REPORT

TECHNICAL MEETING ON “STRENGTHENING QUALITY ASSURANCE/QUALITY CONTROL PROTOCOLS IN RADIATION FACILITIES THROUGH DOSIMETRY INTER-COMPARISON”

01-05 October 2018

IAEA Headquarters Vienna, Austria
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BACKGROUND

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. Quality assurance is vital for implementing these technologies with standardized and harmonized procedures of process validation and process control. Further, the QA/QC 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), World Health Organization (WHO), American Society for Testing and Materials (ASTM), Food and Agriculture Organization (FAO), etc.

Dosimetry activities, as described in international standards (ISO 11137 and ISO/ASTM), play a significant role in installation qualification, operational qualification and performance qualification, as well as routine control of irradiation processes. As such it remains the backbone and one of the most sensitive aspects of radiation processing quality management practices. 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 through the following IAEA initiatives:

- Guidelines for the Development, Validation and Routine Control of Industrial Radiation Processes (IAEA Radiation Technology Series No 4, 2013)
- Training Module - Guidelines on Control and Validation of Processes in Radiation Facilities

These initiatives have been instrumental in formulating Regional TC Projects in Europe and Latin America aimed at enhancing the Quality Management Practices in Irradiation Facilities. The Technical Department of the IAEA has been interacting with the designated Collaborating Centers in ensuring these activities specially by conducting inter-comparison dosimetry exercises.
OBJECTIVES OF THE MEETING

The objectives of the meeting were the following:

(i) to assess the present status of Quality Assurance/Quality Control (QA/QC) practices being followed in radiation facilities worldwide

(ii) to develop a systematic strategy for conducting a radiation dosimetry inter-comparison

(iii) review and finalize the e-learning modules to strengthen QA/QC practices in member states.

HIGHLIGHTS OF THE MEMBER STATES PRESENTATIONS

ARGENTINA

CNEA

Buenos Aires

Argentina counts with a long expertise on applied sciences and radiation technology, starting in the early’s 60. The actual state-of-art regarding to irradiators include: a **Gammacell 220** ($^{60}$Co) - Nordion (1964), which is been reloading and upgrade by an argentine company – DIOXITEK S.A., with 12 kCi; 3 **Gamma Facilities**, multipurpose, panoramic, Cat IV, (CNEA – 1970 - Source $^{60}$Co: 820 kCi; IONICS 1 - 1989, Source $^{60}$Co: 600 kCi and IONICS II – 2017, Source $^{60}$Co: 850 kCi) ; 2 Movil Irradiators: IMO ($^{60}$Co) – CNEA (1971) and IMCO20 ($^{60}$Co) – INVAP (1991) and 3 Ebeam low energies for polymer modification (tires and wire) in private companies.

CNEA has also the expertise for establishing the properly product and process specification, trough the determination of the minimum and maximum dose, to be applied on the commercial process. This product and process specification is established for food, health care products, pharmaceuticals, biological tissues, among others.

Irradiation facilities have implemented the IQ, OQ and PQ Validation stages, and also have been certified for ISO 9001:2015, extended to a extended Management Integrated System.

Argentina has been coordinating the first and second round of an Inter-comparison exercise in the Latin-American Region for the Dosimetry Systems of Radiation facilities. The first round was conducted since March 2017 to December 2017, with the participation of 8 countries. The second round is being carried out since June 2018 and it is expected to finalise in April 2019.
10 countries are very actively participating. The INTERLAB Group joint with the High Dose Dosimetry Laboratory (SSDL) of the Applied Science and Technology Management of CNEA, are coordinating these exercise, in the frame on the RLA1013.

CHINA

Nuctech Co. Ltd.
Beijing

There are many kinds of applications of radiation facilities. Phytosanitary Irradiation is one kind of the application.

In China, we study on the plant insects, such as fruit fly, fruit borer, fruit mites and so on, to find the minimum dose to achieve the phytosanitary purpose. And we also study on the plant quality, such as appearance, chemical indicators and so on to determine the maximum (tolerance) dose for radiation. Now, a series of Chinese National Standards, Operation Guides and Professional Standards of phytosanitary irradiation have been published or to be established. The government is also developing the phytosanitary irradiation, building laboratories and demonstration projects. And there are many applications of imported fruit treatment in China.

There are E-beam and X-ray phytosanitary irradiation facilities in China. CHINA-ASEAN Pingxiang Fruit Phytosanitary Irradiation Processing Center, which adopts NUCTECH™ IS1007D E-Beam Irradiation Quarantine System, is now in experimental running status. The facility uses two 10MeV/7.5kW LINAC as its radiation source. There are some on-going works, including confirmation of quarantine pest species and minimum dose, determination of fruits’ tolerance to radiation, fruit packing and dose distribution, and also regulations and specifications. As a good demonstration for phytosanitary irradiation in China, this project will vigorously promote the practical application, as well as the implement of technology and standards.

Two self-shielding, miniaturized radiation facilities have been provided to IAEA, with accelerator and X-ray tube as radiation source respectively.

In China, quality assurance / quality control is usually implemented by the owner of radiation facility. There are many standards for IQ, OQ, and PQ in China. National Institute of Metrology gives technical support of QA/QC to radiation facilities. China Isotope & Radiation Association
communicates all radiation facility members to enhance QA/QC. Monte Carlo method has been used in China to help the dose mapping.

Standards and regulations of dosimeter calibration for radiation facility have been established. There are one national calibration laboratory and two regional calibration laboratories in China, which have the capacity to do dosimeter calibration for radiation facility. Alanine dosimeters are used for dosimeter calibration, and thin film dosimeters are used for reference and routine dosimetry.

CROATIA

Ruder Bošković Institute
Zagreb

The panoramic $^{60}$Co gamma irradiation facility at the Rudjer Bošković Institute (RBI) is the only of its kind in Croatia. It is located at the Radiation Chemistry and Dosimetry Laboratory (RCDL) at RBI in Zagreb, Croatia. A dry storage type irradiator was designed for up to 120kCi in 1962 and the first loading with $^{60}$Co sources was in 1966. The last source replenishment was in 2015 thanks to IAEA TC Project. Today the activity is 65 kCi. Ionising radiation is applied for research and development purposes as well as for services in various fields of industry. Treatments of the variety of products are provided: sterilization of medical equipment, accessories, instruments and hygienic supplies; microbiological decontamination of pharmaceuticals, cosmetics, horticultural aids and peat; tissue bank treatment; cold pasteurization of food ingredients; desinsection, disinfestation and decontamination of cultural heritage objects; testing of electrical devices and detectors for use in high dose irradiation fields.

There is no conveyer in the irradiation unit and for industrial purposes boxes with products are manually placed around the source and their positions are exchanged after half of the irradiation time.

Routine dosimetry at the facility is performed with ECB dosimeters (10% ECB; 5ml and 2.5 ml ampoules). Readings of the dosimeters are performed using oscillotitratos Radelkis OK.302 and V 3.0 (Budapest, Hungary). Traceability with the primary standard is achieved through the Risø High Dose Reference Laboratory (Denmark). ECBs are irradiated together with reference standard dosimeters (alanine from Risø) in calibration phantoms at RBI to required doses (five ECB for each dose) and calibration curve is made. The dose mapping of the irradiation chamber is performed after every replenishment with an ionization chamber (IC). Good agreement of
measured dose rates measured with IC and ECB with the values provided by Geant4 Monte Carlo calculations is achieved. For each product dose maps are made and positions for routine dosimeters are determined.

The last inter-comparison exercise in which RBI participated was conducted by IAEA RER/1017. Routine dosimeters (ECB) were irradiated at RBI together with reference dosimeters (alanine, Poland) for four nominal doses and good agreement was achieved as shown in TABLE 1. Uncertainty of the irradiation was 5.1 %.

