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# INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

## FOLLOW-UP MISSION

**TO**

# THE REPUBLIC OF CROATIA

Zagreb, Croatia

***21 to 29 October 2019***

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

IAEA Integrated Regulatory Review Service IRRS

Integrated
Regulatory
Review Service

IAEA | IRRS

# REPORT OF THE
# INTEGRATED REGULATORY REVIEW SERVICE (IRRS) FOLLOW-UP MISSION
# TO
# THE REPUBLIC OF CROATIA

Integrated Regulatory Review Service

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# TO

# THE REPUBLIC OF CROATIA

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|---|---|
| **Mission dates:** | *21 to 29 October 2019* |
| **Regulatory body visited:** | *Ministry of the Interior (MoI), Civil protection Directorate (CPD)* |
| **Location:** | *Zagreb, Nehajska 5, Croatia* |
| **Regulated facilities and activities in the mission scope:** | *Radiation Sources in Industrial and Medical facilities, Waste Management facilities, Decommissioning activities, Emergency Preparedness and Response, Medical Exposure, Occupational Exposure, Public and Environmental Monitoring* |
| **Organized by:** | *International Atomic Energy Agency* |

| IRRS REVIEW TEAM | |
|---|---|
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IAEA-2019

**The number of recommendations, suggestions and good practices is in no way a measure of the status of the national infrastructure for nuclear and radiation safety. Comparisons of such numbers between IRRS reports from different countries should not be attempted.**

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# EXECUTIVE SUMMARY

At the request of the Government of Croatia an international team of senior safety experts met with representatives of the Ministry of Interior (MoI) and Civil Protection Directorate (CPD) from 21 to 29 October 2019 to conduct an Integrated Regulatory Review Service (IRRS) follow-up mission. The purpose of the IRRS follow-up mission was to review Croatia's progress against the recommendations and suggestions identified in the initial IRRS mission, which was carried out from 7 to 17 June 2015. The follow-up mission took place at the Ministry of the Interior (MoI) Headquarters in Zagreb, Croatia. Activities of radiation and nuclear safety are performed within the Civil Protection Directorate (CPD)[1], which is an internal organizational unit of the MoI. The scope of the IRRS follow-up mission was the same as the scope of the initial mission in 2015, namely the regulatory framework for all radiation and nuclear facilities and activities in Croatia.

The IRRS review team consisted of seven senior regulatory experts from seven IAEA Member States, and three IAEA staff members.

The IRRS team carried out a review of the progress made on each recommendation and suggestion that was documented in the 2015 IRRS mission report. These recommendations and suggestions cover the following areas: responsibilities and functions of the government; the global safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body, including authorization, review and assessment, inspection, enforcement and the development and content of regulations and guides; emergency preparedness and response; control of medical exposure; occupational radiation protection; control of radioactive discharges, materials for clearance and control of existing exposure situations and remediation; and environmental monitoring for public radiation protection.

To assess progress, the IRRS review team conducted a series of interviews and discussions with Ministry of the Interior (MoI), and the CPD staff, and staff of the Ministry of Health, and reviewed the advance reference material provided by the CPD.

Overall, the IRRS review team concluded that Croatia, through the MoI and the CPD, has been responsive to each recommendation and suggestion made in 2015, and continues to place appropriate focus on implementing a framework that provides for effective radiation and nuclear safety for workers, patients, the public and the environment. Nineteen out of 36 recommendations and 14 out of 22 suggestions identified in 2015 have been closed.

[1] At the time of the request, the national organization in charge of regulatory oversight for nuclear and radiation safety was the State Office for Radiological and Nuclear Safety (SORNS). SORNS was merged into the MoI in January 2019 and regulatory functions were assigned within the MoI to the Civil Protection Directorate (CPD). This report systematically refers to the CPD as the regulatory body.

**Since 2015, Croatia has taken the following positive steps:**

- It has adopted a Nuclear and Radiation Safety Strategy;
- It has updated the legal and regulatory framework for safety in line with international standards by issuing a number of new amendments of the Act and Ordinances;
- The Croatian Emergency Preparedness and Response Plan has been drafted which will be implemented through the revision of the Ordinance on Emergency;
- Existing exposure situations that are deemed to give rise to occupational exposures and public exposures have been identified. Moreover, a Radon Action Plan has been developed and remediation plans for sites containing naturally occurring radioactive materials are under development.

The IRRS review team identified new findings warranting attention or needing improvement that the team believes would enhance the legal and regulatory framework for radiation and nuclear safety in Croatia. In particular, during the follow-up mission, the IRRS review team developed one new recommendation.

To complete the implementation of the recommendation and suggestion from 2015 and to implement the new recommendation from this follow-up mission, Croatia needs to take further actions to:

- Provide the CPD with human and financial resources enabling the CPD to completely fulfil its statutory obligations for regulatory control;
- Strengthen the capacity and competence of the CPD to carry out its regulatory functions, especially inspections and the licensing of complex facilities and activities;
- Develop an integrated management system for the CPD that clearly specifies the interfaces among different internal sections and units performing tasks related to radiation and nuclear safety in an integrated manner;
- Continue its efforts to coordinate and harmonize emergency planning zones with its Slovenian counterparts in relation to Krsko NPP;
- Continue its efforts to establish the criteria for the qualification and recognition of medical physicists;
- Continue its efforts to establish a national waste management centre.

The specific findings of the follow-up mission are summarized in Appendices IV and V.

A press release was issued by the IAEA at the end of the IRRS follow-up mission.

# I. INTRODUCTION

At the request of the Government of Croatia, an international team of senior safety experts met representatives from the Ministry of the Interior (MoI), Civil Protection Directorate (CPD) from 21 October to 29 October 2019 to conduct an Integrated Regulatory Review Service (IRRS) follow-up mission.

The purpose of the follow-up mission is to review the implementation of the recommendations and suggestions given to the Government of Croatia during the IRRS Mission in June 2015. The follow-up mission was formally requested by the Government of Croatia in July 2017. A preparatory meeting was conducted from 3 to 4 July 2018 and an additional preparatory meeting on 3 June 2019 at the Ministry of the Interior (MoI), Civil Protection Directorate in Zagreb to discuss the purpose, objectives and detailed preparations of the review in connection with regulated facilities and activities in Croatia and their related safety aspects.

The IRRS review team consisted of seven senior regulatory experts from seven IAEA Member States, and 3 IAEA staff members. The IRRS review team carried out the review in the areas covered by the main mission in 2015.

The follow-up self-assessment report and supporting documentation were provided to the IRRS review team as advance reference material (ARM) for the mission. During the mission, the IRRS review team performed a systematic review of all topics by reviewing the advance reference material, additional information, and by conducting interviews with management and staff of the CPD.

All through the mission, the IRRS review team received excellent support and cooperation from the CPD.

# II. OBJECTIVE AND SCOPE

The purpose of this IRRS follow-up mission was to conduct a review of the implementation of the recommendations and suggestions given to the Government of Croatia during the IRRS Mission in June 2015 and to exchange information and experience in the areas covered by the IRRS. The IRRS review scope included all facilities and activities regulated by MoI, CPD. The review was carried out by comparison of existing arrangements against the IAEA safety standards.

It is expected that the IRRS follow-up mission will facilitate regulatory improvements in Croatia and other Member States from the knowledge gained and experiences shared between MoI, CPD and IRRS reviewers and through the evaluation of the effectiveness of Croatia's regulatory framework for radiation and nuclear safety.

# III. BASIS FOR THE REVIEW

## A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of Croatia, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 3 to 4 July 2018 and an additional meeting on 3 June 2019. The preparatory meeting was carried out by the appointed Team Leader Ms Ritva Bly, and IAEA Coordinator Mr Ronald Pacheco and the CPD representatives.

The IRRS Follow-up mission preparatory team had discussions regarding regulatory programmes with the senior management of the CPD represented by Ms Nevenka Novosel, Civil Protection International Unit, and Zdravka Tečić, Sector for Radiological and Nuclear Safety, as the Liaison Officers. The discussions resulted in agreement that the regulatory functions covering the following facilities and activities were to be reviewed by the IRRS follow-up mission:

- Waste management facilities;
- Decommissioning;
- Radiation sources facilities and activities;
- Control of medical exposure;
- Occupational radiation protection;
- Public exposure control.

Ms Zdravka Tečić, Head of Sector on Radiological and Nuclear Safety made presentations on the national context, the current status of the CPD and the progress made since the initial mission of June 2015.

IAEA staff presented the process and methodology of conducting an IRRS mission follow-up. This was followed by a discussion on the tentative work plan for the implementation of the follow-up mission in Zagreb in October 2019.

The proposed IRRS review team composition (senior regulators from Member States to be involved in the review) was discussed and the size of the IRRS follow-up team was tentatively confirmed. Logistics including meeting and work space, counterparts and Liaison Officer, lodging and transport arrangements were also addressed.

The Liaison Officers for the preparatory meeting and the IRRS follow-up mission were Ms Nevenka Novosel and Ms Zdravka Tečić.

The CPD provided the IAEA (and the review team) with the advance reference material for the review in August 2019 and additional materials. In preparation for the mission, the IRRS review team members conducted a review of the advance reference material and provided their initial review comments to the IRRS Team Coordinator and Team Leader prior to the follow-up mission.

## B) REFERENCES FOR THE REVIEW

The relevant IAEA safety standards and the Code of Conduct on the Safety and Security of Radioactive Sources were used as review criteria. The complete list of IAEA publications used as the references for this mission is provided in Appendix VII.

