



ANALYSIS OF INFORMATION ON REGULATORY IMPLICATIONS OF THE PANDEMIC SITUATIONS, COLLECTED DURING INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSIONS CONDUCTED FROM 2021 TO 2023

Abstract

This report presents the analysis of the information collected during IRRS missions conducted from 2021 to 2023 on regulatory implications of pandemic situations. It identifies key issues and challenges faced by the Member States, and the mechanisms and good practices used by them to overcome those issues and challenges to ensure business continuity.

Nuclear Safety and Security Department

Analysis of Information on Regulatory Implications of the Pandemic
Situations Collected during Integrated Regulatory Review Service
(IRRS) Missions Conducted from 2021 to 2023.

May 2024



Integrated
Regulatory
Review Service

IRRS

EXECUTIVE SUMMARY

The COVID-19 pandemic was declared as a public health emergency of international concern by the World Health Organization (WHO) in January 2020 and continued until May 2023. The pandemic challenged national regulatory bodies' resilience in ensuring continuity for delivering their statutory regulatory functions under extraordinary circumstances. Globally, regulatory bodies developed their own solutions to the challenges they faced during the pandemic ensuring safe operation of facilities and conduct of activities.

The IRRS missions conducted in Member States during and immediately after the pandemic were recognized as an effective mechanism and opportunity to gather information on solutions developed and measures taken by Member States and regulatory bodies. In total, 18 initial IRRS missions and one follow up IRRS missions were implemented in Member States in 2021-2023. Information in IRRS mission reports regarding the COVID-19 pandemic was reviewed and the results are documented in this report.

In addition to national responses to the pandemic such as lockdowns, hygiene measures and travel bans, some governments provided their national regulatory bodies with additional guidance through special task groups established to manage nationwide implementation of the pandemic measures. Moreover, most of the regulatory bodies developed their own measures through plans or the establishment of task groups in order to pursue discharging their regulatory functions.

The governmental lockdowns and travel bans impacted the conduct of regulatory functions, particularly authorizations and inspections, especially in the early days of the pandemic. Most regulatory bodies used a working-from-home approach to face the challenges posed by the pandemic. Thus, besides the performance of regulatory activities, other functions such as communications, meetings and staff trainings were conducted virtually through electronic platforms to minimize face-to-face interactions in compliance with governmental measures, when their information technology (IT) infrastructure allowed them to do so.

Almost all regulatory bodies updated their inspection plans, and cancelled, deferred, or changed the scope or type of inspections in accordance with a graded approach. Hybrid inspections were conducted when there were resident inspectors in person at a site. In most cases, reactive inspections were conducted in person. Some Member States used external technical experts or support organizations, or virtual inspections to conduct inspections abroad.

While some regulatory bodies continued all their authorization activities as usual, as their IT infrastructure allowed them to carry out authorization processes online, others extended the validity periods of existing authorizations automatically or upon application.

During the emergency exercises that had not been deferred, a hybrid participation was utilized. Nevertheless, this participation mode was never used by Member States to respond to a real

emergency situation; they kept sending experts to the site as they used to do before the pandemic.

The pandemic conditions highlighted the importance of regulatory bodies having a business continuity plan, as a part of the management system, and a capable IT infrastructure to ensure their resilience to face extraordinary circumstances.

Overall, the regulatory bodies stated that they managed to reduce the impact of the pandemic on regulatory work to a negligible level of impact on the safety of facilities and activities.

When conducting this analysis, it was identified that the IAEA safety standards do not contain any provision directly referring to the need for having arrangements to ensure business continuity in exceptional circumstances, such as a COVID-19 pandemic, to maintain delivery of statutory duties and responsibilities for safety. The IAEA and Member States may consider in the future whether this issue should be addressed in IAEA safety standards.

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1. INTRODUCTION

1.1 Background

The IRRS is recognized as an effective mechanism for reviewing national governmental, legal and regulatory framework for safety against IAEA safety standards while facilitating experience sharing and exchange of lessons learned amongst the international regulatory community. At the request of Member States, 19 IRRS missions provided an opportunity to evaluate and discuss the national regulatory implications of the COVID-19 pandemic.

The information shared by Member States during most of the IRRS missions conducted in the period 2021-2023 revealed that regulatory bodies and other relevant competent authorities initiated a number of measures to maintain the delivery of their statutory regulatory functions and to contribute to the safe operation of facilities and conduct of activities during the COVID-19 pandemic. In response to pandemic-related circumstances and challenges presented to existing regulatory systems, several regulatory bodies reviewed their legal and regulatory framework to ensure that there is an appropriate basis and regulatory documentation for performing their required functions under exceptional circumstances, such as pandemics, and instigated in some cases special procedures to perform their functions online.

1.2 Objective

This report provides an analysis of the information collected during IRRS missions conducted from 2021 to 2023 on regulatory implications of the pandemic situations in order to identify the key issues and challenges faced by the Member States as well as the mechanisms and good practices used by them to overcome those issues and challenges to ensure business continuity.

1.3 Structure of the Review Conducted during IRRS Missions

A review of GSR Part 1 (Rev.1) Governmental, Legal and Regulatory Framework for Safety [1] has identified the IAEA Safety Requirements, listed in Appendix 2, that merit special attention during an IRRS mission due to the possible impact on maintaining delivery of statutory duties and responsibilities for safety. They were selected due to their importance for ensuring business continuity by mitigating the challenges faced during a pandemic situation, including: reduced availability of resources; restricted ability to travel or to access authorized facilities; and prioritization of implementation of regulatory oversight, authorization and other regulatory functions.

The emerging issue, the regulatory implications of an exceptional situation such as a pandemic, was addressed in IRRS missions in a complementary manner, providing an opportunity to discuss and identify ways to strengthen the governmental, legal and regulatory framework for safety, without undue effect on the proper evaluation of a national regulatory infrastructure with respect to the IAEA safety standards, as set up by the IRRS Guidelines IAEA-SVS-37.

In order to share their experiences with the IRRS team the host countries were invited to have a policy discussion on the implications of a pandemic situation and associated challenges for regulatory bodies, and/or to add an additional section to the ARM summary report on relevant feedback and main conclusions regarding national regulatory implications of a pandemic situation.

When the policy discussion approach was adopted by the host country, the host organization(s) was expected to follow the typical IRRS mission practice for discussion of policy issues, to prepare views and discussion points relating to the regulatory implications of a pandemic situation and forward it to the IAEA prior to the mission. In this regard, the policy discussions covered, inter alia, the following issues:

- Maintenance and operation of the nationwide emergency system;
- Management of disused sources for which immediate actions should be taken;
- Implementation of workforce management practices to a widespread teleworking situation and reliable and secure access for the regulatory body's staff to tools, information, and equipment to telework effectively;
- Access of inspectors to authorized facilities, and relevant information and data systems;
- Consideration of authorized parties' requests for regulatory flexibility, and deferral of license conditions and regulatory commitments;
- Prioritization and rescheduling activities to maintain regulatory oversight in accordance with a graded approach while considering licensee restrictions on access to facilities and activities;
- Implementation of virtual or hybrid inspections taking into consideration legal aspects and IT support systems; and
- Communication and consultation with the interested parties given the prevailing circumstances.

When the host country added a supplementary section to the ARM report on the COVID-19 pandemic, the requirements included in Section 3 were carefully considered throughout the IRRS process, including the self-assessment and the mission itself. Based on the supplementary section provided by the host and the discussions between the national counterparts and the IRRS team, a dedicated chapter was added at the end of the core part of the IRRS mission reports. This chapter was compiled by an IRRS team member from the contributions prepared by different IRRS reviewers who were identified to discuss the actual implementation requirements covered by their assigned review area. The objective was to document relevant experiences deemed useful for sharing with the international community.

