONGJAE JANG, YEONG-ROK KANG, HYOJIN KIM, HOON CHO, JEONGIN KIM, JUNGIL LEE, HYOUNGTAEK KIM, JANG-LYUL KIM

Radiation Technology & Research Center, Korean Association for Radiation Application, 17, Cheomdan-ro, Jeongeup-si, Jeollabuk-do, Republic of Korea

National Radiation Emergency Medical Center, Korea Institute of Radiological and Medical Sciences, 75, Nowon-ro, Nowon-gu, Seoul, Republic of Korea

Research Center, Dongnam Institute of Radiological and Medical Sciences, 40, Jangan-eup, Gijang-gun, Busan, Republic of Korea

Radiation Health Institute, Korea Hydro and Nuclear Power Co., Ltd., 172, Dolma-ro, Bundang-gu, Seongnam-si, Gyeonggi-do, Republic of Korea

Radiation Safety Management Division, Korea Atomic Energy Research Institute, 111, Daejeok-daero 989beon-gil, Yuseong-gu, Daejeon, Republic of Korea
Abstract

This paper presents the results of the first intercomparison exercise performed by the Korea dosimetry (KREDOS) working group using electron paramagnetic resonance (EPR) spectroscopy. The intercomparison employed the alanine dosimeter, which is commonly used as the standard dosimeter in EPR methods. Four laboratories participated in the dose assessment of blind samples, and one laboratory carried out irradiation of blind samples. Two types of alanine dosimeters (Bruker and Magnettech) with different geometries were used. Both dosimeters were blindly irradiated at three dose levels (0.60, 2.70, and 8.00 Gy) and four samples per dose were distributed to the participating laboratories. Assessments of blind doses by the laboratories were performed using their own measurement protocols. One laboratory did not participate in the measurements of Magnettech alanine dosimeter samples. Intercomparison results were analyzed by calculating the relative bias, E_n value, and z-score. The results reported by participating laboratories were overall satisfactory for doses of 2.70 and 8.00 Gy but were considerably overestimated with a relative bias range of 10 - 95% for 0.60 Gy, which is lower than the minimum detectable dose (MDD) of the alanine dosimeter. After the first intercomparison, participating laboratories are working to improve their alanine-EPR dosimetry systems through continuous meetings.

1. INTRODUCTION

EPR dosimetry is one of the physical dose assessment methods. It can be used for retrospective dosimetry for external radiation exposure, detection of irradiated food [1], [2], [3], and dating [4]. In South Korea, the Korea retrospective dosimetry (KREDOS) working group formed in 2016 to improve the capability of dosimetry techniques and to offer prompt joint assistance during radiation emergencies. There are three methodology groups in KREDOS: biodosimetry, electron paramagnetic resonance (EPR) dosimetry, and thermoluminescence (TL) / optically stimulated luminescence (OSL) dosimetry. Currently, intercomparison exercises are ongoing in each methodology group. Many intercomparison programs using EPR dosimetry have been conducted internationally [5], [6], [7]. However, South Korea has not yet participated in intercomparison using the EPR method. Therefore, the KREDOS-EPR group has planned a gradational domestic intercomparison program to reach international levels.

Alanine-EPR dosimetry systems are used in reference or transfer-standard or routine dosimetry systems in radiation applications that include sterilization of medical devices and pharmaceuticals, food irradiation, polymer modifications, medical therapy, and radiation damage studies in materials [8]. In general, the range of absorbed doses for which the alanine dosimeter can be used is between 1 and $1.5 \times 10^5$ Gy for photons and electrons irradiation. This dosimeter is used at relatively high dose compared to TL dosimeter (TLD) or radio-photoluminescence glass dosimeter (RPLGD). It is also suitable for long-term accumulated dose assessment because it has very low fading and repeated measurements are possible. Therefore, the alanine dosimeter, which is well known as the standard dosimeter in EPR dosimetry, was selected as the first intercomparison sample even though it is not an appropriate sample for retrospective dosimetry in radiation emergencies.

This report presents the results of alanine dosimeter intercomparisons performed in the KREDOS-EPR group. Previous literature mainly used standard deviation or relative bias when analysing intercomparison results. Also, the E_n value or z-score are commonly used for absolute
evaluation of reported results by participating laboratories in various accredited international intercomparison programs [9]. Therefore, the results of this intercomparison were analysed by calculating the relative bias, $E_n$ value, and z-score.

2. PARTICIPANTS AND INTERCOMPARISON SCHEMA

Five laboratories participated in this alanine-EPR intercomparison. The Korean Association for Radiation Application (KARA), Korea Institute of Radiological and Medical Sciences (KIRAMS), Dongnam Institute of Radiological and Medical Sciences (DIRAMS), and Radiation Health Institute (RHI) participated in the dose assessment of blind samples. A fifth laboratory, the Korea Atomic Energy Research Institute (KAERI) was in charge of irradiation of the intercomparison samples to maintain the neutrality of the blind doses. The dose ranges of the blind samples were divided into three levels: low dose level (0-2 Gy), medium dose level (2-5 Gy), and high dose level (5-10 Gy). Four alanine dosimeters for each dose level were distributed to participants. The irradiated blind samples were received by each participant on the day of irradiation. Dose assessments of the blind samples were carried out by the participating laboratories using their own measurement protocols. Dosimetry results were reported as a single value using the average of the four samples. At the KREDOS-EPR group meeting held after two months following irradiation, the participating laboratories presented their measurement protocol and dosimetry results, including uncertainties and KAERI revealed the reference values of the blind doses. In this report, the randomly assigned laboratory numbers were used instead of the laboratory names in analysing the methods and results.

2.1 SAMPLE PREPARATION

Two commercially available L-α-alanine dosimeters manufactured by Bruker and Magnettech were used in this intercomparison exercise. Both dosimeters are pellet-shaped and have similar characteristics except for their geometry. The Bruker alanine dosimeter has a diameter of 4.8 mm, the thickness of 3 mm, and mass of 64.5 ± 0.5 mg, while the Magnettech alanine dosimeter has a diameter of 4 mm, the thickness of 2.45 mm, and mass of 37.95 ± 0.06 mg. Intercomparison samples used dosimeters of the same lot number stored in the same environmental conditions. Four laboratories participated in the analysis of the Bruker alanine sample, and three laboratories participated in the analysis of the Magnettech alanine sample.

2.2 Irradiation conditions

Irradiation of blind samples was performed with an OB40 irradiator (Buchler, Germany) using a $^{137}$Cs gamma ray source at ambient temperature (approximately 22°C). The gamma ray irradiator was calibrated with respect to air kerma using a standard ionization chamber, and the irradiation dose rate was controlled at 10 mGy·min$^{-1}$. The nominal values of the irradiated reference doses are 0.60 (low dose level), 2.70 (medium dose level), and 8.00 Gy (high dose level).
2.3 Dosimetry methods

The dosimetry method used by each laboratory is described below and summarized in Table 1. Table 2 presents the EPR measurement parameters. In the dosimetry procedures of all laboratories, X-band EPR spectrometers were used and the spectra were recorded at room temperature (22-25°C). The peak-to-peak value of the alanine spectrum was applied to the determination of signal intensity.

2.3.1. Technique used by laboratory 1 (Lab 1)

Lab 1 performed dosimetry with a calibration method using an EXEXSYS E500 spectrometer (Bruker, Germany) and an exclusive alanine pellet tube (5 mm I.D., Bruker). Lab 1 has been using its own alanine-EPR dosimetry protocol, which was created using Bruker alanine, for various radiation studies since 2016. Therefore, intercomparison samples were measured using this procedure. The calibration samples were irradiated with 1, 5, 10, 20, and 30 Gy calibrated with respect to absorbed dose to water using approved 60Co irradiation systems of Korea Research Institute of Standards and Science (KRISS). The regression equation of the calibration curve was obtained using linear fitting, and the coefficient of determination ($R^2$) was 0.99991. The signal intensity was corrected based on the Bruker reference marker value and the dosimeter mass. The correction for gamma-ray energy was not considered, and doses below 1 Gy were calculated using extrapolation. The determination of blind doses used the mean value of four samples that were calculated after eight measurements per sample; the doses of Magnettech alanine samples were reported using the mean value of three replicated measurements obtained employing the same procedure. The final dose values were reported by converting the absorbed dose to water into that for air kerma.

2.3.2. Technique used by laboratory 2 (Lab 2)

Dosimetry in Lab 2 was performed using an EMX spectrometer (Bruker, Germany) and the additive dose method (back-extrapolation technique). The additive dose method generally estimates the initial dose in the process of obtaining a specific response curve for the same incrementally irradiated sample. The optimal spacing of the applied dose and the number of spectra were decided by referring to related literature [23, 24]. The estimated initial dose was far from the center of the calibration range, so this method increased the confidence interval. The single high point distribution method was applied to diminish the error of the x-intercept using least square analysis and 10 times the estimated initial dose (initially estimated as 5 Gy) was supplied to the alanine pellet samples to ensure a small relative error. However, these trials were not very efficient in decreasing the relative error because measurement uncertainty at low dose ranges is much higher than at high dose ranges. This unusual situation could be caused by extremely low dose ranges for dose estimation of alanine dosimeters.
2.3.3. Technique used by laboratory 3 (Lab 3)

Lab 3 performed this intercomparison using an MS-5000 benchtop spectrometer (Magnettech, Germany). The calibration method was used to determine the dose of blind samples. Irradiation of the calibration samples was carried out using a $^{137}$Cs irradiation system in their laboratory. The calibration curve was prepared using samples irradiated with 0.8, 1, 3, 7, and 10 Gy calibrated with respect to air kerma. To efficiently measure low dose samples in the range of 1 to 10 Gy, one and four-pellet setups were used. The detection point was set in the center of the lowest alanine sample. In the four-pellet setup, the positions of the alanine samples were changed to minimize the uncertainty due to the deviation of each sample.

2.3.4. Technique used by laboratory 4 (Lab 4)

EPR measurements at Lab 4 were carried out using a Bruker EXEXSYS E500 spectrometer and an alanine pellet tube. The calibration method was used to determine the dose of blind samples. Irradiation of the calibration samples was carried out using a $^{60}$Co irradiator (Gamma beam X200, Best Theratronics Ltd., Canada) in their laboratory. The air kerma value for the $^{60}$Co irradiator was measured using an ionization chamber (TM30011, PTW, Germany) and an electrometer (6517B, KEITHLEY, USA) at a distance of 100 cm from the cobalt source to the center of the ionization chamber. Standard irradiation was performed for four alanine dosimeters in a build-up cap. The calibration curve was prepared using samples irradiated with 1, 2, 3.5, 5, 7.5, and 10 Gy calibrated with respect to air kerma. Regression equations were determined using linear fitting for the Bruker alanine and a 2$^{nd}$ order polynomial fitting for the Magnettech alanine, respectively. The mean value of four samples was used for determining the blind doses.

### TABLE 1. CHARACTERISTIC FEATURES OF METHODS USED BY PARTICIPATING LABORATORIES.

<table>
<thead>
<tr>
<th></th>
<th>Lab 1</th>
<th>Lab 2</th>
<th>Lab 3</th>
<th>Lab 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>EPR Spectrometer</td>
<td>Bruker</td>
<td>Bruker</td>
<td>Magnettech</td>
<td>Bruker</td>
</tr>
<tr>
<td></td>
<td>EXEXSYS E500</td>
<td>EMX</td>
<td>MS-5000</td>
<td>EXEXSYS E500</td>
</tr>
<tr>
<td>Cavity</td>
<td>ER4122SHQE</td>
<td>Dual cavity</td>
<td>Rectangular</td>
<td>ER4122SHQE</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ER-4105DR</td>
<td>TE 102</td>
<td></td>
</tr>
<tr>
<td>Reference for EPR</td>
<td>Bruker</td>
<td>Not used</td>
<td>Magennech</td>
<td>Not used</td>
</tr>
<tr>
<td>signal</td>
<td>reference</td>
<td></td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td></td>
<td>marker</td>
<td></td>
<td>Marker</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(Ruby Crystal)</td>
<td></td>
</tr>
<tr>
<td>Subtracted background</td>
<td>Not used</td>
<td>Not used</td>
<td>Not used</td>
<td>Not used</td>
</tr>
<tr>
<td>Dose assessment method</td>
<td>Cal. curve</td>
<td>Additive dose</td>
<td>Cal. Curve</td>
<td>Cal. curve</td>
</tr>
<tr>
<td>Calibration source</td>
<td>$^{60}$Co</td>
<td>$^{137}$Cs</td>
<td>$^{137}$Cs</td>
<td>$^{60}$Co</td>
</tr>
</tbody>
</table>

### TABLE 2. MEASUREMENT PARAMETERS USED BY PARTICIPATING LABORATORIES.

<table>
<thead>
<tr>
<th>ISO/ASTM  51607</th>
<th>Lab 1</th>
<th>Lab 2</th>
<th>Lab 3</th>
<th>Lab 4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
2.4 UNCERTAINTY

The uncertainties of irradiation of the blind samples are given in Table 3, and the measurement uncertainties of the participating laboratories are presented in Table 4. The uncertainties were reported as relative expanded uncertainty at a confidence level of 95% ($k=2$).

**TABLE 3. UNCERTAINTY BUDGETS OF IRRADIATION FOR BLIND SAMPLES.**

<table>
<thead>
<tr>
<th>Uncertainty source</th>
<th>Type A (%)</th>
<th>Type B (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference dose</td>
<td>1.65</td>
<td>-</td>
</tr>
<tr>
<td>Irradiation time</td>
<td>0.00</td>
<td>-</td>
</tr>
<tr>
<td>Distance correction factor</td>
<td>0.12</td>
<td>-</td>
</tr>
<tr>
<td>Decay correction factor</td>
<td>-</td>
<td>0.01</td>
</tr>
<tr>
<td>Field size of beam</td>
<td>1.44</td>
<td>-</td>
</tr>
<tr>
<td>Combined uncertainty of irradiation</td>
<td>2.19</td>
<td>-</td>
</tr>
<tr>
<td>Relative expanded uncertainty ($k=2$), $U$ (%)</td>
<td>4.38</td>
<td></td>
</tr>
</tbody>
</table>

**TABLE 4. MEASUREMENT UNCERTAINTY FOR BLIND SAMPLES IN PARTICIPATING LABORATORIES.**

<table>
<thead>
<tr>
<th>Laboratory</th>
<th>low dose level</th>
<th>medium dose level</th>
<th>high dose level</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Bruker Magnettech Bruker Magnetech Bruker Magnettech Bruker Magnettech</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lab 1</td>
<td>11.38 11.38 6.64 6.64 5.65 5.65</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lab 2</td>
<td>- - 16.55 - 19.79 -</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lab 3</td>
<td>5.68 6.45 5.82 6.34 5.29 5.86</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lab 4</td>
<td>14.78 11.52 13.12 10.30 13.12 9.52</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3. RESULTS AND DISCUSSION

Table 5 and Figure 1 present the dosimetry results obtained by all participating laboratories, including uncertainties. In Table 5, uncertainties are expressed by converting the relative expanded uncertainties into doses.
For the low dose level (0.60 Gy), Lab 2 did not report the measurement results owing to equipment performance issues. The measurement values of the three laboratories that reported the results were considerably overestimated with a relative bias range of 10 - 95% compared to the reference dose. This is because the EPR signal is more affected by noise because 0.60 Gy is lower than 1 Gy, which is the general minimum detectable dose (MDD) of the alanine dosimeter [20]. It should also be taken into account that extrapolation was used for dose assessment as the lowest dose of the calibration samples for all laboratories is greater than 0.6 Gy. In the medium dose level (2.70 Gy), the relative biases of all measurement doses were evaluated within ±8%, except for the Magnettech samples of Lab 3, which were evaluated at approximately -12%. This bias occurred because the result for one sample among four samples was out of range. This problem appeared to be caused by the integrity of the alanine sample. In the high dose level (8.00 Gy), the result obtained in Lab 2 was approximately 15% lower than the reference dose, and the results in the other labs were within ±7%.