## C) CONDUCT OF THE REVIEW

An initial IRRS review team meeting was conducted on Sunday 20 October 2019, in Zagreb by the IRRS Team Leader and IAEA Team Coordinator to discuss the general overview, the focus areas and the specific issues of the mission; to clarify the basis for the review and the background and objectives of the IRRS; and to agree on the methodology for the review. The agenda for the mission was also presented.

The Liaison Officers, Ms Nevenka Novosel and Ms Zdravka Tečić were present at the initial IRRS team meeting in accordance with the IRRS guidelines, and presented logistical arrangements planned for the mission.

The reviewers also reported their first impressions of the advance reference material. General approaches for mission conclusions drafting were agreed.

The IRRS entrance meeting was held on Monday 21 October 2019, with the participation of Assisstant Minister Damir Trut, senior management and staff of the MoI, CPD. Opening remarks were made by the Assistant Minister Mr Damir Trut, and the Team Leader, Ms Ritva Bly, gave a presentation on the expectations of the IRRS follow-up mission. Ms Zdravka Tečić, from the CPD gave an overview of the CPD activities and response to the 2015 mission findings.

During the mission, a review was conducted for all the mission scope areas with the objective of reviewing the Government and the CPD's response to the recommendations and suggestions identified during the initial mission[2]. The review was conducted through meetings, interviews and discussions regarding the national practices and activities.

The IRRS review team performed its activities based on the mission programme given in Appendix III.

The IRRS exit meeting was held on Tuesday 29 October 2019 where the IRRS Team Leader Ms Ritva Bly presented the results of the follow-up mission highlighting the main findings. This was followed by a statement by Ms Zdravka Tečić, in response to the Team Leader's presentation. Closing remarks were made by Mr. Ronald Pacheco on behalf of the Director of the Division of Radiation, Transport and Waste Safety, Department of Nuclear Safety and Security.

A press release was issued by the IAEA at the end of the IRRS follow-up mission.

[2] In this report, the 2015 initial mission recommendations and suggestions are addressed to the current regulatory body CPD, instead of to SORNS, which was the name of the regulatory body in 2015.

# 1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

## 1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** The Croatian Government has not established a comprehensive national policy outlining its commitment to safety and strategy for implementing a national policy with the objective to demonstrate the Government's long-term commitment to safety and provide a national co-ordinated plan to ensure the appropriate national infrastructure. | |
| **(1)** | **BASIS: GSR Part 1 Requirement 1 states that** *"The government shall establish a national policy and strategy for safety, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities, to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamentals."* |
| **R1** | **Recommendation: The Government should establish a national policy and strategy for safety in accordance with Requirement 1 of GSR Part 1.** |

**Changes since the original IRRS mission**

**Recommendation 1:** The Government of the Republic of Croatia adopted the Radiological and Nuclear Safety Strategy for the Period 2017-2025 on 6 July 2017 and it is published in Official Gazette No. 65/17. The Strategy covers the following parts of the Requirement 1 of GSR Part 1:

- the fundamental safety objective and the fundamental safety principles in accordance with Safety Fundamentals established in No. SF-1;
- domestic and international legislative framework;
- objectives of radiation and nuclear safety and measures for their achievement;
- functions and financing of the regulatory body.

The current strategy does not fully address the following items:

- other authorities and organization which are a part of the institutional framework (i.e. Ministry of Health, Fund for Financing the Decommissioning of the Krško Nuclear Power Plant and the Disposal of NEK Radioactive Waste and Spent Nuclear Fuel etc.);
- the need and provision for human and financial resources beyond the current 3 year period which expires at the end of 2019;
- research and development activities;
- mechanisms for taking into account social and economic developments.

The 2014 Strategy for the Management of Radioactive Waste, Disused Sources and Spent Nuclear Fuel which is also a part of national policy and strategy, covers all parts of the Requirement 1 of GSR Part 1.

However, this Strategy in some parts does not reflect the current situation, in relation to the obligation for the establishment of the central storage facility for institutional radioactive waste and disused sources. This obligation is now assigned to the Fund through the 2015 Act on Amendments to the Act on Radiological and Nuclear Safety and in the National Programme for the Implementation of the Strategy for Management of Radioactive Waste, Disused Sources and Spent Nuclear Fuel.

**Status of the finding in the initial mission**

**Recommendation R1 is closed on the basis of progress made and confidence in effective completion in due time,** as the Government of the Republic of Croatia adopted a national policy and strategy which is subject to periodic review to be in accordance with GSR Part 1(Rev 1)**.**

## 1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

| **Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES** | |
|---|---|
| **Observation:** In the national framework on safety certain, provisions are missing or are not covered fully in line with GSR Part 1, Requirements 2 and 6 refer to provisions ensuring the continuity of responsibility where activities are carried out by several persons or organizations successively; provisions of a graded approach; provisions on release from regulatory control; provision that stipulates that compliance with regulations does not relieve the person or organization responsible for a facility or an activity of its prime responsibility for safety. | |
| **(1)** | **BASIS: GRS Part 1 Requirement 2, para. 2.5. states that** *"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:*<br>*(1) ....*<br>*(3) The type of authorizations that is required for the operation of facilities and for the conduct of activities, in accordance with a graded approach….*<br>*(6) Provision for assigning legal responsibility for safety to the persons or organizations responsible for the facilities and activities, and for ensuring the continuity of responsibility where activities are carried out by several persons or organizations successively…*<br>*(8) Provision for the review and assessment of facilities and activities, in accordance with a graded approach…*<br>*(10) Provision for the inspection of facilities and activities, and for the enforcement of regulations, in accordance with a graded approach…*<br>*(17) The criteria for release from regulatory control…"* |
| **(2)** | **BASIS: GRS Part 1 Requirement 6 states that** *"The government shall stipulate that compliance with regulations and requirements established or adopted by the regulatory body does not relieve the person or organization responsible for a facility or an activity of its prime responsibility for safety.*" |
| **R2** | **Recommendation: The Government should complement the framework for safety with: provisions for ensuring the continuity of responsibility where activities are carried out by several persons or organizations successively; provisions related to a graded** |

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| | **approach; provisions on criteria for release from regulatory control; provision that stipulates that compliance with regulations does not relieve the person or organization responsible for a facility or an activity of its prime responsibility for safety.** |

**Changes since the original IRRS mission**

**Recommendation 2:** The Act on Radiological and Nuclear Safety (The Act) (Official Gazette (OG) 141/13, 39/15, 130/17 and 118/18) provides that all activities including the use of ionizing radiation sources must not be performed before MoI issues an approval or registration permission. Every organization in the chain of successive activities must comply with this requirement, which can be checked during inspections.

The Amendment to the Act (OG 130/17) introduced a new definition of graded approach, and through the provisions of the Ordinance on Notification, Registration, Approval and Placing on the Market of Sources of Ionizing Radiation (Ordinance on Sources) (OG 54/18) the principle of the graded approach now covers authorization and inspection activities. Through these new provisions and different enforcement options the graded approach has been introduced into the legal and regulatory framework.

Article 4 of the Ordinance on the Conditions and Measures of Ionising Radiation Protection for Performing Activities Involving Ionising Radiation Sources (Ordinance on Radiation Protection) (OG 53/18) sets down clearance levels for the release from regulatory control.

In Part 2 of the Radiological and Nuclear Safety Strategy for the Period 2017-2025 and in different parts of the Act, the principle of prime responsibility for safety is explicitly prescribed.

**Status of the finding in the initial mission**

**Recommendation R2 is closed,** as the legal and regulatory framework for safety has been complemented with provisions for ensuring the continuity of responsibility, provisions related to a graded approach and provisions on prime responsibility for safety.

## 1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** The Croatian Government has established SORNS as an effectively independent regulatory body, however the resources provided to SORNS are not adequate to perform all of its regulatory responsibilities**.** | |
| **(1)** | **BASIS: GRS Part 1 Requirement 3 states that** "*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."* |
| **(2)** | **BASIS: GSR Part 1 Requirement 18 states that** *"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."* |
| **R3** | **Recommendation: The Government should provide SORNS with human and financial** |

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| | **resources enabling SORNS to completely fulfil its statutory obligations for regulatory control.** |

## Changes since the original IRRS mission

**Recommendation 3:** There are 32 working places planned in the field of radiation and nuclear safety but currently, there are only 15 employees.

- The number of planned posts in the Radiological and Nuclear Safety Sector is 19 while the number of current employees is 9.
- The number of planned posts in the Radiological and Nuclear Emergency Unit is 5, but currently there is only one person employed.
- The planned number of employees dealing with tasks of radiation and nuclear safety in the International Relations and Projects Department is 2 but currently, one person is employed.
- The planned number of radiation and nuclear safety inspectors in the Inspection Sector is 6 of which 5 will be inspectors but currently, 4 persons (3 inspectors) are employed. However, IRRS team was informed that at the time of the mission one inspector, as the head of the Radiological and Nuclear Safety Inspections has administrative duties in addition to inspection, one inspector is undergoing on the job training and the third inspector is on long term leave.

The IRRS team noted the age profile and regulatory experience of the existing staff. It is evident that some staff are approaching retirement and some others are inexperienced and lack the required competencies for working in the field of radiation and nuclear safety. The IRRS team also noted that a trend of decreasing staff numbers has continued from the Initial Mission in 2015 up to 2019 with the additional loss of 5 employees but only 3 new staff are employed. Some of the staff that have left the organization were conducting tasks related to radiation and nuclear safety i.e. inspection (one inspector), performing emergency preparedness (one employee), authorization (3 employees) and 2 employees which worked in Section for legal, general and finance tasks in SORNS who were involved in developing management system.

Since 2015, there were significant employees turnover and no knowledge transfer (mentors, schooling, skills development and apprenticeships). A great deal of knowledge gained through the cooperation with the IAEA and within the scope of EU projects was lost. There is continuous lack of staff with expertise in various fields of radiation and nuclear safety.