1.4 Missions Covered by the Report

The information on measures taken by the Member States, including the regulatory bodies, regarding the COVID-19 pandemic have been collected from the reports of IRRS missions carried out during or after the pandemic period. Appendix I lists these Member States, their respective mission dates, and provides the information on how the COVID-19 pandemic has been handled in each IRRS mission report. The management of the COVID-19 pandemic by the government and the regulatory bodies was included in the mission report as a supplementary chapter of the report or as a part of the policy discussions, depending on the request of the host country. In a few cases, the management of the COVID-19 pandemic has only been mentioned within the text where relevant.

Within the context of this report, the term “Member States” is used to address only the Member States which are listed in Appendix I.

2. RELEVANT IAEA SAFETY STANDARDS

The IAEA safety standards have various provisions regarding the role and responsibilities of the national regulatory body but there are no provisions directly referring to the management of crises such as was demonstrated by the COVID-19 pandemic. The IAEA and Member States may then consider in the future whether this issue should be addressed in IAEA safety standards. However, the IAEA safety standards do require governments, regulatory bodies, and authorized parties to ensure compliance with their statutory obligations.

GSR Part 1 (Rev. 1) [1] requires the government to establish a national policy and strategy for safety in which, according to the Paragraph 2.3:

“2.3 ..., account shall be taken of the following:

(d) The need and provision for human and financial resources;

(f) Adequate mechanisms for taking account of social and economic developments;”

Particularly, the item (f) includes the need to have mechanisms to address any social development such as the consequences of a pandemic. Additionally, paragraph 2.4 states that:

“2.4. The national policy and strategy for safety shall be implemented in accordance with a graded-approach, depending on national circumstances...”

This statement, while not specifying what national circumstances may be applicable, still requires that the national policy and strategy is implemented to ensure that appropriate attention is given to radiation risks.

To implement the policy and strategy for safety, the government is required to establish a framework for safety:

“2.5. The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following:

(5) Provision for the involvement of interested parties and for their input to decision making;

(10) Provision for the inspection of facilities and activities, and for the enforcement of regulations, in accordance with a graded approach;

(12) Provision for preparedness for, and response to, a nuclear or radiological emergency;

(15) Provision for acquiring and maintaining the necessary competence nationally for ensuring safety;”

GSR Part 1 (Rev. 1) [1] also delegates to the regulatory body the responsibility to ensure that authorized parties have necessary capabilities to ensure the safety of facilities and activities under all circumstances and over the lifetime of the facility or the duration of the activity:

“ 4.3. ... The regulatory process shall provide a high degree of confidence, until the release of facilities and activities from regulatory control, that:

(f) Authorized parties have the human, organizational, financial and technical capabilities to operate facilities safely or to conduct activities safely under all circumstances until the release of the facilities or activities from regulatory control.”

To fulfil this responsibility GSR Part 3 Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards [2] reiterates that the government shall ensure:

“2.17. ... that the regulatory body has the legal authority, competence and resources necessary to fulfil its statutory functions and responsibilities.”

This requirement does not include or imply limitations on this responsibility thus the regulatory body should retain legal authority, competence and resources to fulfil its functions and responsibilities under all circumstances.

The management system of the regulatory body should provide for business continuity under a range of challenges to include during exceptional situations. According to GSR Part 1 (Rev. 1) [1], the management system of the regulatory body:

“4.15. ... has three purposes:

(1) To ensure that the responsibilities assigned to the regulatory body are properly discharged;

(2) To maintain and improve the performance of the regulatory body by means of the planning, control and supervision of its safety related activities;

(3) To foster and support a safety culture in the regulatory body through the development and reinforcement of leadership as well as good attitudes and behaviour in relation to safety on the part of individuals and teams.”

The management system should ensure that the regulatory body properly discharge its activities which need to be stable and consistent according to GSR Part 1 (Rev. 1) [1]:

“Requirement 22: Stability and consistency of regulatory control

The regulatory body shall ensure that regulatory control is stable and consistent.”

There are other requirements in GSR Part 1 (Rev. 1) [1] that provide bases for establishing and sustaining an effective framework for safety of facilities and activities at any time, including during circumstances that challenge the capabilities of the regulatory bodies. These requirements are given in Appendix II.

Further elaboration on the management of circumstances, like the COVID-19 pandemic, by the regulatory body can be found in IAEA General Safety Guide No. GSG-12 [2], which assigns the responsibility of ensuring the proper response to crisis situations to the senior management of the organization:

“3.1 Senior management, managers and leaders at all levels of the regulatory body should demonstrate, by their own behaviour, consistent adherence to the values of the regulatory body. This should typically include the following:

- Developing and maintaining leadership capabilities at all levels in the regulatory body, including capabilities for competence management, change management and crisis management⁷;*

where footnote 7 states that *“Crisis management here means the ability to manage different types of crisis situation that might have an impact on the regulatory body’s capability to perform its functions.”*

Therefore, the senior management of the regulatory body should demonstrate its leadership in crisis situations, such as the COVID-19 pandemic, to ensure the continuance of regulatory control over the facilities and activities and the resilience of the regulatory body under unexpected circumstances.

GSG-12 further states that:

“3.22 There are other types of resources necessary for the regulatory body to perform its functions and to discharge its responsibilities. These may include the following:

- Arrangements for conventional emergencies;*

While other resources mentioned in paragraph 3.22 of GSG-12 [2] may also be needed in extraordinary circumstances additional measures for their deployment need to be formulated under the leadership of the senior management.

3. REGULATORY IMPLICATIONS OF PANDEMIC SITUATIONS

3.1 Governmental and Legal Framework for Safety

Upon outbreak of the COVID-19 pandemic, the governments established task forces, in various forms in accordance with the national framework. These task forces decided on a set of national measures with due consideration given to the recommendations of international organisations like WHO particularly on measures regarding the personal hygiene, social distancing and bans on international travels for managing the impact of pandemic on the public. These measures were updated as necessary by the task groups. In some countries like the Netherlands the regulatory body was part of this task group providing information and collaboration.

In some Member States, these task groups also identified and prioritised the critical services that needed to be conducted at the workplace and required special attention, monitoring and exemptions from restrictions in the country. Health services were obviously given the highest priority in that respect, but services related to the safety of nuclear and/or radiation facilities and activities and to emergency preparedness and response were also among the other prioritized services.

Most of the governments provided a legal framework that empowered regulatory bodies to establish their own additional measures ensuring the safety of facilities and activities. For example, the Belgian government provided the adequate legal basis to the regulatory body for maintaining the discharge of its regulatory duties with additional measures. Additionally, the Belgian government registered the relevant staff of the regulatory body to a dynamic telecommunication service that prioritizes their phone calls using all communication mobile networks, including during national emergency situations. Another support by the governments was providing the regulatory bodies with legal basis to extend the duration of authorizations.

Lockdowns, limiting the movement of people for minimizing the encounters that would increase the spread of the COVID-19 pandemic, was one of the main measures taken by the governments. The governments, in general, imposed restrictions to keep people at home to the extent possible and feasible, including requesting state organizations, such as regulatory bodies, to make necessary arrangements for their staff to work from home. The stringency of the lockdown measures was different in each Member State. The lockdown was not absolute in any Member State.

Regarding the lack of technical services in relation to safety, such as services for personal dosimetry, environmental monitoring and the calibration of equipment, the difficulties encountered at the beginning of the outbreak were overcome by the Member States in a short while.

Some Member States experienced delays in dosimetry services or in calibration services for radiation measuring devices due to lockdown provisions. However, all these delays were

remedied in a short period of time because of measures taken by the governments and the regulatory bodies on business continuity.

Most Member States with established environmental monitoring systems reported unaffected continuation of such systems and uninterrupted environmental monitoring. However, Türkiye reported experiencing some difficulties. Since the transfer of information from local measurement stations was carried through land-based telephone lines, some delays were experienced due to travel limitations when there were problems with the landlines. Belgium also reported on some difficulties experienced in response to the alarms raised by the system, as the right person could not always respond or be present at the facility site.