**TABLE 5. DOSIMETRY RESULTS OF PARTICIPATING LABORATORIES FOR BLIND SAMPLES.**

<table>
<thead>
<tr>
<th>Reference Doses</th>
<th>Dosimetry results</th>
<th>Dose (Gy, ( k=2 ))</th>
<th>Relative Bias, %</th>
<th>Dose (Gy, ( k=2 ))</th>
<th>Relative Bias, %</th>
<th>Dose (Gy, ( k=2 ))</th>
<th>Relative Bias, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.60 ± 0.03 Gy</td>
<td>Lab 1</td>
<td>0.72 ± 0.08</td>
<td>+20.00</td>
<td>2.84 ± 0.19</td>
<td>+5.19</td>
<td>8.18 ± 0.46</td>
<td>+2.25</td>
</tr>
<tr>
<td></td>
<td>*N.R.</td>
<td>0.94 ± 0.14</td>
<td>+56.67</td>
<td>2.61 ± 0.34</td>
<td>-3.33</td>
<td>7.82 ± 1.03</td>
<td>-2.25</td>
</tr>
<tr>
<td>Low dose level</td>
<td>Bruker alanine dosimeter</td>
<td>0.66 ± 0.04</td>
<td>+10.00</td>
<td>2.89 ± 0.17</td>
<td>+7.04</td>
<td>8.55 ± 0.45</td>
<td>+6.88</td>
</tr>
<tr>
<td></td>
<td>Lab 2</td>
<td>0.79 ± 0.05</td>
<td>+31.67</td>
<td>2.37 ± 0.15</td>
<td>-12.22</td>
<td>8.47 ± 0.50</td>
<td>+5.88</td>
</tr>
<tr>
<td></td>
<td>Lab 3</td>
<td>1.16 ± 0.13</td>
<td>+93.33</td>
<td>2.62 ± 0.27</td>
<td>-2.96</td>
<td>7.56 ± 0.72</td>
<td>-5.50</td>
</tr>
<tr>
<td>2.70 ± 0.12 Gy</td>
<td>Lab 1</td>
<td>0.81 ± 0.09</td>
<td>+35.00</td>
<td>2.89 ± 0.19</td>
<td>+7.07</td>
<td>7.92 ± 0.45</td>
<td>-0.99</td>
</tr>
<tr>
<td></td>
<td>*N.R.</td>
<td>0.94 ± 0.14</td>
<td>+56.67</td>
<td>2.61 ± 0.34</td>
<td>-3.33</td>
<td>7.82 ± 1.03</td>
<td>-2.25</td>
</tr>
<tr>
<td>Medium dose level</td>
<td>Bruker alanine dosimeter</td>
<td>0.79 ± 0.05</td>
<td>+31.67</td>
<td>2.37 ± 0.15</td>
<td>-12.22</td>
<td>8.47 ± 0.50</td>
<td>+5.88</td>
</tr>
<tr>
<td></td>
<td>Lab 3</td>
<td>1.16 ± 0.13</td>
<td>+93.33</td>
<td>2.62 ± 0.27</td>
<td>-2.96</td>
<td>7.56 ± 0.72</td>
<td>-5.50</td>
</tr>
<tr>
<td>8.00 ± 0.35 Gy</td>
<td>Lab 1</td>
<td>0.94 ± 0.14</td>
<td>+56.67</td>
<td>2.61 ± 0.34</td>
<td>-3.33</td>
<td>7.82 ± 1.03</td>
<td>-2.25</td>
</tr>
<tr>
<td>High dose level</td>
<td>*N.R.</td>
<td>0.94 ± 0.14</td>
<td>+56.67</td>
<td>2.61 ± 0.34</td>
<td>-3.33</td>
<td>7.82 ± 1.03</td>
<td>-2.25</td>
</tr>
</tbody>
</table>

*N.R.: Not Reported
FIG. 1. Results of assessed dose values and relative bias obtained by each laboratory for the two alanine dosimeters (top: Bruker alanine dosimeter; bottom: Magnettech alanine dosimeter).

The $E_n$ value and z-score are standard values that can be used to perform conformity analysis of results of intercomparison exercise or proficiency testing. Generally, the $E_n$ value is mainly used when the reference value is clearly known, whereas the z-score is mainly used when there is no reference value or there are many participating laboratories. Therefore, the intercomparison results were analyzed by calculating the $E_n$ value and z-score to avoid the issues found through this analysis in the second intercomparison. The measurement results of the 0.60 Gy reference dose were excluded from the analysis.

The results of calculated $E_n$ value and z-score are presented in Table 6 and Figure 2. All $E_n$ values except for the result of the medium dose level for Magnettech samples of Lab 3 were judged "satisfactory". However, as the $E_n$ value has a limitation in that it decreases with the increasing uncertainty of the result reported by the participant, it is not recommended to judge the conformity of intercomparison result by only the $E_n$ value. This experiment also showed that the $E_n$ value was lower even though the relative bias of Lab 2 was higher than that of Lab 3. In the conformity analysis using the $E_n$ value, better results will be obtained if standardization for uncertainty budgets of participants is performed. In the case of the z-score, all the results of
the participants were found to be “Satisfactory” although the number of participants was relatively small.

When comparing the results of the Bruker and Magnettech alanine dosimeters, the relative biases of the Magnettech alanine dosimeters were observed to be slightly higher at the low dose level, but similar results were obtained at other dose levels. This was attributed to the difference in the mass of the two dosimeters.

In this intercomparison exercise, it was a minor mistake to irradiate the same blind doses in both the dosimeters. This is because participating laboratories can compare each other's results when measuring two types of alanine dosimeters. Additionally, it was impossible to discuss the results based on relative precision or root mean square error (RMSE) as the final results were reported as a single dose value at each dose level. Therefore, a second intercomparison exercise will be planned and performed considering these issues. However, when looking at the overall result of this intercomparison exercise in terms of the relative bias, $E_n$ value, and z-score, it was considered very satisfactory.

| Table 6. Results of Conformity Assessment Obtained Using $E_n$ Values and Z-Scores of the Intercomparison Results. |
|---|---|---|
| **Reference Dose** | **Medium Dose Level** | **High Dose Level** |
|  | $E_n$ Value | Conformity Assessment | $E_n$ Value | Conformity Assessment |
| **Bruker Alanine Dosimeter** |  |  |  |  |
| Lab 1 | 0.63 | Satisfactory | 0.31 | Satisfactory |
| Lab 2 | 0.40 | Satisfactory | -0.85 | Satisfactory |
| Lab 3 | 0.92 | Satisfactory | 0.96 | Satisfactory |
| Lab 4 | -0.25 | Satisfactory | -0.17 | Satisfactory |
| **Magnettech Alanine Dosimeter** |  |  |  |  |
| Lab 1 | 0.85 | Satisfactory | -0.14 | Satisfactory |
| Lab 3 | -1.73 | Unsatisfactory | 0.77 | Satisfactory |
| Lab 4 | -0.27 | Satisfactory | -0.55 | Satisfactory |
|  | $z$-score | Conformity Assessment | $z$-score | Conformity Assessment |
| **Bruker Alanine Dosimeter** |  |  |  |  |
| Lab 1 | 0.22 | Satisfactory | 0.45 | Satisfactory |
| Lab 2 | 0.66 | Satisfactory | -1.37 | Satisfactory |
| Lab 3 | 0.59 | Satisfactory | 0.95 | Satisfactory |
| Lab 4 | -1.47 | Satisfactory | -0.03 | Satisfactory |
| **Magnettech Alanine Dosimeter** |  |  |  |  |
| Lab 1 | 1.01 | Satisfactory | -0.14 | Satisfactory |
| Lab 3 | -0.99 | Satisfactory | 1.06 | Satisfactory |
| Lab 4 | -0.03 | Satisfactory | -0.92 | Satisfactory |
4. CONCLUSIONS
The first EPR-intercomparison exercise in South Korea was performed using two types of alanine dosimeters. Intercomparison was carried out for samples irradiated by three blind doses at less than 10 Gy. Doses below 10 Gy are considerably lower doses in the alanine dosimetry, but overall satisfactory results were obtained for doses above MDD. This intercomparison is especially meaningful as it is the first attempt toward establishing a cooperation system among the laboratories using EPR dosimetry methods in South Korea. This was also an opportunity to improve the reliability of the EPR measurement system in each laboratory. After the first intercomparison, participating laboratories are having continuous meetings discussing various aspects, such as standardization of EPR measurement uncertainties, sharing measurement results of various dosimetry samples.

FIG. 2. Intercomparison results between participating laboratories in terms of $E_n$ values and z-scores (top: Bruker alanine; bottom: Magnettech alanine).
REFERENCES

[1] Committee European de Normalisation (CEN), Detection of irradiated food containing bone, Method by ESR spectroscopy, European Committee for Standardization EN 1786, 1996.


MALAYSIA

QA/QC ACTIVITIES OF IRRADIATION FACILITIES IN MALAYSIA

R. BAHARIN, C.C. KEONG, S. RAMLI, R. AHMAD & M.S. OTHMAN

Malaysian Nuclear Agency

Bangi, 43000 Kajang, Selangor, Malaysia

ABSTRACT

There are ten irradiation facilities available in Malaysia with six of them are using gamma radiation and another four are using electron beam machine. Most facilities cater for sterilization of medical devices and, wire and cable crosslink industries. Only one plant provides food irradiation services. To fulfill the requirement of stakeholders; customers, regulators and importing countries; the irradiators have to adhere to required standards, guidelines and regulations. It is an obligation for them to have the license for operating radiation facility from the authority and, to follow the standards and guidelines provided by the International Standards body (ISO) and the IAEA. An irradiation facility provides quality services as required by its customers through their QAQC activities and as well as carry out safe operation as required by the regulator.

1. INTRODUCTION

Malaysia is blessed with an ideal climate and soil for the plantation of many species of commercial crops. One of the major crops is rubber. Malaysia is one of the largest natural rubber producers in the world. In 2016, Malaysia ranked fifth after Thailand, Indonesia, Vietnam, China, with a total natural rubber production of 673,513 tonnes. Besides producing natural rubber, Malaysia is also one of the world’s largest rubber consumers. Malaysia’s natural rubber consumption amounted to 12,670 tonnes in 2016, ranking eighth behind China, India, the USA, Japan, Thailand and Indonesia. Latex products manufacturing industries accounts for more than 85% of annual natural rubber consumption in Malaysia. Major latex products are gloves, catheters, condom, rubber band and rubber sheet. Other rubber products include tyres, inner tubes and footwear. Malaysia is well-known as the world largest rubber gloves producer. Malaysia currently dominates world rubber gloves market with a market share of 60% to 65%, followed by Thailand (21%), China (5%) and Indonesia (3%). Such a huge industry demands various kinds of supporting industries and services to ensure sustainability of the business, and radiation sterilization is one of them.
Gamma irradiation has proven to be an effective and versatile method for the sterilization of medical devices such as surgical glove and catheter, and pharmaceuticals. In gamma sterilization, products are exposed to a specific dosage of gamma radiation at room temperature conditions which may only cause minimal or no rise in temperature of the exposed products. It leaves no residue to the irradiated products and there is no need for quarantine after completion of the sterilization process. Some product sterilization can only be done by means of gamma irradiation due to their design and manufacturing process, e.g. specific soft tissues used for implants, serums and filled syringes. Hence, the bloom of gamma irradiation sterilization industry in Malaysia fulfills the needs for product sterilization of a large number of rubber gloves and catheters manufacturers.

2. IRRADIATION FACILITIES IN MALAYSIA

There are ten irradiation facilities in Malaysia. All these facilities are located in Peninsular Malaysia; one in the north, one in the south and the rest are distributed in the central region of the peninsular. Obviously, this distribution pattern is driven by the industries demanding irradiation related services where these industries are heavily located at the central region of Peninsular Malaysia. Among these irradiation facilities, three of them are government owned, i.e. Malaysia Nuclear Agency, and the rest are run by private entities, i.e. four multinational and two local companies. Those privately owned irradiation facilities are mostly for commercial or in-house applications, while the government owned irradiation facilities also offers R&D services besides commercial activities. R&D activities are mostly sample irradiations for universities, research institutes and also private companies.

The irradiation facilities in Malaysia are listed in Table 1. These consist of six gamma irradiators and four electron beam machines. Most of the irradiation facilities are used for the purpose of medical devices sterilization for third parties. Positive factors favouring the use of ionizing radiation for sterilization of medical devices have been discussed in previous paragraph. Among the gamma sterilization facilities, Sinagama has the lowest source activity. Despite its low source activity, Sinagama is suitable for food irradiation that requires low radiation dose. The gamma irradiation facility with the lowest source activity is RAYMINTEX located in Malaysian Nuclear Agency. It is a pilot plant for the preparation of radiation vulcanization of natural rubber latex (RVNRL). The purpose of this plant is to demonstrate the viability of RVNRL technology and also to promote and transfer this technology to interested
parties. It has the capability to supply RVNRL to latex dipped product manufacturers for their commercial application, as well as to conduct R&D related activity at a pilot plant scale. Two electron beam facilities in Malaysia with higher accelerator voltage are used for sterilization of medical devices, while two others with lower accelerator voltage are suitable for crosslinking of wire and cable.