<table>
<thead>
<tr>
<th>Nominal dose (kGy)</th>
<th>Measured dose by reference dosimeter (kGy)</th>
<th>Deviation of reference dosimeter from nominal dose (%)</th>
<th>Measured dose by routine dosimeter (kGy)</th>
<th>Deviation of routine dosimeter from nominal dose (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1.02</td>
<td>+1.9</td>
<td>0.98 ±0.06</td>
<td>-2.0</td>
</tr>
<tr>
<td>5</td>
<td>5.01</td>
<td>+0.2</td>
<td>5.0 ± 0.1</td>
<td>0.0</td>
</tr>
<tr>
<td>10</td>
<td>9.88</td>
<td>-1.2</td>
<td>10.08 ± 0.08</td>
<td>+0.8</td>
</tr>
<tr>
<td>25</td>
<td>24.3</td>
<td>-2.8</td>
<td>25.6 ± 0.2</td>
<td>+2.4</td>
</tr>
</tbody>
</table>

FRANCE
Aerial CRT – Parc d ’innovation
Illkirch

Aerial is a French technology resources centre specialized in three fields:
- Techniques and industrial applications of radiation processing,
- Quality and security of food products,
- Freeze-drying for the bio-industries.
Created in 1985, the institute is accredited by the French Ministries of Research and Food Industry. Aerial dosimetry laboratory is accredited as SSDL for high-dose dosimetry.

Its main equipment includes an electron beam and X-Ray experimental facility based on a 2.5 MeV electron accelerator and a well equipped dosimetry laboratory with optical and ESR equipment. In the near future, within the framework of a specific investment project (FEERIX), Aerial will also host a Rhodotron accelerator with two separated beam lines for E-beam and X-Ray treatment and a novel low energy electron accelerator (<300 keV). Both new irradiators will complement Aerial’s current experimental irradiation capability.

Over its 30 years of existence, which have been dedicated to research, training and dissemination of information on radiation processing Aerial made a focus on process control.

Irradiation process control can cover many aspects. Aerial has concentrated its efforts in:
- developing and marketing dosimetry systems and softwares, namely AerODE, AerEDE, DosASAP;
- accompanying the industry and laboratories in simulating (RayXpert-TRAD) their specific process and irradiation products/geometries;
- performing installation, operational and performance qualifications;
- helping in establishing traceable calibrations;
- coordinating dose inter comparisons and finally,
- training the stakeholders on industrial dosimetry theory and practices;

All these aspects dedicated to better control the process of irradiation in the light of the relevant ISO and ISO/ASTM standards, have been presented during the technical meeting. Additionally, objectives and proposals for a new dosimetry inter comparison have been presented and discussed within the group.

GHANA

Quality Management Practices in Radiation Processing Facilities in Ghana
Ghana Atomic Energy Commission
The Ghana Atomic Energy Commission (GAEC) was established by an Act of Parliament (Act 204 of 1963) as the sole Agency in Ghana responsible for all matters relating to the peaceful uses of atomic energy. In order to fulfil its mandate, GAEC has established 6 Institutes and a University: National Nuclear Research Institute, Radiation Protection Institute, Biotechnology and Nuclear Agriculture Research Institute, Radiological and Medical Sciences Research Institute, Ghana Space Science and Technology Institute, Nuclear Power Institute and School of Nuclear and Allied Sciences (in collaboration with the University of Ghana). The Biotechnology and Nuclear Agriculture research Institute has a mandate to undertake research, development and commercialisation of peaceful and safe biotechnology and nuclear techniques to enhance agricultural productivity, health delivery and industrial output for socioeconomic advancement of Ghana and Africa. The Institute has created 5 R&D centres: Radiation Technology Centre, Nuclear Agriculture Research Centre, Radiation Entomology and Pest Management Centre, Biotechnology Centre and the Soil and Environmental Sciences Research Centre. The Radiation Technology Centre houses the Gamma Irradiation Facility (GIF) which was initially commissioned in 1995 with a source loading of 50,000Ci (maximum capacity – 500,000 Ci) and further upgraded in 2010 with the support of the International Atomic Energy Agency (IAEA) and the Export Development and Agricultural Investment Fund. The irradiator is category IV wet storage, multi-purpose facility with a transport system and can be operated in the batch/continuous mode. It currently has a source activity of 20 kCi, a maximum processing load capacity of 1.5 tons per batch and is mainly used for commercial processing of food, medical and pharmaceutical items. It also serves as a facility for research and training activities.

Currently the Management of the GIF is working towards implementation of a Quality Management System (QMS). A number of standards are voluntarily used in validation and routine control of the process such as the ISO 11137, ISO 11737 (Sterilisation of Healthcare Products), ISO 14470 (Food Irradiation-Requirements for the development), ASTM E, ISO/ASTM (Dosimetry) and ISO 17025 (Microbiology). Other Standards by the Ghana Standards Authority and International Standards are used such as the Food Technology-Specification for Irradiated Food (GS 210:2007) 2nd Edition; Dosimetry – Standard Practice for Dosimetry in Gamma Irradiation Facilities for Food and Non-Food Processing (GS 928: 2008); International Code of Good Irradiation Practice and the Codex General Standard for Irradiated Foods. There is also compliance to other requirements such as regular Internal Audits, the
Safety Analysis Report (License Document), Safety and licensing inspections by Nuclear Regulatory Authority as well as the Emergency Response Plan.

Red Perspex and Gammachrome (Poly-methylmethacrylate, PMMA); Ethanol-monochlorobenzene (ECB) dosimeters. Fricke dosimeter is used for calibration of dosimeters and dose mapping. In-plant calibration of dosimeter system is undertaken yearly. UV-VIS Spectrophotometer and High Frequency Dosimetry Reader are used as readout instruments and traceability of ECB is to Risø National Laboratory. Radiation indicator labels are frequently used to check status of processed loads.

The main challenges to implementation of a QMS are lack of resources, difficulty of staff understanding and interpreting the provisions of ISO Standard documents and the absence of dosimetry inter-comparison exercises in QA/QC procedures.

The Ghana Atomic Energy Commission is contributing to national prosperity through effective utilisation of nuclear, biotechnology and other related technologies. The Gamma Irradiation Facility is providing irradiation services to the food and medical sectors of the country to support national development. Although the Gamma Irradiation Facility is using some QA/QC procedures, improving the overall Quality Management Practices is essential and a necessary pre-requisite for certification to remain competitive. There is therefore the need for increased stakeholder collaboration among GAEC, the government of Ghana and international partners such as the IAEA for a full implementation of a Quality Management System.

HUNGARY

Status

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 are 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 Institute of Isotopes Co. Ltd.

Centre for Energy Research, Hungarian Academy of Sciences
Budapest

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 (ISO/ASTM 51538) and aqueous alanine solutions.

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 60Co 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.

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, 60Co 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.

**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 500 kCi nominal activity. The facility is in continuous operation with well established quality management system (ISO 9001:2008, MSZ EN ISO 9001:2009), where the radiation technologies are performed on the basis of ISO 11137 using various liquid and solid state reference and routine dosimeter 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).

**INDIA**

**Radiation Standards Section, Radiation Safety Systems Division, Bhabha Atomic Research Centre (BARC), Mumbai**

Radiation Standards Section, Radiation Safety Systems Division, BARC is the Designated Institute (DI) 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 dosimetric 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. 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. The RPP at Vashi, Navi Mumbai is designed for a maximum of one million Ci of Co-60 and is capable of processing wide varieties of products with an approximate throughput of 12,000 Te/year at an average dose of 10 kGy. Radiation processing plant at Vashi has acquired accreditation for compliance with ISO 9001:2000 and ISO 22000:2005 and also features on the list of approved facilities of the European Union. This plant being in the vicinity of agricultural produce market, traders and exporters 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.

