



Integrated
Regulatory
Review Service

IRRS

Proposal for the consideration of the Regulatory Implications of Pandemic Situations during the IRRS

Vienna, 05 May 2021

BACKGROUND

The information shared by Member States with the IAEA revealed that regulatory bodies and 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 are reviewing their legal and regulatory frameworks to ensure that there is an appropriate basis and regulatory documentation for performing their required functions under exceptional circumstances such as pandemics, and have instigated in some cases special procedures to perform their functions.

The IRRS is recognized as an effective mechanism for reviewing national governmental, legal and regulatory frameworks for safety against the relevant IAEA Safety Standards while facilitating experience sharing and exchange of lessons learned amongst the international regulatory community. Therefore, the IRRS provides an opportunity, at the request of Member States, to evaluate and discuss the national regulatory implications of the COVID-19 pandemic. This paper describes the basis for incorporating the topic as a Policy Discussion within IRRS missions and aligning with the existing mission structure.

PROVISIONS

A preliminary review of GSR Part 1 (Rev.1) Governmental, Legal and Regulatory Framework for Safety has identified a baseline list of IAEA Safety Requirements which merit special attention during an IRRS mission due to the possible impact on regulatory provisions of exceptional circumstances such as natural disasters or pandemics. These requirements listed in the [Annex](#) have been 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. It should be noted that the focus of the provisions in this paper is on 'Business Continuity' to maintain delivery of statutory duties and responsibilities for safety.

It is worthwhile highlighting that the consideration of the regulatory implications of an exceptional situation as a pandemic should not affect 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. Instead, this emerging issue should be addressed in a complementary manner and provide an opportunity to discuss and identify ways to strengthen the governmental, legal and regulatory framework for safety.

PROPOSAL

In view of the above and at the request of the Member State, it is proposed that:

1. IRRS missions include a policy discussion on the implications of a pandemic situation and associated challenges for regulatory bodies.

The discussion could cover, inter alia, the issues highlighted as examples in the Annex, such as:

- Maintenance and operation of the nationwide emergency system;
- Management of disused sources on which immediate actions should be taken;
- Implementation of workforce management practices to a widespread teleworking situation and reliable and secure access to regulatory body's staff with tools, information, and equipment to telework effectively;
- Access for 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;
- Communication and consultation with the interested parties given the prevailing circumstances.

Following the Mission practice for the other policy issues, the host organization(s) is expected to prepare views and discussion points relating to the regulatory implications of a pandemic situation that should then be forwarded to the IAEA Coordinator prior to the mission.

2. Host Countries and IRRS Review Teams ensure a careful consideration of the requirements listed in the Annex throughout the IRRS process, including the self-assessment and the mission itself.

The host organization(s) may consider adding to the ARM summary report a section in order to share relevant feedback and main conclusions on national regulatory implications of a pandemic situation with the IRRS Review Team.

In the course of the mission, IRRS Reviewers address the relevant considerations of their assigned areas, including the issues highlighted in the Annex. A dedicated section summarizing the regulatory implications of an exceptional situation as a pandemic will be included at the end of the core part of the IRRS mission report. This section comprises both: the overview and main conclusions of the policy discussion on the topic, referring to Proposal No. 1, and contributions from different reviewers who have identified in the course of their review of their assigned area any relevant feedback considered useful for sharing with the international community.

ANNEX

List of relevant GSR Part 1 (Rev. 1) Requirements requiring special attention due to the regulatory implications of exceptional circumstances such as pandemics.

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. 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.

GSR Part 1 (Rev. 1) Requirements	IRRS Modules	Examples of issues related to the resilience of the regulatory infrastructure.
<p>Requirement 3: Establishment of a regulatory body. 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> <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>1</p>	<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.
<p>Requirement 8: Emergency preparedness and response. 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>	<p>10</p>	<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.

GSR Part 1 (Rev. 1) Requirements	IRRS Modules	Examples of issues related to the resilience of the regulatory infrastructure.
<p>Requirement 10: Provision for the decommissioning of facilities and the management of radioactive waste and of spent fuel. 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: (c) Management of disused radioactive sources and radiation generators...</p>	<p>1 5 to 9 (for radiation sources and radioactive waste management facilities)</p>	<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. 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>	<p>1</p>	<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.
<p>Requirement 16: Organizational structure of the regulatory body and allocation of resources 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>	<p>3</p>	<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.

GSR Part 1 (Rev. 1) Requirements	IRRS Modules	Examples of issues related to the resilience of the regulatory infrastructure.
<p>Requirement 18: Staffing and competence of the regulatory body. 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>	<p>3</p>	<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. 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>	<p>4</p>	<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. – Administrative decision-making processes adapted to teleworking (e.g., electronic signature). – Documents and records management system available for teleworking.

GSR Part 1 (Rev. 1) Requirements	IRRS Modules	Examples of issues related to the resilience of the regulatory infrastructure.
<p>Requirement 20: Liaison with advisory bodies and support organizations. 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>	<p>3</p>	<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. 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> <p>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>	<p>3</p>	<ul style="list-style-type: none"> - Maintenance of the effective communication channels and meetings according to each especial situation with authorized parties.

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<p>Requirement 22: Stability and consistency of regulatory control. 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>	<p>3</p>	<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. 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>	<p>5</p>	<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.

GSR Part 1 (Rev. 1) Requirements	IRRS Modules	Examples of issues related to the resilience of the regulatory infrastructure.
<p>Requirement 25: Review and assessment of information relevant to safety. 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>	<p>6</p>	<ul style="list-style-type: none"> – Performance of review and assessment activities remotely. – 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.</p> <p>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>	<p>6</p>	<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.

GSR Part 1 (Rev. 1) Requirements	IRRS Modules	Examples of issues related to the resilience of the regulatory infrastructure.
<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. – 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. 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. 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.

GSR Part 1 (Rev. 1) Requirements	IRRS Modules	Examples of issues related to the resilience of the regulatory infrastructure.
<p>Requirement 36: Communication and consultation with interested parties. 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>	<p>3</p>	<ul style="list-style-type: none"> – Publication of regulatory decisions; – Consultation of interested parties.