The IRRS team was informed by the CPD that three additional employments have already been approved and it is envisaged that these will be filled in 2020. For the years following 2020, the CPD intends to continue with new employments, however there are no actual plans or arrangements in place for this.

The IRRS team noted that staff of the CPD are very professional and committed to their work. However, it was also recognized that all sectors and units in the area of radiation and nuclear safety face a significant challenge with a lack of suitably qualified staff. With existing staff the CPD is unable to completely fulfil its statutory obligations for regulatory control in the field of radiation and nuclear safety.

The CPD is financed from the State budget through the MoI. The State budget is the only financial resource for the CPD to perform its assigned responsibilities. The current operations of the CPD for the activities formerly conducted under SORNS are funded through appropriation approved before the incorporation. This funding expires in 2019. By integration SORNS into MoI, the 2019 budget for SORNS was approved

and transferred to MoI for the same activities as planed in SORNS. The same budget amount is planned by the CPD for the next year budget forecast. The budget is approved yearly. New funding will be based on the existing budgetary process used by MoI.

Availability of sufficient financial resources is closely related to availability of sufficient competent staff, since available financial resources is a prerequisite for both employing and training of a new staff.

**Status of the finding in the initial mission**

**Recommendation R3 remains open,** as no significant progress has been made in this area**.**

| **Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES** | |
|---|---|
| **Observation:** The 2015 amendments of the 2013 Act assigned SORNS with the responsibility to "organize additional professional training and skills refreshment courses on application of radiology safety measures". | |
| **(1)** | **BASIS: GRS Part 1 Requirement 4, para.2.9 states that** *"No responsibilities shall be assigned to the regulatory body that might compromise or conflict with its discharging of its responsibility for regulating the safety of facilities and activities."* |
| **(2)** | **BASIS: RS-G-1.4, Para 2.8 states that** "*The regulatory body should not be responsible for providing training, except for training of its own staff. However, whenever appropriate, the regulatory body should provide guidance in respect of the types of training required, the course content, the duration and level of training, and the assessment of trainees. Training centers and courses dealing with safety and with protection related aspects of nuclear, transport and waste safety may be accredited by the regulatory body or by other professional bodies recognized by the regulatory body."* |
| **S1** | **Suggestion: The Government should consider organizing training and refresher courses in a way that do not compromise effective independence of SORNS.** |

**Changes since the original IRRS mission**

**Suggestion 1:** Following the original 2015 IRRS mission there have been no changes in the area of developing and organizing professional training and refresher training courses given by the CPD on the application of radiation safety measures and nuclear security measures. According to Article 7 of the Act, one of the functions of the regulatory body is still "organizing additional professional training and refresher training on the application of radiation safety measures and nuclear security measures".

The CPD intends to prepare the curriculum for education and a practical training for Radiation Protection Experts (RPEs) and RPOs which would later be implemented by assigned educational organizations.

**Status of the finding in the initial mission**

**Suggestion S1 remains open,** as no significant progress has been made in this area**.**

## 1.4. COMPLIANCE WITH REGULATIONS AND RESPONSIBILITY FOR SAFETY

There were no findings in this area in the original IRRS mission.

## 1.5. COORDINATION OF AUTHORITIES WITH RESPONSIBILITIES FOR SAFETY WITHIN THE REGULATORY FRAMEWORK

There were no findings in this area in the original IRRS mission.

## 1.6. SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE EXISTING OR UNREGULATED RADIATION RISKS

There were no findings in this area in the original IRRS mission.

## 1.7. PROVISIONS FOR THE MANAGEMENT OF RADIOACTIVE WASTE

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** There is an absence of active central storage facility for radioactive waste, disused sources or orphan sources and foreseen spent nuclear fuel in the Republic of Croatia. | |
| **(1)** | **BASIS: GSR Part 1 Requirement 10 states that** *"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."* |
| **R4** | **Recommendation: The Government should implement the provisions for the safe management of radioactive waste in particular with the construction and operation of the Central National Storage Facility in compliance with the Strategy for the Management of Radioactive Waste, Disused Sources and Spent Nuclear Fuel.** |

**Changes since the original IRRS mission**

**Recommendation R4:** The National programme for Implementation of the Strategy for Management of Radioactive Waste, Disused Sources and Spent Nuclear Fuel was adopted in 2018. This National programme sets down the basic principles and objectives of the programme, legal and regulatory framework in the area of radioactive waste, disused sources and spent nuclear fuel management, liabilities for programme implementation, requirements on promoting sustainable development in local communities, transparency and public participation, radioactive waste classification, inventory, implementation activities for the management of radioactive waste, cost estimates and funding, performance indicators etc.

The National programme is based on the assumption that the Central National Storage Facility for the institutional radioactive waste and disused sources as well as for the long-term storage of low and intermediate level waste from Krško NPP shall be established in the area of the location Čerkezovac, Dvor Municipality on the southern slopes of the Trgovska gora massif.

The Amendment of the Act (OG 39/15) appointed the "Fund for Financing the Decommissioning of the Krško Nuclear Power Plant and the Disposal of NEK Radioactive Waste and Spent Nuclear Fuel" as the state organization responsible for establishing and operating the Central National Storage Facility.

The IRRS team was informed that the main activities regarding the establishment of the storage facility have been postponed in recent years due to the search of a common solution with Slovenia on disposal of radioactive waste. As a common solution has not been reached, the Fund is now going to strengthen activities in establishing the storage facility. Currently the design documentation and preliminary safety assessment is under preparation. Siting procedures are to be started, and environmental impact assessment

is to be carried out in 2021. The IRRS team was informed that construction may start in 2023 and operation commence within the following year or two.

The new Ordinance on the Management of Radioactive Waste and Disused Sources (Ordinance on Waste) OG12/18, containing requirements for licensing the site, construction, operation and closure of the radioactive waste management facility is harmonized with the EU and IAEA safety standards in this area.

The IRRS team was informed that a draft Regulation on funding the Radioactive Waste Management Centre (including fees for the management of radioactive waste and disused sources and financing the local community where the centre would be located) has been prepared and is to be sent to all stakeholders for their approval.

Despite the ongoing activities and described efforts the construction and the operation of the Central National Storage Facility has not started yet. Currently there is no facility available in Croatia for the storage of institutional radioactive waste. Therefore, the planed Central National Storage Facility is of crucial importance for the safe management of radioactive waste in Croatia.

**Status of the finding in the initial mission**

**Recommendation R4 remains open,** as the construction and operation of the Central National Storage Facility has not been implemented yet**.**

## POLICY ISSUE 1

### Fund for financing the decommissioning of the Krško Nuclear Power Plant (Nuklearna elektrarna Krško / NEK) and the disposal of NEK radioactive waste and spent nuclear fuel

During the policy discussion, the CEO of the Fund, and two of its team members provided an overview about the Fund´s main objectives and the next steps in its Radioactive Waste Management activities.

The Fund was established for financing the Krško NPP Decommissioning and radioactive waste management. Later it was additionally commissioned with the establishment of the radioactive waste management centre, at the preferred location is the area of Čerkezovac. The decision to designate the Fund with operational tasks resulted from both an IAEA recommendation as well as an advice from the European Union, that the regulatory authority should not have any operational tasks related to the establishment of the central storage facility.

The initial schedule for the construction of the waste management centre has already experienced a significant delay. According to a bilateral agreement between Slovenia and Croatia, half of the low and intermediate level radioactive waste generated in Krško NPP that is co-owned by the public utility HEP of Republic of Croatia will have to be taken over by the waste management centre from 2023 onwards. The Fund is responsible for planning the centre, for obtaining the licence and for completing the construction of the facility by 2023. Although great effort is currently undertaken by the Fund, the timeline for this new facility appears to be very ambitious. Close exchange of information with the regulatory body is foreseen in all stages of licensing. The regulatory body must be formally notified 2 years before license application.

The joint strategy of the Republic of Croatia and the Republic of Slovenia related to spent fuel management is the long-term dry storage of SF at Krško NPP location. As the disposal facility is not expected to become operational before 2058, the dry storage facility will be designed for a lifetime until between 2080 and 2100.

## 1.8. COMPETENCE FOR SAFETY

There were no findings in this area in the original IRRS mission.

## 1.9. PROVISION OF TECHNICAL SERVICES

There were no findings in this area in the original IRRS mission.

# 2. THE GLOBAL SAFETY REGIME

## 2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

There were no findings in this area in the original IRRS mission.

## 2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** SORNS has not established arrangements for analysing and disseminating the lessons learned from national and international operating experience and regulatory experience. | |
| **(1)** | **BASIS: GSR Part 1 Requirement 15 states that** *"The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities."* |
| **R5** | **Recommendation: SORNS should established and maintain process and procedures for analysing and disseminating the lessons learned from national and international operating experience and regulatory experience to be used by SORNS, other authorities and authorized parties.** |

### Changes since the original IRRS mission

**Recommendation R5:** Nationally, licensees submit information on events related to licensed activities through a central clearinghouse within the CPD from where it is distributed to the Radiological and Nuclear Safety Sector and the Radiological and Nuclear Inspection Unit, and, if required, to the Radiological and Nuclear Emergency Unit.

There is no formal process or procedure established by the CPD for the analysis and dissemination of lessons learned from operating experience from other States, regulatory bodies of other States, international organizations and authorized parties.

### Status of the finding in the initial mission

**Recommendation R5 remains open,** as the CPD has not developed and maintained processes or procedures for reviewing, analysing and disseminating the lessons learned from national and international operating or regulatory experience. For events at a national level, there is no process for the incorporation of lessons learned into the regulatory process.