ISOMED plant (for radiation sterilisation of medical products) was set up in 1974 by the Department of Atomic Energy, India to provide gamma sterilization services for various ranges of medical and healthcare products in India. The advantages of radiation sterilization over conventional methods prompted a large number of manufacturers to use this technology. ISOMED has acquired compliance to ISO 9001:2008, ISO13485:2003, ISO 11137:2006, ISO 22000:2005 - HACCP and also features on the list of approved facilities of the European Union. BARC regularly carries out dose inter-comparison exercise for all the radiation processing facilities in India that involves standardization / calibration of high dose dosimeters. Under this programme, dosimeters belonging to the RPP (like alanine-EPR, ceric cerous, dichromate, radiochromic film, radiochromic waveguide etc.) are calibrated against Fricke dosimeters, maintained as primary reference standard in the laboratory. The dose values are required to be within 3.5% for the exercise to be successful. Once the inter-comparison exercise is successfully carried out, transfer standard dosimeters are sent to the RPP to perform dose verification exercise with the actual food products to be radiation processed. Thus, in the first step the ability of facility to measure and maintain working dosimeter is tested. In the second step ability of the facility to irradiate the food products within the stipulated dose limits is verified. Based on these techniques, quality assurance is carried out for high dose applications of radiation processing plants. BARC has also been participating in the international Dose Assurance Programs and providing calibrated high dose rate gamma fields to users.
JORDAN

Gamma Irradiation Facility in Jordan

Amman

The medical and pharmaceuticals industry represents Jordan’s second leading industrious sector. So, in order to develop Jordanian pharmaceuticals industry into world class standards, new quality process was adopted satisfying the services provided to clients and their quality demands. Jordan gamma irradiation facility assists the interested manufacturer in sterilization of their products; hereby these products could be exported or released to the local market.

Radiation technology started in Jordan in 1993; through the technical cooperation with the International Atomic Energy Agency in two phases. The International Atomic Energy Agency through the technical cooperation project JOR/8/005 supplied Jordan in Jan 1996 a Co-60 Gamma Cell. The purpose of the project was to introduce Gamma Radiation in Jordan as a new technology and training human resources in that aspect. Jordan commenced sterilization in industrial applications using Gamma Irradiation facility setup under the Agency Project “Cobalt 60 Irradiation Facility JOR/7/002”, The irradiator started providing service on commercial basis from the beginning of 2001. There are two irradiators:

1-Commercial Gamma Irradiation, Category IV, wet storage.

2-Research Irradiator - Gamma Cell, Category I, self-contained, dry source storage irradiator.

Dosimetry in Jordan Gamma Irradiation Facility; Dosimetric systems in use:

- Fricke solution: used as reference standard, to calibrate the dose rate of Gamma Cell, in order to produce working standard of Ethylene Chlorobenzene (ECB), as ECB is the routine dosimetry system.
- Also, there is Perspex, Sauna, and FWT-60-00 Radiachromic Dosimeters, used from time to time to make inter-comparison between dosimetry systems
- EPR machine / Alanine: Newly, not working yet

Radiation dose measurement is the only method as quality control used in the sterilization process according to international standards ISO 11137, so process is controlled and documented to end up with the dosimetric release. For Process Definition; the maximum acceptable dose established by irradiating specimens of product irradiated to incremental doses 2.5kGy or less using research irradiator. And for sterilization dose Both VDmax15&25 is used according to ISO11137. Specifying of the maximum acceptable dose and the sterilization dose is done for each product also transference of maximum acceptable, verification or sterilization
dose between research irradiator and industrial irradiator. For validation, Installation qualification, Operational qualification was carried out by irradiating dummy material. Also, for performance qualification a dose is done for each product. Now applying QA in Jordan Gamma Irradiation Facility is carried out.

KOREA

Korea Atomic Energy Research Institute
Daejon

The Korea Atomic Energy Research Institute is only comprehensive research and development institute for nuclear power in Korea. In Daejeon, headquarter of KAERI, there is a multi-purpose research reactor called HANARO. It can achieve a maximum thermal neutron flux of \(5 \times 10^{14} \text{n/cm}^2\text{/sec}\) based on an open canned core of 30 MWth of heat output. HANARO is utilized in basic science research using neutrons, advanced new materials development, nuclear fuel and reactor materials development, research and production of radioisotope production for medical and industrial use, high quality semiconductor production through neutron doping.

In particular, the advanced radiation research institute located in Jeongeup is representative of radiation irradiation facilities using gamma rays emitted from Co-60. There are facilities for investigating high irradiation doses or low irradiation doses on samples as required, and they are operated in wet and dry form, respectively.

In order to be used as a chemical dosimeter, the amount of change of the substance by radiation should be proportional to the dose and should not be influenced by various conditions before and after irradiation such as temperature, light, dose rate, small size. A measuring instrument should be simple, cheap and reproducible. Commonly used dosimeters are Fricke, Alanine and Ceric-Cerous sulphate dosimeter systems. The Fricke dosimeter is used as a standard dosimeter because the g value is measured accurately. Alanine dosimeter is the most widely used dosimeter to date. It is easy to measure and does not generate chemical wastewater, but it is used as auxiliary dosimeter because it is sensitive to environment such as temperature and humidity. And Ceric-Cerous sulphate dosimeter is used to measure the dose distribution at the distance of the irradiation facility by applying the dose correction from the IDAS and apply it as the reference dose at the time of the sample irradiation.
Future plans can be summarized as follows. First, mutual comparisons among IAEA member states are essential to the improvement of the QA / QC protocol, which requires establishing common criteria such as dose, temperature, humidity, and physical unit. Secondly, it is applied to neutron beam utilization, isotope production, and radioactive waste, leading to the formation of a community among user groups.

MALAYSIA

Nuklear Malaysia

Malaysia is a major producer of natural rubber gloves and catheters. A survey was carried to find out the status of quality management practices implemented at radiation facilities in Malaysia. A total of nine radiation facilities in which three are government owned and six are run by private entity i.e. four multinational and two local companies. Main applications of radiation processing are medical devices sterilization, wire and cable crosslinking and food irradiation. As an export oriented nation, our industry is required to follow certain international standards. All of these facilities are certified with the common quality management system such as ISO 9001:2015 and as well as specific quality management system such as ISO13485:2016 and ISO 11137-1:2015. In addition, all of these facilities have licenses to operate and carry out irradiation activities in accordance to the Malaysian legislations. SSDL of Nuclear Malaysia has been designated as competent national authority for measurement related to ionizing radiation which include providing a high dose dosimetry for industrial radiation processing in Malaysia.

MEXICO

Medfly Program México

Chiapas

Since the beginning, the Mediterraneam fruit fly program in México has used the gamma radiation from Cobalt 60 as sterilization method, reaching 99.95% sterility in *Ceratitis capitata* with a high degree of effectiveness of this insect in the field. With the start of the National Campaign Against Fruit Flies, the need was created to irradiate other species, specifically, *Anastrepha Ludens* and *A. Obliqua* which, like the previous one, handled the partial absence of
oxygen (or hypoxia) in the moment of the irradiation, has shown to be an effective method to assure a good quality of the material processed. The doses of irradiation used for the sterilization of *Ceratitis capitata* was 145 Gy (14.5 Kilorads) for the standard strain (females and males), currently the TSL strain needs a dose of 125 Gy for its sterilization; On the other hand, for the sterilization of *Anastrepha ludens* and *Anastrepha obliqua* a dose of 80 Gy is used. And finally, to achieve the inhibition of *A. ludens* adults of larvae exposed to parasitoids, irradiated larvae are used at a dose of 45 to 50 Gy. Considering that the activity of irradiation sources decays over time, it is necessary to constantly increase the exposure times to maintain a constant dose of irradiation, so it is necessary to apply different dosimetric systems to determine this increase factor. The dosimetric systems used are the Fricke method (Food Irradiation Dosimetry, 1977); and the Gafchromatic dosimetry system (FAO/IAEA, 2006), assisted with radiosensitive radiation indicators.

Currently the Moscafrut Plant is certified only in ISO 9001:2015.