No Member State reported issues with managing disused radioactive sources. Both Belgium and Sweden stated that no problems or disruptions were encountered in the management of disused sources that required urgent action to prevent such sources from becoming out of regulatory control.

3.2 Regulatory Framework

Regulatory bodies, usually, prioritised their functions in accordance with a graded approach, considering the need for physical presence in the workplace or at the site of the activity and the safety significance of the regulatory function or action. The results of the prioritization were used by the regulatory bodies to help determine their own measures. Among the prioritized activities were:

- Emergency preparedness and response functions;
- Security-related activities such as during transport of radioactive materials, including cybersecurity;
- Reactive inspections;
- Import/export authorizations for radioactive materials; and
- Maintaining environmental radiation monitoring.

All regulatory bodies were keeping close contact and working in cooperation with the bodies that were deciding on national measures and updating their own measures periodically or if necessary, in line with the national developments.

The Argentinian regulatory body established and approved the General Protocol on Prevention and Safety Measures for Health Emergency by COVID-19 in coordination with central bodies. This protocol was certified by the National Institute of Certification, pursuant to a national standard. The IRRS team considered this certification as a good performance.

In addition to governmentally imposed precautions, the most common measure used by regulatory bodies was a transition to home working. The regulatory bodies that had the necessary IT infrastructure arranged for home working of their staff with different approaches.

The Swiss, Moroccan, and Romanian regulatory bodies reduced their office presence to a minimum having most of the staff working from home. The Swiss regulatory body required the presence of one person for each section of the regulatory body to coordinate of activities conducted by staff working from home.

Some others, like the regulatory bodies of Bangladesh and Türkiye opted to limit office presence to one staff per office room which amounted to less than 50% home working. This approach warranted the full-time presence of managers at the office to facilitate the decision-making processes of the regulatory body during the lockdown.

All regulatory bodies that used home working also used daily or weekly rotation of staff, determined and communicated by the top management. Türkiye stated that the use of daily rotations maintained high awareness of ongoing activities of the regulatory body amongst the staff.

Most of the regulatory bodies established some additional requirements on authorized parties through regulatory decisions. Swedish and Romanian regulatory bodies established requirements on authorized parties to take additional measures to minimize the spread of COVID-19 on their sites.

Most of the regulatory bodies postponed some of their activities that were not essential for safety under the COVID-19 pandemic circumstances. For example, the Swedish regulatory body suspended its internal audits until the return to normal operations.

There were some less common measures taken by some governments or regulatory bodies, as follows:

- Slovakia gave vaccination priority to the staff of operating organizations of the nuclear power plant;
- The Swedish government made a one-time payment to governmental workers in appreciation of their commitments after the normal life was resumed after the COVID-19 pandemic;
- The Swiss regulatory body established a requirement to approve the measures taken by the authorized party, particularly on minimum number of personnel, specific regulations prepared regarding the pandemic, the postponement of some in-service inspections and shortened outages by reduced testing and maintenance;
- The Belgian regulatory body established a requirement for Class I facility licensees to produce contingency plans for use if critical individuals contracted COVID-19. These plans were to be reviewed by the regulatory body;
- The Belgian government exempted the individuals within the regulatory body and authorised parties from required medical check-ups. Likewise, the frequency of routine dosimetry badge returns or exchanges was lowered to reduce the potential for contamination;

- The Singaporean regulatory body introduced a safe management system in 2020, including measures such as split team arrangements and contact tracing, in addition to general hygienic measures.

Readiness of national and/or organizational IT infrastructure emerged as an important factor on continuation of the regulatory control and on smooth implementation of identified measures, mainly the home working. Most of the Member States only needed minor additional improvements of their IT infrastructure for smooth implementation of the measures taken in response to the COVID-19 pandemic. There were very few regulatory bodies who already had a sufficient IT infrastructure to address all needs.

Only the Slovenian regulatory body reported budget cuts because of the governmental budget changes due to COVID-19 pandemic measures, with minor impact on some planned training activities.

3.3 Training of Staff and Individuals

Almost all regulatory bodies, like the authorized parties, switched to the online trainings, to the extent possible, for their own staff with the outbreak of the pandemic, cancelling most of trainings that required physical presence. The participation in international online trainings, such as workshops and webinars, were also used by the Member States. Some Member States reported on the low efficiency of online trainings because of diminished direct communication and interaction.

The Moroccan regulatory body reported the use of IAEA Cyber Learning Platform for Network Education and Training (CLP4NET) to continue online trainings of its staff.

In Argentina the staff of authorized parties require annual retraining and in some cases authorizations that, during the pandemic, were largely transferred to online platforms with the exception of some exams that were conducted in-person with participation of relevant inspectors.

In Belgium, there was a pause in retraining of reactor operators for three months at the peak time of the epidemic. This postponement of 3 months was reviewed by the regulatory body which concluded it had a negligible impact on safety.

The Netherlands reported problems encountered by radiation protection experts to undergo refresher trainings required to renew their certificates of competence. The regulatory body established provisional rules to allow them to retain their certificates.

3.4 Regulatory Functions

3.4.1 *Decision Making and Authorizations*

The pandemic conditions had considerable impact on the decision-making and authorization processes of the regulatory bodies. The main factor that defined the extent of this impact was

the readiness of the IT infrastructure of the regulatory bodies to continue carrying out their functions in electronic platforms.

The meetings of decision-making bodies for deliberation or of advisory bodies to provide input to the decision-makers had to be carried out virtually. Even if the regulatory bodies were ready for using tools for on-line meetings, the inefficiency of such on-line meetings was highlighted by several Member States.

On the other hand, the lack of secured electronic signature system in most regulatory bodies necessitated the physical presence of decision makers in office to sign the reports and records relevant to authorizations. Only two countries, the Netherlands and Türkiye mentioned that they had an e-signature system prior to the outbreak of the pandemic, facilitating measures taken by them. Such a system was adopted by Slovenia immediately after the outbreak of the pandemic.

The regulatory bodies of Argentina, Bangladesh, Bosnia and Herzegovina, Slovenia and Romania extended the validity of existing authorizations for a year or so, automatically or upon application. Most regulatory bodies reported reduced number of applications during the pandemic because of the reduced number of activities. However, this decline in number of applications, in addition to the extensions of validity of authorizations, increased the backlog of authorization work upon returning to normal.

The Netherlands reported an increase in the number of diagnostic equipment, such as X-ray and CT Scanners, in hospitals due to pandemic conditions, exceeding the limits imposed by license conditions. This issue was addressed by the regulatory body establishing a fast authorization process to enable hospitals to keep ensuring health care activities particularly those related to COVID cases.

The regulatory bodies implemented their authorization process nearly as usual, carrying out review and assessment from home, using on-line technical meetings needed for authorization, and minimizing the site visits related to authorizations in accordance with a graded approach. Some regulatory bodies, such as in Morocco, transferred their authorization process online, developing application forms, guidance, payment gateways, etc. Türkiye reported that the authorization activities were carried out as usual since the whole processes, applications, review and assessments, fee payments and license documents were already transferred into electronic platforms prior to the pandemic.

Only a few regulatory bodies reported on review and assessment being slowed because of home working, leading to minor delays in authorizations.

3.4.2 Regulations

Preparing, drafting or updating the regulatory requirements is the least mentioned impacted activity in IRRS mission reports, since it was an activity which was the most easily transferred to home working. However, some regulatory bodies used the opportunity of declining workload

during the pandemic due to decrease in activities to further develop their regulatory infrastructure.

Morocco took the opportunity of the lockdown period to expedite the upgrading of the regulatory framework relating to nuclear and radiological safety and security and drafted, developed, or revised multiple regulations, guides, and internal processes and procedures. The Moroccan regulatory body also used this opportunity to carry out a comprehensive self-assessment of the regulatory infrastructure for safety in Morocco using the SARIS1 tool of the IAEA in preparation for their upcoming IRRS mission.

