

Updated in September 2020



Impact of COVID-19 Pandemic on the Regulatory Activities for the Safety of Radiation Sources

Version 2

September 2020

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	ANSWERS TO THE IAEA SURVEY ON THE IMPACT OF COVID-19 PANDEMIC ON THE REGULATORY ACTIVITIES FOR THE SAFETY OF RADIATION SOURCES, MAY 2020..	16

1 Introduction

1.1 Survey

The survey on the Impact of the COVID-19 Pandemic on the Regulatory Activities for the Safety of Radiation Sources was designed as a fast 15 minutes exercise for the regulatory bodies that regulate radiation safety and control of radiation sources. First time the survey was sent to all regulatory bodies (RBs) using the Directory of National Regulatory Bodies for the Control of Radiation Sources on the 30th of April 2020. 93 responses were received at 26th of May 2020. Based on the survey answers a report was prepared and disseminated. The report had a positive impact and it was decided to extend the survey for the Countries that had not answered in May 2020. The second survey questionnaire, distributed in August 2020, was slightly modified in the “General Comments” part, which was structured into: “challenges faced by Regulatory Body when executing regulatory programme”; “lessons learned to share”; “new regulatory practices that mitigate COVID-19 restrictions in safety regulation”; “areas where the IAEA Safety Standards could be strengthened”. 30 additional responses were received as 23rd September 2020. The questions of the survey and statistics of 123 regulatory bodies responses are attached in Annex 1.

1.2 Objective and scope

The main objective of the survey is to have a first overview on the impact of the COVID-19 pandemic crisis restrictions on the regulatory activities for the safety of radiation sources and an overview of the reaction of the regulatory bodies. Secondly, the survey aims to understand MSs’ needs in the COVID-19 pandemic situation and its impact on the IAEA Safety Standards. The third objective is to collect notable practices and lessons learned, where applicable.

1.3 Structure of the report

Chapter 1 is introductory and explains the scope and objective of the report. Chapter 2 of the report summarizes the answers provided by the regulatory bodies the areas of potential radiation risks as a result of the pandemic, influence of the pandemic on the regulatory activities and on the level of control over the radiation sources. Chapter 3 covers additional issues that RBs consider important in connection with the COVID-19 pandemic and summarizes recommendations to the IAEA Secretariat for guidance and advice, to ensure radiation safety during such unprecedented pandemic situations.

2 Analysis of the impact of COVID-19

COVID-19 severely influenced all aspects of human activities. The use of radiation sources and regulation of the safety of the sources are an integral part of the global activities and cannot avoid the impact of the COVID-19 pandemic. This impact is present in the financial and human resources, logistics, and other radiation safety infrastructure elements. Analysis of the impact gives IAEA and MSs a first evaluation on the improvements that should be made in preparation for any future pandemic.

2.1 General Information

National regulatory bodies from 127 Countries provided their feedback on the impact of COVID-19 pandemic on the regulatory activities for the safety of radiation sources. Regulatory bodies from 123 Countries answered the questions of the Survey of Impact of COVID-19 Pandemic on the Regulatory Activities for the Safety of Radiation Sources: **Albania, Angola, Antigua and Barbuda, Argentina, Armenia, Australia, Bahamas, Kingdom of Bahrain, Bangladesh, Barbados, Belgium, Bosnia and Herzegovina, Botswana, Brazil, Bulgaria, Burkina Faso, Cambodia, Cameroon, Canada, Central African Republic, Chad, Chile, China, Colombia, Republic of Congo, Costa Rica, Cote d'Ivoire, Croatia, Cuba, Czech Republic, Cyprus, Denmark, Dominica, Dominican Republic, El Salvador, Ecuador, Egypt, England, Ethiopia, Finland, France, Gabon, Ghana, Georgia, Germany, Greece, Guatemala, Guyana, Haiti, Honduras, Hungary, Iceland, Iran, Iraq, Ireland, Jamaica, Jordan, Kenya, Republic of Korea, Kuwait, Kyrgyzstan, Latvia, Lebanon, Lithuania, Luxemburg, Madagascar, Malawi, Malaysia, Mali, Malta, Mauritania, Mauritius, Mexico, Moldova, Mongolia, Montenegro, Morocco, Mozambique, Myanmar, Namibia, Netherlands, Nicaragua, Niger, Nigeria, North Ireland, Northern Macedonia, Norway, Kingdom of Saudi Arabia, Oman, Panama, Papua New Guinea, Paraguay, Peru, Philippines, Poland, Qatar, Romania, Rwanda, Senegal, Serbia, Seychelles, Singapore, Slovak Republic, Slovenia, South Africa, Spain, Sri Lanka, Sudan, Sweden, Switzerland, Syrian Arab Republic, Thailand, Togo, Tunisia, Uganda, Ukraine, United Arab Emirates, United Republic of Tanzania, United States of America, Uruguay, Venezuela, Viet Nam, and Zimbabwe.** Additionally, regulatory bodies provided their feedback on the COVID-19 impact during online meetings¹. IAEA in cooperation with regional RBs' organizations/forums conducted 4 online meetings with regulatory bodies in different regions (Latin America, Africa, Europe, and Asia and the Pacific). 308 regulators participated in these online events. During these meetings all RBs had the opportunity to provide feedback and comments about challenges faced by each regulatory body when executing regulatory programme; lessons learned; new regulatory practices that mitigate COVID-19 restrictions in safety regulation; and areas where the IAEA Safety Standards could be strengthened.