**MYANMAR**

**Ministry of Education**

Nay Pyi Taw

Ministry of Education (Science and Technology) is implementing to promote radiation processing technology in Ministry itself and for private sectors in country. Currently, Myanmar has only one research scale gamma chamber with current dose-rate 0.923 kGy/hr and it is versatile equipment for research activities and some applications. The research works for preservation of tissue grafts, mutation breeding, food irradiation, radiation effect on agricultural products, sterile insect technique, biological genetic effects of radiation, radiation Chemistry, radiation effects on materials, radiation sterilization, modification of polymer materials, waste water treatment are done by using this irradiator. The preliminarily dose rate is 12 kGy/hr while it was commission by BIRT, India in 2000 and the dose rate measurement was carried out with Fricke dosimetry system in 2016 and Graphite probe calorimeter in 2017 by MYA1015 project team member. The Ministry is implementing to establish 2.5 MeV, 100 kW electron beam for R & D and semi-commercial activities and future gamma irradiator. The Ministry has established secondary standard dosimetry laboratory (SSDL) and the facility is finished. The establishment of electron beam irradiation facility project is implementing with the assistance of IAEA and under the MYA 1015 (2016-2017) and MYA1017 (2018-2019) program, the
Ministry has received expert mission, human resource development program as fellowship and scientific visit. The project implementation team is doing the research works with existing gamma irradiator on food irradiation as shelf-life extension, microbe decreasing and analysis on nutritional changes, polymer modification, research work on hydrogel for wound dressing, plant group promoter, gem irradiation, bio-fertilizer, waste water treatment and etc. Project team is implementing national activities for awareness on radiation processing technology (electron beam, gamma and X-ray) to the stakeholders and also participating in Research forum, Conference, Science and Technology Fair and etc. In addition, the project team is actively participated in dosimetry system of QA/QC for radiation facility under MYA1015 & MYA1017 program for future irradiators and is doing dosimetry inter-comparison practice for existing gamma irradiator.

PHILIPPINES

Status of QA/QC Practices in Radiation Processing in the Philippines

Philippine Nuclear Research Institute (PNRI)

To demonstrate radiation processing in the Philippines, irradiation facilities were established at the Philippine Nuclear Research Institute (PNRI) with the technical and financial assistance of the International Atomic Energy Agency under various technical cooperation projects with extra-budgetary contributions from the governments of the Philippines, United States of America and Japan.

The Multipurpose Gamma Irradiation Facility was established in 1989. This was initially designed for R&D and pilot scale studies, however, it also catered to the needs of the industry in the absence of a commercial irradiation facility. Due to increasing demands for gamma irradiation services, it was upgraded in 2008 to a two-pass tote box system with a semi-automated conveying system and a single source rack with four modules. Even operating at 24/7, it still cannot the meet the demands of the industry. Hence, it will again be upgraded in 2019 to a four-pass tote box system with a fully-automated conveying system with additional source rack of two modules. Additional source rack will enable to facility to irradiate products requiring doses from low to medium to high dose. The Co-60 source will also be replenished since the current activity of the source, as of January 2018, is only 55 kCi (2 PBq). Products
that are being irradiated in the gamma facility are spices, herbal products, dehydrated vegetables, cosmetic raw materials and accessories, tissue grafts, medical devices and packaging materials (empty aluminum tubes, eye dropper bottles) and samples for R&D such as hydrogel, and hemostat.

PNRI has a Gammacell-220 irradiator used for the irradiation of small volume of samples requiring low doses and for calibration of dosimeters. The activity of the Co-60 source is only 18 Ci, as of January 2018. A new self-shielded gamma irradiator with a higher source activity is now being acquired.

In order to further demonstrate the other applications of radiation processing, PNRI established the Electron Beam Irradiation Facility in 2014 with the following specifications: Model ELV 8 from EB-Tech Co. Inc. of South Korea, 1.0 to 2.5 MeV energy, maximum current of 50 MeV and maximum power of 100 kW. The facility has two (2) product handling systems: the cart conveyor and liquid handling system. The facility is being used for the irradiation of plant growth promoter and other R&D samples such as beef patties, non-woven fibres and wound dressings (honey alginate, hydrogel).

There is also one electron beam facility that is being operated by a private company, TERUMO, for in-house irradiation of disposable syringes. They have three (3) 10 MeV linear accelerators.

There is currently an increasing interest from the private industry to put up a commercial irradiation facility. PNRI is giving them consultative services in this aspect.

The summary of gamma irradiation services from 2008 to 2017 was also presented. The volume of products increased from 2008 (after the 1st upgrading of the irradiator) to 2012. It is slowly decreasing due to the decay of the source which was last replenished in 2009. However, there is a significant increase in the number of clients showing increasing interest in this technology.

The following are the relevant local regulations:

1. Code of PNRI Regulations (CPR) Part 15-"Licenses for Large Irradiators"
2. Department of Health Administrative Order 152, s. 2004 – “Prescribing Regulations of Irradiated Food”
3. Bureau of Plant Industry (BPI) Quarantine Administrative Order No. 02, s. 2008-
“Rules and Regulations for the Important, Exportation and Domestic Movement of
Irradiated Plant and Plant Products and the Use of Irradiation as Phytosanitary
Treatment”

For gamma facilities, the regulator is the Philippine Nuclear Research Institute, Department of
Science and Technology while for EB and X-ray facilities, the regulator is the Centre for Device
Regulation, Radiation Health and Research, Food and Drugs Administration, Department of
Health

The gamma irradiation services provided by the PNRI is ISO 9001:2015 certified while the EB
irradiation services will be certified in 2019.

Installation qualification, operational qualification and performance qualification were
performed in the gamma and EB irradiation facilities after every upgrade/installation using
dosimetry systems (TABLE 2) traceable to the National Physical Laboratory.

<table>
<thead>
<tr>
<th>Dosimeters</th>
<th>Dose Range Used</th>
<th>Readers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol chlorobenzene</td>
<td>1 to 20 kGy; 15 to 55 kGy; 10 to 130 kGy</td>
<td>Oscillotitrator</td>
</tr>
<tr>
<td>Gafchromic</td>
<td>50 to 500 Gy</td>
<td>FWT radiochromic reader</td>
</tr>
<tr>
<td>Fricke</td>
<td>40 to 400 Gy</td>
<td>UV-VIS spectrophotometer</td>
</tr>
<tr>
<td>Alanine</td>
<td>1 to 40 Gy; 30 to 800 Gy; 0.7 to 130 kGy</td>
<td>ESR reader (Magnetech MiniScope MS 5000 spectrometer)</td>
</tr>
<tr>
<td>B3 Windose film</td>
<td>1 to 60 kGy</td>
<td>UV-VIS spectrophotometer</td>
</tr>
<tr>
<td>Polystyrene Calorimeter</td>
<td>3 to 40 kGy</td>
<td>Ohm meter</td>
</tr>
<tr>
<td>Cellulose Triacetate (CTA) film</td>
<td>10 to 100 kGy</td>
<td>DOS’ ASAP spectrophotometer</td>
</tr>
</tbody>
</table>

These dosimetry systems are also used for process control during routine irradiations in the
gamma and EB irradiation facilities.

The challenges encountered in the irradiation facilities are the following:
• No available national laboratory for high dose dosimetry. PNRI SSDL is only for personnel dosimetry (low dose)
• No available dose inter-comparison activities in the region. IAEA Dose Assurance Service (IDAS) was discontinued
• Dosimetry system for liquid handling system has not been established
• Uncertainty in dose measurements not yet fully established

POLAND

Institute of Nuclear Chemistry and Technology (INCT)
Warsaw

The Institute was established in 1983. INCT is composed of three centers: Centre of Radiation Research and Technology, Centre of Radiochemistry and Nuclear Chemistry, Centre of Radiobiology and Biological Dosimetry and seven laboratories: Laboratory for Measurements of Technological Doses, Laboratory for Detection of Irradiated Food, Laboratory of Nuclear Control Systems and Methods, Laboratory of Stable and Environmental Isotopes, Laboratory of Nuclear Analytical Methods, Laboratory of Material Research, Pollution Control Technologies Laboratory.

The activities of the INCT include basic research, R&D as well as various services. Basic research is focused on: radiochemistry, chemistry of isotopes, physical chemistry and engineering of separation processes, cellular radiobiology and radiation chemistry, particularly that based on pulse radiolysis method. Scientific Council has rights to grant D.Sc. and Ph.D. degrees in the field of chemistry, and the Institute carries out third level studies (doctorate) in the field of nuclear and radiation chemistry. It is editor of the scientific journal “Nukleonika” (listed on ISI IF journals).