Romania included specific provisions to address preparedness for pandemic conditions in its regulation on emergency situations in nuclear power plants (NPP), which was already in the updating process when the pandemic started. The provisions included detailed requirements on the verification and validation of emergency operating procedures and specific requirements to ensure that all the necessary resources and measures for responding to transients, accidents and emergency situations are available and feasible also in case of pandemic.

Some Member States reported that the drafting of regulations, guides or internal documents through online meetings of the staff working from home was much less efficient than usual.

3.4.3 Inspection and Enforcement

Inspection was the regulatory function that was impacted the most from the governmental measures such as lockdown or travel bans during the pandemic. Limitations on travelling locally or abroad and minimization and limitation of social interactions necessitated special measures to be taken to ensure the continuation of regulatory control. In Belgium, regulatory inspectors were considered among the critical staff under the national arrangements allowing them to travel during lockdown, provided that they complied with the authorized party's measures.

The regulatory bodies reported that they reviewed and revised their inspection plans to reduce the number and/or frequency or to change the type and/or the scope of inspections in accordance with a graded approach. Reduction of number of staff in inspections, cancellation of team inspections particularly in nuclear facilities and cancellation of non-essential inspections were the other means utilised for managing the inspection function during the pandemic. The Swedish regulatory body developed and implemented a methodology for the entire organization to support decision-making processes, including whether to postpone an inspection or to replace it with a remote inspection.

Most of the regulatory bodies introduced virtual inspections as a new tool for the continuation of regulatory control over facilities and activities. Bosnia and Herzegovina and Portugal reported that remote inspections were considered but were not used. Both of them reduced the number of inspections in accordance with a graded approach, cancelling non-essential ones.

¹ Self-assessment of Regulatory Infrastructure for Safety

The Moroccan regulatory body suspended the conduct of its routine inspections and permitted only the physical inspections to support the authorization process and in response to emergency situations. The Romanian regulatory body reduced the workload of resident inspectors to minimize their interaction with the nuclear power plant staff.

The regulatory bodies of some Member States with nuclear installations utilised hybrid inspections, supporting the resident inspectors with teleworking experts. Denmark, Argentina, Türkiye and Belgium reported the use of hybrid inspections.

The Dutch regulatory body carried out inspections at nuclear facilities during the pandemic using the minimum necessary number of inspectors and with observance of health measures like social distancing. Inspections at nuclear sites were only performed if the inspection was critical or the inspection could not be conducted at a later date. It has been reported that most of the planned inspections were conducted.

Bangladesh, in which the construction of an NPP was underway, reported that the construction inspections were rescheduled in accordance with a graded approach and an external technical support organization were used to conduct manufacturing inspections.

Being in a similar stage of NPP construction, Türkiye reported that inspection plans were revised by reducing or changing the scope of inspections, in accordance with a graded approach. Local external experts were hired to support the remote inspection of manufacturing activities abroad. Additionally, the Turkish regulatory body decreased the reporting period of third-party inspection organizations to enhance the regulatory oversight of construction and manufacturing activities.

The Belgian regulatory body requested the relevant unit of an authorized party to conduct particular activities and to report the results back to the regulatory body in order to avoid inspectors needing to go on site. Similarly, the Romanian regulatory body deferred all inspections in the areas of radioactive waste management and decommissioning but requested weekly reports from the relevant authorized parties. For waste facilities, the Swedish and Argentinian regulatory bodies carried out remote inspections.

The Swedish regulatory body reported that in-person inspections conducted during the pandemic were found to be more difficult to conduct because of measures taken by authorized parties to protect people from the COVID-19 virus. In this regard, additional guidance was provided to the inspectors, that considered governmental-level guidance, on risk management and how to adapt inspection protocols to minimise the infection risk during on-site inspections. Similarly, the Slovenian regulatory body developed written instructions for authorized parties on how to participate in successful and effective remote inspections, which was considered as a good performance by the IRRS team.

The Belgian regulatory body reported that the outage work programme of one of the NPP units was reduced to only necessary work, postponing the elective work with a suitable justification

to a later outage when the situation would be back to normal. Regulatory inspections during the outage were carried out with inspection teams minimized as far as practicable.

The Dutch, Swedish and Belgian regulatory bodies reported that most hospital inspections, other than reactive ones, were postponed reducing the burden on hospitals swamped by COVID-19 cases for the public interest.

There were some specific activities other than the essential inspections deemed by the regulatory body that were carried out in person. Among them were:

- safeguards inspections as reported by the Argentinian regulatory body;
- reactive inspections as reported by the Belgian and Moroccan regulatory bodies;
- site visits of radiation protection experts as reported by the Belgian regulatory body; and
- inspections of non-destructive testing facilities as reported by the Netherlands.

The Finnish regulatory body reported that the remote inspections were found to be a useful tool and will be used to carry out inspections after the pandemic ended. Additionally, the Swedish regulatory body mentioned the benefit of being able to utilise even quarantined experts for remote inspections.

No regulatory body reported on implementation or a challenge encountered for using enforcement instruments during the pandemic.

3.4.4 Communications

Transferring communications to virtual platforms was the most common measure taken regarding continuation of communication inside the regulatory bodies and with stakeholders during the pandemic. Some Member States like Bangladesh and Türkiye reported that the transfer was easy owing to extensive use of virtual meetings with external technical support organizations or applicants prior to the pandemic.

Most regulatory bodies reported that the communications remained unaffected from the pandemic conditions. However, some special measures were taken to ensure the continuity of the communication, such as further enhancement of IT infrastructures to allow external access to intranet and internal document management systems.

The Argentinian regulatory body (ARN) established a special page on the Intranet to ensure that staff were aware of current measures and initiated a digital monthly bulletin to keep home working staff in communication. The most relevant regulatory decisions made by the Argentinian regulatory board were published on the website. In fact, the ARN's website and social media were expanded during the pandemic.

The Belgian government, considering the services of the regulatory body critical, registered the staff in a dynamic telecommunication service that prioritizes their phone calls using all communication mobile networks, including during national emergency situations. During the

pandemic, Belgian regulatory body and the authorized parties of class I facilities held meetings using video conferencing facilities, initially daily but evolving over time to become weekly or bi-weekly. These alignment meetings were designed to ensure that regulatory body had an up-to-date understanding of the pandemic situation on site, which changed rapidly.

3.5 Emergency Preparedness and Response

Maintaining emergency preparedness and response capabilities was one of the most challenging areas as it requires a physical presence of staff in emergency centres. The conduct of regular exercises also presented a challenge during the pandemic.

Member States took additional measures to ensure the readiness of their systems to respond to emergencies. The Swedish government required public agencies with an EPR mandate to submit weekly reports on the impact of the pandemic to the Swedish Civil Contingencies Agency (MSB). In addition, the Swedish regulatory body requested authorized parties to assess their ability to handle a nuclear or radiological emergency with a reduced on-site staff during the pandemic.

Similarly, the government of the Netherlands recognized the EPR personnel, including the ones in regulatory body, as “vital workers”, granting a special discharge from lockdown to be able to comply with any duties related to EPR matters. Emergency exercises were also deemed to be “vital work” and continued to be physical, except for the peak months of the pandemic.

The Romanian regulatory body activated its existing “Emergency Committee” and issued new instructions establishing weekly continuity plans. Similarly, the Dutch regulatory body activated its own crisis response organization during the pandemic.

Most of the regulatory bodies reported difficulties in manning emergency centres and their needs for additional staff to support dedicated personnel. Slovakia, Türkiye, Belgium, Romania and the Netherlands reported that daily roster schedules had to be supported by more regulatory staff from other departments to ensure 24/7 presence in their emergency centres.

The Swedish regulatory body reported that additional arrangements were made in the emergency centre, such as re-positioning response functions to separate rooms and implementing personal protective measures.

