

2nd Draft Project Concept Template
Project Proposals for the RCA Programme 2022/2023
2nd Round Project Concept Template

Part 1: Information Sheet

2nd Round Concept Project proposals for the RCA Programme 2022/2023 are to be prepared USING THE 1ST ROUND CONCEPT PROJECT PROPOSAL.

The 2nd Round Concept should show the text changes that have occurred through the updating of the 1st Round Concept through THE USE OF TRACK CHANGE MODE.

The 2nd Round Concept Proposals will be evaluated against the response to the feedback you have received from RCA PAC on your 1st Round Concept Proposals as well as the criteria listed below:

- **Is its aims and objectives in line with priorities set out the RCA Medium Term Strategy for 2018/2023?**
- **Identify which elements of the MTS are being complied with.**
- **Why it should be a regional project.**
- **The essential role of the nuclear technology in the project.**
- **Does the proposal identify links to previous projects in this area of technology?**
- **Does the proposal overlap or duplicate current or previous RCA projects?**
- **Is a convincing case made to justify further projects in this area?**
- **Is there a strong TCDC component to exploit the benefits from the earlier projects?**
- **Is there a readily available baseline against which to measure the effectiveness of the project?**
- **If the proposal is essentially an extension of previous projects in this area that have been implemented for more than 2 TC Cycles, does the proposal include arrangements for the transfer of project leadership to others?**

Completed templates will be reviewed by the RCA PAC at the Meeting in Vienna planned to be held January / February 2020.

In addition to the above, please address the following specific questions:

Was this concept identified at the 48th RCA GCM as requiring merger with other similar concepts?	YES/NO.
If “YES” – was this concept prepared as a result of consultation with the other proposers?	YES/NO.
If “NO” - why was this not undertaken?	There was no other similar concepts.

Your National Representative will be reviewing this 2nd Draft Concept document to ensure that it has been prepared in compliance with the RCA special requirements.

(Please be aware that, if your concept design does not take account of the special requirements for the RCA programme, it will be rejected.)

Part 2: Concept Template¹

Title:

The title should be as concise as possible and should summarize the objective of the project.

~~*Quality management practices at radiation processing facilities*~~

Improving the quality management practices in radiation processing facilities for better performances and applications

Compliance with the RCA Medium Term Strategy for 2018/2023:

All RCA projects have to comply with the RCA MTS for 2018/2023 - please refer to the MTS document. Briefly indicate to which specific MTS priorities this project proposal contributes and how will these be achieved?

~~Improve safety and efficiency of radiation processing applications for medical products sterilization, material development and food safety. Human resource development and skills retention, including the need to create, manage, share and exploit knowledge, skills and capabilities more effectively.~~

This propose project would contribute to the aligned RCA MTS priority in 1) food and agriculture and SDG targets, Goal 2: End hunger, achieve food security and improved nutrition, and promote sustainable agriculture; and 2) industry sector for SDG targets, Goal 9: to build resilience infrastructure, promote inclusive and sustainable industrialization and foster innovation, of the Regional Programme Framework. It is in line with the RCA strategic direction in building human capacity and a strategic priority in food and agriculture. This work will enable GPs to have the necessary capability and expertise in managing the changes in global food and trading standards.

Overall Objective:

State the objective to which the project will contribute. Note this has to be in line with the RCA MTS for 2018/2023. It should be a short description expressed as: To do

Quality management practices play a vital in radiation processing. It will ensure consistency in the process and enable to achieve the purpose of irradiation processes such as sterilization of medical product, decontamination of food and wire and cable crosslinking. Thus, enhance the economic well-being and contribute to sustainable development within the region

To establish quality management practices in radiation processing facilities of the RCA GPs for ensuring to ensure the process consistency in radiation process system sterilization of medical products, decontamination of food, and wire and cable crosslinking.

RCA Projects are to be designed to have a Socioeconomic Benefit:

¹ If you have not been involved in drafting a concept before and if you are not fully acquainted with the RCA and its Programme you are encouraged to support advice and assistance from your RCA National Representative.

What is the potential socioeconomic benefit that might be realised from the project concept over a 5 to 7-year horizon? Having appropriate quality management practices could benefit radiation processing industry such as less reject, produce product compliance to customer requirement, safer working environment, and penetrate export market

Proposed Participating Government Parties:

List the Government Parties expected to participate in the project:

Malaysia, Sri Langka, Myanmar, Indonesia, Philippines, India, Thailand, Viet Nam, Bangladesh, Jordan, Korea, Republic of (ROK)

1. [Bangladesh](#)
2. [India](#)
3. [Indonesia](#)
4. [Jordan \(non-RCA GP\)](#)
5. [Malaysia](#)
6. [Myanmar](#)
7. [Philippines](#)
8. [Republic of Korea](#)
9. [Sri Lanka](#)
10. [Thailand](#)
11. [Vietnam](#)

Technical Cooperation among Developing Countries (TCDC) Project Component:

Review the resource documentation provided on-line – www.rcaro.org/ ????. Outline the TCDC strategies to be used in the project to enhance regional cooperation:

Will the project design feature partnering arrangements between those advanced and those less advanced in the technology? Yes, provide training workshop at regional level, expert mission- to develop quality management practices at specific countries and provide audit to verify quality system if needed by member states

If so, list those expected partnerships.