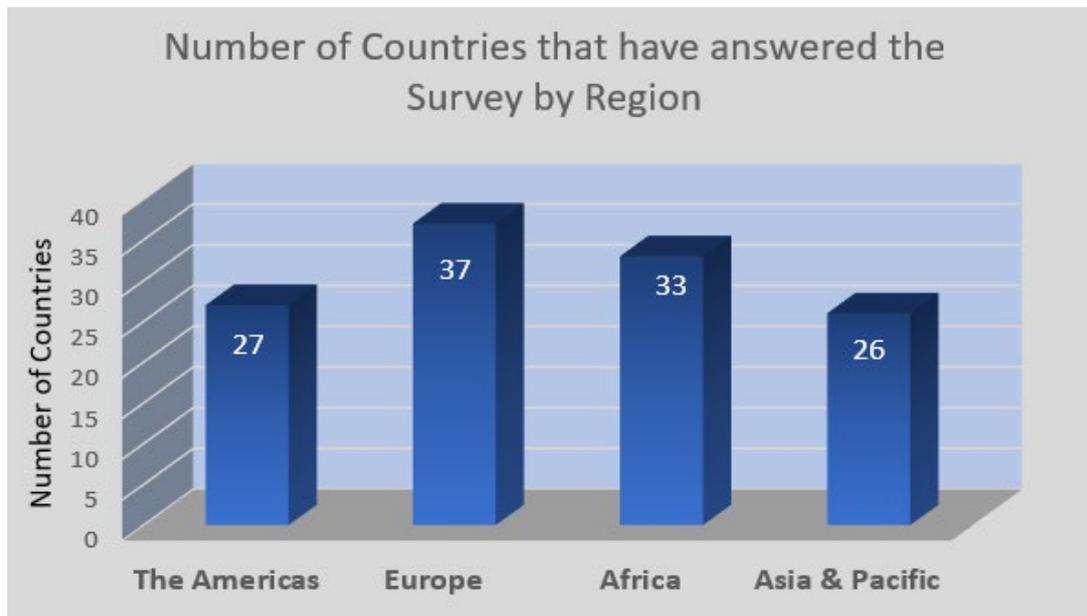


Fig1. Number of Countries' RBs that have answered the Survey by Region

¹Belarus, India, Portugal, and Russian Federation

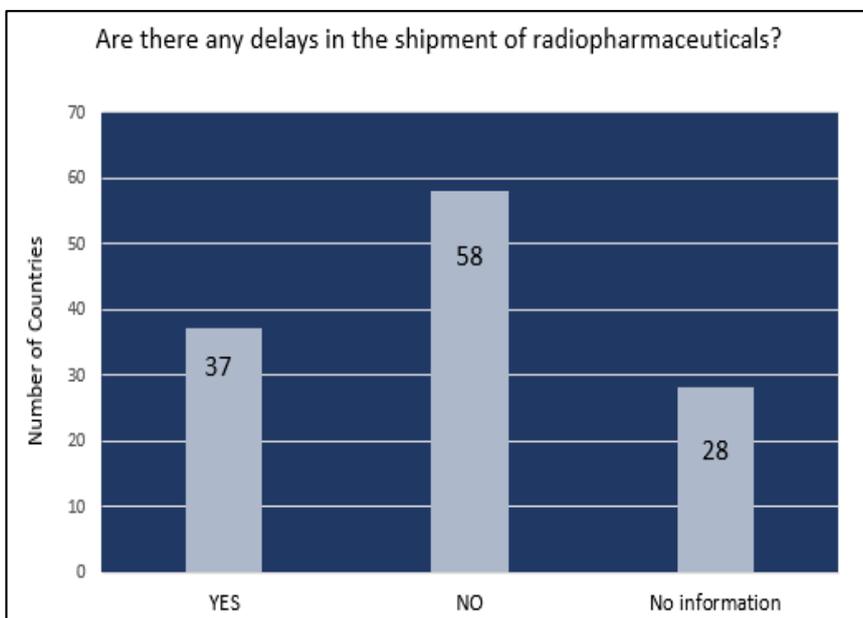
2.2 Special circumstances and potential radiation risks in the COVID-19 situation

2.2.1 Special circumstances connected to the COVID-19 pandemic

Special circumstances differ from country to country; however, these circumstances can be summarised as following:

Almost half of the MSs' regulatory bodies (RBs) reported certain radiation facilities as locked down and the ceasing of activities with radiation sources. However, continual functions of facilities that are part of the critical national infrastructure are reported by almost all RBs, such as medical facilities and certain industrial facilities. Countries continue production of radiopharmaceuticals, management of disused sources, research activities, security checks and transport of radioactive material. However, it was reported that technical services (dosimetry, monitoring, calibration, emergency response, return of the disused sources, training etc.) are often provided not in a full scope, especially when service was provided from abroad. In some MSs the use of radiation sources for sterilization of protective equipment, veterinary, educational and dental purposes and use of gauges has not been suspended.

Similarly, many RBs noted that personnel important for safety are available in the facilities (such as



radiation protection officers, radiologists, medical physicists, medical technicians). However, RBs indicate that these personnel are affected by SARS-Cov2 disease, transportation problems (stopping of the public transport, bans for the free moving²) and quarantine established for the elder people. Some MSs suffer from delays in the shipment of radiopharmaceuticals (Fig 2), while in some MSs certain shipments of radioactive sources are delayed due to quarantine

practices.

Fig 2 Delays in the shipment of radiopharmaceuticals

Several RBs mentioned that return of the disused sources was not possible due to the canceled flights. RBs reported delays in Co-60

radiotherapy source and Ir-192 radiography sources import and exchange of Ir-192 brahytherapy sources. Two RBs noted that some shipments have been postponed to support social distancing, for example, shipment of high active waste was postponed due to risk of spreading COVID-19 among personnel involved in safety and security measures. One RB considers that due to shipments cancellations and delays there is a need to strengthen the control over storage facilities related to transport.

² The same problem appears with RBs' inspectors – see Section 2.3.5

In most of the MSs internal public transport was/is stopped as well as international transport. Where radioactive sources are transported only by air shipments are cut off. Transport bans influence not only shipment of radioactive material but also availability of the personnel vital for safety at the facilities such as radiation protection officers, radiologists, medical physicists, medical technicians and regulators for programme implementation (see 2.3). One RB is concerned that due to travel restriction (inside the country) movement of some sources (such as industrial radiography devices) is complicated and may lead to industrial safety problems. One RB noted that insurance in general does not provide coverage for events occurring in pandemics or other catastrophes.

Users requested the regulatory body to accelerate and simplify import and export of radiation sources authorization procedures, to develop guidance on the authorization procedures for COVID-19 related diagnostic radiation equipment and protocols for safe use of mobile X-ray units in patient rooms and triage tents.

Notable practices from Regulatory Bodies:

- Shipments of radiopharmaceuticals have been delayed due to the lack of air transport options and competition for air freight space. Letters have been sent to the major airlines by nuclear medicine professional associations appealing for priority to be given to radiopharmaceutical shipments.
- Regarding the supply of medical isotopes, a working group was established that monitor medical isotope supply chains and reports any issues in regular intervals. It is expected that nuclear medicine procedures will be increased and resumed, but no shortage of medical isotopes is expected. The transportation routes have been gradually increased with more operating scheduled flights.
- RB was informed that licensees co-operated and shared lung imaging protocols of computed tomography (CT) for Covid-19 patients in intensive care.