In order to maintain periodic emergency exercises, Member States took measures like reducing exercise teams to bare minimums, adopting a hybrid approach in exercises, and altering the scope of exercises. While Argentina carried out their annual exercises virtually, Switzerland, Slovenia, Sweden and Belgium postponed some of their exercises. These Member States, including Türkiye, also reduced the scope of exercises, minimizing the number of exercising staff using the hybrid approach and providing expert support remotely. Slovenia introduced additional exercises to facilitate the exercising of all EPR staff.

The contribution of the hybrid approach to emergency exercises drew special attention from Belgium. The Belgian regulatory body still uses and regularly tests in every second exercise

the use of hybrid approach, noting that remote support can be provided quickly and immediately without any travel needed.

Morocco developed a system for virtual training and tabletop exercises. The Moroccan regulatory body participated in two ConvEx exercises and conducted one tabletop and one virtual field exercise during the pandemic but had to cancel some activities that would be carried out in collaboration with IAEA.

The Swedish regulatory body used its virtual emergency response capability during a real incident that occurred at an NPP in a neighbouring country. On the other hand, the EPR team of Türkiye was challenged twice during the pandemic requiring physical presence, once for the investigation of a suspected radioactive package in an apartment block, and once for the concerns associated with forest fires around thermal powerplants which contained a large number of radioactive sources. It has been reported that the responses confirmed the ability of the regulatory body to maintain an appropriate emergency response capability through the pandemic.

Training of EPR personnel were changed to virtual platforms in most of the Member States to the extent possible, with due consideration given to the disadvantages of virtual trainings based on lack of interaction.

4. FEEDBACK

4.1 Challenges

The most common challenge encountered by the regulatory bodies was to establish business continuity plans to manage the impact of the pandemic in regulatory functions, particularly at the early stages of the outbreak. Only the Swedish, Swiss and Belgian regulatory bodies were ready for such contingencies, while others needed to develop their own methods of managing the impact after the pandemic to improve the resilience of the regulatory body. Updating these contingency plans to be in line with the national measures to contain the spread of COVID-19 and adapting to new conditions was another challenge, requiring agility of the management and staff of the regulatory bodies.

Another common challenge was the IT infrastructure of the regulatory bodies. The pandemic conditions necessitated an IT infrastructure allowing actions such as remote and secure access of staff to the internal databases, virtual meetings, remote inspections, remote access to electronic document management systems, electronic applications, electronic signature systems and electronic payments. Again, only the Dutch and Turkish regulatory bodies had their IT infrastructure ready for all aspects prior to the pandemic. Other regulatory bodies needed to develop or enhance their IT systems to address shortcomings while they were also tackling with the management of the impact of the pandemic on regulatory functions.

Regarding home working, Belgium reported that during the early stage of the pandemic, some challenges were identified such as the presence of family members at home.

While a general challenge on conducting remote inspections was overcome by the regulatory bodies in a short period of time, several minor challenges were highlighted by the Member States encountered during the implementation of the remote inspections. Denmark questioned the efficiency of virtual or hybrid inspections. Sweden pointed out that inspections need to be based on sampling, observations and walk downs, and written text, drawings and pictures cannot fully substitute a physical presence of the inspector on site, while most security-related documents were not available remotely. Virtual meetings were less effective in facilitating a trustful atmosphere, providing the licensee with clear signals that activities are being effectively regulated. Switzerland highlighted the challenge ensuring the confidentiality of information gathered during a remote inspection.

While Slovakia reported the challenging situation on losing inspectors because of quarantines, infections and risk groups, the Swedish regulatory body reported on the utilization of quarantined inspectors in remote inspections during the pandemic.

The Bangladesh and Türkiye regulatory bodies reported challenges with conducting manufacturing inspections abroad as international travels were hindered by the pandemic lockdown. Both Member States used external experts or expert organizations to conduct these inspections, with Türkiye using the hybrid approach providing virtual participation of local experts in the inspections.

Conducting virtual meetings for communication or training purposes was considered very inefficient by many regulatory bodies. Denmark reported challenges on providing communication with interested parties and providing trainings on radiation protection for relevant experts during the pandemic owing to the inefficiency of the virtual meetings. Portugal reported the challenges on providing training to their new staff hired for inspections.

The Netherlands reported that virtual meetings were the main challenge in working from home, since there was no previous experience, which were overcome relatively soon. Both Bangladesh and Türkiye reported a smooth transition to using virtual meetings since this method was in extensive use for communication with external technical support organizations of the regulatory body and the external experts of the authorized party, prior to the outbreak of the pandemic.

Almost all Member States reported that remote working in emergency preparedness and response is not practicable, and at least a hybrid approach was used in case of an emergency or during exercises. Slovakia additionally reported that difficulties encountered in remote access by exercise personnel to the necessary information due to security reasons and remote communications may lead to loss of critical time during an actual accident.

Türkiye reported being challenged by two emergency cases that required physical presence and stated that the responses provided confirmed the ability of the regulatory body to maintain an

appropriate emergency response capability despite the limitations because of pandemic conditions. Similarly, Sweden reported that experiencing two crises, epidemic and war in Ukraine at the same time have tested the capabilities in emergency preparedness and response, but also demonstrated the effectiveness of relevant procedures.

The transition back to normal was a challenge reported by several Member States such as Denmark, Switzerland, Sweden and Romania. Measures taken regarding regulatory functions such as automatic extension of authorizations, postponed or reduced number of inspections, or accumulation of waste in facilities for reconditioning or transferring to waste facilities created a backlog that needed to be addressed upon returning to normal after the pandemic. Some Member States highlighted their intention on continuing the use of home working and remote inspections as a new normal.

In addition to these common challenges:

- Sweden reported needing additional health measures for non-vaccinated staff;
- The Slovenian regulatory body reported on the impact of budget cuts due to the pandemic resulting in reduction of training activities;
- Türkiye reported the challenge of ensuring calibration of radiation measuring devices of the regulatory body by external sources at early stages of the outbreak;
- Belgium reported on some disruption in the control of the contract support available to the regulatory body, adding to the backlog of work because of deferred audits of supply chain;
- Türkiye reported on having no legal basis to perform remote or virtual inspections in hospitals and medical facilities, hence inspectors were provided additional protective equipment to perform in-person inspections;
- The Kingdom of Saudi Arabia reported that the pandemic started shortly after the establishment of the regulatory body in 2018 which presented a challenge to the staff due to their limited operational experience and the need for adjustment to work remotely.

4.2 Good Practices and Performances

Having contingency plans on business continuity for potential threats to carry out its functions emerged as an undeniable necessity for the regulatory bodies and authorized parties to ensure maintaining the safety and security at the facilities and activities.

In Belgium, the regulatory body had their Business Continuity Plan already in place, that originated from a past event of hydrogen flaking in nuclear reactor pressure vessels. This plan was based on the scenario of a nationwide blackout and was reviewed and updated to specify working arrangements for the pandemic situation. The regulatory body also developed a

procedure and a special plan for the management of its 24/7 duty role and the organization of nuclear crisis management in the event of a pandemic.

In Sweden, the regulatory body's pandemic plan had already been established in 2011. In this plan, functions critical for carrying out the authority's regulatory functions, and associated staffing requirements were identified. The pandemic plan included scenarios where 15% of the staff could be absent for an extended period and up to 50% of the staff unavailable for a shorter period. At the beginning of the pandemic, the plan was updated primarily to include new tools and routines for working and meeting remotely and a dedicated group was established that met regularly to monitor the situation, evaluate the ability of the authority to carry out its mission, assess the status of radiation safety, and plan communications.

In Switzerland, the regulatory body triggered the implementation of the Risk Management procedure of their management system upon outbreak of the pandemic. In accordance with this procedure, a working group composed of senior management of the regulatory body, including the regulatory body's risk manager was set up to assess the risks periodically and identified measures to ensure that critical business functions were maintained. Then, a pandemic plan was developed and implemented to face the pandemic situation. Inter alia, this plan provided for the minimum level of personnel to be present at the office.