The Institute has two commercial irradiation plants and two pilot plants equipped in six electron accelerators: for radiation sterilization of medical devices and tissue grafts, for radiation modification of polymers, for removal of SO2 and NOx from flue gases and for food decontamination.
Both commercial irradiation plants are equipped with electron beam accelerator Elektronika 10/15. Radiation Sterilization Plant (RSP) is accredited by Polish Centre for Accreditation (PCA) according to the requirements of the PN-EN ISO/IEC 13485:2015. Dosimetric systems used in INCT facilities are: calorimeters, PVC foil, B3 film, Harwell Amber. To ensure reliable technological dose measurements in INCT facilities the Laboratory for Measurements of Technological Doses (LMTD) was established. The LTMD was accredited in 2004 by Polish Centre for Accreditation (PCA) as a testing laboratory according to the requirements of the PN-EN ISO/IEC 17025:2005. All results of the dose measurements in INCT are traceable to the National Physical Laboratory (NPL) primary standard. RSP is under inspection of the Main Pharmaceutical Inspectorate that carries out the inspection every second year and issues the Certificate of GMP Compliance of a Manufacturer.

PORTUGAL

Unidade Tecnológica de Radioesterelização (UTR)
Bobadela Lisbon

The “Unidade Tecnológica de Radioesterelização (UTR)” is operating since 1988 and is a pilot Unit used to provide services to Industry and Research. The unit is certified ISO 9001:2008 since 2016 and follows all the control and quality protocols imposed by the legislation. Dosimetry, are implemented according the norm ISO 11137-3 and safety and radiation protection IAEA SAFETY STANDARDS N.º SSG - 8 - Radiation safety of gamma, electron and x-ray irradiation facilities. The dosimetry in the unit is performed using a ceric-cerous solution for reference dosimetry and Red Perspex for routine dosimetry. The unit is routinely audited (every 1-2 years) by customers (pharmaceutical companies) and national authorities. As an irradiator operator, Portuguese gamma facility ensure that irradiation process and delivered dose are appropriately and correctly performed with quality assurance procedures. Dosimetry used in the development, validation and routine control of the sterilization process shall have measurement traceability to national or international standards. Inter-comparison exercises between industrial irradiation facilities and calibration laboratories are very important on the development of written protocols describing standard methods for the calibration of industrial dosimetry systems. Regarding QA and QC in service of sterilization/decontamination by gamma radiation, follow:
➢ Document control (e.g. documents codification)
➢ Record system
➢ Operational procedures (work instructions, technical documents and specifications)
➢ Inspection and testing;
➢ Batch traceability;
➢ Preventive maintenance actions;
➢ Non-conformance identification, analysis and measure (important to corrective and preventive actions;
➢ Periodical review

For the participation on the inter-comparison exercise we used our Red Perspex dosimeters placed beside the reference alanine pellets. For each dose we used 4 routine dosimeters to estimate an average value of the dose. Due the high dose rate in our calibration spot and low accuracy of the dosimeters for the lowest dose (1 kGy) this value is affected by a higher uncertainty compared to the others.

ROMANIA

Cernavoda Nuclear Power Plant:

- two CANDU 600 MW reactors in operation.

Cernavoda NPP has an Integrated Management System for Quality, Environment, Health and Safety.

The Environmental Monitoring Laboratory of Cernavoda NPP is member of the IAEA’s ALMERA Network (Analytical Laboratories for the Measurement of Environmental Radioactivity) and regularly participates within proficiency tests.

National Institute of Physics and Nuclear Engineering - Horia Hulubei (IFIN-HH)

Bucharest:

- IRASM - Irradiator, class IV type (source storage in a pool, automatic transport system), with product overload and tote-box system, SVST Co-60/B type (designed by the Institute of Isotopes Co. Ltd. Budapest), is loaded with 100 kCi representing 5% of
its maximum capacity.

- **CYCLOTRON Accelerator**, ions (protons, deuterons and alpha particles with maximum energy 13MeV/amu) and fast neutrons irradiation with maximum fluxes 10E11 n/cm²*s.

- **9MV FN Pelletron TANDEM Accelerator**, upgraded from the original terminal voltage of 7.5 MV (FN machine) to 9MV

- **3MV TANDETRON Accelerator**, is designed and custom-built by High Voltage Engineering Europe B.V., Amersfoort, Netherlands and was installed in 2012

- **1MV TANDETRON Accelerator**, using the following isotopes: Be-10, C-14, Al-26, Ca-41, I-129

- **VVRS REACTOR** - Nuclear research reactor in advanced state of decommissioning.

- **High Energy Beam Facility** from Extrem Light Infrastructure – Nuclear Physics, under construction.

IFIN-HH has a *Quality Management System based on SR EN ISO9001/2015* and IRASIM is regularly participating in IAEA inter-comparison tests.

**Institute for Nuclear Research (ICN) Pitesti:**

- **TRIGA Steady State Reactor (TRIGA SSR) 14 MW**, in operation

- **TRIGA Annular Core Pulsing Reactor (TRIGA ACPR) 20000 MW**, in operation

- **High Activity Gamma Irradiator (SIGMA)**, in preservation. Gamma irradiation has been conducted with Co-60 standard sources having an initial activity of about 150 kCi. In 2014, all gamma sources have been transferred in the storage pool of the Post-Irradiation Examination Laboratory, connected with TRIGA Reactor.

ICN has an *Integrated Management System for Quality (ISO 9001), Environment (ISO 14001), Health and Safety (OHSAS 18001).*

**Neutron Activation Analysis (NAA) Laboratory** from TRIGA Reactor department, conducting neutron activation analysis, participates to inter-comparison tests organized by IAEA.

**Radiation Protection, Environmental Protection and Civil Protection (RPPMPC) Laboratory** of ICN Pitesti is member of AIEA’s ALMERA network and RANET network (Response
Assistance Network, a network for mutual assistance between member states in case of nuclear accidents) and regularly participates within proficiency tests.

National Commission for Nuclear Activities Control (CNCAN) – Romanian Nuclear Regulatory Body licensed RPPMPC as analysis laboratory for radiological characterization of materials with Quality System according to ISO 17025.

SERBIA

Radiation unit at Vinca, Institute of Nuclear Sciences

Belgrade

Vinča Institute of Nuclear Sciences is the largest and leading scientific institution in the Republic of Serbia. The Institute comprises 19 departments with about 800 permanent employees. Each department has its own management structure with responsibility for scientific, technological and financial matters.

Gamma radiation facility in Vinča Institute of Nuclear Sciences is the part of the Department for Radiation Chemistry and Physics. Gamma radiation facility provides commercial services to industry mainly in the fields of sterilization of medical devices, food irradiation and modification of polymer insulators. It has maximum capacity of 25,000 m³ irradiated products per year and it has operated since 1978. The facility core is cobalt–60 gamma irradiator with wet storage working in batch mode. Current activity of source is around 140 kCi. Facility is designed for the maximum value of 1MCi.

Quality control of the irradiation process was confirmed by the introduction of ISO international standards in the Radiation Facility. In June 2018 we have implemented ISO 9001:2015 international standard for Quality management system and ISO 13485:2016 standard for Medical devices in accordance with a series of ISO 11137 standards (Sterilization of health care products).

Dosimetry system in routine use at irradiation facility is Ethanol-monochlorobenzene (ECB) dosimeter. Dosimetry systems used for measure of low doses are Fricke dosimeter solution and alanine-EPR dosimetry system. Measuring equipment for ECB is the instrument OK-302/2 type oscillotitrator of Radelkis (Budapest, Hungary). Absorbed dose is determined through measurement results and calibration curve. Calibration curve is based on the values obtained from reference laboratory Risø High Dose Reference Laboratory (Denmark). Dosimetry system
used for measure low doses is Fricke dosimeter solution and for internal control of dose measurement we use alanine-EPR dosimetry. 

In 2017 we have participated in Inter-Laboratory Comparison in Technological Dosimetry which was a part of IAEA TC project RER 1017. ECB dosimetry comparison was done in the accredited INCT Laboratory for Measurements of Technological Doses from Poland. The comparison results are shown in the TABLE 3.