Lessons Learned:

- The emergencies' critical infrastructure list should include: transport and arrangements for the free moving for the facility personnel that is important for safety and radiation protection and inspectors; providing international and internal transport of critical radiation sources such as radiopharmaceuticals; availability of the technical services that are important for safety of radiation sources, including services provided from abroad; reliable network for the remote work.

2.1.2 Potential radiation risks due to the COVID-19 situation

RBs that answered positively have concerns in the area of reduced regulatory oversight, financial failure of the users to ensure safety and security of the radiation sources, including disused radioactive sources; lack of medical staff for the medical use of radiation sources; unjustified exposures and technical services provision. The following information in the survey has been presented as potential risks:

- Reduced oversight of facilities and activities by the regulatory body,
- Economic crisis may lead to State budget and staff reduction for the regulatory body,
 - Prolonged economic strain may affect operators' capabilities of taking care of the radioactive sources and/or decommissioning and export of radioactive sources (disused sources return to the supplier or return of the temporary imported sources),
- Number of orphan sources may increase due to the possible closure of business operations in connection to the economic situation. Physical protection may not be ensured due to facilities lock down and /or limited number of security personnel. Security biometric devices may be a source of a virus spread,

- Reduced number of medical staff in radiotherapy and nuclear medicine facilities (physicians, nurses, etc.). In some facilities, these professionals are moved to assist with COVID-19 patients. Additionally, many treatments are postponed, and extreme workload is expected after the end of the crisis,
- Medical exposures: Unjustified radiation exposures for suspected SARS-Cov2 and asymptomatic patients; use of the equipment for different practices other than the ones being authorized (for example, portable x-ray machines are used in standard rooms); high workload of the staff in charge of X-ray equipment; unqualified staff carrying out examinations as qualified staff is not allowed to visit “hot” zones; usage of nuclear medicine rooms for the COVID-19 patients among others,
- Technical service providers temporarily reduced or stopped services. Most often potential safety problems are mentioned due to the following services termination: performing quality control (QC) of radiation generators and radioactive sources; radiological monitoring of the workplace; training in radiation protection, radiation sources equipment maintenance and tests; technical services that are provided by foreign service providers.

One Country reported that during the incident with the radioactive source emergency response service was not available in time and in the full scope.

Notable practices from Regulatory Bodies:

- During the crisis a special attention was paid by the regulatory body to the potential risk of Cobalt-60 irradiation facilities for sterilization of medical protective clothing, masks, etc. that suffered from reduced personnel and increased working pressure. During the crisis video monitoring and other means were used to strengthen supervision.

Lessons Learned:

- Regulatory bodies, health authorities and professional bodies need to have guidance for medical exposure in the case of medical emergencies considering unjustified radiation exposures and optimization.
- Regulatory bodies need to be prepared to reorganize their activities for X-ray equipment use in the hospitals: expedite the process of authorization and commissioning process, authorization of use of the premises and equipment in special circumstances; providing recommendations on dealing with the high workload and lack of qualified staff, training of the additional staff that is allowed to work in the “hot” zone.
- Prescriptive regulatory requirements that are established at the level of the law do not allow regulatory bodies to adjust their regulatory activities to the crisis limitations (established in the law frequency of tests, no options for authorization validity extension, requirement for the inspection visit before license issuing, etc.);
- Regulatory bodies need to be prepared to address the limited financial resources of the users and regulatory bodies themselves after the significant situations that are followed by economical crisis.
- Governments need to ensure availability of important radiation safety technical services as part of the critical infrastructure and ensure delivery of the technical services from abroad if applicable.

2.3 Regulatory activities in COVID-19 situation

2.3.1 Introduction

In most of the MSs, the regulatory activities were affected by the COVID-19 situation (Fig3) and it is reported that majority of regulatory bodies were/are³ not currently implementing a full scope regulatory programme as was before the COVID-19

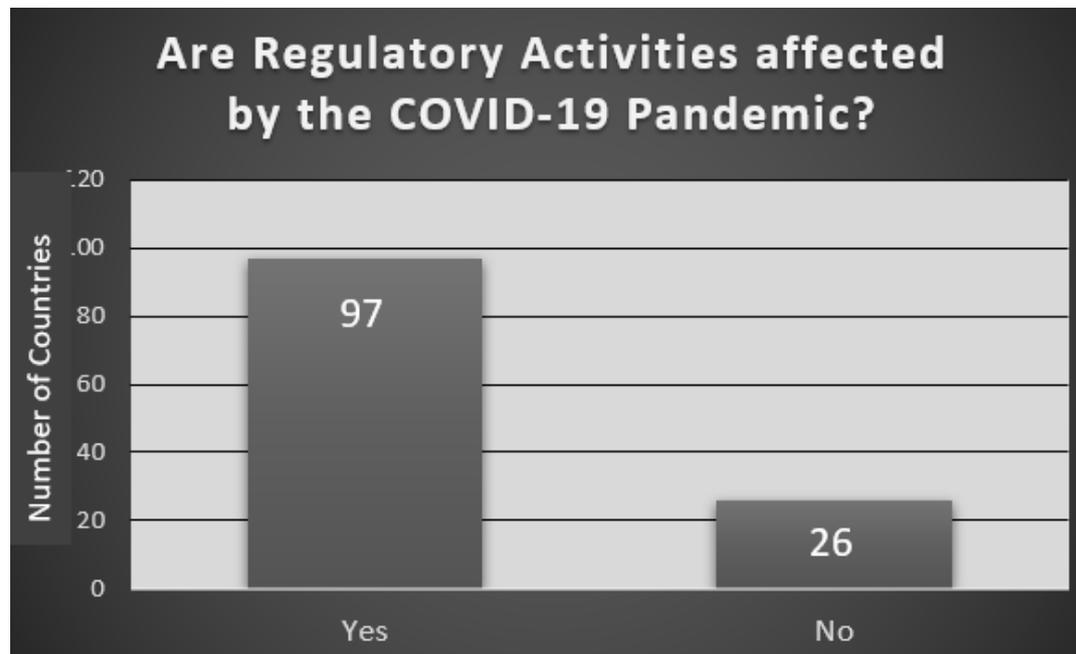


Fig 3 Regulatory activities affected by COVID-19

pandemic crisis. Only in a few regulatory bodies, their premises were/are not under quarantine conditions. In the majority of the RBs, only critical personnel worked/works from the office. One RB mentioned that working from home was not efficient due to the quality of internet connection and also for the staff having young children, this RB stressed that female staff was seriously challenged.