~~Example Malaysia/India could help Myanmar/ Sri Langka develop quality management system; SSDL of Malaysia could coordinate inter-comparison of high dosimetry region with the participating member states; Malaysia/India could conduct regional workshop on quality managements practices including dosimetry in radiation processing~~

Through the regional cooperation platform, it will provide support for the sustainability of GPs in fulfilling current and future and requirement in quality management. Almost all expected participating RCA GPs have developed sufficient physical infrastructures are (irradiating equipment and test facilities/laboratories)

and human resources (personnel and staff) as a results of their involvement in earlier regional and national project. National institutes with their infrastructures and facilities will provide the necessary drive in the project implementation through a mixture of technical cooperation among developing countries (TCDC) and partnership between the advanced RCA GPs and those at the lower stage of development. These facilities would provide additional boost in terms of physical infrastructures for the implementation of the project. National laboratories, academic institutions and technology practitioners in each GP will also provide support and extend their resources through involvement as the national project team members. Malaysia, having designated as the IAEA collaborating centre will play a major role in the provision of training facilities and human resources support. RCA GPs recognized with adequate expertise and facilities will contribute their expertise, experience and utilization of their national training programmes for the regional activities. Other participating countries will actively provide assistance in the related supporting logistics. It is expected that the successful implementation of the project will provide benefits to all participating GPs of Asia and the Pacific regions.

Analysis of gaps / problems / needs as applied to the RCA region:

Outline the major gaps / problems/specific needs to be addressed by the project (~ 300 words):

Radiation processing has become a well-accepted technology with over 250 gamma radiation facilities and over 1600 electron beam accelerators working throughout the world. Member States (MS) in Asia have been implementing programs in radiation processing with the assistance of the IAEA over years. Applications such as radiation sterilization of medical devices, food irradiation, polymer crosslinking and curing, phytosanitary treatment and conservation of cultural heritage artifacts have been utilized by MS. However, important aspects of radiation processing such as quality assurance/quality control, dosimetry inter-comparison, microbiology and Quality Management System (QMS) have not received the much-needed attention and support. While a few MS were able to introduce QA/QC and QM procedures, some have had difficulties in initiating and sustaining such vital program. There is a limited technical expertise in some MS and information on implementation of QM practices is not readily available. These gaps are presumed to be addressed in this program with more focus onto basic standard, ISO 9001 and medical devices requirements, ISO 13485. These standards are the best practices for irradiators to implement and expected to be adopted among the participating GPs. There is a limited technical expertise in some MS and information on implementation of QM practices is not readily available. The revised standard (ISO 9001:2015) create challenges to the radiation processing facilities with major changes including a new requirement such as overall risk analysis. GPs especially the operator of radiation processing facilities Besides this basic standard(ISO 9001), radiation processing facilities need to comply with other standards such as ISO13485(Medical devices Quality Management Systems Requirements for Regulatory Purposes), ISO11137(Sterilization of Healthcare Products Requirements for validation and routine control Radiation Sterilization) and ISO 11737(Sterilization of Healthcare products), ISO 13004 (Sterilization of healthcare products Radiation Substantiation of selected sterilization dose: Method VDmax SD), ISO14470(Food Irradiation Requirement for the Development, Validation and Routine Control of process of irradiation using ionizing radiation for treatment of food), inter-comparison for high dose region between laboratories and etc. Countries with longer and more advanced practices could share their expertise and give support to other countries those at lower development through regional/national workshops and expert mission assisting in the development of QMS. Further contribution on this project is as well conducting voluntary audit to verify the compliance and effectiveness of the implemented QMS as well as inter-comparison exercise on dosimetry. In technical meeting in August 2019, MS are requested to initiate the integrated management system which will be the motivation for this project to execute.

Review the resource documentation and list any past RCA projects that have addressed similar problems/needs in this area of technology.