<table>
<thead>
<tr>
<th>Required dose</th>
<th>5 kGy</th>
<th>10 kGy</th>
<th>25 kGy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose measured in our facility using the ECB-oscillotitrator dosimetry system</td>
<td>5.02 kGy</td>
<td>10.01 kGy</td>
<td>25.40 kGy</td>
</tr>
<tr>
<td>Dose measured with reference laboratory dosimeter (alanine)</td>
<td>5.25 kGy</td>
<td>9.91 kGy</td>
<td>24.10 kGy</td>
</tr>
<tr>
<td>Deviations from reference laboratory</td>
<td>4.50%</td>
<td>-0.99%</td>
<td>-4.00%</td>
</tr>
<tr>
<td>Uncertainty</td>
<td>± 5%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**TABLE 3. COMPARISON RESULTS**

**SLOVAKIA**

University Centre of Electron Accelerators, Slovak Medical University in Bratislava Trencin

The University Centre of Electron Accelerators (UCEA) in Trencin was designed for research and industrial applications and it is the only facility dealing with radiation processing in Slovakia. It started its operation in 2012 with the main aim to bring this technology into the practise in the country. The facility runs a 5 MeV electron accelerator with maximum power of 1kW equipped with a beam-scanning system, a conveyor line and an X-ray converter. The facility possibilities are wide in terms of deliverable types of radiation (electron beam or bremsstrahlung X-rays), available doses (regulated by the conveyor velocity) and dose-rates according to a type of radiation and adjustable beam repetition rate. We are able to irradiate with accelerated electrons in dose rates from 10 to 5600 kGy/h and also by X-rays created by conversion in tungsten target in a dose rate range from 26 up to 1440 Gy/h.
A routine dosimetric system used at the UCEA accelerator is based on B3 radiochromic films (1 cm in diameter and 18 μm thick films of pararosaniline dye dissolved in polyvinyl butyral). 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. The radio chemical yield of the dye results in a colour change that is evaluated by a Spectrophotometer Genesys20. The routine dosimetric system can be used in the range of doses of 1 – 100 kGy. The B3 dosimetric system 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.

Since 2014 we have 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.
IAEA INITIATIVES ON QA/QC IN REGIONAL PROJECTS

a. Africa

Member States (MS) in Africa have been implementing programmes in radiation processing with the assistance of the IAEA over the years. Applications such as radiation sterilization of medical devices, food irradiation, polymer crosslinking and curing and conservation of cultural heritage artifacts have been utilized by MS. However important aspects of radiation processing such as Quality Assurance and Quality Control (QA/QC), dosimetry, microbiology and Quality Management Systems (QMS) have not received the much-needed attention and support. Previous efforts by the IAEA to assist MS introduce QA/QC and QM practices have not been entirely successful. While a few Member States were able to introduce QA/QC and QM procedures, most have had difficulties in initiating and sustaining such vital programmes. There is limited technical expertise in most Member States and information on implementation of QM practices is not readily available.

In order to improve on the quality management practices in radiation processing facilities, relevant information on status of implementation and associated challenges in Member States are required to enable formulation of appropriate projects. There is therefore the urgent need for new initiatives to strengthen quality assurance and quality control protocols through relevant workshops, dosimetry/microbiology inter-comparison exercises and greater intra/inter-regional collaborations to ensure safe operation of radiation processing facilities in Member States.

b. Asia

Member States (MS) in Asia have been implementing programmes in radiation processing with the assistance of the IAEA over the years. Applications such as radiation sterilization of medical devices, food irradiation, polymer crosslinking and curing and conservation of cultural heritage artefacts have been utilized by MS. However important aspects of radiation processing such as Quality Assurance and Quality Control (QA/QC), dosimetry, microbiology and Quality Management Systems (QMS) have not received the much-needed attention and support. While a few Member
States were able to introduce QA/QC and QM procedures, some have had difficulties in initiating and sustaining such vital programmes. There is limited technical expertise in some Member States and information on implementation of QM practices is not readily available.

In order to improve on the quality management practices in radiation processing facilities, relevant information on status of implementation and associated challenges in Member States are required to enable formulation of appropriate projects. There is therefore the urgent need for new initiatives to strengthen quality assurance and quality control protocols through relevant workshops, dosimetry/microbiology inter-comparison exercises and greater intra/inter-regional collaborations to ensure safe operation of radiation processing facilities in Member States. Initial step, IAEA will conduct TM on QA/QC and Management system of irradiation facilities on 5th-9th August 2019 in Kuala Lumpur. Malaysia will take the lead to propose Regional project in this QA/QC of radiation facilities.

c. Europe

A historical retrospection analyzed the introduction of radiation chemistry and radiation technology in Member States of European TC Region from the early 60es up to 1990. It was shown, that the former nuclear research centres in many countries served as a basis for R&D in nuclear technologies and are still active in this fields nowadays, although in different structure.

Significant changes happened at around the turn of the century resulting in the weakening or even the disappearance of research institutions and companies using radiation processing technologies. In order to stop these tendencies and even to strengthen the still existing R&D institutions and companies the IAEA together with some Member States initiated the establishment of regional projects in radiation technologies. The first RER project started in 2005 as “Quality Control Methods and Procedures for Radiation Technology (2005-2006). The main task of the project was to enhance the capabilities of European Member states in applying harmonized quality control methods and procedures in radiation processing of health care related products and advanced materials. A survey was produced in order to have an up to date view about the irradiation facilities in operation in the region together with applied
technologies, QA/QC methods, applied standards and QM systems, participation in dosimetry inter-comparison exercises, etc. This first survey included the reports from the following countries: Albania, Bulgaria, Croatia, Czech Republic, Hungary, Portugal, Poland, Romania, Serbia, Slovakia, Turkey, Ukraine. Based on the results of the survey the program of the RER projects in the introductory period (up to about 2016) included the following tasks:

- Safe operation of irradiation facilities
- Quality assurance and quality control in the validation and routine process control of irradiation technologies
- Introduction/upgrading of QMSs and ISO and ISO/ASTM standards
- Initiation and introduction of new irradiation facilities and technologies
- Inter-comparison exercises (dosimetry and microbiology).

From the second half of the present decade radiation processing has significantly strengthened in a number of countries and at the same time new Member States their intention to join the RER projects and/or to introduce radiation processing. Due to this situation, as well as due to the elapsed time another survey was performed including a number of new countries like Azerbaijan, Belarus, Estonia, Kazakhstan, Latvia, Lithuania, Russian Federation and Uzbekistan.

Based on the outcome of this survey a detailed regional plan was worked out for future projects aiming at to strengthen, improve, expand and in certain countries, even to introduce the use of radiation technologies in the region taking into account that new Member States considered or even indicated their intention to join the program and/or of introducing radiation processing like Bosnia-Herzegovina, Greece, Macedonia, Moldova, Montenegro.

This new regional plan includes – due to the existing differences among Member States in the state-of-the-art of radiation processing - partly traditional tasks, like development of human resources technical conditions and infrastructural background, to fill in gaps in QA/QC/QMS procedures and to organize and perform inter-comparison in dosimetry and in microbiology. Beside these aims, new initiatives were also planned, like:
informal, voluntary audits in irradiation facilities,
- introduction of EB technologies,
- production of nanomaterials,
- R&D in environmental technologies (waste water treatment),
- cooperation with educational institutions (secondary schools, universities (capacity building),
- support for accreditation (dosimetry, microbiology, material testing, etc),
- bilateral cooperation’s,
- Initiation and establishment of interregional TC projects.

In order to fulfil these tasks and achieve the aims significant efforts are being made in the present RER 1019 project and even preparations started for the establishment of a new project for the next TC cycle.

d. Latin America and the Caribbean

With the support of the "Atoms for Peace" program of the IAEA, at the end of the decade of the 50s, research and development in radiation applications began in some countries of Latin America and the Caribbean. That program continues to operate to this day and has incorporated more countries in the region over time. The experiences obtained in Member States (MS) of the Region from the training of human resources and the use of irradiation technology has allowed applying techniques for local benefits in the areas of agriculture, pest control, food, health, the medical and veterinary industry, the development of materials and studies for the protection of the environment.