# 3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

## 3.1. ORGANIZATIONAL STRUCTURE OF THE REGULATORY BODY AND ALLOCATION OF RESOURCES

Since 1st of January 2019, MoI took over the responsibilities of the SORNS in the field of radiation and nuclear safety together with the staff of the former SORNS.

The CPD, which is an internal organizational unit of MoI now performs all regulatory activities in the field of radiation and nuclear safety. The tasks in relation to radiation and nuclear safety are performed by the following sectors and units of the CPD:

- Radiological and Nuclear Safety Sector;
- Radiological and Nuclear Emergency Unit under the Civil Protection Operation Centre;
- Radiological and Nuclear Safety Inspection Department under the Inspection Sector and;
- Civil Protection International Relations Unit under the Office of Civil Protection Directorate.

The Directorate is managed by the Assistant Minister who is responsible to the Minister of the Interior. Organizational structure and competences of the CPD are prescribed in the Decree of the Government on the Internal organization of the Ministry of the Interior.

| **Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES** | |
|---|---|
| **Observation:** SORNS does not have sufficient resources to fully implement a graded approach to discharge its responsibilities and perform its functions effectively**.** | |
| **(1)** | **BASIS: GSR Part 1 Requirement 16 states that** *"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."* |
| **R6** | **Recommendation: SORNS should have sufficient resources and optimize them in order to discharge its responsibilities and perform its functions in a manner commensurate with the radiation risks associated with facilities and activities.** |

**Changes since the original IRRS mission**

**Recommendation R6:** A graded approach to authorization has been implemented following the findings of the initial 2015 IRRS mission through the promulgation of the Ordinance on Sources (OG 54/18).

Elements of a graded approach were also introduced into inspection planning and inspection activities. A graded approach is used for annual planning of the type and number of inspections, with the number and scope of inspections being informed by the risk of the licensed activity.

The lack of sufficient resources impacts the full implementation of the graded approach.

**Status of the finding in the initial mission**

**Recommendation R6 remains open,** as the full implementation of the graded approach has not been realised due to a lack of resources and major organizational changes.

## 3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY

There were no findings in this area in the original IRRS mission.

## 3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** SORNS training needs are not systematically assessed and training plans are not established. | |
| **(1)** | **BASIS: GS-G-3.1 para. 4.9. states that** *"The organization's training plans should include:*<br>*—The objectives of the organization's training plan;*<br>*—An analysis of any areas not covered and a needs assessment for the training;*<br>*—A description of the training programmes and methods to be employed;*<br>*—The resources necessary and responsibilities;*<br>*—Measurement of the transfer of knowledge (questionnaire, diploma, qualification, accreditation, assessment);*<br>*—….."* |
| **(2)** | **BASIS: GSR Part 1 para.4.13 states that** *"A process shall be established to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management. This process shall include the development of a specific training programme on the basis of an analysis of the necessary competence and skills. The training programme shall cover principles, concepts and technological aspects, as well as the procedures followed by the regulatory body for assessing applications for authorization, for inspecting facilities and activities, and for enforcing regulatory requirements."* |
| **R7** | **Recommendation: SORNS should prepare and implement comprehensive training plans in order to improve knowledge, skills and abilities to perform all the functions and responsibilities.** |

**Changes since the original IRRS mission**

**Recommendation R7**: The CPD has acknowledged the need for the development of a systematic training program for its staff in the field of radiation and nuclear safety.

Considerable progress has been made in the Radiological and Nuclear Safety Sector. The process document "Training in the field of nuclear and radiological safety" lays out the resources and syllabus for training staff, and is intended as guidance for supervisors and new employees. This document has recently been approved and is now being implemented. The training program for inspectors is under development.

The IRRS team was informed that generally, for job-related competencies, there is heavy reliance on training provided by external agencies. Due to the considerable loss of knowledge in the organization following the decreasing number of experienced personnel, it will be essential that the CPD ensures that persons evaluating the trainees are themselves adequately trained and maintain their competences.

**Status of the finding in the initial mission**

**Recommendation (R7) remains open** as there is no approved training program for every aspect of conducting regulatory functions.

### 3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

There were no findings in this area in the original IRRS mission.

### 3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

There were no findings in this area in the original IRRS mission.

### 3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** Most of the ordinances issued by SORNS are outdated; meanwhile 2010 and 2013 Acts have been adopted, which provides the opportunity to establish and approve new ordinances. | |
| **(1)** | **BASIS: GSR Part 1, para. 4.27 states that** "*Prospective changes in regulatory requirements shall be subject to careful scrutiny, to evaluate the possible enhancements in safety that are to be achieved."* |
| **S2** | **Suggestion: SORNS should consider performing systematic periodic screening/review of radiological and nuclear safety legislation, to ensure keeping regulatory safety requirements complete and up-to-date.** |

**Changes since the original IRRS mission**

**Suggestion S2:** The IRRS mission in 2015 issued a number of recommendations and suggestions related to improvements in the regulatory process (R10-12, R16, R17, R21, S4 and S10). Since the initial mission, a significant number of previously outdated ordinances have been revised which addressed the suggestions of the IRRS team. The regulatory framework does not, however incorporate the process of a periodic review of the regulation, but this is addressed in S10.

**Status of the finding in the initial mission**

**Suggestion S2 is closed,** as the Act and Ordinances have been comprehensively updated.

### 3.7. SAFETY RELATED RECORDS

There were no findings in this area in the original IRRS mission.

### 3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

There were no findings in this area in the original IRRS mission.

# 4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

## 4.1. IMPLEMENTATION AND DOCUMENTATION OF THE MANAGEMENT SYSTEM

There were no findings in this area in the original IRRS mission.

An integrated management system (IMS) would support the CPD's information management processes, knowledge management processes and competence management processes and would enable the storage and retrieval of all documents and records that are used and produced by the CPD as inputs to and outputs of the regulatory processes.

## 4.2. MANAGEMENT RESPONSIBILITY

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** The staff in charge of coordinating the development, implementation and maintenance of the management system and reporting directly to the Director General and senior management has not been officially appointed. | |
| **(1)** | **BASIS: GS-R-3 para. 3.13 states that** *"An individual reporting directly to senior management shall have specific responsibility and authority for:*<br>*—Coordinating the development and implementation of the management system, and its assessment and continual improvement;*<br>*—Reporting on the performance of the management system, including its influence on safety and safety culture, and any need for improvement;*<br>*—Resolving any potential conflicts between requirements and within the processes of the management system.* |
| **R8** | **Recommendation: SORNS should appoint an individual with the authority to coordinate and develop the integrated management system and to raise issues relating to the management system to the senior management.** |

### Changes since the original IRRS mission

**Recommendation R8:** SORNS had appointed two persons to take the responsibility of establishing the IMS for the regulatory body, these staff members were trained to prepare the plan for establishment, development, and implementation of IMS. However, the IRRS team was informed that those staff members are not involved in the CPD's radiation and nuclear safety functions.

In 2019, the Assistant Minister has verbally appointed the head of the Radiological and Nuclear Safety Sector as the person responsible to coordinate the development the IMS, for all processes related to Radiation and Nuclear Safety in the CPD. The IRRS team was informed that the development process, due to lack of training of the appointed person, human resources and time, has not been finished.

### Status of the finding in the initial mission

**Recommendation R8 remains open,** as there is no officially nominated individual with the authority and competence to coordinate and develop the integrated management system.

### 4.3. RESOURCE MANAGEMENT

There were no findings in this area in the original IRRS mission.

### 4.4. PROCESS IMPLEMENTATION

There were no findings in this area in the original IRRS mission.

The CPD has not implemented a process management plan in order to identify and ensure that all processes are systematically and consistently developed, implemented and maintained in a controlled and integrated fashion taking into account the possible interfaces with other processes within the four sectors discussed in Section 3.1 as well as other parts of the Ministry like purchasing, training, knowledge management, etc.

### 4.5. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** SORNS management system is not in line with the requirements of the IAEA safety standards related to an integrated management system. SORNS management system is not documented in accordance with the IAEA safety standard GS-R-3. The strategic plan only covers quality assurance. | |
| **(1)** | **BASIS: GSR, Part 1, Requirement 19 states that** *"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…"* |
| **(2)** | **BASIS: GS-G-3.1 para. 2.24 states that** *"Senior management should prepare a plan to achieve full implementation of the management system….."* |
| **R9** | **Recommendation: SORNS should develop an integrated management system in line with IAEA safety standard GS-R-3.** |
| **S3** | **Suggestion: SORNS should consider revising its strategic plan to expand the requirements on management system from the quality assurance programme to the integrated management system.** |
| **S4** | **Suggestion: SORNS should consider preparing the plan for establishment, development, and implementation of an integrated management system where the priorities are stressed out such as defining responsibilities for the management system, defining key processes related to inspection, licensing, etc. and defining the interactions among the processes.** |

**Changes since the original IRRS mission**

**Recommendation R9:** Some elements of the IMS have been developed. The Recommendation 9 requests that the IMS should be developed in line with the GS-R-3, however a new standard GSR Part 2 "Leadership and Management System for Safety" has been established in 2016. Therefore, any actions to further implement the IMS should be in line with this standard. The IAEA Safety guides GSG-12 "Organization, Management and Staffing of the Regulatory Body for Safety" and GSG-13 "Functions and Processes of the Regulatory Body for Safety" should be used as reference material.

Regulation on Internal Organization of the Ministry of the Interior (OG 24/19) requires development of a management system including processes and procedures.