Most of the other regulatory bodies developed business continuity plans after the pandemic, establishing ad hoc groups, usually composed of senior managers, to monitor the measures taken and the effectiveness of the regulatory functions. The Dutch, Romanian and Moroccan regulatory bodies were among those. The Saudi Arabian regulatory body acquired an ISO 22301 "Business continuity management systems" certificate which was recognized as good practice by the IRRS team.

Readiness of the IT infrastructure was also an important asset to the regulatory bodies for smooth transition to measures like home working, virtual meetings, and facilitating authorization applications and related reviews and assessments.

Among the regulatory bodies, the Netherlands and Türkiye were the ones that reported full readiness, transferring functions to virtual platforms without any improvement needed. Both regulatory bodies had the necessary infrastructure for home working and virtual communications, and electronic signature systems to facilitate the decision-making process. While the Netherlands reported some difficulties in virtual communications due to the lack of experience, Türkiye didn't experience such difficulties because of the use of virtual meetings with the external technical support organizations and the external experts of the applicants, particularly during the licensing of its first nuclear power plant, prior to the pandemic.

Belgium reported that the regulatory body had already taken and implemented measures to strengthen its IT infrastructure to allow 100% of its staff to work from home as a lesson learned from a terrorist attack that occurred in Brussels in 2016. However, the regulatory body needed

to improve its infrastructure, particularly on updating the tools used for virtual communications.

The Swiss regulatory body introduced working from home before the pandemic. Before the pandemic, around 20% of the regulatory body staff were already working from home on an irregular basis. Some improvements were further made shortly after the lockdown started, including the installation of several electronic communication tools, facilitating further the work from home.

Other regulatory bodies reported the establishment or improvements of their IT infrastructure upon the outbreak of the pandemic.

4.3 Lessons Learned

Main lessons learned that can be drawn from the experience collected during the IRRS missions were:

- The regulatory bodies and the authorized parties need to establish business continuity plans in response to exceptional circumstances, like pandemics, and associated challenges that the organizations may face during such situations. These plans should be part of the management system of the organizations. The need for business continuity plans should be subject to specific provisions in the IAEA safety standards, e.g. GSR Part 1 (Rev. 1) [1], GSR Part 2 [4] or GSG-12 [2];
- It is important for regulatory bodies to have a robust, secure and comprehensive IT infrastructure to strengthen their resilience in unpredicted conditions. The regulatory bodies need to be familiar with and able to use the most up-to-date technologies;
- Careful use of remote working can be beneficial for work-life balance for employees. Staff can be just as productive or even more so when working from home. Moreover, the increased familiarity with, and use of, IT tools for remote meetings may also provide lasting benefits, such as preserving the competence in teleworking and virtual inspections for future crisis cases or reducing the need for long domestic and/or international trips;
- Virtual and hybrid inspections were demonstrated to be useful tools despite some challenges, facilitating the human resources management regarding inspection and reducing loss of time in travelling nationally or abroad. Additionally, resident inspectors proved to be useful for conducting hybrid inspections.

4.4 Policy Discussions

The national responses to the pandemic were addressed under the policy discussions in six IRRS missions, in which the IRRS reviewers shared their experiences and concerns in addition to the issues brought up to the agenda by the host country. While Denmark, Portugal and the Slovak Republic addressed the issue only in policy discussions, Switzerland, Slovenia and

Argentina brought up the issue under policy discussions in addition to a dedicated chapter in the report. In summary, the following issues are discussed and highlighted by the participants of these policy discussions:

- Contingency planning for business continuity under different threats and challenging conditions, including IT infrastructure for effective remote working, should be considered by both regulatory bodies and authorized parties;
- Confidentiality of the information in remote inspections required special attention;
- Limitations of the virtual meetings and trainings introduced some challenges to the regular functions of the regulatory bodies;
- Arrangements for working from home caused additional difficulties in 24/7 staffing the emergency centres;
- Limited IT infrastructure of regulatory bodies for remote access and availability of digital information and online approvals were the challenges encountered in working from home. Office presence was needed for most regulatory bodies;
- Several countries highlighted that the authorization process was not affected. In specific cases, authorization process was prioritized by the regulatory body and extension of authorizations was used to facilitate the process;
- Some regulatory bodies updated their inspection programme in accordance with a graded approach to enable them to conduct hybrid inspections and/or remote inspections in addition to face-to-face inspections. Role of the resident inspectors proved to be useful during the pandemic. The issue to be considered is the possibility of use of the evidence collected remotely for the enforcement actions;
- A full response to an emergency situation in a remote format is challenging. While some regulatory bodies postponed drills and emergency exercises during the pandemic, some others considered that a hybrid approach for emergency response was feasible when the essential personnel is identified and trained in advance;
- Regulatory bodies had to respond to large numbers of questions, particularly at the beginning of the pandemic, less from the public but more from the other governmental organizations;
- Restrictions on quitting jobs during the lockdown resulted in increased loss of human resources in this area after the restrictions are lifted, that may have safety implications in the country;
- Delays or postponements of inspections or authorizations during the pandemic led to a backlog of issues to be addressed after returning to normal;
- The careful use of remote working can be beneficial for work-life balance for employees. Staff can be just as productive or even more so when working from home. Moreover, the increased familiarity with, and use of, IT tools for remote meetings may

also provide lasting benefits, not least in terms of reducing the need for long domestic and/or international trips. Some regulatory bodies are adopting this flexibility to optimize resources within and outside the regulatory body while ensuring the continuity of effective regulatory activities;

- Remote working and reduced workloads due to reduced applications created an opportunity for developing regulations;
- A challenge needing attention is the financial difficulties 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 due to lockdown; unjustified exposures and the lack of technical services, such as services for personal dosimetry, environmental monitoring and calibration of equipment.

5. CONCLUSIONS

The regulatory bodies of the Member States, in general, reported that the COVID-19 pandemic had some impact on regulatory functions, but the remedies were developed rapidly demonstrating the resilience of the regulatory bodies, with negligible impact on safety and security of facilities and activities. While the review and assessment activities are the least impacted regulatory function, the inspections and emergency preparedness and response were the areas that required the most attention.

Existence of business continuity plans of the regulatory bodies and the authorized parties emerged as the most important tool to improve the resilience of the organizations in unpredictable cases. The regulatory bodies with such plans already in place had the least impact from the pandemic circumstances. The business continuity plans should be flexible to address any threat on safe conduct of activities or regulatory functions and should be a part of the management system of the organization. The regulatory bodies with sufficient IT infrastructure experienced smoother transition to the measures taken or imposed by the governments, proving the IT infrastructure as an essential part of business continuity plans.

It has been identified that the IAEA safety standards do not contain any provision directly referring to the need for having arrangements to ensure business continuity in exceptional circumstances to maintain delivery of statutory duties and responsibilities for safety. The IAEA and Member States may consider in the future whether this issue should be addressed in IAEA safety standards.

REFERENCES

- [1] INTERNATIONAL ATOMIC ENERGY AGENCY, Governmental, Legal and Regulatory Framework for Safety, IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), IAEA, Vienna (2016).
- [2] INTERNATIONAL ATOMIC ENERGY AGENCY, Organization, Management and Staffing of the Regulatory Body for Safety, IAEA Safety Standards Series No. GSG-12, IAEA, Vienna (2018).
- [3] EUROPEAN COMMISSION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014).
- [4] INTERNATIONAL ATOMIC ENERGY AGENCY, Leadership and Management for Safety, IAEA Safety Standards Series No. GSR Part 2, IAEA, Vienna (2016).

