

Information sheet attachment

TO BE SUBMITTED TO THE IAEA BY 26 JUNE 2020

Regional Workshop on Drafting Regulations for Radiation Safety

10-21 of August 2020

**Ref. No.: ME-RER9148-1904669**

Thematic Module on Radiation Safety

QUESTIONNAIRE

COUNTRY:

|  |  |  |
| --- | --- | --- |
| **Names and functions of persons and organizations providing the information in this questionnaire:** | | |
| **Name** | **Function** | **Organization** |
|  |  |  |
|  |  |  |
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|  |  |  |
|  |  |  |
| **Date of completion of this questionnaire:** | ……/……/ 2020 | |

**Background and clarifications**

**1. Purpose**

This questionnaire aims to collect information about on-going or planned efforts to create new or enhance existing regulations in countries of Europe region.

The information that will be collected is intended to provide better support to the participants of the Workshop on Drafting Regulations for Radiation Safety (the workshop henceforth).

**2. Methodology**

The workshop will be organized in accordance with the methodology of the Virtual School of Drafting Regulations (VSDR). The VSDR envisages a process that includes four segments: in-country preparation, pre-work, face-to-face segment (workshop) and community of users.

The VSDR can delivered in the form of various offerings (i.e. each of them with different scope and programme) to facilitate drafting regulations for different thematic areas. In this particular case, the selected offering of the workshop is the combined thematic module on **radiation safety.**

**3. Information requested**

Countries participating in the workshop are kindly requested to provide the Secretariat with information about:

1. The existing legislation (as the legal base of new or amended regulations) and existing regulations to identify what is already subject to regulation and existing gaps and areas for improvement.
2. The regulations on radiation safety that will be developed or revised with the facilitation of the IAEA.
3. The processes that will be followed to complete, approve and issue the regulations under development or revision.

**4. Use of terms**

*Legislation*: refers to legal instruments (e.g. law, act, bill…) passed by a Parliament, the Head of State with the force of law.

*Regulation*: refers to secondary or delegated legislation made by governmental bodies - and in some case public bodies - which have been authorized to issue provisions developing or implementing existing legislation (e.g. a law) that are mandatory for the subject of such legislation.

*Guide:* refers to non-mandatory legislation, intended to provide advice regarding how to best comply with a particular piece of legislation or regulation.

*Authorized party*:refers to the holders of authorizations (either persons or organizations).

**5. Instructions to fill up the questionnaire**

The questionnaire has four parts.

The first part collects information about the legislative organization of the country (section I.1), existing legislation (section I.2) and existing regulations (section I.3). Most of the questions in sections I.2 and I.3 have been posed in a way that can be replied with a yes or a no. Only a limited number of questions require additional clarification. The purpose of these questions is simply to determine if the legislation provide appropriate legal base to develop new or revise existing regulations (section I.2) and if the existing regulations cover relevant IAEA safety requirements (section I.3) within the scope of the selected offering of the workshop.

The second part is intended to better understand the concrete plans of the country towards completing the drafting of new or revised regulations and the procedures and schedule for having them approved.

The third part aims to collect general information about existing practices and radiation sources and the fourth about the technical services available in the country to have a better understanding of the practices and services subject to regulation.

**Deadline for submitting the response to the questionnaire to the Secretariat**

The Secretariat encourages participating countries to complete the questionnaire and send it to the Secretariat no later than **26 June 2020**.

**Part I: Governmental, Legal and Regulatory Framework**

**I.1** **Authorities and processes**

1. Identify which authority(ies) in your country are empowered to issue regulations on radiation safety.
2. Briefly describe the general process followed for preparing, reviewing and issue regulations in your country on radiation safety (e.g. who start the process, which authority issues the regulations, who need to be involved). If there are several types of regulations, please clarify the process for the relevant ones.

1. In general, several governmental authorities may have a role in the regulatory control of ionizing radiation (i.e. Health, Environment, or Labor authorities, customs, etc). Fill in the following table to gain a better understanding of the situation in your country (note: where there is no authority(ies) designated for a particular topic leave the row blank. The same if there are no relevant laws or regulations)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Governmental authorities with a role in the regulatory supervision of:** | **Name of the authority(ies)** | **Functions** | **Legal base of the competence** | **Relevant laws or regulations** |
| Uses of radiation sources in medical applications |  |  |  |  |
| Uses of radiation sources in non-medical applications of radiation (such as industry, agriculture and research) |  |  |  |  |
| Import/export of radiation sources |  |  |  |  |
| Medical exposure |  |  |  |  |
| Occupational exposure |  |  |  |  |
| Public exposure |  |  |  |  |
| Enforcement and prosecution |  |  |  |  |

1. What mechanisms are used in your country to engage authorities with competences for regulating radiation safety in the process of drafting regulations? Are there standing committees or working groups to conduct the process? Which authority takes the lead and coordinate process?