Several processes and procedures to be included in the IMS have been identified during discussions between the CPD and the IRRS team. These are examples but are not limited to:

- a process of communication/information exchange in particular between the Department for Radiological Safety and Department for Nuclear Safety and the Radiological and the Nuclear Inspection Department;
- a procedure of a systematic review of all regulatory safety requirements to be up-to-date;
- a procedure to perform pre licensing verification of documents on site by the Radiological and Nuclear Safety Sector before authorization has been granted.

**Status of the finding in the initial mission**

**Recommendation 9 remains open,** as an Integrated Management System has not been established.

**Changes since the original IRRS mission**

**Suggestion S3:** The Radiological and Nuclear Safety Strategy for the Period 2017-2025 has been established. However, the Article 5 of the Strategy requires the establishment of the quality management system instead of the IMS as requested in the IAEA safety standards.

**Status of the finding in the initial mission**

**Suggestion 3 remains open,** as no further amendments of the strategy are planned for the near future.

**Changes since the original IRRS mission**

**Suggestion S4:** The CPD has not developed a strategic plan for the establishment of the IMS. The IRRS team was informed that due to staff constraints, they are not in position to develop the IMS.

**Status of the finding in the initial mission**

**Suggestion 4 remains open,** as there is no strategic plan for the development of the integrated management system.

**New observations from the follow-up mission**

Interfaces and the lines of communication of organizational sectors and units of the CPD have not been clearly defined and assigned, particularly with respect to the complementary functions of licensing and inspection, to allow for the effective and efficient implementation of the core functions and supporting functions.

The effective communication and exchange of relevant information is an essential part of an effectively functioning regulatory body. As an example, the RAIS database, could be one of the tools for effective exchange of information between two core units dealing with licensing and inspection.

| FU Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES |
| --- |
| **Observation:** Interfaces and the lines of communication of the CPD's organizational sectors and units, have not been clearly defined and assigned, particularly with respect to the complementary functions of |

| FU Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| licensing and inspection, to allow for the effective and efficient implementation of the core functions and supporting functions. | |
| **(1)** | **BASIS: GSR Part 1 (Rev 1) Requirement 16, para. 4.5 states that** *"The regulatory body has the responsibility for structuring its organization and managing its available resources so as to fulfil its statutory obligations effectively."* |
| **(2)** | **BASIS: GSR Part 2 Requirement 6, para. 4.11 states that** *"The organizational structures, processes, responsibilities, accountabilities, levels of authority and interfaces within the organization and with external organizations shall be clearly specified in the management system."* |
| **(3)** | **BASIS: GSR Part 2 Requirement 12, para. 5.2.c states that** *"Senior managers and all other managers shall advocate and support… an organizational culture that supports and encourages trust, collaboration, consultation and communication."* |
| **(4)** | **BASIS: GSG - 12, para. 4.61 states that** *"The roles, responsibilities and lines of communication of organizational units, managers and staff should be clearly defined and assigned, in accordance with the organizational structure, to allow for the effective and efficient implementation of the core functions and supporting functions."* |
| **RF 1** | **Recommendation: The CPD should clearly specify the interfaces and exchange of information within the CPD in the integrated management system taking into account sectors and units in performing tasks related to radiation and nuclear safety to be able to fulfil statutory obligations effectively.** |

# 5. AUTHORIZATION

## 5.1. GENERIC ISSUES

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** Notification as a document submitted to SORNS by the applicant to notify an intention to carry out a practice, and criteria when notification only is sufficient, are not defined under the existing legal framework. | |
| **(1)** | **BASIS: GSR Part 3 Requirement 3 para. 2.30 states that** "*The regulatory body shall establish a regulatory system for protection and safety that includes [8]:(a) Notification and authorization;* |
| **(2)** | **BASIS: GSR Part 3 Requirement 7 states that** *"Any person or organization intending to operate a facility or to conduct an activity shall submit to the regulatory body, as appropriate, a notification or an application for authorization."* |
| **(3)** | **BASIS: GSR Part 1 Requirement 23 states that** *"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."* |
| **R10** | **Recommendation: The Government should establish a regulatory system for protection and safety that includes notification process, with criteria for when notification only is sufficient.** |

**Changes since the original IRRS mission**

**Recommendation R10:** The Amendment to the Act (OG130/17) defines notification as a document by which a legal or natural person, state administration body or other state body or local and regional self-government body informs the regulatory body of its intent to perform work activities, activities with ionising radiation sources or practices for management of radioactive waste and spent source. The Article 8a of the Act specifies responsibility of "the director of the regulatory body" to develop detailed criteria for the notification, including the case when notification only is sufficient.

Furthermore, Section 4 of the Ordinance on Sources (OG 54/18), specifies the criteria and requirements regarding duties of legal or natural person and the content of notification, as well as the obligation of the regulatory body to inform the applicant about the further proceedings. According to the information provided, there have been several cases where criteria for the notification have been applied.

The notification process has been fully integrated in to the legal and regulatory framework.

**Status of the finding in the initial mission**

**Recommendation R10 is closed,** as a regulatory system for protection and safety has been established which includes a notification process, with criteria for when notification only is sufficient.

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** The authorization process established by SORNS is implemented as a two-step licencing process in forms of a general Licence for practice and additionally, for each particular source of ionizing radiation every year a Licence for use of ionizing radiation sources, which is not commensurate with the radiation risk associated with facilities and activities, in accordance with graded approach. As a result this approach does not lead to the optimization of resources. | |
| **(1)** | **BASIS: GSR Part 1 Requirement 2, para. 2.5 states that** *"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:*<br>*(3) The type of authorization that is required for the operation of facilities and for the conduct of activities, in accordance with a graded approach;* |
| **(2)** | **BASIS: GS-G-1.5, para. 3.23 states that** *"The Basic Safety Standards apply the terms notification, and authorization by registration or licence to indicate broadly an appropriate type of control based upon the levels of risk or complexity associated with non-exempted practices, notification being applied to the lowest level of risk or complexity and licence to the highest…"* |
| **S5** | **Suggestion: SORNS should consider developing a system of authorization commensurate with the radiation risks associated with the facility or activity taking into account a graded approach.** |

## Changes since the original IRRS mission

**Suggestion S5:** The Ordinance on Sources (OG 54/18) establishes the requirements and criteria for exemption, notification, registration and licensing.

The list of activities for which registration or licence for activities involving sources of ionising radiation is provided, as well as a list of documents used in the procedure for granting registration or licence in order to prove that the conditions prescribed by law have been fulfilled.

Additionally, a graded approach in the authorization process is reflected in the different validity of an authorization, for example the validity of the registration is ten years, and of the licence it could be three or five years, e.g. for sealed sources category 1, 2, and 3 it shall be issued for a validity period of 3 years, for X-ray units for industrial radiography it shall be issued for a validity period of 5 years, and for a registration permission for the use of X-ray units in dental (intraoral) or veterinary medicine (stationary) it shall be issued for a validity period of 10 years.

The previous practice of issuing individual licences for each radiation source every year has been eliminated.

## Status of the finding in the initial mission

**Suggestion (S5) is closed,** as the authorization system is developed in accordance with a graded approach, based on the radiation risks associated with the facilities and activities.

## 5.2. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** The Act on Radiological and Nuclear Safety stipulated formally requirements for licensing the site, construction, operation and closure radioactive waste management facility without specific requirements. The requirements described in existing regulation OG-44/08 are not sufficient for all radioactive waste management activities described in the 2013 Act and the regulation is not in line with the provision of the 2013 Act. The new Ordinance prescribed in the 2013 Act (Article 49 (8) and Article 50(4)) is still not drafted. | |
| **(1)** | **BASIS: GSR Part 1 Requirement 23 para 4.34 states that** *"The regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization. The applicant shall be required to submit or to make available to the regulatory body, in accordance with agreed timelines, all necessary safety related information as specified in advance or as requested in the authorization process."* |
| **(2)** | **BASIS: SSR - 5 Requirement 2 states that** *"The regulatory body shall establish regulatory requirements for the development of different types of disposal facility for radioactive waste and shall set out procedures for meeting the requirements for the various stages of the licensing process. It shall also set conditions for development, operation and closure of each individual disposal facility and shall carry out such activities as are necessary to ensure that the conditions are met."* |
| **R11** | **Recommendation: SORNS should develop and approve Ordinance regarding the detailed requirements for licensing the site, construction, operation and closure radioactive waste management facility as prescribed in the 2013 Act.** |

### Changes since the original IRRS mission

**Recommendation R11:** The Ordinance on Waste (OG 12/18) covers detailed requirements for licensing the site, construction, operation as well as decommissioning and dismantling of a radioactive waste management facility. Moreover the Ordinance determines the conditions and method of radioactive waste and disused sources management, the obligation to keep its records and content, manner of keeping and deadlines, scope and manner of reporting as well as the list and conditions for performing the activities involving management of radioactive waste and disused sources, activity concentration values for clearance of materials, and a list of documents which, in the process of issuing the approval, prove that it has been complied with the prescribed conditions.

### Status of the finding in the initial mission

**Recommendation R11 is closed,** as the Ordinance on Waste (OG 12/18) covers detailed requirements for licensing the site, construction, operation as well as decommissioning and dismantling of a radioactive waste management facility.

## 5.3. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

There were no findings in this area in the original IRRS mission.

# 6. REVIEW AND ASSESSMENT

## 6.1. GENERIC ISSUES

There were no findings in this area in the original IRRS mission.