The survey shows that there has been a notable effort by regulatory bodies in their approach to organise and implement their core activities during the COVID-19 pandemic.

Notable practices from Regulatory Bodies:

- RBs developed and implemented special measures to protect their personnel. These measures included: working remotely; development of the schedules with minimum staff on duty; working in shifts that are not contacting with each other; rearrangement of the working places; providing of the personal protective equipment for the inspectors.
- Additional information about measures adopted and/or imposed by the regulatory body have been posted at the RB's information website (in several languages).
- A general survey on the impact of COVID-19 has been sent to the licensees.

³ In many Countries quarantine ended in June-August 2020.

- RB has sent a general email to all licensees letting them know that RB is working and available to assist if there are any licence amendments required or emergencies. RB also contacted 30-40 higher risk licensees to check their situation. RB is also taking the time to catch up on preparing guidance documents.
- RB defined a Contact Point person at each radiation facility and was constantly in touch with this person;
- RB has established an action plan to continue and pursue the regulatory activities adopting Information and Communications Technologies. RB has established IT tools to facilitate the information exchange and follow up actions with licensees on regulatory issues.
- RB established COVID-19 Operational Headquarters.
- RB collected COVID-19 crisis feedback from radiation sources users on how the regulations can be improved.
- RB intensified exchange of information and interaction with the other authorities with radiation safety regulatory functions, including authorities that are responsible for health and labour protection.
- RB worked closely with the professional societies (radiotherapy, nuclear medicine, medical physics, radiology) so that they produced recommendations.
- RB issued regulatory positions during the pandemic for such as extension of reporting period for regular monitoring results and longer period for accumulation of radioactive waste to enable licensees comply with license conditions.

Lessons Learned:

- Regulatory bodies need to revise management systems including all procedures to be prepared for the activities in non-radiological crisis.
- Regulatory bodies need to revise regulatory requirements to consider pandemic crisis feedback.

2.3.2 Emergency preparedness

About half of MSs' regulatory bodies activated their radiological emergency centres. This activation indicates that there is no clear position among RBs as to whether medical emergencies should be considered as a situation that needs radiological emergency responses.

For example, position of the RB in one country is that regulatory body staff is not physically present in the Radiological Emergency Center and they do not follow up the developments at the regulated facilities.

Notable practices from Regulatory Bodies:

The emergency management exercise for to be checked according to the new statistics COVID-19 response and correlation was organized.

2.3.3 Communications

Since regulatory body staff is working from home it is very important to have good communication. The majority of the RBs reported that they do not have any internal communication problems. Very few RBs also reported problems of communicating with other authorities and in communicating with applicants and licensees.

Notable practice from Regulatory Bodies:

- RB is fully operational remotely with laptops loaded with all regulatory files for each staff. All related authorities, like customs, national airlines and security agency are fully operational and import/export control of radioactive sources is fully implemented.
- COVID-19 Communication Team is operating;
- Electronic communication channels to all licensees are developed. All licenses should submit annual reports to RB. The submission is made through the special secure electronic channel. RB staff review reports and produce feedbacks.
- Constant communication with the Radiation Safety Officers is ensured.
- New guidance for the licensees to apply for a regulatory consideration based on their situation with COVID-19 was developed.

2.3.4 Authorization

Less than half of the regulatory bodies are able to fully implement their authorization programme (Fig 4). For the RBs that implement the authorization programme in a limited scope the reasons are inspectors staying home and lockdown of the facilities. In several States special authorization procedures (import/export and usage) are developed for the equipment using radiation sources that is important for combatting COVID-19. In some Countries the law requires an inspection to be done before the authorization is granted and the lockdown has delayed the authorization of facilities and activities. Many RBs that authorization electronic systems are implemented. Such systems are working without face-to-face contacts and allow to fulfill authorization programme in a full scope during the pandemic quarantine.

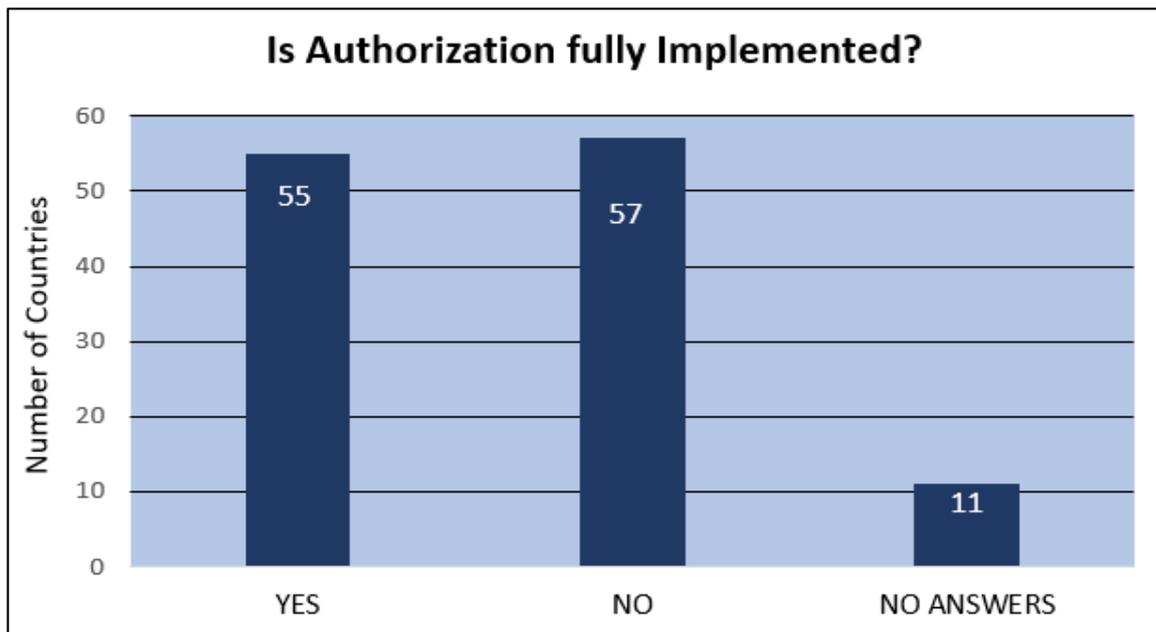


Fig 4 Implementation of the authorization programme

Notable practices from Regulatory Bodies:

- During the COVID-19 pandemic RB developed a special procedure for authorizing dedicated to COVID clinics. Such procedure is developed in order to facilitate authorization of diagnostic practices in dedicated clinics dealing with potential COVID-19 infected patients. Procedure allows for the fast development and review of the licensing submittals that consist of relevant data on the x-ray device(s) used, staff and area where the practice is being performed;

- During the COVID-19 situation, inspectors are continuously working on-line in terms of licensing, evaluating license applications and authorizing import and transport of radioactive materials. Their inspection agency developed the online licensing system and each license holder submits the application electronically;
- RB in implementing its authorization/licensing activities consolidated some of the administrative aspects of reviews. In addition, several administrative tasks have been digitized and streamlined to support the increased use of telework;
- Authorization process is performed by remote digital way;
- Regulatory body produces transport certificate immediately through online;
- Modifications are done of the authorised regulated activities for alternative solutions to achieve the same safety, security, and safeguards outcome, e.g.: facsimile signature supported by additional communication, extension in individual monitoring periods for medium and low risk activities, changes in QC and maintenance schedules, more frequent inventory and dose records reporting, permit to store more disused sources, more frequent evaluation of radiation burden due to screening of potential COVID-19 patients, etc.;
- Local RBs have been encouraged to use, where appropriate, their margin of discretion widely when applying the radiation protection requirements in order to meet the challenges due to the COVID-19 pandemic;
- RBs may deviate from legally non-binding regulatory guidance where their application seems to be inappropriate, e.g. where the availability of the required medical staff according to the guidance cannot be ensured;
- An ordinance on the suspension of deadlines in civil and administrative proceedings was introduced during the pandemic;
- Issuance of over 100 emergent licensing actions to provide regulatory relief or exempt licensees from certain requirements to enable social distancing and personnel protection;
- Validity of authorizations:
 - o the validity of licences of the facilities and activities with expiration date during the crisis have been extended and temporary licences were issued without certain submittals provided that the licensees will send the documents when the crisis end;
 - o a national decree is applied where authorizations that expire during the emergency period remain in force until one month after the end of the emergency;
 - o Certificates of Radiation Protection Officers were extended by RB for 6 months;
- RB authorized an extension of the measurement period for determining radiation doses.

Lessons Learned:

- Improvements in digital infrastructure and quality for remote work and video conferences are necessary.
- Electronic authorization systems make RBs' authorization programme resistant to pandemic crisis.
- Secure and easy remote access to the regulatory information management system and the electronic documents provided by the applicants need to be insured for the relevant regulatory staff.
- Authorization and permits issuing working load may increase due to increasing number of amendments connected to the crisis limitations.

2.3.5 Inspection

Almost all RBs did/do not implement their inspection programme fully (Fig 5). Many RBs decided to limit physical inspection visits using a graded approach only to the safety most significant facilities. The following reasons are listed: inspectors staying home/social distancing; staff from the facilities staying at home, lockdown of the facilities; duty travel restrictions; transport limitations, and prohibition to enter medical facilities. Several RBs mentioned that inspectors could not enter the facilities to conduct inspection especially medical facilities.

In several MSs, governmental decisions were taken to impose a moratorium for all types of inspections. Two RBs decided to postpone physical inspections to medical facilities that are combatting COVID-19 in order to reduce the burden on the facilities. On the contrary, another RB, continues inspections only for the medical facilities. Several RBs mentioned that they decided to minimise regulatory supervision burden on all authorised persons during the crisis. Some RBs have reported the use of certain virtual inspection elements, however a comprehensive virtual inspection have not been implemented. One RB concluded that some inspections are more suitable to be performed while remote/teleworking such as those that are data and document review oriented while others require onsite presence. One RB identified the need for secure communication systems and data storage to implement remote inspections and exchange of sensitive information.

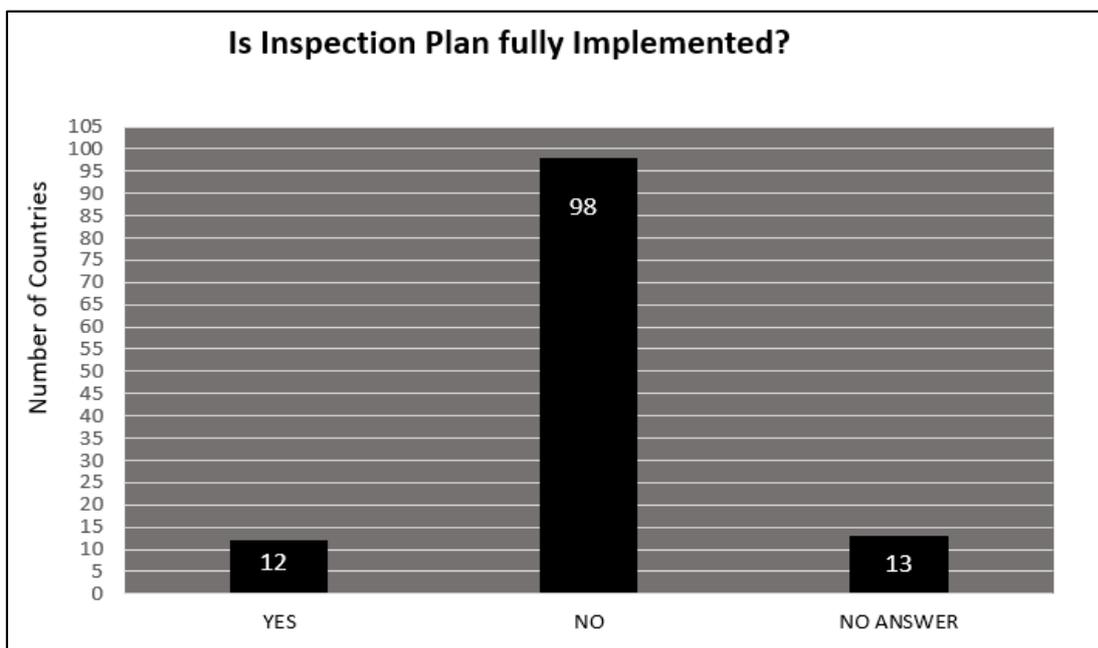


Fig 5 Implementation of the Inspection Plan

Notable practice from Regulatory Bodies:

- Graded approach is adopted during the crisis period. Inspections are only conducted at essential facilities such as medical facilities;
- Remote⁴ inspections are carried out for smaller operators;

⁴ Supervising activities without the physical visits to the facility are referred as “remote inspections”, ‘administrative inspections”, “virtual inspections”, “electronic inspections”, etc.