### TABLE.1 LIST OF IRRADIATION FACILITIES IN MALAYSIA

<table>
<thead>
<tr>
<th>No</th>
<th>Name</th>
<th>Ownership</th>
<th>Radiation Source</th>
<th>Activity (June 2018)/ Machine Specification</th>
<th>Application Service</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Ansell NP Sdn. Bhd.</td>
<td>Private</td>
<td>Co-60</td>
<td>2.4 MCi</td>
<td>Sterilization of medical devices</td>
<td>In house, third party</td>
</tr>
<tr>
<td>2</td>
<td>Synergy Sterilisation (M) Sdn. Bhd.</td>
<td>Private</td>
<td>Co-60</td>
<td>7 M Ci (total for 2 facilities)</td>
<td>Sterilization of medical devices</td>
<td>Third party</td>
</tr>
<tr>
<td>3</td>
<td>Synergy Sterilisation Rawang (M) Sdn. Bhd.</td>
<td>Private</td>
<td>Co-60</td>
<td></td>
<td>Sterilization of medical devices</td>
<td>Third party</td>
</tr>
<tr>
<td>4</td>
<td>Grand Ten Holdings Sdn. Bhd.</td>
<td>Private</td>
<td>Co-60</td>
<td>2.5 M Ci</td>
<td>Sterilization of medical devices</td>
<td>In house, third party</td>
</tr>
<tr>
<td>5</td>
<td>MINTec-Sinagama</td>
<td>Government</td>
<td>Co-60</td>
<td>450 kCi</td>
<td>Sterilization of medical devices and irradiation of food, R&amp;D</td>
<td>In house, third party</td>
</tr>
<tr>
<td>6</td>
<td>RAYMINTEX</td>
<td>Government</td>
<td>Co-60</td>
<td>24 kCi</td>
<td>Latex vulcanization, R&amp;D</td>
<td>In house, third party</td>
</tr>
<tr>
<td>7</td>
<td>Meditop Corporation (M) Sdn. Bhd.</td>
<td>Private</td>
<td>Electron beam</td>
<td>10 MeV; 200 mA</td>
<td>Sterilization of medical devices</td>
<td>In house</td>
</tr>
<tr>
<td>8</td>
<td>Electron Beam Sdn. Bhd.</td>
<td>Private</td>
<td>Electron beam</td>
<td>10 MeV; 8 mA</td>
<td>Sterilization of medical devices</td>
<td>Third party</td>
</tr>
<tr>
<td>9</td>
<td>ALURTRON</td>
<td>Government</td>
<td>Electron beam</td>
<td>3 MeV; 30 mA</td>
<td>Cross linking of wire and cable, R&amp;D</td>
<td>In house, third party</td>
</tr>
<tr>
<td>10</td>
<td>Sumitomo Electric Interconnect Products (M) Sdn. Bhd.</td>
<td>Private</td>
<td>Electron beam</td>
<td>2 MeV; 50 mA and 0.8 MeV; 100 mA</td>
<td>Cross linking of wire and cable</td>
<td>In house</td>
</tr>
</tbody>
</table>
3. QA/QC PRACTICES IN IRRADIATION FACILITIES IN MALAYSIA

Quality assurance and quality control (QA/QC) is an important process required in almost any industries. In general, QA/QC is a systematic way to ensure that the quality of product or service is achieved as required. Quality assurance refers to the process used in order to prevent mistakes and defects and avoid problems along the process chain of providing products and services to customers. On the other hand, quality control is a process to identify the defect, for example in carrying out an inspection.

In radiation processing facilities in Malaysia, QA/QC activities rely on the implemented quality management system. There are several standards and guidelines which are adhered to by these facilities when they such as ISO 9001, ISO 13485 and ISO 11137. In addition, conforming to regulations from the enforcement and authority bodies in Malaysia help the facilities to operate safely. It is mandatory for each facility to get a license from the licensing authority, Atomic Energy Licensing Body (AELB) of Malaysia, which is aligned with the requirements of Act 304 of the Malaysian government. If a facility is irradiating food, it must be registered with the Ministry of Health as a Food Irradiation Premise. This is a requirement under Food Irradiation Regulations 2011 of Food Act 1985. The standards, guidelines and regulations are the important aspects for facility to adhere to and at the same time can ensure that the facility delivers the quality service as required by customer.

The key to QA/QC practice in radiation processing industries is dosimetry system and procedures. How much dose to be delivered to product? Is objective of irradiation is achieved with that dose? What is the absorbed dose of the irradiated product? These are all related to dosimetry. Especially in sterilization requirement, dosimetry is vital at every stage of development, validation and also in routine monitoring.

Besides that, the elements of quality management system also play an important role in QA/QC practice. As stated in most standards and guidelines provided by ISO, these elements are:

i. Leadership
ii. Responsibilities
iii. Control of documents and records
iv. Maintenance
v. Training
vi. Internal audit
vii. Support – resources, competence, awareness, communication, documented information
viii. Operation
ix. Planning
x. Risks

When the quality management system is implemented, QA/QC activity is easier to practice.

Below is the description of the current practice of QA/QC in one of our plant in Malaysia, MINTec-Sinagama. It is a gamma irradiator plant with cobalt-60 radioactive source. Having started its operation in 1989, this Malaysian government plant is certified with of ISO 9000 since 2000 and ISO 13485 since 2003.

4. CASE STUDY: QA/QC AT MINTEC-SINAGAMA

MINTec-Sinagama irradiation plant operates the JS10000 (IR 219) irradiator which is able to irradiate various products requiring different doses simultaneously. This gamma irradiator facility delivers the dosage specified by the customer. Its main customers are from medical devices, food and herbs and R&D sectors.

MINTec-Sinagama has established a QMS based on the ISO 13485:2016 and ISO 9001:2015 requirements. The plant activities are diverse and to offer services to public and private entity, as in the following:

• Sterilisation of medical products and packaging materials.
• Decontamination of food, pharmaceuticals, herbs and animal feed,
• Disinfectations of insects in agricultural commodities, including for quarantine purposes.
• Samples for R&D purposes.

FIG. 1 shows the process cycle with the steps described as below.

• Product Arrival and Receiving Inspection: The product arrives with complete documents needed and is unloaded at the processing facility
• Pre-irradiation Process: The product is received and details entered in the scheduling for irradiation process preparation.
- Dosimeter Placement, Product Loading, Product Un-loading and Dosimetry Analysis: The product is loaded into the processing container and dosimeters placed as per established configurations, and the product is exposed to the gamma radiation field. The dosimeters are analyzed after irradiation of the product to confirm that the required dose has been delivered.

- Final Inspection and Product Release: All documentation and processing history records are reviewed, and if they are acceptable and customer specifications are met, the product is released and shipped out.

Product packaging that impact outer dimensions, weight, or product orientation is required for specification handling to ensure that the efficiency and effectiveness of gamma process is maintained. When a package is initially received at MINTec-Sinagama, it is weighed and measured, and a carrier/tote loading specification is developed. This loading specification becomes a critical component of the Performance Qualification (PQ), and provides routine handling instructions for future processing of the same product.
The validation requirements for sterilization is conducted by dose-mapping procedure. Routine product processing is performed in a validated system in order to ensure reliability and reproducibility of the process. Performance qualifications (PQ), referred to as dose mappings, are performed to identify the location and magnitude of the minimum and maximum delivered radiation dose.

4.1. Dosimetry Analysis

In radiation processing (sterilization, food irradiation, etc.), validation and process control depend on the measurement of absorbed dose. Measurements of absorbed dose is performed using a dosimetry system or systems having a known level of accuracy and precision. MINTec-Sinagama uses dosimeters supplied by the Secondary Standard Dosimetry Laboratory (SSDL) of Malaysian Nuclear Agency. The laboratory has acquired the status as a national standard dosimetry laboratory.

Dosimetry, as part of the total quality system, provides quality assurance and documentation that the irradiation procedure has been carried out according to specifications. Quality control has to be based on the assurance that the process was carried out within prescribed dose limits. Once completed, where dose readings are within customer specification, QA will verify the Certificate of Irradiation or Results of Irradiation Analysis report as a final process stage before products are released.

4.2. Normal Routine Activities

Once the package loading configuration, package density and dose mapping is completed, the results become part of the product routine processing specification or work instructions. To perform both the normal and routine quality activities, starting with customer inquiries followed by the process, a sufficient control over the flow of irradiation process which include activities for verification the relevant procedure and all the various activities, are carried out in a coordinated manner, as depicted in FIG. 2.
5. CONCLUSION

As a conclusion, the QA/QC activities of the irradiation plants in Malaysia have ensured that irradiation plant is able to deliver its irradiation services, as required by the customers. These activities conform to the quality management system of the international standards of ISO. In addition, safe operation is ensured through abiding to the legal requirements of the regulators. These conformance have given confidence to customers in the quality of their irradiation services and confidence to the public that their operation of the irradiators adheres to standard safety practices, which thus ensures public safety.
REFERENCES


MYANMAR

CURRENT STATUS OF QA/QC PRACTICES FOR IRRADIATION FACILITY

LEI LEI OO, MOE MIN HTWE, CHO THU THU ZAW
dlleioo@gmail.com, mnht11@gmail.com, cho1980@gmail.com

Ministry of Education (Science and Technology)
Nay Pyi Taw, Myanmar

Abstract

Currently, the only research irradiator; Gamma Cell 5000 with dose rate ~ 0.792 kGy/hr is functioning and it is used as a versatile tool for research and development activities and services for sterilization of tissue grafts and health care products. Ministry of Education (Science and Technology) has been implementing national projects to establish electron beam irradiation facility with the assistance of IAEA as MYA1015 and MYA1017 and commercial gamma irradiator for future. Quality Management System is vital for radiation processing technology and capacity building for Quality Management System is enhanced under the MYA1015, MYA1017 and India-Myanmar joint program. The project members performed IQ, OQ, PQ and QC practices for electron beam accelerator and also gamma irradiator under national projects and India-Myanmar joint program. The experiments for calibration of gamma irradiator are done with Fricke dosimeter and Ceric-cerous dosimeter and FWT-60 Film and Gamma Chrome YR Perspex dosimeters are also calibrated. Moreover, dose distribution experiments are done with Fricke dosimeter for low dose and Ceric-cerous dosimeter for high dose. A comparison exercise between Ceric-cerous and alanine dosimeters and dose mapping experiment will also be done.
1. INTRODUCTION

Myanmar is implementing to promote radiation processing technology in Ministry of Education and in private sectors. Ministry of Education is implementing to establish electron beam irradiation facility with the assistance of IAEA as national projects and commercial gamma irradiator for future. Currently, only one research gamma irradiator is functioning and it is used as versatile tool for research and development activities and service for health care products. Secondary Standard Dosimetry Laboratory (SSDL) is established in Ministry of Education to use dose rate calibration laboratory. Quality Assurance and Quality Control is vital for radiation processing technology with integrated quality standards and guidelines by international standards and national organizations. Capacity building program of Quality Management System for radiation processing technology is enhanced under the MYA1015, MYA1017 and India-Myanmar program. The project team is performing the dosimetry system practices for calibration, dose distribution and comparison exercises between dosimeters with existing gamma irradiator for future irradiators.

2. IRRADIATION FACILITY AND ITS APPLICATION

In Myanmar, only one research irradiator; Gamma Cell 5000 with current dose-rate ~0.792 kGy/hr is functioning and it is used for research and development activities and service for health care products. The research works for preservation of tissue grafts, mutation breeding, radiation effects on food and agricultural products, sterile insect technique, biological genetic effects of radiation, radiation chemistry, radiation effects on materials, radiation sterilization, modification of properties of materials and waste water treatment are done by using this irradiator. The contribution institutions are Department of Health, Department of Medical research and hospitals, Myanmar Agricultural Service, Division of Atomic Energy, Material Science Research Division, Biotechnology Research Division, universities and institutions.

Radiation Source : Co-60 12000 Ci
Dose Rate: 9 kGy/hr (in 2000)
Current dose rate : ~0.792 kGy/hr (in 2019)
Exposure: 5000 cc (1.175 ft3)
Sample holder: 17.2 cm(dia), 20.5 cm (h)
Shielding material: Lead & Stainless Steel
Time taken to convey: 6 sec
3. PROMOTING ACTIVITIES FOR RADIATION PROCESSING TECHNOLOGY

Myanmar is implementing to promote radiation processing technology in country and national projects MYA1015 and MYA1017 are implementing with the assistance of IAEA. Under the program, Myanmar has received expert missions, fellowship and scientific visit for electron beam application technology and gamma irradiation technology. National awareness seminar for radiation processing technology (electron beam and gamma) was conducted with the Asia-Pacific regional experts to stakeholders and policy makers under RCA/UNOSSC program at Nay Pyi Taw in 2017. Executive management seminar for electron beam application technology was conducted with IAEA experts to stakeholders, policy makers and private sectors under MYA1017 program at Nay Pyi Taw in 2018. The project team is doing research works with the existing gamma irradiator on food and agricultural products, industrial products, polymer modification, gemstone color enhancement, biofertilizer, plant growth promoter, health care products, waste water treatment and etc,. The project team participated in Research Forum and Science and Technology Fair to aware on radiation processing technology by research results, posters and delivered pamphlet to stakeholders and public in 2017. Human resource development program for electron beam application technology and gamma irradiation technology has enhanced under the national projects with IAEA and India-Myanmar joint program.

FIG. 2. National Awareness Seminar for Radiation Processing Technology with RCA Experts in 2017
4. DOSEMISTRY SYSTEM PRACTICES FOR IRRADIATION FACILITY

Quality Management System is important for radiation processing technology and human resource program for Quality Management System is implemented. The project team performed hand-on experiments for IQ, OQ, PQ and QC for electron beam application technology and OQ and PQ for gamma irradiator are also performed under the MYA1015, MYA1017 and India-Myanmar joint program. The dose rate accuracy is vital for radiation processing and the practices for dosimetry systems are performing with the existing gamma irradiator for future irradiators. The Fricke dosimeter, Ceric-cerous dosimeter, FWT-60 Film, Gamma Chrome YR dosimeters are used for dose rate measurement and calibration. The dose distribution experiments are done with Fricke dosimeter for low dose and Ceric-cerous dosimeter for high dose. A comparison study between Ceric-cerous dosimeter and alanine dosimeter and dose mapping experiment will also be carried out.

4.1 FRICKE DOSIMETER

Fricke dosimeter is the best known and extensively used chemical dosimeter. It provides a reliable means for measurement of absorbed dose and is widely accepted as a standard reference dosimeter and because of its accuracy and reliability it is often used for calibrating other dosimeters. Calibration of Gamma Cell 5000 and dose distribution measurement inside the chamber are performed using Fricke dosimeters.

4.1.1. Preparation of Fricke Dosimeter and Experiment

The standard Fricke dosimeters were prepared at the lab using 1x10^{-3} \text{ mol.L}^{-1} ferrous ammonium sulphate (Fe(NH)_{2}.6H_{2}O), 1x10^{-3} \text{ mol.L}^{-1} sodium chloride (NaCl), and 0.4 \text{ mol.L}^{-1} concentrated sulphuric acid (H_{2}SO_{4}) [1]. 0.392g of ferrous ammonium sulphate and 0.058 g of sodium chloride were dissolved in 0.4 \text{ mol.L}^{-1} sulphuric acid and prepared for 1 L dosimetric solution.
For calibration experiment, polypropylene tubes (13 mm diameter and 53 mm length) were filled with the Fricke solution and the tubes were surrounded by (5 mm thick) Perspex phantom to establish electronic equilibrium. For dose distribution experiments, the Fricke dosimeter solution was filled in polypropylene tubes (16 mm diameter and 58 mm length) and they were placed in prefabricated dosimeter phantom for irradiation. The irradiation was carried out in a Gamma Cell 5000.

**FIG. 4.** Placement of Fricke dosimeter for calibration (a) top view and (b) front view

**FIG 5.** Placement of Fricke dosimeters for dose distribution (a) top view and (b) front view
During calibration experiment, Fricke dosimeters were irradiated with the estimated period of time for five different dose points and three dosimeters were irradiated every dose point shown in FIG 4. In dose distribution experiment, Fricke dosimeters were irradiated with the target dose (283.9 Gy) for three replications. Each replication contains five dosimeters for upper layer and five dosimeters for lower layer shown in FIG 5. The absorbance of Fricke solution was measured with (Genesys 10S) UV-Visible spectrophotometer at 304 nm wavelength, 34.5°C. After measurement, the relation graph of corrected absorbance and time of irradiation was plotted. Then, the absorbed dose in the Fricke solution, D_\text{F} was calculated.