**I.2 Legal Framework**

The information in this table is intended to gain a better understanding about the legal base in the country to draft or revise regulations. The School does not address legal provision. The information will be used only to ascertain if the regulations to be develop or revised are consistent with existing legislation. No details are necessary except where specifically requested.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **no.** | **Question** | **Yes** | **No** | **Comments** |
|  | Does the State have in place **specific legislation on radiation safety**? If yes, please provide a reference |  |  |  |
|  | Does the existing legislation establish an **effectively independent Regulatory Body (RB)** for the regulatory control of radiation safety? If yes, specify the name(s) of the RB(s) and the responsibilities assigned to the RB(s). |  |  |  |
|  | If the RB consists of more than one body, are responsibilities for drafting regulations **clearly defined**. |  |  |  |
|  | Does the existing legislation give the RB **authority to issue regulations** and guides? |  |  |  |
|  | Does the existing legislation give the RB authority to enter a site or a facility to carry out **inspections** to verify observe the conduct of business and verify compliance with legal or regulatory requirements? If yes, clarify if the RB has access at any time or if the access is subjected to certain restrictions. |  |  |  |
|  | Does the existing legislation provide for **enforcement** for the failure to comply with legal and regulatory requirements and specify offences/violations in the matters of radiation safety and the corresponding penalties (criminal, administrative, monetary or other enforcement actions)? |  |  |  |
|  | Does the existing legislation provide for the **justification** of facilities and activities and for the effective implementation of the principles of **optimization and limitation** of doses to individuals? |  |  |  |
|  | Does the existing legislation require to establish and maintain a **national registry of radiation sources**? If yes, please indicate the authority responsible for establishing and maintaining the registry. |  |  |  |
|  | Does the existing legislation provide for establishing arrangements for the **import and export of radioactive sources** in line with the requirements of the IAEA safety standards and with the provisions of the Code of Conduct and complementary guidance at the minimum for category 1 and 2 sealed sources? |  |  |  |
|  | Does the existing legislation provide for adequate infrastructural arrangements are established for **interfaces of safety measures with nuclear security measures** in order to optimize safety with factors relating to nuclear security, to oversight and enforcement to maintain arrangements for safety and nuclear security, to liaise with law enforcements agencies and to integrate emergency arrangements for safety relater and nuclear security related incidents? |  |  |  |