Installations, equipment and experience in operation and radiological protection of radioactive facilities (both industrial and laboratory level) is diverse, as well as the people currently working in these facilities; the systems of quality assurance, quality control and quality management are not the exception in relation to the differences in the countries of the region.

Most of the irradiation facilities (80%) are cobalt-60 gamma radiation and although we have a cobalt-60 producer country in the region, the reloading of some irradiators has not been possible in years, becoming indispensable in these days.
Currently in all MS at least international standards are followed to process products or in some cases also national standards are followed and met. Now in the case of Quality Management Systems (QMS) implementation, private facilities usually have a certified QMS by an authorized entity, and in the public sector some institutions apply standards and norms for the quality control and quality assurance that are not enough to be considered a QMS, and therefore that are not enough to obtain a certification. Nevertheless, we can consider that there is experience in the MS of the Latin America Region in the matter of QMS as well as its implementation and maintenance.

Fortunately, in the last 7 years, two dosimetric inter-comparison exercises have been carried out among countries of the region, funded by the IAEA and coordinated by CNEA de Argentina. The previous cooperation and knowledge exchange in the region encourages us of continuing to carry out this type of activities.
CONCLUSIONS

All 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.

The e-learning module, namely CLP4NET, which was reviewed during the meeting, will be a valuable tool in implementing quality management systems in radiation facilities of member states. Participants committed to send relevant questions and answers for self-assessment in the e-learning modules.

The experiences from RER and RLA TC Projects were evaluated and observed to be applicable for all MS. Sharing the knowledge through Interregional Cooperation may result in a better use of existing resources. It was observed there is limited knowledge in dosimetry system calibration and estimation of associated uncertainties as well as QMS practices. The inter-comparison exercise has been discussed and all members have agreed to participate in the proposed interregional exercise.

RECOMMENDATIONS

e. Training

The participants of the meeting recommend organizing hands-on training on calibration and evaluation of uncertainties of dose measurements during irradiation. The participants also recommend organizing QMS training for radiation facilities.

The sustainability and improvement of human capacity (i.e. succession planning) needs to be supported by utilizing the available IAEA resources. Consequently, the
organization of Summer Schools is suggested by involving the relevant Collaborating Centers from different regions.

f. **E-learning**
Participants agreed to test the e-learning modules before they are made available to the public.

g. **Dosimetry inter-comparison**
Two options of coordinating dosimetry inter-comparison exercises were suggested by the participants:
1. with one single coordinator worldwide,
2. with multiple regional coordinators.

Participants suggested organizing a separate meeting of inter-comparison coordinators and the main suggested topics are:
- definition of detailed protocol
- data analysis methodology
- specific irradiation configuration (e-beam, gamma, X-ray)
- irradiation form content
- maximum number of participants to be invited
- requested information from participants (uncertainty budget, calibration methodology).

h. **Interregional programme**
In the light of success achieved in implementation of the regional projects (ARCAL 8046, RER 1017, RLA 1013, RLA 1015), the participants strongly recommend conducting an interregional programme which would cover the above-mentioned topics.

In order to focus the attention of MS in these regions, appropriate workshops should be conducted, which may subsequently lead to the establishment of similar regional projects in other regions (Asia, Africa).
i. **Voluntary audits**

Due to the persistent efforts of the IAEA and MS in enhancing the implementation of QM practices, the program has started taking roots in many MS. Conducting voluntary audits in various fields of radiation processing will further strengthen these initiatives and are strongly recommended by the participants.
# ANNEX I

## TABLE 4: LIST OF RADIATION FACILITIES AND THEIR DOSIMETRIC SYSTEMS IN COUNTRIES PARTICIPATING AT THE MEETING.

<table>
<thead>
<tr>
<th>Country</th>
<th>Radiation type</th>
<th>Dosimetry system</th>
<th>Traceable to…</th>
<th>1 Calibr. Plant/2 Industr. Plant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Argentina</td>
<td>Gamma Co-60</td>
<td>Red &amp; Amber Perspex, Alanine, radiochromic</td>
<td>NPL (Alanine from SSDL Argentina)</td>
<td>2</td>
</tr>
<tr>
<td>China</td>
<td>EB 10 MeV</td>
<td>B3</td>
<td>NIM China (Alanine)</td>
<td>1 (NIM)</td>
</tr>
<tr>
<td>Croatia</td>
<td>Gamma Co-60</td>
<td>ECB</td>
<td>RISO</td>
<td>2</td>
</tr>
<tr>
<td>Ghana</td>
<td>Gamma Co-60</td>
<td>ECB</td>
<td>RISO</td>
<td>2</td>
</tr>
<tr>
<td>Hungary</td>
<td>Gamma Co-60</td>
<td>ECB (all)</td>
<td>RISO</td>
<td>2 (all)</td>
</tr>
<tr>
<td>India</td>
<td>Gamma Co-60</td>
<td>Fricke, Alanine EPR, Glutamine SPM</td>
<td>NPL (SSDL BARC), Fricke</td>
<td>1</td>
</tr>
<tr>
<td>Jordan</td>
<td>Gamma Co-60</td>
<td>ECB</td>
<td>Fricke</td>
<td>1</td>
</tr>
<tr>
<td>Korea</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malaysia</td>
<td>Gamma Co-60</td>
<td>Ceric-CEROUS</td>
<td>Fricke</td>
<td>1</td>
</tr>
<tr>
<td>Mexico 1</td>
<td>Gamma Co-60</td>
<td>Red Perspex, Alanine</td>
<td>NIST</td>
<td>2</td>
</tr>
<tr>
<td>Mexico 2</td>
<td>Gamma Co-60</td>
<td>radiochromic</td>
<td>Fricke</td>
<td>2?</td>
</tr>
<tr>
<td>Myanmar</td>
<td>Gamma Co-60</td>
<td>Fricke</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Philippines</td>
<td>Gamma Co-60, EB 2.5 MeV</td>
<td>ECB, B3, Alanine</td>
<td>NPL</td>
<td>2</td>
</tr>
<tr>
<td>Poland</td>
<td>EB 10 MeV</td>
<td>Calorimeter, B3</td>
<td>NPL (SSDL Poland)</td>
<td>2</td>
</tr>
<tr>
<td>Portugal</td>
<td>Gamma Co-60</td>
<td>Red Perspex</td>
<td>Nordion (Ceric-CEROUS)</td>
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<tr>
<td>Serbia</td>
<td>Gamma Co-60</td>
<td>ECB</td>
<td>RISO</td>
<td>1</td>
</tr>
<tr>
<td>Slovakia</td>
<td>EB 5 MeV</td>
<td>B3</td>
<td>RISO (calorimeter)</td>
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IAEA Technical Meeting on


01-05 October 2018
IAEA Headquarters Vienna, AUSTRIA
(Meeting Room – C0343, VIC)

Monday, 01 October 2018

Session I: Introductory Session

9.00 - 9.40
Opening of the meeting:
Mr Joao Alberto OSSO JUNIOR, Head, Radioisotope Products and Radiation Technology Section
Mr Sunil Sabharwal, Scientific Secretary
Mr Bumsoo Han,
Introduction of Participants
Scope and Objectives of the Meeting
Adoption of the agenda

Session II: Participants’ Presentations

09.40 – 10.40
Mr Florent Kuntz- France
Quality Management Practices in Radiation Processing

10.40 – 11.00
Coffee Break

11.00 – 12.00
Mr Andras-KOVACS - HUNGARY
Initiatives in Quality Management Practices in Under IAEA Regional Programme in Europe
12.00 – 13.30  
*Lunch break and administrative matters*

13.30 – 14.30  
Mr Othman SIDEK - MALAYSIA  
Quality Management Practices in Radiation Processing Facilities in Malaysia

14.30 – 15.30  
*Coffee Break*

15:30 – 16:30  
Mr Miguel-IRAN ALCÉRRECA SÁNCHÉZ - MEXICO  
Initiatives in Quality Management Practices in Under IAEA Regional Programme in Latin America

16:30 – 17:30  
Mr Abraham-ADU-GYAMFI - GHANA  
Quality Management Practices in Radiation Processing Facilities in Ghana