4.1.2. Calibration of Gamma Cell and Dose Distribution Experiments by Fricke Dosimeter

From the experiment, the dose rate of Gamma Cell 5000 is 0.792 kGy/hr on 16 July, 2019. The calibration curve of Gamma Cell 5000 is expressed in FIG 6. Dose distribution pattern inside the chamber is shown in FIG 7. The target dose at the center of the chamber is 283.9 Gy but the dose at the center of upper layers (247.1 Gy) and the dose at the center of lower layer is (289.9 Gy). Moreover, the dose at 5.1 cm away from the center is always higher than the dose at the center.

![FIG.6. Calibration curve for gamma cell 5000](image)

![FIG.7. Dose distribution inside the Gamma Cell 5000 (a) upper layer and (b) lower layer](image)
4.2. CERIC-CEROUS DOSIEMTER

The Ceric-cerous system provides a reliable means for determining absorbed dose to water and it is based on a process of reduction of ceric ions to cerous ions in acidic aqueous solution by ionizing radiation [3]. Radiation leads to the reduction of Ceric ions $\text{Ce}^{4+}$ to Cerous ions $\text{Ce}^{3+}$ in 0.4M sulphuric acid. 25.2 g cerous sulphate (NH$_4$)$_2$Ce(SO$_4$)$_2$H$_2$O salt and type 2 water is used for this experiment. At high dose laboratory, the prepared Ceric-cerous dosimeter can be in two range: low dose which in range of absorbance 0.4-0.45 while for high dose is 0.7-0.75. The Ceric-cerous used as the routine dosimeter for sterilization and food irradiation industry. To check the stability of Ceric-cerous solution, (Genesys 10S) UV-Vis spectrophotometer is used at 320nm wavelength. These dosimeters can be used as the dose range of 500 Gy- 5 kGy.

![Fig. 8. Preparation of Ceric-cerous Dosimeter Solution](image1)

![Fig. 9. Irradiation of Ceric-cerous Dosimeter and read out by Electrochemical Potentiometer](image2)

4.2.1 Calibration of Gamma Cell and Dose Distribution Experiment by Ceric-cerous Dosimeter

In calibration experiment, the dose of 500 Gy, 1 kGy and 3 kGy are used with absorbance 0.4-0.45. Electrochemical potentiometer is used as Read out for absorbed dose. From these results, radiation doses of 500 Gy is not suitable for use and 1 kGy and 3 kGy can be used. So, it is concluded that this solution can be useful above 1 kGy. The calibrated electrochemical potentiometer can be used as read out for different doses for calibration. In dose distribution experiment, at that time, the absorbance A is around 0.75, Ceric-cerous dosimeters were irradiated with 7 kGy. Potentiometric read out (mV) temperature is 27°C. The dosimeters are placed in nine positions to check the dose uniformity inside Gamma Cell. The absorbed doses of Ceric-cerous dosimeters can be determined by using the electrochemical potentiometer. The results of this experiment are as shown in following Table 1.
TABLE 1. AVERAGE DOSE INSIDE THE GAMMA CELL AT 7 kGy

<table>
<thead>
<tr>
<th>Dosimeters placement</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
</tr>
</thead>
<tbody>
<tr>
<td>mV readout by</td>
<td>6.2</td>
<td>6.3</td>
<td>6.8</td>
<td>6.7</td>
<td>6.0</td>
<td>6.5</td>
<td>6.7</td>
<td>6.2</td>
<td>6.0</td>
</tr>
<tr>
<td>Electrochemical</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>potentiometer</td>
<td>6.1</td>
<td>6.4</td>
<td>6.8</td>
<td>6.7</td>
<td>6.0</td>
<td>6.6</td>
<td>6.8</td>
<td>6.1</td>
<td>6.0</td>
</tr>
<tr>
<td></td>
<td>6.0</td>
<td>6.3</td>
<td>6.8</td>
<td>6.6</td>
<td>6.0</td>
<td>6.6</td>
<td>6.8</td>
<td>6.1</td>
<td>5.9</td>
</tr>
<tr>
<td>Average mV</td>
<td>6.1</td>
<td>6.3</td>
<td>6.8</td>
<td>6.7</td>
<td>6.0</td>
<td>6.6</td>
<td>6.8</td>
<td>6.1</td>
<td>6.0</td>
</tr>
<tr>
<td>Doses from</td>
<td>6.8</td>
<td>7.0</td>
<td>7.5</td>
<td>7.4</td>
<td>7.7</td>
<td>7.3</td>
<td>7.5</td>
<td>6.8</td>
<td>6.7</td>
</tr>
<tr>
<td>Calibration curve</td>
<td>kGy</td>
<td>kGy</td>
<td>kGy</td>
<td>kGy</td>
<td>kGy</td>
<td>kGy</td>
<td>kGy</td>
<td>kGy</td>
<td>kGy</td>
</tr>
<tr>
<td>Range</td>
<td>D_{min} ~ 6.7 kGy - D_{max} ~ 7.5 kGy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average dose</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>inside the Gamma</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cell</td>
<td>D_{avg} ~ 7.1 kGy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

According to this data, it can be concluded that the dose distribution in Gamma Cell 5000 is quite different due to different positions shown in FIG10. The highest dose will be at circumference and the lowest dose will be at the centre.

4.3. GAMMA CHROME YR PERSPEX DOSIMETER

A new dyed poly (methylmethacrylate) (PMMA) dosimeter can be used for radiation processing dosimetry (100 Gy to 3 kGy) and measured by spectrophotometer (Genesys 10S) at 530 nm wavelength. In this experiment, Gamma Chrome YR Perspex dosimeters are irradiated with doses of 100 Gy, 250 Gy, 350 Gy, 500 Gy, 800 Gy, 1100Gy gamma radiation. The calibration can be done using Gamma Cell 5000 and Genesys10 Spectrophotometer can be used as read out system at 530nm wavelength. The response between absorbed dose and specific absorbance (abs/mm) can be achieved at 30 C, 45% humidity. This dosimeter reads out after 1 week. The curve shows the response of dose increases and its specific absorbance increase linearly. Calibration data can be compared for QA purpose with the Harwell generated graph ISO/ASTM standard 51276.
4.4. FWT-60 FILM

The FWT-60 series of dosimeters use hexa (hydroxyethyl) amino triphenylacetonitrile (HHEVC) dye and analysis of the dosimeters is done using (Genesys 10S) UV-Vis spectrophotometer at 600 nm. In this experiment, gamma radiation doses of 100 Gy, 250 Gy, 350 Gy, 500 Gy, 800 Gy, 1100 Gy are applied to the FWT-60 films (its thickness is 42.5 um).
K (response) is specific absorbance and is determined from its thickness t and final and initial absorbance $A_f$ and $A_i$,

$$K = \frac{A_f - A_i}{t}$$

$K =$ specific absorbance,  
$A_f =$ final absorbance,  
$A_i =$ initial absorbance,  
$t =$ thickness,

At 28°C and 50% humidity, the Calibration curve is shown in FIG 13.

![FIG.14. Calibration Curve by FWT-60 Film](image)

According the response results, FWT-60 film dosimeters are suitable for the doses of above 500 Gy. Under this dose, the response is unstable. This calibration curve can be compared with the response provided FWT-60-00 Radiochromic detectors to ionizing radiation. This result almost fit the manufacture’s response. The actual response depends on processing parameters and instrumentation used to measure absorbance and thickness.

5. CONCLUSION

Myanmar is implementing national projects with the assistance of IAEA to promote radiation processing technology in Country. Human resource development program for radiation processing technology is enhanced under the national projects and India-Myanmar program. Private organizations and stakeholders emphasized on radiation processing technology after national awareness seminars with IAEA experts and RCA experts. Quality Management System is vital for radiation processing technology and project members performed validation process and process control practices under the program. The project members are practicing for dose rate measurement, calibration and dose distribution and a comparison study between the dosimeters with existing Gamma Cell for future irradiators.
REFERENCES:


[2] Investigation of the effect of temperature, dose rate and short term post irradiation change on the response of various types of dosimeters to Co-60 gamma radiation for quality assurance in Thailand


PHILIPPINES

INSTALLATION AND OPERATIONAL QUALIFICATION OF THE PNRI ELECTRON BEAM IRRADIATION FACILITY

H.M. SOLOMON\textsuperscript{a}, L.G. LANUZA\textsuperscript{a}, F.A. PARES\textsuperscript{a}, A.G. BAULE\textsuperscript{a}, G.F.O. DEAN\textsuperscript{a}, A.R. VALENZUELA\textsuperscript{a}, F.C.C. VALDEZ\textsuperscript{a}, F. KUNTZ\textsuperscript{b}

\textsuperscript{a}Philippine Nuclear Research Institute
Commonwealth Avenue, Diliman, Quezon City 1101 Philippines

\textsuperscript{b}Aerial, 250 rue Laurent Fries, Parc d'innovation, 67412 Illkirch, France

Abstract

The Electron Beam Irradiation Facility of the Philippine Nuclear Research Institute was established in 2014, with the technical and financial assistance from the International Atomic Energy Agency, to demonstrate the applications of radiation processing in the Philippines using electron beam. Prior to operation, installation qualification and operational qualification experiments were performed to determine the main characteristics of the facility and to evaluate its capability to accurately deliver specified, controllable doses in a reproducible manner. Using Al wedge and stack techniques, depth-dose distribution measurements were performed to determine beam energy. Beam width and beam length at different distances from the scanner, dose uniformity in scanning and traveling direction, and dependence of surface dose to product height were determined. With the use of homogenous materials such as polystyrene, polyactic acid and cardboard sheets, dose distribution, edge effect, the relationship of surface dose as a function of beam current and cart conveyor speed, and irradiation reproducibility were established. CTA and B3 WINdose dosimetry systems were used for dose measurements.

1. INTRODUCTION

Radiation processing using electron accelerators, X-rays and gamma sources, has become an accepted and established industry in developed and developing countries. In the past years, electron beam (EB) accelerator was the preferred alternative radiation source for industrial radiation processing as it offers advantages over radioisotope sources such as a) higher dose
rates which result in high throughputs, b) possible hook up with industry for on-line processing, and c) increased public acceptance since the storage, transport, and disposal of radioactive material are not an issue [2].

The Electron Beam Irradiation Facility (EBIF) of the Philippine Nuclear Research Institute (PNRI) was established in 2014 under an International Atomic Energy Agency (IAEA) Technical Cooperation (TC) and the Philippines’ Department of Science and Technology Grants-In-Aid Projects. The governments of the United States of America and Japan also gave extrabudgetary contributions. The electron accelerator Model ELV-8, manufactured by EB Tech Co., Ltd., can be operated from 1 to 2.5 MeV, with a maximum current of 50 mA and a maximum power of 100 kW. Accelerators of this energy are mainly used for polymer modification which includes radiation crosslinking, radiation-induced polymerization (graft polymerization and curing) and degradation of polymers. In certain cases, it is also applicable for food irradiation and radiation sterilization of medical devices [2, 3]. The EBIF has two handling systems used for irradiating samples/products. The cart conveyor system (CCS) is used for the irradiation of solid and small volume of liquid samples while the liquid handling system (LHS) is used for the irradiation of large volume of liquids/solutions such as carrageenan solution for plant growth promoter.

Installation qualification (IQ) and operational qualification (OQ) of the EBIF were carried out to determine the main characteristics of the facility and to evaluate its capability to accurately and reproducibly deliver doses over the range conditions [6, 7].

2. MATERIALS AND METHODS

2.1 The EB Irradiation Facility

IQ and OQ experiments were performed using the CCS and samples were placed on top of a cart. The internal dimension of its tray is 79 cm (L) x 79 cm (W) x 3.5 cm (H). The speed of the CCS can be adjusted from 2 m/min to 20 m/min.

2.2 Dosimetry systems and reference materials

The dosimetry systems used were GEX B3 WINdose (B3) film dosimeters (Batch BD, with average thickness of about 0.0183 mm ± 0.0002 mm at k=2, and dose range of 5 to 50 kGy) [5] and cellulose triacetate (CTA) film strip dosimeters (type FTR-125, with film thickness of 125 µm, width of 8 mm and usable dose range of 5 to 300 kGy) [4]. B3 dosimeters were measured at 554 nm using AerODE dose measuring device while CTA dosimeters were measured at 280 nm using DosASAP PC controlled dosimetry device [1].

Homogenous materials such as polystyrene (PS), polylactic acid (PLA) and cardboard (CB) sheets were used as reference materials. Risö Al wedge and stacks of PLA were used to determine beam energy.

2.3 IQ and OQ experiments were performed following standardized procedure [6].
3. RESULTS AND DISCUSSION

3.1 IQ Experiments

3.1.1 Beam energy measurements using Al wedge and stack technique

Electron beam energy was determined at 50 cm and 16.5 cm below the scanner using Al wedge and stack technique. For the Al wedge technique, 2 CTA strips were placed along the sloping surface between the two wedges [6]. For the stack technique, twelve 1mm thick PLA plates were stacked together with B3 dosimeters placed in between each plate and on the top and bottom of the stack. Both set-up passed below the beam scanner on the conveyor (Fig. 1).

CTA and B3 dosimeters were evaluated and the practical electron range (Rp) from the measured depth dose curve was determined.

For the Al wedge technique, electron energy (E) was calculated using the formula A4.14 from ISO/ASTM 51649:2015:

\[
E = 0.423 + 0.469 \times Rp + 0.0532 \times Rp^2
\]

where E is given in MeV, and Rp in g/cm².

At 50 cm from scanner, Rp = 0.348 cm and the energy of the electron beam was determined to be 2.06 MeV. At 16.5 cm from scanner, Rp = 0.361 and the energy of the electron beam increased a little to 2.123 MeV (Fig. 2).
For the stack technique, electron energy ($E$) was calculated using the formula A4.13 from ISO/ASTM 51649:2015:

$$E = 1.876 \times R_p + 0.298$$

At 50 cm from the beam scanner, $R_p$ is graphically determined to be 0.94 g/cm$^2$, giving $E = 2.06$ MeV. At 16.5 cm from the beam scanner, $R_p$ is graphically determined to be 1.0 g/cm$^2$, thus, $E = 2.17$ MeV (Fig. 3). There is a significant difference between the target (2.5 MeV) and actual energy. This may be caused by the differences in the energy spectra of the beams measured compared to the spectra upon which equations (1) and (2) are based [6]. Additional experiments on beam energy measurements will be conducted to confirm the results.

3.1.2 Beam width measurement at different distances from the scanner

A strip of CTA dosimeter was attached to a wood plate. The wood plate was placed on top of a cart parallel to the beam scanning direction (Fig. 4).

FIG. 3. Depth-dose curve measured in PLA stack at (a) 50 cm; (b) 16.5 cm below the beam scanner

FIG. 4. Experimental set-up for beam width measurement
Irradiation was performed at 6.5, 16.5, 25 and 50 cm from the beam scanner using the following parameters: 2.5 MeV, 12 mA and cart conveyor speed of 4 m/min.

Results of beam width measurements at different distances from the scanner is shown in Table 1.