### 6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** SORNS has not established a documented process for review and assessment, and written procedures and internal guidance are missing. As a result this can lead to subjectivity in decision-making by the individual staff involved in the review and assessment process. | |
| **(1)** | **BASIS: GSR Part 1 Requirement 24, para. 4.33 states that** *"Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment [8], which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures. The extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach."* |
| **(2)** | **BASIS: GSR Part 1 Requirement 26 states that** *"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."* |
| **R12** | **Recommendation: SORNS should establish process and procedures governing the review and assessment activities for all types of facilities and activities under their regulatory control, taking into account graded approach.** |

**Changes since the original IRRS mission**

**Recommendation R12:** The CPD has initiated several activities on establishing the procedures governing the review and assessment. Currently, the procedures for review and assessment of an application for authorization in nuclear medicine, radiotherapy, industrial radiography and for NORM activities have been developed and officially approved. In addition, the working procedures for assessment on nuclear security plan, plan for management of radioactive waste and disused sources and plan in the case of emergency are in the process of development. Once developed, all these procedures, as part of a systematic and formalized process, will contribute to the stability and consistency of regulatory control and prevent subjectivity in decision making by individual staff members of the CPD.

**Status of the finding in the initial mission**

**Recommendation R12 is closed on the basis of progress made and confidence in effective completion in due time**, as progress in developing the procedures governing review and assessment activities has been made and should be part of a systematic and formalized process to be developed.

### 6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

There were no findings in this area in the original IRRS mission.

### 6.1.3. BASES FOR REVIEW AND ASSESSMENT

There were no findings in this area in the original IRRS mission.

### 6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** SORNS does not verify the contents of the documents submitted for review and assessment of an application for authorization by means of inspection. | |
| **(1)** | **BASIS: GS-G-1.5 para. 3.42 states that** *"A fundamental feature of the process of review and assessment of an application for authorization by the regulatory body is its consideration of the documentation submitted by the applicant. For significant risk sources or unusual or complex practices, the regulatory body should also verify the contents of the documents submitted by means of inspection of the site where the radiation sources are to be installed or used. These inspections will also allow the regulatory body to supplement the information and data needed for review and assessment. Additionally, the regulatory body will be able to extend its practical understanding of the managerial, engineering and operational aspects of the application for authorization and to foster links with specialists of the operating organization."* |
| **S6** | **Suggestion: SORNS should consider introducing pre-licensing verification of the contents of the documents submitted for review and assessment of an application for authorization to confirm credibility of submitted documents, where appropriate.** |

**Changes since the original IRRS mission**

**Suggestion S6:** The IRRS team was informed that under the existing legal and regulatory framework in Croatia there is no possibility to verify, by means of inspection, the contents of the documents submitted in support of an application for the authorization with the objective to confirm validity of submissions. Currently, authorization and inspection activities are fully separated and performed by different sectors of the CPD, and staff in the Radiological and Nuclear Safety Sector are not involved in inspection activities on site. Based on the information provided, the CPD is looking for solutions that could be used in the next revision of the regulatory framework or during the development of management system to enable authorization staff to perform verification on site to confirm validity of the submitted documents during review process before granting a licence.

This pre-licensing verification is specifically important for high risks or unusual or complex facilities or activities. This verification will allow the CPD to supplement the necessary information and data during the process of review and assessment to grant an authorization and to foster cooperation with the authorized party. The need for verification at this stage is further stressed by the new Safety Guide GSG-13, Functions and processes of the regulatory body for safety in paragraph 3.151. This issue is also addressed in Section 4.2.

**Status of the finding in the initial mission**

**Suggestion S6 remains open,** as there has not been sufficient progress in improving the existing situation with respect to introducing pre-licensing verification.

## 6.2. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

There were no findings in this area in the original IRRS mission.

Although findings were not given in this area in the 2015 report, the IRRS team identified in the Follow-up mission several challenges in particular with regard to human resources and competences with which the CPD will be confronted in the near future.

It is understood that the Fund has sufficient resource to carry out all preparatory work for the new radioactive waste management centre at the preferred location is the area of Čerkezovac.

Further challenges for the CPD related to radioactive waste management are captured in the Section 3 (e.g. staffing, communication/information exchange, or capability).

## 6.3. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

There were no findings in this area in the original IRRS mission.

# 7. INSPECTION

## 7.1. GENERIC ISSUES

### 7.1.1. INSPECTION PROGRAMME

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** SORNS has not established regulatory inspection programme of all facilities and activities. In particular there are no inspections performed at most complex practices, i.e. radiotherapy. The inspections of facilities and activities performed by SORNS are not commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach. | |
| **(1)** | **BASIS: GSR Part 1 Requirement 27, states that** "*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."* |
| **(2)** | **BASIS: GSR Part 1 Requirement 29, states that** "*Inspections of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach."* |
| **R13** | **Recommendation: SORNS should establish inspection programme that commensurate with the radiation risks associated with the facility or activity in accordance with a graded approach that covers all areas relevant to safety and radiation protection and implement this programme.** |

**Changes since the original IRRS mission**

**Recommendation R13:** Since 2017 a detailed annual inspection plan has been developed for all activities and facilities including a complex facility such as radiotherapy. The plan took into account the different regions in the country and the radiation risk associated with the activities and facilities. Additionally, many activities with the purpose to strengthen the competences of inspectors were implemented under the scope of IAEA TC Programme, including several fellowships and scientific visits.

The IRRS team was informed that the annual plans have been only partially implemented due to the lack of sufficient and adequately trained inspectors, and also in 2019, due to the impact of organizational changes only 7 inspections were completed compared to 117 in the plan. Details on lack of human resources are in R3 Section 1.3.

The IRRS team was informed that a new inspection plan for the coming year is under preparation.

The IRRS team was informed that for developing a new plan for year 2020 the radiation risk associated with the facilities or activities will be taken into account together with existing human capacities. The IRRS team highlighted that according to IAEA standards the radiation risk associated with the facilities or activities should be the key parameter.

**Status of the finding in the initial mission**

**Recommendation R13 remains open,** as insufficient progress has been made on the development and especially on the implementation of the inspection programme that covers all facilities and activities in accordance with a graded approach.

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** Although SORNS inspectors carry out announced inspections, the 2013 Act only empowers SORNS inspectors to carry out unannounced inspections. | |
| **(1)** | **BASIS: GSR Part 1 Requirement 28 states that** "*Inspections of facilities and activities shall include programmed inspections and reactive inspections; both announced and unannounced.*" |
| **R14** | **Recommendation: The Government should empower SORNS inspectors to carry out announced inspections.** |

**Changes since the original IRRS mission**

**Recommendation R14:** The Amendment to the Act (OG 130/17), establishes additional requirements providing the inspectors a legal basis for carrying out both, announced and unannounced inspections: "The inspector shall be obliged to inform the responsible person in the supervised legal person and the natural person, if available, of direct inspection at least two days before commencing inspection supervision." and "…inspector may perform an inspection supervision without prior announcement if there is a reason for urgent action but shall be obliged to inform the responsible person in the supervised legal person and the natural person of their presence before commencing their work".

**Status of the finding in the initial mission**

**Recommendation R14 is closed,** as the Act has empowered the CPD inspectors to carry out both, announced and unannounced inspections.

### 7.1.2. INSPECTION PROCESS AND PRACTICE

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** SORNS has not established procedures for its inspection activities. Detailed description of some subjects (rights and obligations of inspectors, as well as inspection protocols (check lists), reporting of findings, etc.) is covered in the draft "Manual for conducting inspection supervision". However, some areas (for example tests and measurements made during inspection) are still not covered by the draft manual. | |
| **(1)** | **BASIS: GSR Part 1 Requirement 32 states that** "*The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based.*" |
| **(2)** | **BASIS: GS-G-1.5 para. 3.61 states that** "*To ensure that all operators are inspected to a common standard and that the level of safety is consistent, the regulatory body should establish procedures for its inspectors…*" |

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **(3)** | **BASIS: GS-G-1.5 para. 3.63 states that** "*The inspection programme of the regulatory body should incorporate and use a variety of methods, as follows:*<br>*(d) Tests and measurements. The extent to which the regulatory body carries out its own tests and measurements independently of the operator varies greatly between States, depending on such factors as the qualifications of the regulatory inspectors, its regulatory philosophy, and the experience and demonstrated performance of the operators. The regulatory body should not carry out tests and measurements that are the responsibility of the operator. In most instances, tests and measurements carried out by the regulatory body should serve as an independent verification of those tests and measurements performed by the operator."* |
| **R15** | **Recommendation: SORNS should review the draft "Manual for conducting inspection supervision" to cover all elements of inspections and approve it.** |
| **S7** | **Suggestion: SORNS should review its inspection programme and include tests and measurements as a method of inspection.** |

**Changes since the original IRRS mission**

**Recommendation R15:** The Manual for conducting inspection supervision was developed and approved in 2018. The Manual is a comprehensive document that contains several chapters e.g. legal basis for inspection, obligations and conditions to be fulfilled by inspectors, rights, duties and powers of inspectors, types of inspections, organization and planning of inspections, preparation of annual inspection plan and how to conduct an inspection. A major part of the Manual are the different forms and checklists, which reflects the regulatory requirements, and cover the range of radiation activities and facilities currently existing in the country.

**Status of the finding in the initial mission**

**Recommendation R15 is closed,** as the Manual for conducting inspection supervision was developed and officially approved.

**Changes since the original IRRS mission**

**Suggestion S7**: Test and measurements are not included as a method in the inspection programme and inspectors do not perform tests and measurements when conducting regulatory inspections. Several steps need to be taken to adequately respond on this suggestion. It is necessary to have adequate equipment for tests and measurements and trained inspectors to be able to perform those measurements and analyse the measurement results.