- Physical inspections visits are done only to the medium-high risk facilities; virtual inspections are taking place;
- No physical inspections to the users with the history of the development of good user practices;
- Physical inspections as response to incidents and accidents and other essential reactive inspections are carried out;
- A combination of remote and focused on-site inspections is currently being conducted in consideration of local conditions and necessary precautions for each facility. RB management continues to evaluate future inspections on a case-by-case basis to determine if inspections should be deferred, conducted on-site, remotely, or a combination thereof;
- Overall, the oversight of the users is maintained aside from the physical inspection that are typically performed on site. During quarantine only desktop review of information submitted by licensees are conducted, such as the review of event reports and the assessment of annual compliance reports. The organisation is ready to deploy if there is a need (i.e. emergency) as inspectors have all the required personal protective equipment. Plans are being developed for resuming physical inspections in the field;
- RB has used document reviews and teleconferences to reduce the time for onsite inspections.;
- At the end of the lock-down period RB issued inspection guidance on transition from COVID-19 telework to the nuclear materials and waste safety program;
- Passes were issued by the Government for the inspectors that allowed them to move without any restrictions during the quarantine; and
- Personal hygiene protocols and disinfection protocols for the equipment and accessories used during inspections are introduced for the safety of inspectors.

RBs in almost all MSs applied measures that compensate the limited scope of inspections with physical presence of the inspectors in the facilities. Such measures include video conferences (reported by more than one third of the RBs) for checking documents and doing interviews, regular reporting by licensees (many RBs), using other authorities' inspection information (some RBs); telephone conferences; communication with operators by e-mail or by phone. One RB mentioned that the regulatory body analysed the information gathered from various information systems or provided by service providers (quality control, dose rate measurements, etc.). Another RB use a radiation source tracking system.

RBs that have renewed after crisis their inspections to the facilities are making both planned and postponed inspection visits that leads to the high working load.

Notable practice from Regulatory Bodies:

- Hospitals which use radioisotopes are online monitored 24/7.

Several RBs established specific reporting requirements as a substitute to the physical inspection during the quarantine period such as: self-assessment of the compliance with regulations and authorization conditions; the status of the installation and implementation of the Radiation Protection Program; reports on the management of the workforce, management of activities during facility shutdowns, safety and security; and requirement to report if any difficulties with regards to radiation safety due to the COVID-19 prevention measures are foreseen or experienced.

Notable practice from Regulatory Bodies:

- Regularly reporting requirement on the Covid-19 situation has been established towards the users.

Some RBs introduced remote inspections' practice asking images and following the process of inspections to gather information from the facility.

Notable practice from Regulatory Bodies:

- Remote inspections are taking place via Microsoft Teams interviews and document reviews.
- RB gives 2 weeks' notice and the licensees upload a list of specified documents to the regulatory body portal in advance; regulatory body reviews and ask a series of questions from inspection form and can ask further questions or clarifications if required. The 'inspection' can be done by MS Teams or by phone. Report is issued and authorized person has 28 days to upload the response to any findings.
- Remote inspection by Video Conference, using photographs and videos and collecting information electronically are done.

Lessons Learned:

- Some inspections are more suitable to be performed remotely such as those that are data and document review oriented while others require onsite presence.
- Developing priority areas, standards and expectations is important for assessing compliance using remote inspections
- After the end of quarantine and renewal of the inspection visits RBs need to be prepared for the increased number of inspections to catch up postponed inspections visits that leads to the high working load.

2.3.6 Other postponed global and regulatory activities

Many international activities are postponed. For example, an exit meeting of an IRRS follow-up Mission had to be completed by video calls. Physical attendance at NEA/ICRP/IAEA meetings such as the IAEA Safety Standards Committee meetings is halted. One RB mentioned that development of regulations and guides is on hold; the other RB noticed that national regulations' approval procedure includes involvement of many stakeholders and proved to be very lengthy in quarantine situation; however, some other RBs reported active work on the regulation's promulgation. One RB informed about the cancellation of radiation protection training sessions and awareness campaign. The RB in the other MS is concerned that COVID-19 pandemic has disrupted the adoption and enactment of nuclear laws, as well as establishment of the regulatory body, although this is a current Government priority.

Several RBs reported cancellations of the training events for users, radiation protection experts and RB staff. They reported that converting training into the remote mode was an issue and took significant efforts.

Opportunities:

- Several RBs concluded that pandemic crisis provided new opportunities in the postcrisis regulatory activities' development by facilitating graded approach and promoting remote techniques and new information technologies. For example, inspections that include remote techniques may become not a crisis but routine RB's instrument.

- Some RBs reported that quarantine time was an opportunity for intensifying development of legislation, development of internal procedures, distance staff training, administrative search for the orphan sources, etc.

2.4 Radioactive sources

Many of the RBs continue to authorize import and export of radioactive sources and few RBs report that safe storage of radioactive sources is not provided if delivery of the imported source to the end user is delayed. In most of the MSs safe management of any detected orphan sources is not influenced by the pandemic. Less than a half of MSs are notified of the operational difficulties of the radiation sources used in facilities and activities.