### TABLE 1. RESULT OF BEAM WIDTH MEASUREMENTS AT DIFFERENT DISTANCES FROM THE SCANNER

<table>
<thead>
<tr>
<th>Distance from scanner (cm)</th>
<th>6.5</th>
<th>16.5</th>
<th>25</th>
<th>50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beam Width (cm)</td>
<td>133</td>
<td>140</td>
<td>145</td>
<td>157</td>
</tr>
<tr>
<td>Beam Uniformity (better than at 1σ)</td>
<td>± 15%</td>
<td>± 4%</td>
<td>± 5%</td>
<td>± 5%</td>
</tr>
</tbody>
</table>

Analysis of data demonstrates that beam width increases with increasing distance from the beam scanner. It was estimated that beam uniformity at a distance of 16.5 cm from the beam scanner is better than ± 5% (at 1σ). This result will lead to homogeneous surface dose irradiations.

#### 3.1.3 Beam length measurement at different distances from the beam scanner

A strip of CTA dosimeter was attached to a wood plate. The wood plate was placed on top of a cart perpendicular to the beam scanning direction (Fig. 5).

![FIG. 5. Experimental set-up for beam length measurement](image)
Irradiation was performed at 6.5, 16.5, 25 and 50 cm from the beam scanner using the following parameters: 2.5 MeV, 12 mA and cart conveyor speed of 4 m/min. During irradiation, the conveyor was stopped while the cart was under the beam. After 1 or 3 seconds of static irradiation, the beam was shut down.

Data in Table 2 shows that beam length increases as the distance from the scanner is increased. This is explained by electron scattering in the air and by the triangular shape of the beam scanner.

<table>
<thead>
<tr>
<th>Distance from scanner (cm)</th>
<th>6.5</th>
<th>16.5</th>
<th>25</th>
<th>50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beam Length at half maximum (cm)</td>
<td>6</td>
<td>9</td>
<td>12</td>
<td>22</td>
</tr>
</tbody>
</table>

The plot in Figure 6 may be used to determine the electron beam length at half maximum at any distance from the scanner between 6 and 50 cm.

*TABLE 2. RESULT OF BEAM LENGTH MEASUREMENTS AT DIFFERENT DISTANCES FROM THE SCANNER*

3.1.4 Product height dependence of surface dose

Product height dependence was monitored by irradiating B3 dosimeters at several distances from the scanner. Irradiation was performed at 10, 20, 30, 40 and 50 cm distance between cart and scanner using the following parameters: 2.5 MeV, 12 mA and cart conveyor speed of 4 m/min.

Table 3 shows the relative surface dose at increasing distance from the scanner. Figure 9 illustrates the behavior of the surface dose with increasing distance from scanner.
The surface dose increases as the sample height approaches the scanner. Electron scattering in the air increases as the distance from scanner increases, with geometrical beam width increasing as well. These two effects combined, lead to a surface dose variation of almost 25% for a product height change of 40 cm.

3.1.5 Uniformity in scanning and travelling direction

Six strips of CTA dosimeters were attached to a wood plate as shown in Fig. 10. One strip was placed in scanning direction and 5 strips in traveling direction. The wood plate was placed on top of the CCS.

### TABLE 3. RELATIVE SURFACE DOSE AT INCREASING DISTANCE FROM SCANNER

<table>
<thead>
<tr>
<th>Distance from scanner (cm)</th>
<th>Relative surface dose (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>123</td>
</tr>
<tr>
<td>20</td>
<td>115</td>
</tr>
<tr>
<td>30</td>
<td>108</td>
</tr>
<tr>
<td>40</td>
<td>103</td>
</tr>
<tr>
<td>50</td>
<td>100</td>
</tr>
</tbody>
</table>

*FIG. 9. Plot of relative dose at different distances from the scanner*
Irradiation was performed at 50 cm from the beam scanner using the following parameters: 2.5 MeV, 12 mA and cart conveyor speed of 4 m/min.

**In scanning direction**

Beam homogeneity in scanning direction is about ± 7% (at 1σ) over the cart width. A significant dose increase is measured near the Al tray walls which may be attributed to electron scattering (Fig. 11).

If the irradiation area can be limited to the central part of the cart (at least 5 cm from the cart walls), the irradiation uniformity can be better than ± 4% (at 1σ).

**FIG. 10. Experimental set-up for determination of uniformity in scanning and travelling direction**

**FIG. 11. Plot of absorbed dose in scanning direction**
In travelling direction

Fig. 12 shows 5 CTA dose readings at different positions of the cart, 1F, 3F, 5F, 7F and 9F. Dosimeters in positions 1F and 9F which are near the walls of the Al tray, exhibited higher average doses. This may be attributed to the scattering effect of the electrons.

At the center of the Al tray, the dose profiles are more uniform. The irradiation homogeneity can be estimated to be better than \( \pm 6\% \) at 1\( \sigma \).

Significant variability of the measured surface dose distribution, as confirmed by the wave shape of 3F, 5F and 7F dose profiles may be due to the slight inconsistency in conveyor speed.

![FIG. 12. Plot of absorbed dose in travelling direction at different positions in the cart](image)

3.2 OQ Experiments

3.2.1 Dose distribution in different homogenous materials

Dose distribution measurements were performed in different homogenous materials. The distribution of absorbed dose on the surface of each layer of PS and CB plate was determined.

Separate stacks of PS and CB plates were prepared and B3 dosimeters were placed in between each plate, and on the top and bottom of the stacks. The set-up is similar to Fig. 1(b). One PS plate is equivalent to 0.108 g/cm\(^2\) and 1 CB plate is equivalent to 0.058 g/cm\(^2\).
The plot in Fig. 7 shows that the depth dose distribution in both PS and CB plates overlap. This suggests that dose distribution is independent of material density.

### 3.2.2 Assessment of edge effect

CTA strip dosimeters were placed in several positions in between separate stacks of PLA and CB plates (Fig. 8).

Irradiation was performed at 16.5 cm from the beam scanner using the following parameters: 2.5 MeV, 12 mA and cart conveyor speed of 4 m/min.

The decrease in dose near the edge of the product stack (edge effect) is due to the interface between material and air. Electrons escape from the material and scattering of electrons in air is not efficient enough to balance this effect.

The maximum edge effect represents a dose decrease of about 30% compared to the central dose. On the other hand, the range of the edge effect inside the material is density dependent. It is about 3 mm for PLA and 6 mm for CB, which density is half of the PLA.

### 3.2.3 Dose as function of current and speed
The linearity of the surface dose was verified using the ratio of beam current to cart conveyor speed:

\[ D_{\text{surface}} = K \left( \frac{I}{v} \right) \]  

(3)

where \( K = \frac{(S/\rho)}{SW} \)

\( (S/\rho) \) is the Stopping power of water for 2.1 MeV electrons (MeV.cm²/g);

\( SW \) is the Scan width (cm);

\( I \) is the beam current (µA);

\( v \) is the cart conveyor speed (cm/s)

At 50 cm from the beam scanner, B3 dosimeters were placed on top of a stack of PLA plates and irradiated at 2.5 MeV using different parameters as listed in Table 4. The ratio between beam current and cart conveyor speed is also indicated in this table.

<table>
<thead>
<tr>
<th>Speed/Current</th>
<th>2 mA</th>
<th>4 mA</th>
<th>8 mA</th>
<th>12 mA</th>
<th>24 mA</th>
<th>40 mA</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 m/min</td>
<td>1.00</td>
<td>2.00</td>
<td>4.00</td>
<td>6.00</td>
<td>12.00</td>
<td>20.00</td>
</tr>
<tr>
<td>4 m/min</td>
<td>0.50</td>
<td>1.00</td>
<td>2.00</td>
<td>3.00</td>
<td>6.00</td>
<td>10.00</td>
</tr>
<tr>
<td>8 m/min</td>
<td>0.25</td>
<td>0.50</td>
<td>1.00</td>
<td>1.50</td>
<td>3.00</td>
<td>5.00</td>
</tr>
<tr>
<td>12 m/min</td>
<td>0.17</td>
<td>0.33</td>
<td>0.67</td>
<td>1.00</td>
<td>2.00</td>
<td>3.33</td>
</tr>
</tbody>
</table>

The measured irradiation surface dose (in kGy) is shown in Table 5.

<table>
<thead>
<tr>
<th>Speed/Current</th>
<th>2 mA</th>
<th>4 mA</th>
<th>8 mA</th>
<th>12 mA</th>
<th>24 mA</th>
<th>40 mA</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 m/min</td>
<td>6.86</td>
<td>14.27</td>
<td>28.88</td>
<td>42.58</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td></td>
<td>6.86</td>
<td>14.36</td>
<td>28.72</td>
<td>42.83</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>4 m/min</td>
<td>3.34</td>
<td>7.20</td>
<td>14.76</td>
<td>21.97</td>
<td>42.50</td>
<td>x</td>
</tr>
<tr>
<td></td>
<td>3.43</td>
<td>7.36</td>
<td>14.68</td>
<td>21.97</td>
<td>42.58</td>
<td>x</td>
</tr>
<tr>
<td>8 m/min</td>
<td>1.39</td>
<td>3.43</td>
<td>7.36</td>
<td>11.33</td>
<td>22.29</td>
<td>41.43</td>
</tr>
<tr>
<td></td>
<td>1.48</td>
<td>3.43</td>
<td>7.36</td>
<td>11.25</td>
<td>22.37</td>
<td>41.60</td>
</tr>
<tr>
<td>12 m/min</td>
<td>0.71</td>
<td>1.99</td>
<td>4.69</td>
<td>7.36</td>
<td>14.52</td>
<td>25.91</td>
</tr>
<tr>
<td></td>
<td>0.80</td>
<td>2.16</td>
<td>4.77</td>
<td>7.44</td>
<td>14.68</td>
<td>25.83</td>
</tr>
</tbody>
</table>

X: readout dose is higher than calibration curve

The surface dose was plotted against \( I/v \) and the slope \( K \) of the straight line was estimated (Fig. 13).
The irradiation parameters in the EBIF can be calculated using the following equation:

\[ \frac{I}{v} (\text{mA.min/m}) = \frac{D (\text{kGy})}{7.40} \]  

(4)

### 3.2.4 Irradiation reproducibility

B3 dosimeters were placed on top of a stack of PLA plates, positioned at 50 cm from the beam scanner, and irradiated at 2.5 MeV and I/v ratio of 0.8 and 3.8 mA.min/m. Several current and speed settings, as listed in Table 6, were chosen to get I/v ratio of 0.8 and 3.8

<table>
<thead>
<tr>
<th>I/v (mA.min/m)</th>
<th>0.8</th>
<th>3.8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current (mA)</td>
<td>1.6</td>
<td>3.2</td>
</tr>
<tr>
<td>Speed (m/min)</td>
<td>2</td>
<td>4</td>
</tr>
</tbody>
</table>

### TABLE 6. CURRENT AND SPEED SETTINGS TO ACHIEVE I/V RATIO OF 0.8 AND 3.8

### TABLE 7. ABSORBED DOSE (IN KILOGRAY) AT I/V RATIO OF 0.8 AND 3.8

<table>
<thead>
<tr>
<th>I/v (mA.min/m)</th>
<th>0.8</th>
<th>3.8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current (mA)</td>
<td>1.6</td>
<td>3.2</td>
</tr>
<tr>
<td>Speed (m/min)</td>
<td>2</td>
<td>4</td>
</tr>
</tbody>
</table>
Data in Table 7 show that there is a reproducibility issue for Speed 2 m/min and it is not suitable for performing irradiations. Discarding this value, the reproducibility gets better and becomes acceptable as shown in Table 8.

<table>
<thead>
<tr>
<th>Current (mA)</th>
<th>3.2</th>
<th>6.4</th>
<th>9.6</th>
<th>15.2</th>
<th>30</th>
<th>38</th>
</tr>
</thead>
<tbody>
<tr>
<td>Speed (m/min)</td>
<td>4</td>
<td>8</td>
<td>12</td>
<td>4</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>Dose (kGy)</td>
<td>5.6</td>
<td>5.7</td>
<td>5.8</td>
<td>24.4</td>
<td>27.0</td>
<td>27.6</td>
</tr>
<tr>
<td>Ave. dose and CV%</td>
<td>5.6 ± 4% (1σ)</td>
<td>27.3 ± 9% (1σ)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The cart speed of 2 m/min should not be used when irradiating products. The K value, 7.40 kGy.m/(min.mA), of the EBIF has been validated.

### 4. CONCLUSION

The IQ and OQ of the PNRI EBIF were performed to characterize the accelerator parameters and to evaluate its capability to accurately and reproducibly deliver doses under different operating conditions. Based on experiments, the following conclusions can be drawn:

a. Using the wedge and stack techniques, the beam energy at 16.5 cm and 50 cm from the beam scanner is about 2.15 MeV and 2.06 MeV, respectively.

b. Beam width and beam length increases with increasing distance from the beam scanner. Beam width uniformity at distances of 16.5 cm up to 50 cm from the beam scanner will result to homogeneous surface dose irradiations.

c. Dose distribution was found to be homogenous using reference materials of different densities. This suggests that dose distribution is independent of material density.

d. There is a relative increase on surface dose as the sample height approaches the beam scanner.

e. Surface dose as a function of the ratio of current to speed was determined to have a linear behavior and evaluated to have good reproducibility. It is recommended not to irradiate at a cart conveyor speed of 2 m/min due to reproducibility issues.
ACKNOWLEDGEMENT

IQ and OQ experiments were carried out under an Expert Mission of the IAEA TC Project PHI8026: Establishing an Electron Beam Facility

REFERENCES


SLOVAKIA

QUALITY MANAGEMENT SYSTEM AT UNIVERSITY CENTRE OF ELECTRON ACCELERATORS IN TRENCIN WITH 5 MeV ELECTRON AND BREMSSTRAHLUNG BEAM

A. SAGATOVA and M. FULOP

University Centre of Electron Accelerators, Slovak Medical University in Bratislava, Ku kyselke 497, 91106 Trenčín, Slovak Republic

Abstract

The first and so far the only facility for radiation treatment in Slovakia started its operation at the University Centre of Electron Accelerators of the Slovak Medical University in 2012 in Trencin. The paper reports on basic parameters, operational experience and application potential of this combined electron- and bremsstrahlung-beam irradiation facility. The facility is based on a 5 MeV 1 kW linear electron accelerator UELR-5-1S equipped with a beam-scanning system, a conveyor line and an X-ray converter. Although it could be used also for routine radiation processing in an industrial-like mode, its main purpose
is focused on research and on revealing potential applications. The examples of on-going research activities and the most significant scientific achievements can be found in the paper together with quality management system and dosimetry experiences of the facility.

1. INTRODUCTION

Radiation processing belongs nowadays to modern and widely used tools for modification of material properties in a well-controlled way. However, it belongs to rather new branches in Slovakia. The first facility dedicated to radiation treatment was established in 2012 at the University Centre of Electron Accelerators in Trencin and remains the only one so far. It is a multipurpose facility designed for research purposes as well as for industrial applications in radiation treatment. Its main task is to bring the new technology in country into practise. In this paper, we describe and discuss the operational parameters for the UELR-5-1S linear electron accelerator at the facility in Trencin, its quality management system and its dosimetric system. Discussion is completed by demonstrative examples of some on-going research activities as well as significant scientific results that have been achieved at this laboratory till now.