Currently, inspectors are equipped with several sets of high-quality equipment that could be used during the inspection. Through the IAEA Technical Cooperation Program, several activities with the aim of improving the competencies of inspectors to conduct required tests and measurements have been undertaken. The inspectors had the opportunity to learn about practice in other countries through the IAEA fellowship programme, and an expert visit of inspectors from Greece was recently organized in Croatia. In order to become an integral part of the inspection, it is necessary to update the inspection manual, to maintain the required knowledge, and include tests and measurements as an inspection method. The purpose of tests and measurements carried out by the regulatory body is an independent verification of those tests

and measurements performed by the operator. The IRRS team was informed that inspectors are only using dosimeters for their own safety.

**Status of the finding in the initial mission**

**Suggestion S7 remains open,** as insufficient progress has been made to include tests and measurements as a method of regulatory inspection.

### 7.1.3. INSPECTORS

There were no findings in this area in the original IRRS mission.

## 7.2. INSPECTION OF WASTE MANAGEMENT FACILITIES

There were no findings in this area in the original IRRS mission.

# 8. ENFORCEMENT

## 8.1. ENFORCEMENT POLICY AND PROCESS

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** There are no detail procedures for determining and exercising enforcement actions. Inspectors have limited training in enforcement procedures and do not have the legal support to carry out enforcement actions. | |
| **(1)** | **BASIS: GSR Part 1 Requirement 32 states that** "*The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based.*" |
| **(2)** | **BASIS: GS-G-1.5 para. 3.75 states that** *"Within the legal framework within which it is established, the regulatory body may draft and issue enabling regulations that detail procedures for determining and exercising enforcement actions as well as the rights and obligations of the operator.* |
| **(3)** | **BASIS: GS-G-1.5 para. 3.85 states that** *"The regulatory body should adopt clear administrative procedures governing the taking of enforcement actions. All inspectors and other staff of the regulatory body should be trained in, and knowledgeable about, the procedures. The procedures should specify the policy of the regulatory body with regard to the use of regulatory actions and enforcement measures, and the associated delegated authority given to inspectors and to other staff of the regulatory body. … The procedures should cover in detail the decision making approach of the regulatory body in determining the level of action to take and the way in which actions should be taken, including dealing with the failure of the operator to comply with the regulatory enforcement requirements.* |
| **R16** | **Recommendation: SORNS should establish detail procedures for determining and exercising enforcement actions. All inspectors and other staff of SORNS should be trained in, and knowledgeable about, the procedures.** |
| **S8** | **Suggestion: SORNS should consider providing inspectors with legal support to carry out enforcement actions.** |

**Changes since the original IRRS mission**

**Recommendation R16:** As part of the Manual for conducting inspection supervision the detailed procedures for determining and exercising enforcement actions have been developed. Inspectors of the CPD can carry out enforcement on the basis of existing procedures. The IRRS team was informed that inspectors are knowledgeable about enforcement procedures.

**Status of the finding in the initial mission**

**Recommendation R16 is closed,** as procedures for determining and exercising enforcement actions were developed as part of the Manual for conducting inspection supervision.

**Changes since the original IRRS mission**

**Suggestion S8:** Legal support is available in the MoI to the Radiological and Nuclear Safety Inspectors. The significant experience regarding the enforcement action and legal support that the CPD has, might be beneficial for the inspection programme in general. More specifically, the IRRS team was informed that the five divisions of the CPD Inspection Sector share one legal expert providing legal support for all inspection activities.

**Status of the finding in the initial mission**

**Suggestion S8 is closed,** as the CPD inspectors have access to legal support to carry out enforcement activities.

## 8.2. ENFORCEMENT IMPLEMENTATIONS

There were no findings in this area in the original IRRS mission.

# 9. REGULATIONS AND GUIDES

## 9.1. GENERIC ISSUES

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** SORNS does not prepare and issue guides, as a part of a comprehensive regulatory framework, to provide guidance on how to comply with the safety requirement. | |
| **(1)** | **BASIS: GSR Part 1 Requirement 32 states that** "*The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based.*" |
| **S9** | **Suggestion: SORNS should consider developing guides to help users striving to achieve the high levels of safety.** |

**Changes since the original IRRS mission**

**Suggestion S9:** The CPD has prepared several draft Guides that aim primarily at end-users. The purpose of these guides is to provide recommendations on meeting the requirements for the safe use of ionizing radiation as established in the Act on Radiological and Nuclear Safety and relevant ordinances. The draft guides developed include the Guide for radiation safety in nuclear medicine, the Guide for radiation protection and safety in radiation therapy, the instructions to future holders of licenses for industrial radiography (sealed radioactive sources and/or X-ray devices) and well gauging, the instructions to future holders of licenses for obtaining and operating license for the activity using X-ray devices in medical activities (diagnostic and intervention radiology and dental medicine), the instructions to future holders of licenses for activities of radiation therapy using sealed radioactive sources and/or a linear accelerator, the instructions to future license holders for obtaining the license for the activity of diagnostic and/or therapy using open radioactive sources in nuclear medicine, and the Guide for activities involving Naturally Occurring Radioactive Material (NORM) which already address the majority of end-users.

The IRRS team noted that Guides in the area of nuclear safety are not yet developed. However, the development of further guides is in the planning stage. In particular, a Guide on Nuclear Security which is in the planning stage is considered useful.

**Status of the finding in the initial mission**

**Suggestion S9 is closed on the basis of progress made and confidence in effective completion in due time**, as several guides are already developed, and further work is planned.

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** There is no formalized process in place for the review of regulations, which ensures that a systematically periodical review is done. | |
| **(1)** | **BASIS: GSR Part 1 Requirement 33 states that** "*Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration taken of relevant international safety standards and technical standards and of relevant experience gained.*" |

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **S10** | **Suggestion: SORNS should establish within its regulatory framework processes and procedures for reviewing and revising regulations, taken into account internationally agreed standards and the feedback of relevant experience.** |

**Changes since the original IRRS mission**

**Suggestion S10:** Processes and procedures within the CPD to facilitate its systematic reviewing and revising of regulations, taking into account internationally agreed standards and the feedback of relevant experience has not been developed yet.

The IRRS team was informed that the CPD's internal procedures for reviewing and revising regulations, including criteria for identifying the need for new regulations and the periodicity of the review of the current regulations and guides are planned to be developed as part of an IMS. This is addressed in Section 4.5.

**Status of the finding in the initial mission**

**Suggestion S10 remains open,** as these processes and procedures have not been formally developed and adopted yet.

### 9.2. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

There were no findings in this area in the original IRRS mission.

### 9.3. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** The existing regulations and ordinances for radiation safety are not fully in line with the IAEA GSR Part 3. | |
| **(1)** | **BASIS: GSR Part 1 Requirement 32 states that** *"The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based."* |
| **S11** | **Suggestion: SORNS should consider reviewing its ordinances for compliance with GSR Part 3.** |

**Changes since the original IRRS mission**

**Suggestion S11:** In the process of harmonizing its national legislation with the Council Directive 2013/59/EURATOM the regulatory body aligned its ordinances with GSR Part 3 requirements, in particular in relation to occupational, public and medical exposure control. Minor deviations from GSR Part 3 are discussed in Section 11.

**Status of the finding in the initial mission**

**Suggestion S11 is closed,** as the national legislation regarding radiological and nuclear safety has been amended and revised to be in line with GSR Part 3.

# 10.EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

## 10.1. GENERAL EPR REGULATORY REQUIREMENTS

### Basic responsibilities

There were no findings in this area in the original IRRS mission.

### Assessment of threats

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** SORNS has the responsibility to regulate on-site emergency arrangements of operators based on Act 141/13(39/15). The current legislation in EPR do not comprehensively cover all the necessary functions to be performed by operators in an emergency response and the infrastructure to be put in place by them as required in IAEA Safety Standards (GS-R-2). SORNS does not apply a graded approach in regulating on-site emergency arrangements, does not perform inspections in EPR and does not evaluate any of their exercises. This is not consistent with IAEA Safety Standards (GS-R-2, GS-G-2.1). | |
| **(1)** | **BASIS: GS-R-2 para. 3.2 states that** *"The arrangements for emergency response actions both within and outside facilities, if applicable, or elsewhere under the control of the operator, are dealt with through the regulatory process."*<br><br>**GS-R-2 para. 3.8 states that** "*The regulatory body shall require that arrangements for preparedness and response be in place for the on-site area for any practice or source that could necessitate an emergency intervention. […]"*<br><br>*In addition, the following paragraphs provide basis for this recommendation:*<br><br>***GS-R-2, paras. 3.15, 4.57, 4.58, 4.61, 4.62, 4.78, 4.69, 4.70, 4.60, 4.65, 4.97, 5.3, 5.7, 5.10, 5.14, 5.25, 5.31, 5.33***. |
| **R17** | **Recommendation: SORNS should revise and strengthen its regulatory framework in EPR consistently with IAEA Safety Standards to also include inspection, enforcement and evaluation of some of operator's exercises and should implement a graded approach.** |

### Changes since the original IRRS mission

**Recommendation R17:** Inspectors can observe and inspect operators' exercises. Operators are obliged to perform them and to adjust their plans based on the outcome of the exercises. Currently, inspectors normally just inspect if operators have performed exercises and review the exercise reports.

Ordinance on the Scope and Content of the Plan and Programme of Measures in the Event of an Emergency and of Informing the Public and Competent Bodies (Ordinance on Emergency) (OG 123/12) require the licensees to organize exercises but they are not explicitly obliged to send advance notification of these exercises to the CPD so that relevant personnel of the CPD can decide whether to participate or not.

The planned revision of Ordinance on Emergency (OG 123/12) will contain the obligation that the CPD needs to be informed about the exercises in advance. The CPD will develop programme when and how to observe the exercises, based on the graded approach.

The revised Ordinance on Emergency (OG 123/12) is expected to be published in Q2 of 2020.