Based on the earlier experiences of IAEA TC programmes over the years in this area in Europe Region (RER1015, RER1017) have collected updating information on the existing gamma and e-beam irradiation facilities, irradiation application, QA/QC/QM procedures in use and applied standard. A new instrument for cooperation/improving/benchmarking. While, in Latin America (RLA1013, RLA 1015) currently running to strengthen QMS implementation. Most country need support to evaluate the QMS according to the recently revised ISO standards and detect the gap to comply with regulations. These gaps should address for food irradiation, medical sterilization as well as polymer modification Based on Europe and Latin America, similar programme is proposed to have an integrated approach to enhance quality management practices at radiation facilities in Asia region.

Previous RCA projects that related with radiation processing facilities are RAS5071, RAS5034 and RAS5050. Those projects had implemented various applications and objectives. RAS5050 is focused on harmonizing standards, protocol and procedures in irradiation of horticultural products. RAS5034 is expected to implement a harmonized protocol on irradiation as a quarantine treatment of fresh horticultural commodities. Thereby, the main concern is on standards or protocol that need to be obliged/fulfilled by the operators of radiation processing facilities.

What are the major additional capabilities/skills in this area of technology that will be provided through this project (~ 200 words).

~~Quality management practiced is the vital part of radiation processing. It is the enabler to achieve the purpose of irradiation effectively and efficiently.~~ Major capabilities to the MS, are sharing the experiences and knowledge on how to set up quality management system (quality assurance and quality control in the validation and routine process control) in accordance to relevant international standards ISO 9001 and ISO 13485. ~~MS could establish inter-comparison exercise for calibrating dosimetry system.~~ Also voluntary audit provided by the advanced MS to verify the compliance of the quality management practice as well as the effectiveness of the quality management practices. When the implementation of the basic standard is in place then the way forward for an ~~As part of~~ integrated management system in radiation processing facilities could be achieved. ~~There are, the~~ This would be the application of the high level structure (Annex SL) for integration, at least quality management system (ISO9001), testing and calibration (ISO/IEC 17025), environment management system (ISO 14001) and occupational health and safety (ISO45001) with further verification of compliance with the IAEA GSR pt.2 and their articulation with good irradiation practices standards (ISO11137, ISO14470 and other reference standards).

Requirements for participation:

Indicate the minimum requirements that the counterpart institutions in Government Parties would need to meet in order to participate in this project.

Counterpart institution should operate radiation processing facilities- gamma or electron beam/x-ray

The participating GPs should have at least the radiation processing procedures or process work flow in their work place. To have radiation processing facilities is an advantage. It will not limited limit to the counterpart institutions listed below:

- 1. Ministries: Science and technology; Health; Industrial; Standard Department
- 2. Regulatory bodies
- 3. Research institutes
- 4. Universities

Stakeholder analysis and partnerships:

Briefly describe who are expected to be the principal beneficiaries of this project and any role that will be defined for them in the project.

Have any extrabudgetary funding possibilities, sponsors and partners been identified?

No Yes, from Malaysia's extrabudgetary.

Have they been involved at this concept stage?

IAEA discussion??KL meeting

The need of proposing this project was first mooted during the consultants' meeting on quality management practices in radiation facilities at Vienna on 3-6 July 2018. During technical meeting on strengthening quality assurance/quality control protocols in radiation facilities through dosimetry inter-comparison at Vienna on 1-5 Oct 2018 it was part of the recommendations. Finally, during technical meeting on QA/QC in management systems for irradiation facilities at Kuala Lumpur on 5-9 August 2019 -was attended by 15 MS in which 8 MS from Asia region have unanimously agreed. During the meeting, the concept ~~stage~~ wasstage was discussed. It was agreed that Malaysia take the ~~lead~~ inlead in preparing the necessary documentation and carrying out the required organizational task. Besides, Malaysia had received additional input regarding other MS (Asia region) regarding their basic needs and expectations in preparing this proposal after the Kuala Lumpur's meeting.

Role of nuclear technology:

Indicate the essential nuclear technique that would be used and outline why it is suitable for addressing the problems/needs in question.

Is this the only available technique?

▲ Nuclear technique is the application of radiation processing using gamma and electron beam/ X-ray facilities. The problems are by having appropriate quality management practices could produce product compliance to customer requirements (achieve the purpose of irradiation) effectively and in efficient manner as well as ensure safe operation of the radiation processing facilities. It will enhance- utilization of nuclear science and technology and contribute to sustainable development within the region.

Does it have a comparative advantage over non-nuclear techniques?

▲ Yes, this technique is a cold and clean process compare to thermal(steam) and chemical process(ethylene oxide)

Duration of the project:

Indicate the number of years required to complete the project.

▲ ~~Two~~Four years

Part 2: National Representative Endorsement for Project Concept

This 2nd Round Concept meets the RCA project requirements and I endorse it as a priority for the RCA Programme 2022/2023.

Signed:



Name:

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