2. EQUIPMENT

The University Centre of Electron Accelerators (UCEA) in Trencin runs a 5 MeV UELR-5-1S linear electron accelerator (FIG. 1) with maximum power of 1 kW produced by Russian company NIIEFA. The nominal energy of electrons can be adjusted in the range from 3.6 up to 6.2 MeV. The tungsten target allows to convert the accelerated electrons into continuous spectrum of bremsstrahlung X-rays (FIG. 2). The electron beam can be used in pulse mode impinging one spot of the surface or in usual scanning mode, where the width of scan as well as the scanning frequency can be chosen. The scanning frequency comes from 0.25 Hz up to 5 Hz and the scanning width can be set to 40, 45 or 50 cm. The accelerator gives the 3.5 μs bunches of electrons with frequency from 5 up to 240 Hz which allows the dose rate regulation. Experimentally obtained dose rates with EB (electron beam) are in the range from 10 to 5600 kGy/h at specified distance from accelerator exit window and scanning width. The bremsstrahlung dose rates which we have applied were in the range from 13 to 1440 Gy/h at given accelerator parameters. The minimum value of beam current is of 5 μA and its maximum value is 200 μA. The body of the accelerator is placed on the first floor releasing accelerated electrons downwards to the irradiating room at the ground floor. Beneath the accelerator exit window in irradiating room there is a conveyor bringing the treated objects through concrete labyrinth from the store (FIG. 3). The velocity of the conveyor can be regulated in a wide range of values from 0.1 mm/s up to 100 mm/s controlling the given dose. For example, at a beam repetition rate of 120 Hz and scanning width of 40 cm, the doses from 211 kGy (at 0.1 mm/s) down to 2.3 kGy (at 10 mm/s) at one run can be obtained or lower doses if the conveyor velocity is higher up to 100 mm/s obtainable. As a part of the conveyor there is a turning machine (FIG. 4) in the store near the entrance to the labyrinth allowing automatic double-side irradiation of objects. All these adjustable parameters make the accelerator ideal equipment for research purposes but allow also routine industrial irradiation.
3. DOSIMETRIC SYSTEM

A routine dosimetric system used at the UCEA accelerator is based on B3 radiochromic films (1 cm in diameter and 18 μm thick polyvinyl butyral films), which are evaluated by Spectrophotometer GENESYS20. Ionizing radiation activates the B3 dye centres which in turn cause the B3 film to undergo a predictable colour change from clear to deepening shades of pink magenta (FIG. 5.a). The radio chemical yield of the dye results in a colour change that is easily related to absorbed dose that is independent of the dose rate. The routine dosimetric system can be used in the range of doses of 1 – 100 kGy with both types of ionizing radiation disposal at UCEA: the high energy electrons and the bremsstrahlung X-ray photons. The B3 dosimetric system is calibrated by RISO polystyrene calorimeters (FIG. 5.b), traceable to national standards. For dosimetry of lower doses, in the range of Gy - usually obtained by X-rays, the FARMER ionization chamber is used (FIG. 5.c).
4. QUALITY MANAGEMENT SYSTEM

Since 2014 we have implemented the ISO 9001 standard for Quality Management System (QMS) in Radiation processing by beam of accelerated electrons and the EN ISO 13485 in Sterilization of medical devices using the beam of accelerated electrons.

The Quality Management System structure at UCEA includes:

- QM (Quality Manual) - the main document
- SWP (Standard Working Procedures)
  - general SWP
  - SWP for device utilization and services
- ID (Internal Directives)
- P (Plans for education, calibration etc.)
- SD (Safety Directives)
- Forms.

The standard working procedures (SWP) ensuring and controlling the quality of irradiation, which are included in our QMS and involve dosimetry, are listed in TABLE 1. The first procedure is the Installation Qualification (IQ) which main purpose is to verify the irradiator parameters. The beam current and the power of accelerator are automatically measured by the accelerator itself. The accelerator parameters which require dosimetry are the energy of electrons, the beam scanning width and the beam scanning homogeneity. For measuring the energy of electrons, the aluminium plates and aluminium wedge are used at our facility. For experimental determination of beam scanning uniformity and beam scanning width the strip of B3 films is used. During operational Qualification (OQ) the process interruption is studied and the nominal dose versus conveyor speed, the calibration curve and the dose depth distribution in reference product are experimentally obtained. During Performance Qualification (PQ) the dose mapping in real product is done with an aim to obtain the minimum, the maximum and the reference dose in the product. During routine irradiation the dose is measured in reference position.
TABLE 1. THE STANDARD WORKING PROCEDURES OF QMS INVOLVING DOSIMETRIC MEASUREMENTS:

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Dosimetric measurements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Installation Qualification (IQ)</td>
<td>Verification of parameters of the irradiator</td>
</tr>
<tr>
<td>Operational Qualification (OQ)</td>
<td>Dose mapping for general characterization of the radiation field</td>
</tr>
<tr>
<td>Performance Qualification (PQ)</td>
<td>Dose mapping of the product for establishing maximum, minimum and reference dose position in the product</td>
</tr>
<tr>
<td>Dose setting</td>
<td>Irradiation of samples</td>
</tr>
<tr>
<td>Routine processing</td>
<td>Dose measurement in reference position</td>
</tr>
<tr>
<td>Maintaining process effectiveness</td>
<td>Calibration measurements</td>
</tr>
<tr>
<td></td>
<td>Re-qualification</td>
</tr>
</tbody>
</table>

5. APPLICATIONS

5.1. Electron beam irradiation

Irradiation by electrons is usually done by 5 MeV scanning electron beam. The dose depth distribution of electrons of energies obtainable by our accelerator is determining the suitable applications. The penetration of electrons is in ranges of centimetres as it can be seen in FIG. 6, where the simulations of the dose depth distribution, electron ranges and electron trajectories in various materials are shown for energies: 3.6 MeV, 5 MeV and 6.2 MeV.

At UCEA the EB irradiation was applied in wide range of areas. In medicine we participated on research aimed at decontamination and treatment of human corneas before transplantation (FIG. 7). With Slovak University of Technology, we are running long term collaboration in the field of radiation aging of semiconductor devices dedicated for radiation imaging cameras (FIG. 8). Cultural heritage area is represented by treasurable late-gothic wing altar from the beginning of 16th century made of wood and attacked by woodworms. The painted altar wings depicting scenes from the life of St. George and other saints are of a thickness of 4 cm, which was ideal for 5 MeV electron radiation treatment (FIG. 9). The environmental situation at Eastern Slovakia with factory canal heavily polluted by PCBs (PolyChlorinated Biphenyls) flowing into the Laborec river and lake Zemplinska sirava brings an opportunity for nuclear technology to help the environment (FIG. 10). The first tests showed our ability to decrease the concentration of PCBs in contaminated soil to 60% of initial value using 5 MeV EB. Our facility uses the 5 MeV EB also for radiation sterilization of medical products for commercial purposes, which has covered about 85% of beam time during last few years.
FIG. 6: Simulations of the dose depth distribution of 3.6 MeV, 5 MeV and 6.2 MeV electrons in various materials done by ModeRTL [1] and simulations of electron range probabilities in these materials are in the first row. The second row from left shows the trajectories of 3.6 MeV, 5 MeV and 6.2 MeV electrons in 6.5 cm thick wood of 0.5 g/cm$^3$ density and were done in Casino code [2].

FIG. 7: Cornea before radiation treatment

FIG. 8: Semiconductor detectors tested for radiation hardness with their parameter changing with applied cumulative dose [3].

FIG. 9: Painted altar wings of St. George altar in Spisska Sobota treated by EB.
5.2. Bremsstrahlung beam irradiation

The bremsstrahlung produced by our accelerator converting EB into X-rays is more penetrable into the depth of material than the EB, however its intensity is considerably lower due to the conversion efficiency in tungsten target. Our successful applications of radiation treatment by bremsstrahlung beam are in the fields of medicine, cultural heritage and radiation aging of device components.

The simulations in MCNPX [4] code helped us to plan the irradiation of wooden statues of St. Georges altar from Spisska Sobota in Poprad, Slovakia (mentioned in part 5.1), which were not suitable for EB treatment due to the thickness of wooden material (FIG.11). We have been collaborating with the Slovak Academy of Sciences in Bratislava for many years in the research on influence of ionizing radiation on heart and veins of patients treated by radiotherapy. The accelerator was used to simulate the radiotherapy of oncology patients (FIG. 12).

FIG. 10: Sampling of soil contaminated by PCB from factory canal (left) flowing into the lake Zemplinska sirava (right).

FIG. 11: Main late-gothic wing altar at St. George church in Spisska Sobota in Poprad, Slovakia and the sculpture from its bottom part depicting the Last Supper treated by bremsstrahlung beam.
FIG. 12: Simulation of radiotherapy in the frame of research aimed at optimal protection of heart and veins cells against radiation.

6. CONCLUSIONS

University Centre of Electron Accelerators in Trencin is the first and so far the only facility dedicated to radiation treatment in Slovakia. Its variability enabling the electron beam and also bremsstrahlung beam irradiation with wide range of adjustable parameters leads to its utilization in the field of research as well as in industry. We have already demonstrated the applicability of the technology in the area of health care, culture heritage, environment and technology.

7. ACKNOWLEDGEMENT

Authors would like to thank M. Pavlovic for simulations in Casino code and K. Laffan for photos related to PCB contaminated soil.

REFERENCES

SRI LANKA

DETERMINATION OF MINIMUM TO MAXIMUM DOSE RATIO OF THE CARRIER BYPASSING THE SHUFFLING MECHANISM AND TO DETERMINE % DOSE DISTRIBUTION IN UPPER AND BOTTOM TOTES IN THE CARRIER

A.A.G.MADURAKANTHI

Sri Lanka Gamma Centre of Sri Lanka Atomic Energy Board
Biyagama Export Processing Zone
Sri Lanka

Abstract
Sri Lanka Gamma Centre is the Co-60 wet storage type gamma irradiation facility operates with continuous shuffle type product overlapping geometry. It provides the services mainly for the sterilization of healthcare products and irradiation of food products with different dose requirements. The study was carried out to determine the minimum/maximum dose ratio of the carrier for the irradiation of multi-products with different densities and doses without shuffling mechanism with the initial source loading pattern. From the study the DUR of the carrier for the material with 0.24 gcm\(^{-3}\) density is obtained as 2.38 with non-shuffle mode. The % dose distribution in the upper and bottom tote in the carrier is found as 49.80% and 50.20% respectively.

1. INTRODUCTION

Sri Lanka Gamma Centre is the only open access multipurpose gamma irradiation facility in Sri Lanka belongs to Sri Lanka Atomic Energy Board. It is in commercial operation since 2014 January catering mainly for food and medical product sectors. Medical products especially surgical gloves, surgical aprons and gauze swabs are irradiated at 25 kGy and food products of spices, tea and herbal products are irradiated below 10 kGy doses. Approximately 4070 m\(^3\) of medical products were irradiated in the year 2018 about 60 MT of food products were irradiated for the international market up to now. The bulk density and the dose requirements for food irradiation and medical product sterilization are different and therefore the irradiation is not possible to carry out together according in the facility. Therefore, a huge amount of dummy material is needed to be used in each product change over and it is time consuming and costly process. Therefore, the study was carried out to find out the possibilities to utilization of the plant for the irradiation of multi-products with different densities and doses without shuffling mechanism with the initial source loading pattern.

1.1 Irradiator

The irradiator is panoramic wet storage type Co-60 gamma irradiator and operates as continuous shuffle type with product overlap geometry. The shuffling mechanism contributes to minimize the DUR of the product container and provides an equal dose to products. The products are carried in tote boxes held in carriers. The carriers are transferred in to irradiation cell by overhead conveyor chain with pushers. The tote boxes are with the dimension of 44 (W) x 122 (H) x 104 (L) cm and 70 totes are occupied in 35 carriers inside the chamber. The source pass mechanism is 2+2. The source plaque is split type to raise the whole source plaque or middle part of the source frame in order to carry out both low dose and high dose irradiations as per the requirement.
1.2 Ceric Cerous Dosimetry System

This dosimetry system is classified as a standard reference system and mainly used in radiation sterilization and food irradiation applications. This method can be applied in the dose ranges of 0.5-5 kGy or 5-50 kGy depending on the initial ceric ion concentration used. The system is based on the reduction of ceric ions to cerous ions in an aqueous medium. The evaluation of irradiated doismeters can be carried out by using spectrophotometry or potentiometry. [1.21, 1.22].

2.0 Materials and Methods

The saw dust dummy material packed in the cartons with the dimensions of 40 cm (W) x 50 cm (L) x 29 cm (H) were used for this study with the average density of about 0.24 g/cm³. These dummy material boxes were placed in the arrangement of two columns and four rows in the tote. Ceric Cerous dosimeters (5 mM), batch no DS-5(65) were used for the dose mapping exercise.

2.1 Preparation of dosimetry boxes

The dose mapping exercise was carried out using one carrier placing dosimeters in upper and bottom tote boxes in the same carrier and using three parallel planes in each tote (A, B and C). Dosimeters were placed inside of the product box in a 27 number of positions in a dosimetry plane and in each position two parallel dosimeters were placed (Figure 2.1).

2.2 Irradiation

Irradiation was carried out with the cycle time of 42 minutes without shuffling. The activity to the date was 171.79 kCi.
2.3 Analyzing of dosimeters

After the irradiation the ceric cerous dosimeters were analyzed by using the potentiometric method [2.31]. The Electrochemical cell (Nordion, SN-109) and the calibrated millivolt meter (Nordion, SN 9701079) were used for the measurements.

3.0 Results and Discussion

| Dosimeter position | Upper tote | | | Bottom tote | | |
|-------------------|------------|----------------|----------------|----------------|----------------|
|                   | Dose/kGy   | Dose/kGy       | Dose/kGy       | Dose/kGy       | Dose/kGy       |
| Plane A           |            |                |                |                |                |
| 1                 | 5.21       | 5.08           | 5.12           | 11.99          | 10.77          |
| 2                 | 5.37       | 5.12           | 5.33           | 11.99          | 10.62          |
| 3                 | 5.25       | 5.08           | 5.17           | 11.59          | 10.48          |
| 4                 | 5.50       | 5.25           | 5.42           | 11.99          | 10.70          |
| 5                 | 5.67       | 5.67           | 5.67           | 11.89          | 10.55          |
| 6                 | 5.75       | 5.50           | 5.67           | 11.59          | 10.38          |
| 7                 | 6.65       | 6.33           | 6.61           | 11.76          | 10.52          |
| 8                 | 6.82       | 6.41           | 6.78           | 11.79          | 10.62          |
| 9                 | 6.78       | 6.53           | 6.82           | 10.91          | 10.20          |
| 10                | 8.32       | 7.54           | 8.48           | 11.52          | 9.91           |
| 11                | 8.75       | 7.82           | 8.52           | 11.29          | 9.94           |
| 12                | 8.59       | 7.78           | 8.71           | 10.91          | 9.76           |
| 13                | 9.31       | 8.40           | 9.46           | 10.70          | 9.69           |
| 14                | 9.54       | 8.94           | 9.72           | 10.62          | 9.54           |
| 15                | 9.91       | 8.63           | 9.91           | 10.34          | 9.43           |
| 16                | 10.66      | 9.39           | 10.48          | 9.09           | 8.09           |
| 17                | 11.08      | 9.61           | 10.77          | 9.24           | 8.40           |
| 18                | 10.94      | 9.72           | 10.94          | 8.94           | 8.05           |
| 19                | 11.29      | 9.83           | 10.94          | 8.05           | 7.38           |
| 20                | 11.56      | 9.83           | 11.29          | 8.25           | 7.46           |
| 21                | 11.49      | 10.27          | 11.32          | 8.17           | 7.38           |
| 22                | 10.98      | 10.09          | 11.39          | 6.33           | 5.83           |
| 23                | 12.06      | 10.41          | 11.59          | 6.37           | 5.92           |
| 24                | 11.92      | 10.20          | 11.73          | 6.24           | 5.96           |
| 25                | 11.62      | 9.98           | 10.91          | 5.17           | 5.04           |
| 26                | 11.59      | 10.98          | 11.11          | 5.21           | 5.08           |
| 27                | 11.08      | 9.98           | 10.80          | 5.25           | 5.08           |

3.1 Determination of minimum to maximum dose ratio of the carrier bypassing the shuffling mechanism
The dose distribution throughout the carrier relevant to 27 dosimetry positions in three planes is shown in the table 3.0. It shows the maximum dose and minimum dose throughout the carrier is 12.02 kGy and 5.04 kGy respectively. Accordingly the DUR is calculated as 2.38.