**I.3 Regulatory framework**

The information in this table is intended to know whether existing regulations reasonably cover the provision of the GSR Part 3 or there are gaps. No details are necessary except where specifically requested.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| No. | Provision | Yes | No | Comments |
|  | Does the State have regulations in place on radiation safety? If yes, list the existing regulations. |  |  |  |
|  | Do existing regulations use the concepts of planned, emergency and existing **exposure situations** in line with IAEA Safety Standards? |  |  |  |
|  | Do existing regulations use the concepts of occupational, medical and **public exposure** in line with IAEA Safety Standards? |  |  |  |
|  | Do existing regulations establish requirements for **education, training, qualification and competence** in protection and safety of all persons engaged in activities relevant to protection and safety, including formal recognition of qualified experts and the competence of organizations that have responsibilities relating to protection and safety |  |  |  |
|  | Do existing regulations require persons or organizations intending to operate a facility or to conduct an activity to submit to the RB a **notification** and, as appropriate, an application for **authorization**? |  |  |  |
|  | Do existing regulations determine which practices or sources within practices are to be **exempted** from some or all safety requirements? |  |  |  |
|  | Do existing regulations determine the conditions under which sources, including materials and objects, within notified practices or authorized practices may be **cleared** from regulatory control? |  |  |  |
|  | Do existing regulations on radiation safety specify the responsibilities of authorized parties for protection and safety in **planned exposure situations**? |  |  |  |
|  | Do existing regulations require authorized parties to **justify** any type of practice and for the review of such justification before authorizing the practice and specify those practices that are not deemed justified under any circumstance? |  |  |  |
|  | Do existing regulations provide information about the **process and the authorities** to be involved in the review of the justification? |  |  |  |
|  | Do existing regulations establish requirements for the **optimization** of protection and safety of authorized practices and require authorized parties to apply those requirements? |  |  |  |
|  | Do existing regulations establish **dose limits** for occupational exposure and public exposure during planned exposure situations and require authorized parties to apply those limits? |  |  |  |
|  | Do existing regulations provide for authorized parties to conduct a **safety assessment** and for the regulatory body to review and assess such safety assessment? |  |  |  |
|  | Do existing regulations require authorized parties to conduct **monitoring to verify compliance** with the requirements for protection and safety? |  |  |  |
|  | Do existing regulations require authorized parties to apply good engineering practice and shall take all practicable measures to **prevent accidents** and to mitigate the consequences of those accidents that do occur? |  |  |  |
|  | Do existing regulations require authorized parties to conduct **formal investigations** of abnormal conditions arising in the operation of facilities or the conduct of activities which are significant for protection and to disseminate and made available information about abnormal conditions to the regulatory body and other relevant parties? If yes, do existing regulations specify when authorized parties shall conduct an investigation? |  |  |  |
|  | Do existing regulations establish responsibilities of **manufacturers or other suppliers** for ensuring safety of radiation generators and radioactive sources? |  |  |  |
|  | Do existing regulations establish responsibilities of authorized parties for **ensuring safety** of radiation generators and radioactive sources? |  |  |  |
|  | Do existing regulations establish a **categorization** of sealed sources in line with the IAEA Safety Standards and require the authorized parties to apply such categorization to the sealed sources under their control? |  |  |  |
|  | Do existing regulations require authorized parties to maintain an **inventory** of radiation generators and radioactive sources with records of the location and description of each radiation generator or radioactive source and of the form, activity and category of each radioactive source and to provide information to the RB about the inventory? |  |  |  |
|  | Do existing regulations require authorized parties to make promptly arrangements for the safe management of and control over radiation generators and radioactive sources, including appropriate financial provision, once it has been decided to take them **out of use**? |  |  |  |
|  | Do existing regulations establish responsibilities of authorized parties for the **protection of workers**, including monitoring and recording of occupational exposures, compliance with dose limits for occupational exposure and optimization of protection and safety? |  |  |  |
|  | Do existing regulations require **workers to fulfil their obligations** and carry out their duties for protection and safety? |  |  |  |
|  | Do existing regulations require employers and authorized parties of practices to **cooperate for compliance** with the requirements for protection and safety? |  |  |  |
|  | Do existing regulations require employers, authorized parties to establish a **radiation protection programme for occupational exposure** including organizational, procedural and technical arrangements for designation of controlled and supervised areas, for local rules and for monitoring of the workplace? |  |  |  |
|  | Do existing regulations require employers, authorized parties to make arrangements for **recording and assessing occupational exposures**, for workers’ **health surveillance**, for providing information, instruction and training to the workers and for protection and safety of **female workers** and of **persons under 18 years** of age undergoing training? |  |  |  |
|  | Do existing regulations require establish the responsibilities of registrants, licensees, suppliers and providers of **consumer products** to protect members of the public against exposure? |  |  |  |
|  | Do existing regulations provide for authorized parties to **minimize the generation of radioactive waste** in terms of both activities and volume and that the radioactive waste is managed in accordance with the requirements of applicable IAEA safety standards? |  |  |  |
|  | Do existing regulations require authorized parties to establish programmes for source **monitoring and environmental monitoring**, for recording the results from the monitoring and for making available that information to the RB and to other parties as necessary? |  |  |  |
|  | Do existing regulations provide for authorizing the provision of **consumer products** to the public only when the **justification** of their use by members of the public has been approved by the government or the regulatory body and either their use has been exempted or their provision to the public has been authorized? |  |  |  |
|  | Do existing regulations require authorized parties to ensure that that **no person incurs a medical exposure** unless there has been an appropriate referral, responsibility has been assumed for ensuring protection and safety, and the person subject to exposure has been informed as appropriate of the expected benefits and risks? |  |  |  |
|  | Do existing regulations require the **justification of medical exposures** and the optimization of protection and safety of each medical exposure? If yes, do existing regulations require authorized parties to perform and document dosimetry of patients, to establish diagnostic reference levels for radiological procedures and to use of dose constraints in the optimization of protection and safety in any radiological procedure in which an individual acts as a carer or comforter? |  |  |  |
|  | Do existing regulations require authorized parties to establish a comprehensive programme of **quality assurance for medical exposures**? |  |  |  |
|  | Do existing regulations require authorized parties to make arrangements for appropriate radiation protection in cases where a **female patient is or might be pregnant or is breast-feeding**? |  |  |  |
|  | Do existing regulations require authorized parties to make arrangements to ensure appropriate radiation protection for members of the public and for family members before a patient is **released following radionuclide therapy**? |  |  |  |
|  | Do existing regulations require authorized parties to take all practical measures to **minimize the likelihood of unintended or accidental medical exposures** and to promptly investigate unintended or accidental medical exposures and, if appropriate, implement corrective actions? |  |  |  |
|  | Do existing regulations require authorized parties to periodically perform **reviews at medical radiation facilities and to maintain records**? |  |  |  |
|  | Unless provided for in the legislation, do existing regulations provide for the RB or other relevant authority assigned to establish a protection strategy for an **existing exposure situation** to specify objectives to be achieved and appropriate reference levels and for implementing a protection strategy, including arranging for evaluation of the remedial and protective actions and for ensuring that information is available to individuals subject to exposure about health consequences and means available to reduce exposure and risk? |  |  |  |
|  | Unless provided for in the legislation, do existing regulations provide for the government, the RB or other relevant authority assigned to establish a **protection strategy for an existing exposure** situation to that the protection strategy is commensurate with the radiation risks associated and that the remedial actions yield sufficient benefits to outweigh the detriments associated with taking them and ? |  |  |  |
|  | Do existing regulations provide for requiring the persons or organizations responsible for the planning, implementation and verification of **remedial actions** in areas with residual radioactive material to develop a remedial action plan supported by a safety assessment and including dose estimates, optimize remediation approach, mechanism for public information, monitoring programme, records and procedures, and that such plan will be subject to the review of the RB? |  |  |  |
|  | Do existing regulations provide for requiring the persons or organizations responsible for implementation and verification of remedial actions to conduct the work in accordance with the **remedial action plan** and to inform the RB or other regulatory authority about the outcome of the remedial actions have been completed and about the post-remediation control measures that are needed? |  |  |  |
|  | Do existing regulations provide for assigning responsibility for establishing and implementing an **action plan to 222Rn indoors** and for determining the circumstances under which the measures included in the action plan are mandatory or are voluntary? |  |  |  |
|  | Do existing regulations require authorized parties to ensure that safety measures and nuclear security measures are designed and implemented in an integrated manner so that **nuclear security measures do not compromise safety** and **safety measures do not compromise nuclear security**? |  |  |  |
|  | Do existing regulations require authorized parties to establish and apply an **effective management system** integrating all elements of management so that requirements for safety and for security are established and applied coherently with other requirements? |  |  |  |
|  | Do existing regulations require authorized parties to promote the establishment of a **safety culture** among all individuals and in all bodies involved in the management of radiation sources? |  |  |  |