APPENDIX 1: LIST OF IRRS MISSIONS COVERED BY THIS REPORT

Country	IRRS Mission Date	
Kingdom of Denmark	30 August to 8 September 2021	Policy Discussion
Switzerland	18 to 29 October 2021	Section 12 and Policy Discussion
Portugal	21 February to 2 March 2022	Policy Discussion
Slovenia	4 to 14 April 2022	Section 12 and Policy Discussion
India	9 to 20 June 2022 (Follow up Mission)	In the text
Argentina	22 August to 2 September 2022	Section 12 and Policy Discussion
The Slovak Republic	5 to 16 September 2022	Policy Discussion
Türkiye	5 to 16 September 2022	Section 12
Finland	3 to 14 October 2022	In the text
Singapore	10 to 19 October 2022	In the text
Sweden	14 to 25 November 2022	Section 12
Bangladesh	27 November to 8 December 2022	Section 11
Bosnia and Herzegovina	28 November to 7 December 2022	Section 11
The Czech Republic	15 to 26 May 2023 (Preliminary Report)	In the text
The Netherlands	5 to 16 June 2023	Section 11
Belgium	19 to 30 June 2023	Section 12
Kingdom of Saudi Arabia	1 to 10 October 2023 (Preliminary Report)	Section 11
Romania	30 October to 10 November 2023 (Preliminary Report)	Section 12
The Kingdom of Morocco	27 November to 6 December 2023 (Preliminary Report)	Section 12

APPENDIX 2: IAEA SAFETY REQUIREMENTS

List of relevant GSR Part 1 (Rev. 1) Requirements of focus due to the regulatory implications of pandemic situations

GSR Part 1 (Rev. 1) Requirements	IRRS Modules	Examples of issues related to the resilience of the regulatory infrastructure
<p>Requirement 2: Establishment of a framework for safety.</p> <p>The government shall establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are clearly allocated.</p> <p>2.5. The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following...</p> <p>(5) Provision for the involvement of interested parties and for their input to decision making;</p> <p>(10) Provision for the inspection of facilities and activities, and for the enforcement of regulations, in accordance with a graded approach;</p> <p>(12) Provision for preparedness for, and response to, a nuclear radiological emergency;</p> <p>(15) Provision for acquiring and maintaining the necessary competence nationally for ensuring safety...</p>	1	<ul style="list-style-type: none"> – Legal provisions for business continuity challenges. – Legal basis for taking regulatory actions during exceptional situations and considers provisional authorizations and virtual inspections among others regulatory measures.
<p>Requirement 3: Establishment of a regulatory body.</p> <p>The government, through the legal system, shall establish and maintain a regulatory body, and shall confer on it the legal authority and provide it with the competence and the resources necessary to fulfil its statutory obligation for the regulatory control of facilities and activities.</p> <p>2.13. The regulatory body shall be conferred with the legal authority to require an authorized party or an applicant, whether a person or an organization, to make arrangements to provide:</p>	1	<ul style="list-style-type: none"> – Legal basis to use remote regulatory control or virtual technology for conducting regulatory activities, e.g., authorization, inspection, or enforcement. – Identification and justification of the critical regulatory infrastructure to maintain the essential activities and regulatory body to be provided with the necessary resources.

GSR Part 1 (Rev. 1) Requirements	IRRS Modules	Examples of issues related to the resilience of the regulatory infrastructure
<p>(a) All necessary safety related information, including information from suppliers, even if this information is proprietary;</p> <p>(b) Access, solely or together with the authorized party or applicant, for making inspections on the premises of any designer, supplier, manufacturer, constructor, contractor or operating organization associated with the authorized party.</p>		
<p>Requirement 8: Emergency preparedness and response</p> <p>The government shall make provision for emergency preparedness to enable a timely and effective response in a nuclear or radiological emergency.</p> <p>2.21. In addition to assigning the responsibilities of authorized parties, the government shall establish a nationwide system, including emergency arrangements, to protect the public in a nuclear or radiological emergency declared as a consequence of an incident within or outside the territories and jurisdiction of the State.</p>	10	<ul style="list-style-type: none"> – Maintenance and operation of the nationwide emergency system for nuclear or radiological emergencies even during a pandemic and others exceptional circumstances. – Measures to adapt the regulatory body’s Emergency Response Organization to pandemic situation and related restrictions.
<p>Requirement 10: Provision for the decommissioning of facilities and the management of radioactive waste and of spent fuel</p> <p>The government shall make provision for the safe decommissioning of facilities, the safe management and disposal of radioactive waste arising from facilities and activities, and the safe management of spent fuel.</p> <p>2.33. Appropriate financial provision shall be made for:</p> <p>(c) Management of disused radioactive sources and radiation generators...</p>	1, 5 to 9 (radiation sources and radioactive waste management facilities)	<ul style="list-style-type: none"> – Management of disused sources on which immediate actions should be taken (e.g., close business operations, Bankruptcy). – Appropriate financial provision considered under both normal and exceptional circumstances.
<p>Requirement 13: Provision of technical services</p> <p>The government shall make provision, where necessary, for technical services in relation to safety, such as services for personal dosimetry, environmental monitoring and the calibration of equipment.</p>	1	<ul style="list-style-type: none"> – Essential technical services for radiation safety to be maintained during a pandemic, e.g., calibration, dosimetry, or training, are identified. – Measures taken to assure the provision of essential technical services for radiation safety, according to each particular situation.

GSR Part 1 (Rev. 1) Requirements	IRRS Modules	Examples of issues related to the resilience of the regulatory infrastructure
<p>Requirement 16: Organizational structure of the regulatory body and allocation of resources</p> <p>The regulatory body shall structure its organization and manage its resources so as to discharge its responsibilities and perform its functions effectively; this shall be accomplished in a manner commensurate with the radiation risks associated with facilities and activities.</p> <p>4.5. The regulatory body has the responsibility for structuring its organization and managing its available resources so as to fulfil its statutory obligations effectively. The regulatory body shall allocate resources commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach.</p>	3	<ul style="list-style-type: none"> – Provisions to address significant or even drastic resource reduction: structure of the organization, management of available resources in order to fulfil its statutory obligations in the best possible manner according to the situation and a graded approach. – Implementation of workforce management practices to a widespread teleworking situation. – Contingency plan to discharge regulatory responsibilities according to established priorities.
<p>Requirement 18: Staffing and competence of the regulatory body</p> <p>The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities.</p> <p>4.11. The regulatory body has to have appropriately qualified and competent staff. A human resources plan shall be developed that states the number of staff necessary and the essential knowledge, skills and abilities for them to perform all the necessary regulatory functions.</p>	3	<ul style="list-style-type: none"> – Provisions to address significant staff reduction: temporarily adaptation or re-assignment of the roles and responsibilities amongst the available staff in order to conduct the essential activities during the crisis period, according to a graded approach. – Contingency human resources plan to face situations where regulatory body’s human resources available are limited due to epidemic/pandemic or other special circumstance. – Ability and training of staff for teleworking.
<p>Requirement 19: The management system of the regulatory body</p> <p>The regulatory body shall establish, implement, and assess and improve a management system that is aligned with its safety goals and contributes to their achievement.</p> <p>4.16. The management system shall maintain the efficiency and effectiveness of the regulatory body in discharging its responsibilities and performing its functions. This includes the promotion of enhancements in safety, and the fulfilment of its obligations in an appropriate, timely and cost-effective manner so as to build confidence.</p>	4	<ul style="list-style-type: none"> – Consideration of new threats within the management system: Risk analysis of the regulatory activities during adverse situations such as decrease in budget or significant reduction of available staff. – Maintenance of minimum acceptable level of performance for regulatory oversight when access to resource is limited or regulatory activities cannot be conducted ‘normally’. – Reliable access to tools, information, and equipment for regulatory staff to effectively work from home.