3. Recommendations from the Member States

More than half of the responses from the MSs' regulatory bodies include recommendations for the development and improvement of IAEA documents in the area of safety, based on the lessons learned from the COVID-19 pandemic. Proposals in how IAEA Safety Standards could be strengthened have

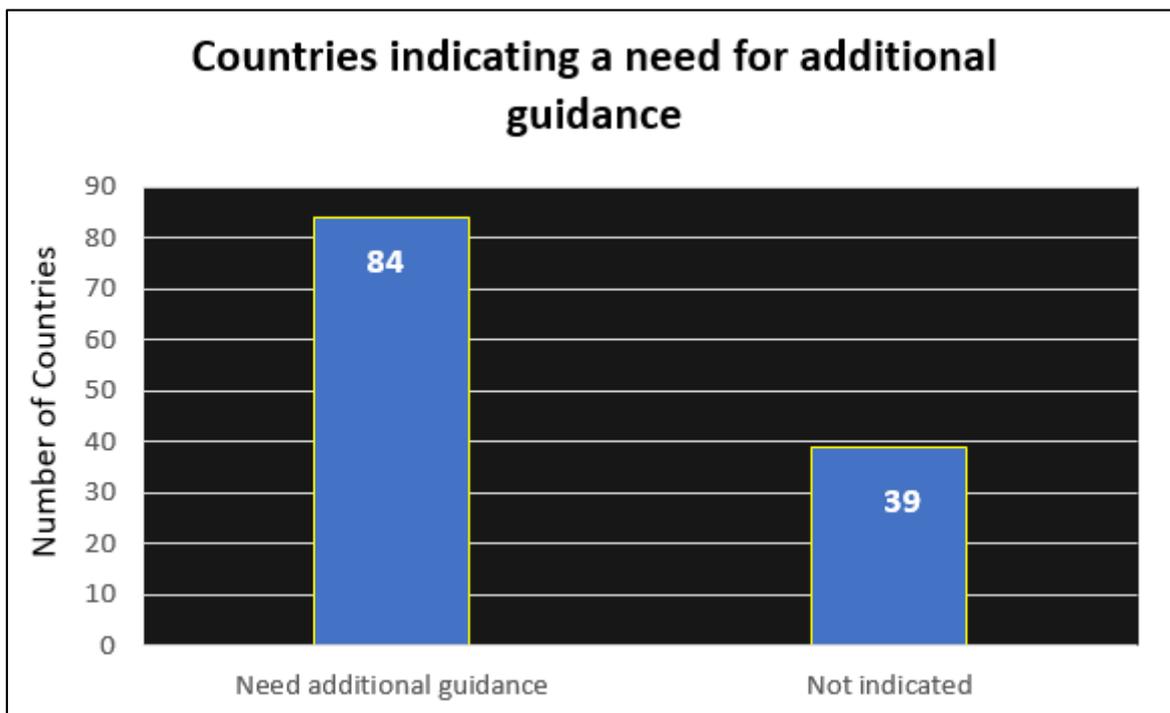


Fig 6 Need for additional IAEA guidance on pandemic situations

been suggested. MSs' regulatory bodies proposals from the surveys can be summarised as follows:

1. It is proposed to provide guidance on the regulatory activities in the crisis (pandemic/medical emergency/disaster//quarantine/social restrictions). According to the RBs proposals it may cover the following aspects:
 - Contingency plan for regulatory activities during crisis, the graded approach in temporary reducing of the regulatory programme, prioritization of services provided by the regulatory body during the lock down, etc.;

- Self-assessment of the compliance with regulatory requirements and authorization conditions by the applicants/authorised persons;
 - How to conduct remote inspections during crisis and advice on the other oversight mechanisms to be used in crisis (inspections should cover how the licensees manage the impact during the pandemic, in particular, on the fact how licensees provide reliable human resources and competencies, inspectors should have enhanced access to licensee systems and programs, etc.);
 - Specific reporting to the regulatory body during crisis as a substitute to physical inspections;
 - Inspectors' protection and other aspects of the physical inspection visits to the facilities with potential health risk;
 - Situations when activities with radiation sources should be stopped;
 - Teleworking, virtual communication as a mechanism for meetings, in-house measures for those working from the office and overall development of electronic communication systems for the regulatory bodies,
 - Inspectors' non-radiological personal protection,
 - The communication strategy with the stakeholders in pandemic situation,
 - Facilitating communications between neighbouring countries to ensure import and export of radioactive sources during pandemic.
2. It is proposed to develop recommendations regarding specific radiation safety and protection measures during a pandemic situation. RBs advise that the following aspects may be covered:
- Specificity of the justification of medical exposure in medical emergency. For example, low dose CT protocol for chest CT COVID-19 imaging for management of confirmed COVID-19 patients may be justified, but higher dose chest CT for initial diagnostic imaging of non-confirmed patient may not be justified;
 - Optimization and temporary reference levels for medical emergency;
 - Procedures for a safe use of radiation sources when potential biological or chemical hazards are present;
 - Requirement to the licensees to define a safety and radiation protection continuity plan defining, besides technical means, the human and organizational necessities in a pandemic situation. The plan should ensure availability of enough staff at the facilities in crisis, which means invoking measures for protecting the people, i.e. users should have a procedure to deal with the pandemic and the necessary protective equipment for a specified period;
 - Specific requirements for the facility radiation protection officer in quarantine situation; and
 - Determination of essential and non-essential activities (such as outages, maintenance and testing and other routine activities).
3. It is proposed to prepare recommendations on the radiation safety part of the national pandemic response plan in terms of transport, communications, radiation safety inspections, provision of technical services (QC, dosimetry, calibration, monitoring), health and other anti-pandemic measures and extra supplies of protective equipment. The radiation facilities which are necessary from the national point of view (so called critical infrastructure) should be identified and given priority.

One RB requested IAEA advice on how to deal with the problems associated with the delays in the Technical Cooperation and extrabudgetary projects at the national and regional levels.

Three RBs proposed to prepare training/exercises for the regulatory activities in the pandemic situation. Another RB recommend developing a webinar in IAEA languages, encouraging regulatory bodies to take the adequate oversight measures, mainly in the inspections process. One RB recommended to include COVID-19 impact on regulatory activities topic into the agenda of the next Open-Ended Meeting of Technical and Legal Experts for Sharing Information on States' Implementation of the Code of Conduct on the Safety and Security of Radioactive Sources and its Supplementary Guidance.

Annex 1:

Answers to the IAEA Survey on the Impact of COVID-19 Pandemic on the Regulatory Activities for the Safety of Radiation Sources, September 2020

Introduction

- A total of 123 countries participated in the survey
- When answers have not been provided, only the specific question without an answer was not considered in the statistics
- No questionnaire was rendered void

PART II. Potential radiation risks in the COVID-19 situation

4. What are the special circumstances connected to COVID-19 in the Country?

4.1 Are certain radiation facilities locked down and activities stopped?

56 regulatory bodies answered Yes;

61 regulatory bodies answered No;

6 regulatory body indicated they have no information;

4.2 Are certain facilities with radiation sources operating and activities being conducted?

4.21. Medical facilities

120 regulatory bodies answered Yes;

3 regulatory bodies answered No;

4.22. Industrial facilities

97 regulatory bodies answered Yes;

12 regulatory bodies answered No;

11 regulatory bodies answered No Information;

3 regulatory body did not answer this question;

4.23. other facilities

(please specify):

- *Details provided in the report*

4.3. Are personnel important for safety available for the facilities (such as radiation protection officers, radiologists, medical physicists, medical technicians)?