**Part II: Plan to draft and issue the new or revised regulation(s)**

**II.1 Drafting process**

1. Provide as much details as possible about the regulations that need to be developed or revised in the short term and intended to be presented and discussed in the workshop.

In particular, clarify aspects such as:

* 1. Scope of the regulation: general radiation safety requirements, regulation addressing specific regulatory functions (notification and authorization, inspection…), other.
  2. Type: new regulation(s), revised regulation(s).
  3. Rationale: gap in regulatory framework, outdated regulatory requirements...
  4. Stage of development of drafting/revision: started, planned, under consideration.
  5. Legal base of the regulation.
  6. Will the new regulation will require changes to existing legislation before approving it?
  7. Link to existing regulations (dependent regulations, connected regulations, complementary regulations…)
  8. Will the new or revised regulation will supersede specific articles of existing regulations that will remain in force for the rest?
  9. Expected date for approval of the new or revised regulation.
  10. International and national standards that will used as reference to develop or revise the regulation (including general and specific aspects).
  11. Other relevant subjects.

1. Describe the team that will be responsible for drafting of the new or revised regulation and the coordination and consultation with other competent authorities, interested parties and the public that will take place during the drafting. Describe the competences that will be covered by the team.
2. Describe the team that will participate in the workshop , the areas of competence of each team member and the person/organization who will be leading the team for coordination purposes (note: for an effective participation in the workshop , it is recommended to include 2 persons in the team: one expert on radiation safety and one expert with legal background).
3. Describe any further plan to develop or revised regulations.