The maximum dose absorbed by the product for the minimum dose of 25 kGy is 34.0 kGy with the shuffle mode and 59.5 kGy without shuffling mechanism. Also for the dose requirement of minimum 5 kGy the maximum dose delivered is 6.8 kGy and 11.8 kGy with and without shuffling mode respectively. Mainly the 5 kGy dose is required for the irradiation of food products. The standard acceptable maximum dose delivery as per government regulations is 10 kGy. And also for the irradiation of any food, the minimum absorbed dose should be sufficient to achieve the technological purpose and the maximum absorbed dose should be less than that which would compromise consumer safety, wholesomeness or would adversely affect structural integrity, functional properties, or sensory attributes. The maximum absorbed dose delivered to a food should not exceed 10 kGy, except when necessary to achieve a legitimate technological purpose. [3.11]

Further the product throughput was also calculated for with and without shuffle made operations. According to the results of the experiment conducted, with the cycle time of 42 minutes per carrier at the activity of 171.79 kCi and the bulk density of 0.24 g cm\(^{-3}\), the product output for 5 kGy minimum dose is about 387.07 kg/hr. Similarly, the product output for 25 kGy minimum dose is about 77.41 kg/hr.

According to the results of the Plant Dosimetry Commissioning Report provided at the commissioning of the facility with continuous shuffle mode, the product throughput per tote at 235.68 kCi activity and cycle time of 56 minutes and 27 kGy minimum dose is about 72.00 kg/hr. Also the DUR is 1.36 with these conditions. Accordingly the calculations were carried out to obtain the product throughput per tote with shuffle mode at 171.79 kCi activity for 5 kGy and 25 kGy minimum dose with the same density and it is about 283.40 kg/hr and 56.58 kg/hr respectively.

Even though the product throughput is higher with non shuffle mode, considering the dose requirements for the products in the facility and dose delivered with this mode it is not acceptable to use this mode of operation with the existing source loading pattern.

In the non shuffle mode the plant will operate in batch mode where in the entire batch of carriers in the system are loaded with fresh boxes and taken into the cell with source in shield (batch mode of operation). Two unirradiated boxes will be loaded into carrier and two irradiated boxes unloaded from the carrier each time when it comes to pullout station. There are about 35 carriers in the system. Once irradiation mode starts the carriers skip pull out & are irradiated at all irradiation positions of the cell in a batch mode of operation. At the end of which the source returns to shield and processed batch is unloaded and new batch is loaded. A new PLC program has to be made and commissioning dosimetry to be done for both continuous and batch mode.

3.2 Determine the source alignment
TABLE 3.2 %DOSE DISTRIBUTION OF THE TOP AND BOTTOM TOTES IN THE CARRIER

<table>
<thead>
<tr>
<th>Tote</th>
<th>Dosimeter position</th>
<th>Dose/ kGy</th>
<th>Symmetrical Ratio</th>
<th>%Dose distribution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper/Top</td>
<td>Top (TT)</td>
<td>5.12</td>
<td>1.01 (TT/BB)</td>
<td>49.80%</td>
</tr>
<tr>
<td></td>
<td>Middle (TM)</td>
<td>8.94</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bottom (TB)</td>
<td>10.98</td>
<td>0.94 (TM/BM)</td>
<td></td>
</tr>
<tr>
<td>Bottom</td>
<td>Top (BT)</td>
<td>10.62</td>
<td></td>
<td>50.20%</td>
</tr>
<tr>
<td></td>
<td>Middle (BM)</td>
<td>9.54</td>
<td>1.03 (TB/BT)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bottom (BB)</td>
<td>5.08</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>50.28</td>
<td></td>
<td>100.00</td>
</tr>
</tbody>
</table>

This is achieved by assessing vertical dose distribution in the central plane of the top and bottom totes. Therefore, the absorbed doses of top, middle and bottom dosimeter positions of the middle plane (B plane) of both top and bottom totes (2, 14 and 26 positions in the Figure 2.1) were considered for the determination of the source alignment. The calculations are shown in the table 3.2.

This ensures the central alignment of the source frame with respect to the totes in the carrier. This reflects maximum utilization of radiation energy of the source by the products. The results shows that the percent dose distributions in top and bottom totes in the carrier are 49.80% and 50.20% respectively. Also the dose values at the two extreme ends are within 5% and therefore the results are acceptable and correctly positioned the source frame to deliver uniform dose to top and bottom totes in the carrier.

REFERENCES


TUNISIA

QA/QC IN MANAGEMENT SYSTEMS FOR IRRADIAITION FACILITIES

M. KRAIEM

CNSTN
Sidi Thabet, TUNISIA

Abstract
Tunisia has two irradiation facilities located at the National Center for Nuclear Science and Technology (CNSTN) in Sidi Thabet: a Cobalt-60 gamma irradiator and a semi-industrial electron beam accelerator. Gamma facility was commissioned in 1999 with maximum capacity of 100 kCi and is used until today for food preservation, sterilization of medical products and treatment of cultural heritage products. EB facility has variable energy (from 5 to 10 MeV) and a maximum power of 5 kW. Since the beginning of warranty period (2010), several defects were encountered and the facility was totally stopped in June 2011 due to breakdown of a part of modulator. It was only in 2017 that the accelerator has become operational again and a part of requalification work (IQ, OQ and PQ) of the facility, with the assistance of an IAEA expert, has been performed.

1. INTRODUCTION

This technical report will describe a part of the requalification work (IQ and OQ) performed in June 2019 by CNSTN under IAEA assistance. As it happens, the following:
- For Installation qualification (IQ): electron beam energy, scan width and beam uniformity, conveyor speed test and scan length measurement / beam spot characterization.
- For Operation qualification (OQ): absorbed dose as function of conveyor speed, beam current, scan width, dose distribution in homogeneous material and process reproducibility.

The main characteristics of the Electron Beam accelerator, object of this work, are 3 energy levels (5, 7.5 and 10 MeV) with a maximum power of 5 kW. The beam is pulsed and each pulse lasts for 15 µs. The repetition rate can vary from 50 Hz to 240 Hz. The beam is scanned on the product at a given length by an electromagnetic device. A fully automatic conveyor is able to transport boxes of minimum 40*30 cm to a maximum of 80*50 cm. Their weight can vary from 1 kg to 35 kg. The under the beam conveyor speed goes from 15 to 500 cm/min.
2. INSTALLATION QUALIFICATION (IQ) [1]

a. Electron Beam energy

The wedge technique is used to perform the energy measurement according the ISO/ASTM 51649 standard. It uses a Risø aluminum wedge (ID: 03-05; density: 2.662 g/cm³; angle: 16°).

The CNSTN’s ab accelerator has a broad energy spectrum, so the most probable energy $E_p$ is:

$$E_p(\text{MeV}) = 0.2 + 5.09 \times R_p \text{ (cm)}$$

$R_p$ (cm) is the practical range in Aluminum and is derived from the CTA strip measurement positions inside the aluminum wedge. The wedge travels through the electron beam on the surface of boxes (FIG 2).

FIG.1 – Electron beam accelerator and conveyor system

FIG.2 - Two distances from scanning window: 96 cm(left) and 40 cm (right)
The Irradiation parameters are:
Energy (E): 10 MeV
Current (I): 500 µA
Scan Width (SW): 600 mm
Conveyor Speed (V): 30 cm/min.

Results (FIG. 3-4):

The results obtained is that target energy of 10 MeV is not reached (in previous tests performed in Feb. 2019, 9.78 MeV was reached). Also, the accelerator is not stable: the measured energy reduced by 600 keV and increased again (FIG. 5).
2.2. Scan width and beam uniformity

Irradiation conditions:
Energy (E): 10 MeV
Current (I): 500 µA
Scan Width (SW): 600 mm
Conveyor Speed (V): 15 cm/min.

Distance from scanning window: 99 cm, 79 cm, 58 cm and 40 cm.

Results:
### FIG. 6 - Scan width and beam uniformity

TABLE 1 - SCAN WIDTH AND BEAM UNIFORMITY

<table>
<thead>
<tr>
<th>Distance from scanning window (cm)</th>
<th>Height of measurement (cm above conveyor)</th>
<th>CTA ID</th>
<th>Width @ 80% of average maximum (cm)</th>
<th>SW (+/- 5% dose uniformity)</th>
</tr>
</thead>
<tbody>
<tr>
<td>99</td>
<td>2</td>
<td>2a</td>
<td>95.3</td>
<td>73.7</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2b</td>
<td>95.3</td>
<td>78.4</td>
</tr>
<tr>
<td>79</td>
<td>22</td>
<td>2c</td>
<td>92.8</td>
<td>78.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2d</td>
<td>92.7</td>
<td>75.8</td>
</tr>
<tr>
<td>58</td>
<td>43</td>
<td>2e</td>
<td>83.9</td>
<td>76.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2f</td>
<td>82.3</td>
<td>74.8</td>
</tr>
<tr>
<td>40</td>
<td>61</td>
<td>2g</td>
<td>72.3</td>
<td>77.8</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2h</td>
<td>71.8</td>
<td>77.7</td>
</tr>
</tbody>
</table>
Conclusion: whatever the height of the product box, a maximum width of 60 cm can be irradiated with good beam uniformity (within +/- 5%).

2.3. Conveyor Speed test

The speed control consists in a time and length measurement. The trial is performed with low (7 kg) and full (110 kg) loaded conveyor conditions. Conveyor Speed (V): 15 cm/min, 30 cm/min, 60 cm/min. Conveyor loading: 1 box of 7 kg and full loading of 110 kg (FIG. 8).

Results: acceptable results in both precision and reproducibility.
3. OPERATIONAL QUALIFICATION (OQ) [1]

3.1. Absorbed dose as function of conveyor speed, beam current, scan width

The surface dose can be approximately calculated from the following formula:

\[ D_{surf} (\text{kGy}) = K \times I (\mu\text{A}) / (\text{Conveyor Speed (cm/min)} \times \text{Scan Width (cm)}) \]

The measurements are intended to determine the K value. Scan width (SW) remains fixed at 600 mm. At each irradiation condition, the dosimeters are placed on the “start and end of irradiation batch” devices (FIG. 9-10 & Table 2-3).

![FIG. 9 – Start and end of irradiation batches (resp. on right and left)](image)

Results:

<table>
<thead>
<tr>
<th>Conveyor speed (cm/min)</th>
<th>15</th>
<th>30</th>
<th>90</th>
<th>150</th>
<th>300</th>
<th>500</th>
</tr>
</thead>
<tbody>
<tr>
<td>I (µA)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>100</td>
<td>6.6</td>
<td>3.3</td>
<td>1.1</td>
<td>0.7</td>
<td>0.3</td>
<td>0.2</td>
</tr>
<tr>
<td>250</td>
<td>16.4</td>
<td>8.2</td>
<td>2.7</td>
<td>1.6</td>
<td>0.8</td>
<td>0.5</td>
</tr>
<tr>
<td>500</td>
<td>32.8</td>
<td>16.4</td>
<td>5.5</td>
<td>3.3</td>
<td>1.6</td>
<td>1.0</td>
</tr>
</tbody>
</table>

TABLE 2 - Absorbed dose measurements using alanine dosimeters
### TABLE 3 - Absorbed dose measurements using Windose and DoseStix dosimeters

<table>
<thead>
<tr>
<th>Conveyor speed (cm/min)</th>
<th>15</th>
<th>30</th>
<th>90</th>
<th>150</th>
<th>300</th>
<th>500</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>6.57</td>
<td>3.16</td>
<td>1.05</td>
<td>0.63</td>
<td>0.35</td>
<td>0.28</td>
</tr>
<tr>
<td>250</td>
<td>21.05</td>
<td>11.36</td>
<td>3.56</td>
<td>2.11</td>
<td>1.10</td>
<td>0.71</td>
</tr>
<tr>
<td>500</td>
<td>40.43</td>
<td>18.60</td>
<td>6.39</td>
<td>3.85</td>
<td>1.98</td>
<td>1.14</td>
</tr>
</tbody>
</table>

**FIG.10** – Absorbed dose as function of conveyor speed (V) and beam current (I)

Conclusion: the linearity of the absorbed surface dose with current and inverse of speed is demonstrated. Nevertheless, this test must be repeated as soon as the electron accelerator is more stable. A less than 5% deviation should be achievable with the same process parameters.

### 3.2. Depth dose distribution in homogeneous product

The Irradiation parameters:
- Energy (E): 10 MeV
- Current (I): 500 µA
- Scan Width (SW): 600 mm
- Conveyor Speed (V): 15 cm/min.

Homogeneous material: Plexiglas plates and wood plates (FIG. 11).
FIG. 11 – Plexiglas plates used as homogeneous material

Results:

FIG. 12 – Single sided irradiation (Plexiglas)

FIG. 13 – Double sided irradiation (wood 0.444 g/cm²)
Conclusion: due to accelerating energy instability, results for single and double sided irradiations are not consistent. These tests need to be repeated with stable accelerator.

3.3. Process reproducibility

was assessed by irradiating routine and reference dosimeters on the "début de lot" (start of batch) device (as shown in FIG. 15). The process ran 10 times with same conditions.

Parameters of irradiation:
Energy (E): 10 MeV
Current (I): 500 µA
Scan Width (SW): 600 mm
Conveyor Speed (V): 15 cm/min
Results (Table 4 and FIG. 16):

### TABLE 4 - PROCESS REPRODUCIBILITY

<table>
<thead>
<tr>
<th>Run #</th>
<th>Ebeam current (µA)</th>
<th>Alanine dose (kGy)</th>
<th>Windose dose (kGy)</th>
<th>DoseStix dose (kGy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>505</td>
<td>35.4</td>
<td>29.9</td>
<td>29.3</td>
</tr>
<tr>
<td>2</td>
<td>503</td>
<td>35.5</td>
<td>28.1</td>
<td>29.2</td>
</tr>
<tr>
<td>3</td>
<td>517</td>
<td>41.0</td>
<td>32.2</td>
<td>34.0</td>
</tr>
<tr>
<td>4</td>
<td>508</td>
<td>40.2</td>
<td>35.2</td>
<td>33.3</td>
</tr>
<tr>
<td>5</td>
<td>512</td>
<td>38.3</td>
<td>31.9</td>
<td>32.4</td>
</tr>
<tr>
<td>6</td>
<td>510</td>
<td>39.9</td>
<td>33.1</td>
<td>33.4</td>
</tr>
<tr>
<td>7</td>
<td>511</td>
<td>39.7</td>
<td>34.3</td>
<td>33.3</td>
</tr>
<tr>
<td>8</td>
<td>502</td>
<td>40.3</td>
<td>32.0</td>
<td>32.9</td>
</tr>
<tr>
<td>9</td>
<td>525</td>
<td>43.0</td>
<td>36.5</td>
<td>35.3</td>
</tr>
<tr>
<td>10</td>
<td>510</td>
<td>39.5</td>
<td>33.6</td>
<td>31.9</td>
</tr>
<tr>
<td>Average</td>
<td>510</td>
<td>39.3</td>
<td>32.7</td>
<td>32.5</td>
</tr>
<tr>
<td>CV%</td>
<td>1.4%</td>
<td>6.0%</td>
<td>7.5%</td>
<td>6.0%</td>
</tr>
</tbody>
</table>
Conclusion:
It appears that the variability measured on dosimeters is significant. An important discrepancy is noticed between dose values measured with Alanine and with Windows/DoseStix dosimeters. These dosimeter systems need to be calibrated. Then, a repetition of this test and a second process reproducibility test should be performed.