112 regulatory bodies answered Yes;

4 regulatory bodies answered No;

7 regulatory bodies indicated they have no information;

4.31 If NO, please indicate the reasons:

4 regulatory bodies indicated staying home;

4 regulatory bodies indicated staying home and transport problems;

1 regulatory body indicated transport problems and illness;

Other reasons:

- *Details provided in the report*

- 4.4. Is transport of the radioactive materials affected:

4.41. Are there any delays in the radiopharmaceuticals' shipment?

37 regulatory bodies answered Yes;

58 regulatory bodies answered No;

28 regulatory bodies answered No Information;

4.42. Are there any cancellations of the radioactive sources' shipments?

33 regulatory bodies answered Yes;

58 regulatory bodies answered No;

31 regulatory bodies answered No Information;

1 regulatory body did not answer this question;

4.43. Are there any other transport issues?

45 regulatory bodies answered Yes;

71 regulatory bodies answered No;

2 regulatory bodies indicated they have no information;

5 regulatory body did not answer this question;

If YES, please indicate:

- *Details provided in the report*

5. Has there been any radiation safety related issues connected to the COVID-19 situation reported to the regulatory body by facilities?

5 regulatory bodies answered Yes;

106 regulatory bodies answered No;

12 regulatory bodies indicated they have no information;

If YES, please indicate:

- *Details provided in the report*

6. Do you foresee any potential radiation risks due to the COVID-19 situation?

30 regulatory bodies answered Yes;

91 regulatory bodies answered No;

1 regulatory body indicated that it has not information;

1 regulatory body did not answer this question;

If YES, please indicate:

- *Details provided in the report*

PART III Regulatory activities in COVID-19 situation

7. Are your regulatory activities affected by the COVID-19 situation?

97 regulatory bodies answered Yes;

26 regulatory bodies answered No;

8. Is your Regulatory Body currently implementing a full scope regulatory programme?

36 regulatory bodies answered Yes;

85 regulatory bodies answered No;

2 regulatory bodies did not answer this question;

If your answer is NO to No. 7 and YES to No.8 above, please skip the questions from 9 to 11

9. Regulatory body functioning:

9.1. Are your premises locked down?

16 regulatory bodies answered Yes;

31 regulatory bodies answered No;

62 regulatory bodies answered Only critical personnel work from office;

14 regulatory bodies did not answer this question;

9.2. Is the RB's radiological emergency centre activated?

54 regulatory bodies answered Yes;

29 regulatory bodies answered No;

26 regulatory bodies answered not applicable;

14 regulatory bodies did not answer this question;

9.3. If regulatory body staff are working from home, do they have communication problems:

9.31. with colleagues

9 regulatory bodies answered Yes;

95 regulatory bodies answered No;

19 regulatory bodies did not provide answer to this question;

9.32. with applicants and licensees

25 regulatory bodies answered Yes;

79 regulatory bodies answered No;

19 regulatory bodies did not provide answer to this question;

9.33. with other authorities

15 regulatory bodies answered Yes;

88 regulatory bodies answered No;

20 regulatory bodies did not provide answer to this question;

10. How is your authorization activity affected?

10.1. Is the authorization programme fully implemented?

55 regulatory bodies answered Yes;

57 regulatory bodies answered No;

11 regulatory body did not answer this question;

10.2. If NO, please, indicate the reasons:

19 regulatory bodies answered because of inspectors staying home;

6 regulatory bodies answered because of lock down of facilities;

11 regulatory bodies answered because of both inspectors staying home and lock down of facilities;

Other reasons:

- *Details provided in the report*

11. How is inspection activity affected?

11.1. Is the inspection plan fully implemented?

12 regulatory body answered Yes;

98 regulatory bodies answered No;

13 regulatory bodies did not provide answer to this question;

11.11. if NO, what are the reasons:

21 regulatory bodies answered because of inspectors staying home;

5 regulatory bodies answered because of lockdown of facilities;

2 regulatory bodies answered because of facilities' staff staying home;

9 regulatory bodies answered because of both inspectors staying home and lock down of facilities;

7 regulatory bodies answered because of inspectors and facilities' staff staying home;

3 regulatory bodies answered because of lockdown of facilities and facilities' staff staying home

17 regulatory bodies answered because of inspectors staying home, lock down of facilities and facilities' staff staying home;

Other reasons:

- *Details provided in the report*

11.2. Are there other measures used to oversight facilities and activities?

11.2.1. Video conferences

46 regulatory bodies answered Yes;

57 regulatory bodies answered No;

20 regulatory bodies did not provide answer to this question;

11.2.2. Regular reporting by licensees

66 regulatory bodies answered Yes;

36 regulatory bodies answered No;

21 regulatory bodies did not provide answer to this question;

11.2.3. Using other authorities' inspection information

25 regulatory bodies answered Yes;

71 regulatory bodies answered No;
27 regulatory bodies did not provide answer to this question;

11.2.4. Others (please indicate):

- *Details provided in the report*

PART IV Radioactive sources control

12. Radioactive sources import/export control

- 12.1. Do you still continue to authorise import/export of radiative sources?

104 regulatory bodies answered Yes;

14 regulatory bodies answered No;

5 regulatory bodies did not provide answer to this question;

- 12.2. Is safe storage of radioactive sources provided if delivery of the imported source to the end user is delayed?

95 regulatory bodies answered Yes;

19 regulatory bodies answered No;

9 regulatory bodies did not provide answer to this question;

13. Is safe management of any detected orphan sources being provided?

96 regulatory bodies answered Yes;

19 regulatory bodies answered No;

8 regulatory bodies did not provide answer to this question;

14. Is your organization notified of any operational difficulties (for example, bankruptcy) of the radiation sources users?

48 regulatory bodies answered Yes;

64 regulatory bodies answered No;

11 regulatory bodies did not provide answer to this question;

PART V General Comments

- *Details provided in the report*