**II.2: Issuance and implementation of the new or revised regulation**

1. Describe the process that will be followed to expedite the conclusion of the drafting after the workshop and until the issuance of the new or revised regulation. Explain the steps to be completed and expected outcome of each, including binding or nonbinding consultations with other authorities, parties and the public, and explain if any supporting studies will be required throughout the process (i.e. cost-benefit analysis, compatibility checks with existing legislation or regulation, subsidiarity and administrative burden considerations, environmental impact assessment…).
2. Identify the organization which will lead the implementation of the new or revised regulation once approved and the role of other organizations with responsibilities for implementing or for supporting the implementation of the provisions of the regulation in whole or in part.
3. Explain if after approval of the new or revised regulation any coordination mechanism (task force, working group…) which will be established to coordinate implementation of the provision of the regulation, review and assess the effective and efficient implementation and the benefit and impact of the new regulation.

**Part III: Practices using Ionizing Radiation**

| **Practices using ionizing radiation** | **Yes** | **No** |
| --- | --- | --- |
| **MEDICAL** | | |
| Radiotherapy: |  | |
| * Linear accelerators |  |  |
| * Cobalt Teletherapy |  |  |
| * Manual brachytherapy |  |  |
| * Remote control brachytherapy |  |  |
| Diagnostic and interventional radiology |  |  |
| Dental radiology (alone) |  |  |
| Nuclear medicine (diagnostic and therapeutic) |  |  |
| Nuclear medicine (diagnostic only) |  |  |
| INDUSTRIAL AND RESEARCH | | |
| Irradiators (agricultural, industrial and research) |  |  |
| Industrial radiography: |  | |
| * Gamma source (192Ir, 75Se, 60Co etc.) |  |  |
| * X-ray sources |  |  |
| * other (identified sources) |  |  |
| Well logging devices |  |  |
| Industrial gauges |  | |
| * fixed |  |  |
| * portable / mobile |  |  |
| Analytical techniques (industrial and research): |  | |
| * x-ray diffraction |  |  |
| * x-ray fluorescence spectroscopy |  |  |
| * other (identify sources) |  |  |
| Research activities (industrial and academic laboratories): |  | |
| * sealed sources and generators |  |  |
| * unsealed radioactive material |  |  |
| Mineral extraction and processing facilities involving significant exposure to natural radiation. |  |  |
| OTHER PRACTICES | | |
| Veterinary radiology (diagnostic only) |  |  |
| Veterinary radiology (diagnostic and therapeutic) |  |  |
| Calibration of detectors and equipment |  |  |
| Security equipment (e.g. baggage x-ray, container inspection) |  |  |
| Radioisotopic thermoelectric generators (RTGs) |  |  |
| Other (describe) |  |  |

|  |  |  |
| --- | --- | --- |
| **Disused sealed radioactive sources and radioactive waste** | **Yes** | **No** |
| Are there a centralized waste management facility where disused sources are stored? |  |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Practice/Application** | **Source Category** | | | | | | |
| 1 | | 2 | | 3 | | |
| **Medical** | **Yes** | **No** | **Yes** | **No** | **Yes** | | **No** |
| * Teletherapy |  |  |  |  |  | |  |
| * High/medium dose rate brachytherapy |  |  |  |  |  | |  |
| * Blood irradiators |  |  |  |  |  | |  |
| * Other (specify) |  |  |  |  |  | |  |
| **Non-medical** | **Yes** | **No** | **Yes** | **No** | **Yes** | | **No** |
| * Irradiators |  |  |  |  |  | |  |
| * Industrial Radiography |  |  |  |  |  | |  |
| * Well logging |  |  |  |  |  | |  |
| * Gauges (High activity) |  |  |  |  |  | |  |
| * Radiothermal generators (RTG’s) |  |  |  |  |  | |  |
| * Other (specify) |  |  |  |  |  |  | |

**Part IV: Availability of technical services for radiation protection services**

1. Individual dosimetry service in the country yes 🞏 No 🞏
2. Calibration service in the country (SSDL) yes 🞏 No 🞏
3. Service for the calibration of medical X-ray equipment yes 🞏 No 🞏
4. Accreditation organization in the country yes🞏 No 🞏

1. Standards organization in the country yes 🞏 No 🞏
2. Organizations providing education and training yes🞏 No 🞏