GSR Part 1 (Rev. 1) Requirements	IRRS Modules	Examples of issues related to the resilience of the regulatory infrastructure
		<ul style="list-style-type: none"> – Administrative decision-making processes adapted to teleworking (e.g., electronic signature). – Documents and records management system available for teleworking.
<p>Requirement 20: Liaison with advisory bodies and support organizations</p> <p>The regulatory body shall obtain technical or other expert professional advice or services as necessary in support of its regulatory functions, but this shall not relieve the regulatory body of its assigned responsibilities.</p> <p>4.18. The regulatory body may decide to give formal status to the processes by which it is provided with expert opinion and advice. If the establishment of advisory bodies, whether on a temporary or a permanent basis, is considered necessary, it is essential that such bodies provide independent advice, whether technical or non-technical in nature.</p> <p>4.22. The obtaining of advice and assistance does not relieve the regulatory body of its assigned responsibilities. The regulatory body shall have adequate core competence to make informed decisions. In making decisions, the regulatory body shall have the necessary means to assess advice provided by advisory bodies and information submitted by authorized parties and applicants.</p>	3	<ul style="list-style-type: none"> – Strengthening of supply chain to the regulatory body, including: <ul style="list-style-type: none"> - Identification of the essential advisory services and external support; - Measures to maintain these services and support or establish the necessary new ones; - Measure to mitigate lack of external services or support. – Maintenance of a minimum core competence and means to make informed regulatory decisions.
<p>Requirement 21: Liaison between the regulatory body and authorized parties</p> <p>The regulatory body shall establish formal and informal mechanisms of communication with authorized parties on all safety related issues, conducting a professional and constructive liaison.</p> <p>4.23. As its primary purpose, the regulatory body shall carry out oversight of facilities and activities. The regulatory body, while maintaining its independence, shall liaise with authorized parties to achieve their common objectives in ensuring safety. Meetings shall be held as necessary to fully understand and discuss the arguments of each party on safety related issues.</p>	3	<ul style="list-style-type: none"> – Maintenance of the effective communication channels and meetings according to each especial situation with authorized parties.

GSR Part 1 (Rev. 1) Requirements	IRRS Modules	Examples of issues related to the resilience of the regulatory infrastructure
4.24. The regulatory body shall foster mutual understanding and respect on the part of authorized parties through frank, open and yet formal relationships, providing constructive liaison on safety related issues and in-depth technical dialogue between experts.		
<p>Requirement 22: Stability and consistency of regulatory control</p> <p>The regulatory body shall ensure that regulatory control is stable and consistent.</p> <p>4.26. The regulatory process shall be a formal process that is based on specified policies, principles and associated criteria, and that follows specified procedures as established in the management system. The process shall ensure the stability and consistency of regulatory control and shall prevent subjectivity in decision making by individual staff members of the regulatory body. The regulatory body shall be able to justify its decisions if they are challenged. In connection with its reviews and assessments and its inspections, the regulatory body shall inform applicants of the objectives, principles and associated criteria for safety on which its requirements, judgements and decisions are based.</p>	3	<ul style="list-style-type: none"> – Impact on the stability and consistency of the regulatory control.
<p>Requirement 23: Authorization of facilities and activities by the regulatory body</p> <p>Authorization by the regulatory body, including specification of the conditions necessary for safety, shall be a prerequisite for all those facilities and activities that are not either explicitly exempted or approved by means of a notification process.</p> <p>4.31. In the granting of an authorization for a facility or an activity, the regulatory body may have to impose limits, conditions and controls on the authorized party’s subsequent activities.</p> <p>4.36. An authorization may have to be reconsidered and/or renewed in the different stages in the lifetime of the facility or the duration of the activity concerned (e.g. as a result of a change in the conditions under which the authorization was granted). This would have to lead to a new regulatory decision which may require the amendment, renewal, suspension or revocation of the authorization.</p>	5	<ul style="list-style-type: none"> – Issuing and renewal of authorizations in exceptional circumstances. – Use of provisory authorizations if the legal and technical assessment have been satisfactorily performed, in particular where the needed regulatory verifications or on-site controls cannot be performed. – Extension of the duration of authorizations. – Modification of the frequency of renewing authorizations.
<p>Requirement 25: Review and assessment of information relevant to safety</p>	6	<ul style="list-style-type: none"> – Performance of review and assessment activities remotely.

GSR Part 1 (Rev. 1) Requirements	IRRS Modules	Examples of issues related to the resilience of the regulatory infrastructure
<p>The regulatory body shall review and assess relevant information — whether submitted by the authorized party or the vendor, compiled by the regulatory body, or obtained from elsewhere — to determine whether facilities and activities comply with regulatory requirements and the conditions specified in the authorization. This review and assessment of information shall be performed prior to authorization and again over the lifetime of the facility or the duration of the activity, as specified in regulations promulgated by the regulatory body or in the authorization.</p>		<ul style="list-style-type: none"> – Consideration of licensee requests for regulatory flexibility and deferral of regulatory commitments. – Modification of the frequency of the periodic safety review of facilities and activities. – Regulatory review and assessment in case of modification of the conditions of the authorization (e.g., overexposure of workers due to high increase of radiodiagnosis procedures, massive radiological procedures in patient, unjustified radiation exposures for suspected SARS-Cov2 and asymptomatic patients; use of the equipment for different practices other than the ones being authorized such as portable x-ray machines used in standard rooms, transport and distribution of radiopharmaceuticals).
<p>Requirement 26: Graded approach to review and assessment of a facility or an activity Review and assessment of a facility or an activity shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach. 4.40. The regulatory body shall review and assess the particular facility or activity in accordance with the stage in the regulatory process (initial review, subsequent reviews, reviews of changes to safety related aspects of the facility or activity, reviews of operating experience, or reviews of long-term operation, life extension, decommissioning or release from regulatory control). The depth and scope of the review and assessment of the facility or activity by the regulatory body shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.</p>	6	<ul style="list-style-type: none"> – Implementation of a graded approach for review and assessment to prioritize the regulatory activities to contribute in the best possible manner to control situations, considering health services’ needs, supporting services or the control of relevant facilities among others. – Optimum number and competency of staff in specific type of facilities and activities, e.g. medical facilities, under pandemic situations and conditions to demonstrate and ensure continued safe operation.
<p>Requirement 27: Inspection of facilities and activities The regulatory body shall carry out inspections of facilities and activities to verify that the authorized party is in compliance with the regulatory requirements and with the conditions specified in the authorization.</p>	7	<ul style="list-style-type: none"> – Access of inspectors to authorized facilities, and information/data systems. – Protection measures against contaminations.

GSR Part 1 (Rev. 1) Requirements	IRRS Modules	Examples of issues related to the resilience of the regulatory infrastructure
		<ul style="list-style-type: none"> – Use of self-assessment by authorized parties to compensate reduced on-site regulatory oversight programmes. – Legal basis to perform virtual inspections and to use the virtual findings as evidence for issuing an authorization or conducting an enforcement process. – Cyber-security certification of the technology applied for conducting such regulatory activities virtually.
<p>Requirement 28: Types of inspection of facilities and activities</p> <p>Inspections of facilities and activities shall include programmed inspections and reactive inspections, both announced and unannounced.</p>	7	<ul style="list-style-type: none"> – Conduct of reactive inspections in facilities and activities where authorization conditions could be exceeded due to the especial conditions.
<p>Requirement 29: Graded approach to inspections of facilities and activities</p> <p>Inspections of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.</p> <p>4.50. The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections), and shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach.</p>	7	<ul style="list-style-type: none"> – Conducting/prioritising and rescheduling compliance activities in order to maintain regulatory oversight, while respecting licensee restrictions on access to facilities and activities considering a graded approach. – Application of a graded approach to the inspection programme, in consideration of especial factors, e.g., the contribution at the control of the extreme conditions, the increase of workload in a specific sector or the prioritization of public health among other factors.
<p>Requirement 36: Communication and consultation with interested parties</p> <p>The regulatory body shall promote the establishment of appropriate means of informing and consulting interested parties and the public about the possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body.</p>	3	<ul style="list-style-type: none"> – Publication of regulatory decisions; – Consultation of interested part