17:30 – 19:00  
*Reception*

**Tuesday, 02 October 2018**

<table>
<thead>
<tr>
<th>Session III &amp; IV</th>
<th>Participants’ Presentations: Status of QA/QC in Radiation Processing in Member States</th>
</tr>
</thead>
</table>
| 09.30 – 10.00    | Ms Celina HORAK  
ARGENTINA |
| 10.00 – 10.30    | Ms Marija MAJER  
CROATIA |
| 10.30 – 11.00    | *Coffee Break* |
| 11.00 – 11.30    | Mr Mukund Shrinivas KULKARNI  
INDIA |
| 11.30 – 12.00    | Mr Mohammad Amer ETOOM  
JORDAN |
| 12.00 – 12.30    | Ms Karina MORALES LUNA  
MEXICO |
| 12.30 – 14.00    | *Lunch Break* |
| 14.00 – 14.30    | Ms Lei Lei OO  
MYANMAR |
| 14.30 – 15.00    | Ms Luvimina LANUZA &  
Ms Haydee SOLOMON  
PHILIPPINES |
| 15.00 – 15.30    | Mr Andrzej RAFALSKI  
POLAND |
| 15.30 – 16.00    | *Coffee Break* |
| 16.00 – 16.30    | Ms Paula MATOS  
PORTUGAL |
| 16.30 – 17.00    | Mr Relu DOBRIN  
ROMANIA |
| 17.00 – 17.30    | Mr Slobodan MASIC  
SERBIA |
| 17.30 – 18.00    | Ms Andrea SAGATOVA  
SLOVAKIA |
## Wednesday, 03 October 2018

<table>
<thead>
<tr>
<th>Session V</th>
<th>Review of the e-learning module and planning for dosimetry inter-comparison: ALL PARTICIPANTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>9:30 – 10:30</td>
<td>Discussion on need and implementation strategies for conducting dosimetry inter-comparison exercise</td>
</tr>
<tr>
<td>10:30 – 11:00</td>
<td>Coffee Break</td>
</tr>
<tr>
<td>11:00 – 12:30</td>
<td>Discussion on need and implementation strategies for conducting dosimetry inter-comparison exercise</td>
</tr>
<tr>
<td>12:30 – 14:00</td>
<td>Lunch Break</td>
</tr>
<tr>
<td>14:00 – 15:30</td>
<td>Ms Dinara ABBASOVA, Mr Sunil SABHARWAL &amp; Mr Bumsoo HAN</td>
</tr>
<tr>
<td></td>
<td>IAEA initiatives in developing e-learning modules for QA/QC protocols in radiation processing</td>
</tr>
<tr>
<td>15:30 – 16:00</td>
<td>Coffee Break</td>
</tr>
<tr>
<td>16:00 – 17:00</td>
<td>Review of the e-learning Module</td>
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## Thursday, 04 October 2018

<table>
<thead>
<tr>
<th>Session VI</th>
<th>Revision of e-learning modules and drafting the meeting report - ALL PARTICIPANTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>9:30 – 10:30</td>
<td>Revision of the e-learning Module</td>
</tr>
<tr>
<td>10:30 – 11:00</td>
<td>Coffee Break</td>
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<tr>
<td>11:00 – 12:30</td>
<td>Finalizing the e-learning Module</td>
</tr>
<tr>
<td>12:30 – 14:00</td>
<td>Lunch Break</td>
</tr>
<tr>
<td>14:00 – 15:30</td>
<td>Drafting of Meeting Report</td>
</tr>
<tr>
<td>15:30 – 16:00</td>
<td>Coffee Break</td>
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<tr>
<td>16:00 – 17:00</td>
<td>Drafting of the Report</td>
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## Friday, 05 October 2018

<table>
<thead>
<tr>
<th>Session VI</th>
<th>Finalizing Future Activities and Preparation of Meeting Report: ALL PARTICIPANTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>9:30 – 10:30</td>
<td>Review of Meeting Report:</td>
</tr>
<tr>
<td>10:30 – 11:00</td>
<td>Coffee Break</td>
</tr>
<tr>
<td>11:00 – 12:30</td>
<td>Acceptance of the Meeting report</td>
</tr>
<tr>
<td>12:30 –</td>
<td>Closing of the Meeting</td>
</tr>
</tbody>
</table>
## ANNEX III

**F2-TM-1703239**

**Technical Meeting on Strengthening Quality Assurance/Quality Control Protocols in Radiation Facilities Through Dosimetry Inter-comparison**

*Vienna, Austria*

*1 October 2018 - 5 October 2018*

### List of Participants

(as of 2018-09-27)

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Authority</th>
<th>Personal Details</th>
</tr>
</thead>
</table>
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<table>
<thead>
<tr>
<th>S. No.</th>
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<th>Personal Details</th>
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</thead>
</table>
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<th>Authority</th>
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<tr>
<td>14</td>
<td>Myanmar</td>
<td>Ms Lei Lei OO&lt;br&gt;Ministry of Education&lt;br&gt;Division of Atomic Energy, Ministry of Education&lt;br&gt;Yarzahtarni Road&lt;br&gt;Building No. 21&lt;br&gt;NAY PY1 TAW&lt;br&gt;MYANMAR&lt;br&gt;Tel: 67404460&lt;br&gt;Email: <a href="mailto:dlleioo@gmail.com">dlleioo@gmail.com</a></td>
</tr>
<tr>
<td>15</td>
<td>Philippines</td>
<td>Ms Luvimina LANUZA&lt;br&gt;Commonwealth Avenue, Diliman&lt;br&gt;P.O. Box 213&lt;br&gt;1101 QUEZON CITY&lt;br&gt;PHILIPPINES&lt;br&gt;Tel: 29208789&lt;br&gt;Email: <a href="mailto:lglanuza@pnri.dost.gov.ph">lglanuza@pnri.dost.gov.ph</a></td>
</tr>
<tr>
<td>16</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>17</td>
<td>Poland</td>
<td>Mr Andrzej RAFALSKI&lt;br&gt;Institute of Nuclear Chemistry and Technology&lt;br&gt;ul. Dorodna 16&lt;br&gt;03-195 WARSAW&lt;br&gt;POLAND&lt;br&gt;Tel: 0048 22 5041313&lt;br&gt;Email: <a href="mailto:a.rafalski@ichtj.waw.pl">a.rafalski@ichtj.waw.pl</a></td>
</tr>
<tr>
<td>18</td>
<td>Portugal</td>
<td>Ms Paula MATOS&lt;br&gt;Instituto Superior Técnico, Instituto Tecnológico e Nuclear; Ministry of Science, Technology and Higher Education (MCTES)&lt;br&gt;Estrada Nacional, 10&lt;br&gt;2686-953 SACA VEM&lt;br&gt;PORTUGAL&lt;br&gt;Tel: 946000&lt;br&gt;Email: <a href="mailto:pcmatos@ctn.tecnico.ulisboa.pt">pcmatos@ctn.tecnico.ulisboa.pt</a></td>
</tr>
<tr>
<td>19</td>
<td>Romania</td>
<td>Mr Relu DOBRIN&lt;br&gt;Institute for Nuclear Research - Pitesti&lt;br&gt;Campului, No. 1&lt;br&gt;PO Box 78R&lt;br&gt;115400 MIOVENI&lt;br&gt;ARGES&lt;br&gt;ROMANIA&lt;br&gt;Tel: 248213400&lt;br&gt;Email: <a href="mailto:relu.dobrin@nuclear.ro">relu.dobrin@nuclear.ro</a></td>
</tr>
<tr>
<td>20</td>
<td>Serbia</td>
<td>Mr Slobodan MASIC&lt;br&gt;Vinca Institute of Nuclear Sciences&lt;br&gt;P.O. Box 522, Mike Petrovica Alasa 12-14&lt;br&gt;11001 BELGRADE&lt;br&gt;SERBIA&lt;br&gt;Tel: 3408449&lt;br&gt;Email: <a href="mailto:slobodan.masic@gmail.com">slobodan.masic@gmail.com</a></td>
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</table>
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