4. CONCLUSION
- Dosimetry system (GENESYS 20/Windose and GENESYS 20/DoseStix) to be calibrated with reference dosimetry (alanine).
- Accelerator reliability (cooling system issues, vacuum issues, heating, klystron, …) must be improved.
- Electron beam energy value and stability issues to solve by involving manufacturer of electron accelerator.
- Process stability to be performed again at higher conveyor speed (50 cm/min).
- After repair/improvements of the plant, all parts of this qualification must be repeated.

REFERENCE

ANNEX II

IAEA Technical Meeting on
“QA/QC in Management Systems for Irradiation Facilities”
05-09 August 2019, Malaysia

MEETING AGENDA

Monday, 05 August 2019

08:30 - 09:00  Registration at AVENUE GARDEN HOTEL

Session I: Introductory Session

09.00 –09:30  Opening of the meeting by:

- Welcoming Remarks: Mr Mohd Sidek Othman, Director of Radiation Health and Safety Division, Malaysian Nuclear Agency
- Welcoming Remarks: Mr Bumsoo Han, Scientific Secretary, RPRT (IAEA)
- Welcome Speech: Dr Abdul Muin Abdul Rahman Deputy Director General, Malaysian Nuclear Agency

Scope and Objectives of the Meeting, Adoption of the agenda

Election of the chairperson of the meeting, introduction of participant

Session II: Participants’ Presentations

09:30 – 10:30  Mr Andras Kovacs

(Hungary)

Development of QA/QC in Applying Reference and Routine Dosimetry Systems and Standardized Procedures in the IAEA European TC Region during the Past Decade. The Role of the IAEA.
10:30 – 11:00  
Coffee Break

11:00 – 11:40  
Mr Andrzej Rafalski  
(Poland)  
“The Role of Dosimetry Inter-comparison Exercises in Establishing/Improving QA/QC in Gamma and EB Irradiation Facilities in the IAEA European TC Member States.” The Contribution of the IAEA.

11:40 – 12:20  
Ms Andrea Docters  
(Argentina)  
Integrated management System and Best Practices at Irradiation Facilities

12:20 – 14:00  
Lunch Break

14:00 – 14:40  
Mr Pablo Vasquez  
(Brazil)  
Brazilian Experience on Quality Assurance and Quality Control in Irradiation Facilities

14:40 – 15:20  
Mr Sunil Sabharwal  
(India)  
QA/QC in Radiation Processing Facilities: Status and Emerging Needs

15:20 – 15:50  
Coffee Break

15:50 – 16:30  
Mr Fatmuanis Basuki  
(Indonesia)  
Project development program on irradiator facility in Indonesia and urgency to develop and applied milestone approach on radiation facility project

Mr Mohammad Amer Etoom  
(Jordan)  
Status of QA/QC in Radiation Processing in Jordan

Tuesday, 06 August 2019

<table>
<thead>
<tr>
<th>Session III:</th>
<th>Participants’ Presentations</th>
</tr>
</thead>
</table>
| 09:00 – 09:40 | Mr Han-Ki Jang  
(Korea, Republic of)  
Introduction of Quality Management System for Irradiation Facility in Korea: According to the ISO/IEC 17025 standard |
| 09:40 – 10:20 | Mr Mohd Sidek Othman  
(Malaysia)  
Quality Assurance Activities of Irradiation Facilities in Malaysia |
10:20 – 10:50  

Coffee Break

10:50 – 11:30  
Ms Lei Lei OO  
(Myanmar)  
Radiation Processing Technology in Myanmar

11:30 – 12:10  
Ms Haydee M. Solomon (Philippines)  
Process Control at the PNRI Gamma and Electron Beam Irradiation Facilities

12:10 – 14:00  

Lunch Break

14:00 – 14:40  
Mr Nikolai Kuksanov (Russia)  
Technical Solutions for Quality of E-beam Irradiation by ELV Accelerators

14:40 – 15:20  
Ms Andrea Sagatova (Slovakia)  
Quality Management System at University Centre of Electron Accelerators in trencin with 5 MeV electron and bremsstrahlung beam

15:20 – 16:00  

Coffee Break

16:00 – 16:40  
Ms. Ganga Madurakanthi (Sri Lanka)  
Milestone Approaches and QA/QC Aspects of Sri Lanka Gamma Centre

16:40 – 17:20  
Mr Moktar Kraiem (Tunisia)  
Restarting and Re-qualification (IQ/OQ/PQ) of the Tunisian semi-industrial electron beam facility

Wednesday, 07 August 2019

<table>
<thead>
<tr>
<th>Session V &amp; VI:</th>
<th>Discussion on the QA/QC implementation in radiation facilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>09:00 – 10:30</td>
<td>Discussion on the QA/QC implementation in radiation facilities</td>
</tr>
<tr>
<td>10:30 – 11:00</td>
<td>Coffee Break</td>
</tr>
<tr>
<td>11:00 – 12:30</td>
<td>Discussion on the routine dosimetry system and advantages/disadvantages of selected systems.</td>
</tr>
<tr>
<td>12:30 – 14:00</td>
<td>Lunch Break</td>
</tr>
<tr>
<td>14:00 – 17:00</td>
<td>Technical Visit to the Irradiation Facilities in Nuclear Malaysia</td>
</tr>
</tbody>
</table>
### Thursday, 08 August 2019

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>09:00 – 10:30</td>
<td>Discussion guidelines for the development, validation and control of QA/QC processes for irradiation facilities</td>
</tr>
<tr>
<td>10:30 – 11:00</td>
<td>Coffee Break</td>
</tr>
<tr>
<td>11:00 – 12:30</td>
<td>Discussion guidelines for the development, validation and control of QA/QC processes for irradiation facilities</td>
</tr>
<tr>
<td>12:30 – 14:00</td>
<td>Lunch Break</td>
</tr>
<tr>
<td>14:00 – 15:30</td>
<td>Discussion and drafting of the TM Report</td>
</tr>
<tr>
<td>15:30 – 16:00</td>
<td>Coffee Break</td>
</tr>
<tr>
<td>16:00 – 17:30</td>
<td>Discussion of Recommendations to IAEA</td>
</tr>
</tbody>
</table>

### Friday, 09 August 2019

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>09:00 – 10:30</td>
<td>Review of the Meeting Report</td>
</tr>
<tr>
<td>10:30 – 11:00</td>
<td>Coffee Break</td>
</tr>
<tr>
<td>11:00 – 12:30</td>
<td>Finalizing and Acceptance of the Meeting Report</td>
</tr>
<tr>
<td>12:40 – 14:00</td>
<td>Lunch Break</td>
</tr>
<tr>
<td>14:00 – 17:00</td>
<td>Closing of the Meeting</td>
</tr>
</tbody>
</table>
### ANNEX III

**F2-TM-1804860**  
Technical Meeting on Quality Assurance and Quality Control in Management Systems for Irradiation Facilities  
Kuala Lumpur, Malaysia  
5 to 9 August 2019

**List of Participants**  
(as of 2019-08-22)

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Authority</th>
<th>Personal Details</th>
</tr>
</thead>
</table>
| 1 | IAEA | Mr Bum Soo HAN  
Vienna International Centre  
P.O. Box 100  
Wagramer Strasse 5  
A-1400 VIENNA  
AUSTRIA  
Tel:  
Email: B.S.Han@iaea.org |
| 2 | Argentina | Ms Andrea DOCTERS  
Comisión Nacional de Energía Atómica (CNEA)  
Avenida del Libertador 8250  
C1429BNP BUENOS AIRES  
ARGENTINA  
Tel:+54 (11)41258152  
Email: adocters@gmail.com |
| 3 | Brazil | Mr Pablo Antonio VASQUEZ SALVADOR  
Instituto de Pesquisas Energeticas e Nucleares (IPEN), Comissão Nacional de Energia Nuclear (CNEN)  
Av. Prof. Lineu Prestes, 2242  
Cidade Universitaria  
CEP 05508-000 SAO PAULO  
BRAZIL  
Tel:+55 (11)31339881  
Email: pavsalva@ipen.br |
| 4 | Ghana | Mr Abraham ADU-GYAMFI  
Biotechnology and Nuclear Agriculture Research Institute; Ghana Atomic Energy Commission (GAEC)  
P.O. Box 80  
Legon ACCRA  
GHANA  
Tel:00233 302 402 286  
Email:adugyamfi21@yahoo.com |
| 5 | Hungary | Mr Andras DR KOVACS  
Atomic energy engineering co.ltd  
National Research, Development and Innovation Office  
Kéthly Anna tér 1.  
H-1077  
BUDAPEST  
HUNGARY  
Tel:+36 (1)3922528  
Email: andras.kovaes@energia.mta.hu |
<table>
<thead>
<tr>
<th>S. No.</th>
<th>Authority</th>
<th>Personal Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>India</td>
<td>Mr Sunil SABHARWAL&lt;br&gt;C1202 Tharwani Heritage, Sector 7, Kharghar&lt;br&gt;410210 NAVI MUMBAI&lt;br&gt;MAHARASHTRA&lt;br&gt;INDIA&lt;br&gt;Tel: Email:<a href="mailto:sunsab57@gmail.com">sunsab57@gmail.com</a></td>
</tr>
<tr>
<td>7</td>
<td>Indonesia</td>
<td>Mr Fatmuanis BASUKI&lt;br&gt;Planning Division; Centre for Education and Training; National Nuclear Energy Agency (BATAN)&lt;br&gt;P.O. Box 1810 Jks, Lebak Bulus Raya, Pasar Jumat&lt;br&gt;Jakarta&lt;br&gt;JAKARTA&lt;br&gt;INDONESIA&lt;br&gt;Tel:6288771775249&lt;br&gt;Email:<a href="mailto:fatmuanis@batan.go.id">fatmuanis@batan.go.id</a></td>
</tr>
<tr>
<td>8</td>
<td>Jordan</td>
<td>Mr Mohammad Amer ETOOM&lt;br&gt;Jordan Atomic Energy Commission (JAEC)&lt;br&gt;P.O.Box 70, Shafa Badran&lt;br&gt;11934 AMMAN&lt;br&gt;JORDAN&lt;br&gt;Tel: Email:<a href="mailto:m.etoom@jaec.gov.jo">m.etoom@jaec.gov.jo</a></td>
</tr>
<tr>
<td>9</td>
<td>Malaysia</td>
<td>Mr Sidek MOHD SIDEK BIN OTHMAN&lt;br&gt;Division of Planning and External Relations; Malaysian Nuclear Agency; Ministry of Science, Technology and Innovation&lt;br&gt;43000 KAJANG&lt;br&gt;SELANGOR&lt;br&gt;MALAYSIA&lt;br&gt;Tel: Email:<a href="mailto:sidek_othman@nm.gov.my">sidek_othman@nm.gov.my</a></td>
</tr>
<tr>
<td>10</td>
<td>Mexico</td>
<td>Mr Miguel ALCERRECA SANCHEZ&lt;br&gt;Instituto Nacional de Investigaciones Nucleares ININ&lt;br&gt;Carretera México-Toluca S-N&lt;br&gt;Km. 36.5, La Marquesa&lt;br&gt;52750 CIUDAD DE MEXICO&lt;br&gt;OCHOYACAC&lt;br&gt;MEXICO&lt;br&gt;Tel:+52 (55)53297251&lt;br&gt;Email:<a href="mailto:miguel.alcerreca@inin.gob.mx">miguel.alcerreca@inin.gob.mx</a></td>
</tr>
<tr>
<td>11</td>
<td>Myanmar</td>
<td>Ms Lei Lei OO&lt;br&gt;Ministry of Education&lt;br&gt;Division of Atomic Energy&lt;br&gt;Yarzahtarni Road&lt;br&gt;Building No. 21&lt;br&gt;15011 NAY PYI TAW&lt;br&gt;MYANMAR&lt;br&gt;Tel:+95 67404460&lt;br&gt;Email:<a href="mailto:dlleioo@gmail.com">dlleioo@gmail.com</a></td>
</tr>
<tr>
<td>12</td>
<td>Philippines</td>
<td>Ms Haydee SOLOMON&lt;br&gt;20 Malinis St.&lt;br&gt;UP Village, Diliman&lt;br&gt;1101 QUEZON CITY&lt;br&gt;PHILIPPINES&lt;br&gt;Tel:00639177910618&lt;br&gt;Email:<a href="mailto:hmsolomon@pnri.dost.gov.ph">hmsolomon@pnri.dost.gov.ph</a></td>
</tr>
<tr>
<td>S. No.</td>
<td>Authority</td>
<td>Personal Details</td>
</tr>
<tr>
<td>-------</td>
<td>-------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| 13    | Poland            | Mr Andrzej RAFALSKI
Institute of Nuclear Chemistry and Technology
ul. Dorodna 16
03-195 WARSAW
POLAND
Tel:
Email:a.rafalski@ichtj.waw.pl |
| 14    | Republic of Korea | Mr Han Ki JANG
korean association for radiation application (KARA)
18th Floor, Seoul Forest IT Valley Building
Sung-Soo 77, Sungdong-Gu
SEOUL
REPUBLIC OF KOREA
Tel:
Email:hkjang@ri.or.kr |
| 15    | Russian Federation| Mr Nikolay KUKSANOV
Budker Institute of Nuclear Physics; Russian Academy of Sciences
Lavrentiev prospekt 11
630090 NOVOSIBIRSK
RUSSIAN FEDERATION
Tel:
Email:kuksanov47@mail.ru |
| 16    | Slovakia          | Ms Andrea SAGATOVA
Slovak Medical University
University center of electron accelerators
83101 BRATISLAVA
SLOVAKIA
Tel:+421 00421904443911
Email:andrea.sagatova@stuba.sk |
| 17    | Sri Lanka         | Ms Ganga Madurakanthi ABEYSUNDARA ARACHCHIGE
60 460 Baseline Road
COLOMBO
SRI LANKA
Tel:
Email:ganga@aeb.gov.lk |
| 18    | Tunisia           | Mr Mokhtar KRAIEM
Centre National des Sciences et Technologies Nucléaires (CNSTN)
B.P. 72, Pôle technologique
2020 SIDI THABET
TUNISIA
Tel:
Email:mokhtar.kraiem@cnstn.rnrt.tn |