**Status of the finding in the initial mission**

**Recommendation R17 remains open,** as the current legislation in EPR does not comprehensively cover all the necessary functions to be performed by operators in an emergency response.

## 10.2. FUNCTIONAL REGULATORY REQUIREMENTS

### Identifying, notifying and activating

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** The current legislation in EPR do not require operators to identify promptly conditions indicative for an emergency situation, to notify the emergency and to activate an emergency response within some reasonable response time objectives as required in IAEA Safety Standards (GS-R-2 and GS-G-2.1). | |
| **(1)** | **BASIS: GS-R-2 para. 3.8 states that** "*The regulatory body shall require that arrangements for preparedness and response be in place for the on-site area for any practice or source that could necessitate an emergency intervention. […]"* |
| **(2)** | **GS-R-2 para. 4.19. states that** *"The operator of a facility or practice in threat category I, II, III or IV shall make arrangements for the prompt identification of an actual or potential nuclear or radiological emergency, and determination of the appropriate level of response. This shall include a system for classifying all potential nuclear and radiological emergencies […]"* |
| **R18** | **Recommendation: SORNS should require that operators develop and implement a system for classifying all potential nuclear or radiological emergencies and for activation of an adequate level of emergency response consistently with IAEA Safety Standards.** |
| **S12** | **Suggestion: SORNS should consider setting response time objectives for notification of an emergency and for activation of an emergency response.** |

**Changes since the original IRRS mission**

**Recommendation R18:** This requirement is developed through the concepts of operations and is in the draft of the Croatian Emergency Preparedness and Response Plan to Nuclear or Radiological Emergencies (the Plan) and will be fully implemented through the revision of the Ordinance on Emergency (OG 123/12).

Based on the Regulation on Measures for Protection Against Ionising Radiation and Activities in Case of Emergency (Regulation) (OG 24/18), and the draft Plan, the Ordinance on emergency (OG123/12) can be revised. The Ordinance further develops the requirement for operators to develop their own emergency plans in line with the draft Plan, providing guidance on the content of those plans in legally obligatory form.

The Regulation (OG 24/18) together with the draft Plan complies with the relevant IAEA safety standards.

The draft Plan specifies the Concept of Operation for radiological and nuclear emergencies in EPC III and IV. It clearly requests the licensee to promptly classify the emergency.

**Status of the finding in the initial mission**

**Recommendation R18 is closed on the basis of progress made and effective completion in due time,** the Croatian Radiological or Nuclear Emergency Preparedness and Response Plan will be issued, giving details of the classification system.

**Changes since the original IRRS mission**

**Suggestion S12:** The draft Plan contains the concepts of operations and time objectives.
On publication of the Plan these time objectives will be set, in line with the proposed principles and numerical values recommended by the international standards.

**Status of the finding in the initial mission**

**Suggestion S12 is closed on the basis of progress made and confidence in effective completion in due time,** the Croatian Radiological or Nuclear Emergency Preparedness and Response Plan will be issued, giving details of the response time objectives.

**Establishing emergency management and operations**

| **Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES** | |
|---|---|
| **Observation:** Regulation 102/12 assigns SORNS a responsibility to manage the on-site emergency response, to implement urgent protective actions at the site of relevant facilities and activities under the responsibility of an operator and in this regard, to provide public information as a single source. This is not consistent with SORNS responsibilities and operator's responsibilities set forth in the 2013 Act 141/13(39/15) and with IAEA Safety Standards (GS-R-2). | |
| **(1)** | **BASIS: GS-R-2 para. 4.84 states that** *"The operator, the response organizations, other States and the IAEA shall make arrangements for co-coordinating the provision of information to the public and to the news and information media in the event of a nuclear or radiological emergency…"* |
| **(2)** | **BASIS: GS-R-2 para. 3.10 states that** *"In planning for, and in the event of [a nuclear or radiological emergency], the regulatory body shall act as an adviser to the government and [response organizations] in respect of nuclear safety and radiation protection."* |
| **(3)** | **BASIS: GS-R-2 para. 4.10 states that** *"Arrangements shall be made for the implementation of a command and control system for the response to a nuclear or radiological emergency. […]"* |
| **(4)** | **BASIS: GS-R-2 para. 5.23 states that** *"On-site emergency plans shall be implemented by [the operators]."* |
| | *In addition, the following paragraphs provide basis for this recommendation:* ***GS-R-2, paras. 4.19, 4.3, 4.51*** |
| **R19** | **Recommendation: The Government should review and revise the responsibility of SORNS to manage the on-site emergency response, to implement urgent protective actions on-site in relation to facilities and activities under the responsibility of an** |

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| | **operator and, in this regard, to provide public information as a single source.** |
| **R20** | **Recommendation: SORNS shall require operators to implement clear command and control system to manage effectively the on-site emergency response.** |

**Changes since the original IRRS mission**

**Recommendation R19:** The Regulation (OG 24/18) requires that, in the case of an emergency in EPC III facilities and EPC IV activities, the CPD shall provide only expert support to the licensee.

The main responsibility for the on-site response is with the license holder (Article 27 and 28).

**Status of the finding in the initial mission**

**Recommendation R19 is closed,** as the new Regulation (OG 24/18) revised the roles and responsibilities of the CPD, regarding the on-site emergency response, limiting it to support functions, and assigned the main responsibility for the on-site response to the license holder.

**Changes since the original IRRS mission**

**Recommendation R20:** The Regulation (OG 24/18) in Articles 20-26 require operators to implement clear command and control system to manage effectively the on-site emergency response.

**Status of the finding in the initial mission**

**Recommendation R20 is closed,** as the Regulation (OG 24/18) in Articles 20-26 require operators to implement clear command and control system to manage effectively the on-site emergency response.

**Taking mitigation actions**

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** Off-site emergency services are available to support the on-site emergency response as required in IAEA Safety Standards (GS-R-2). However, this off-site support has not been formally arranged among operators and support providers to ensure its availability and reliability when needed. | |
| **(1)** | **BASIS: GS-R-2 para. 5.10 states that** *"Arrangements for the co-ordination of emergency response and protocols for operational interfaces between operators and local, regional and national governments shall be developed, as applicable."* |
| **S13** | **Suggestion: SORNS should consider requesting that operators establish formal arrangements or protocols with off-site emergency services providing the operator with an assistance and support during the on-site emergency response.** |

**Changes since the original IRRS mission**

**Suggestion S13:** Emergency services in Croatia are obliged by law to do their job wherever and whenever needed and they cannot sign protocols or arrangements saying that.

It is reasonable to accept the existing arrangement as satisfactory: off-site emergency response services are obliged by law to be available and the licensees are obliged to plan and prepare for coordinating with them. The practical issue is testing it with certain regularity.

Article 16 of the Regulation (OG 24/18) obliges licensees to plan the coordination with external (off-site) emergency services.

**Status of the finding in the initial mission**

**Suggestion S13 is closed,** as the current arrangements guarantee the integration of the off-site emergency services into the coordinated implementation of the on-site emergency response actions.

**Taking urgent protective action**

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** Based on Regulation 102/12, SORNS has a responsibility for defining the emergency planning zones in relation to Krsko NPP in Slovenia and has initiated dialog with Slovenia to harmonize response strategies on both sides of the border. The intervention levels at which protective actions need to be taken in an emergency, which are part of Ordinance 59/13, are not in line with the latest IAEA Safety Standards (GSG-2, GSR Part 3). | |
| **(1)** | **BASIS: GS-R-2 para. 4.50 states that** *"The jurisdictions within the precautionary action zone and/or the urgent protective action planning zone shall make arrangements to take appropriate urgent action promptly upon the notification of a nuclear or radiological emergency […]."* |
| **(2)** | **BASIS: GSG-2 para. 3.6 states that** *"The generic criteria replace the system of generic intervention levels (GILs) and generic action levels (GALs) that have been described in previous standards…."* |
| **S14** | **Suggestion: SORNS should consider continuing its efforts to coordinate and harmonize emergency planning zones with their Slovenian counterparts in relation to Krsko NPP in line with relevant IAEA Safety Standards.** |
| **S15** | **Suggestion: SORNS should consider updating the intervention levels and generic action levels for taking protective actions set forth in Ordinance 59/13 taking account of the latest IAEA Safety Standards.** |

**Changes since the original IRRS mission**

**Suggestion S14:** Efforts to resolve this issue is continuing. The newest attempt was started in 2017 and is based on HERCA-WENRA approach for a better cross-border coordination of protective actions during the early phase of a nuclear accident. Current efforts are concentrated on identifying situations where actions will be different and preparing for how to explain it to the population on both sides of the border.

Both sides are taking part in a new IAEA project aimed at the harmonization of cross-border response. The mentioned new approaches are to be commended, but the issue has not been resolved yet. More will be needed to harmonize the response on the two sides of the border.

**Status of the finding in the initial mission**

**Suggestion S14 remains open,** as emergency planning zones in relation to Krsko NPP have not been harmonized yet.

**Changes since the original IRRS mission**

**Suggestion S15:** The Regulation (OG 24/18) has introduced new terms, and the levels required for intervention are either defined in its Article 18 (Reference level) or are given in the draft Plan (Generic criteria).

Since the IRRS 2015 Mission the suggestion, in its original form has become obsolete. Instead of the mentioned intervention levels and action levels of GS-R-2 the country should develop appropriate protection strategy, with reference level, generic criteria and OILS, as required by the new IAEA Safety Standards GSR Part 7.

**Status of the finding in the initial mission**

**Suggestion S15 is closed on the basis of progress made and confidence in effective completion in due time,** the new Regulation (OG 24/18) and the draft Plan are already using the new terms of GSR Part 7 (reference levels, generic criteria and OILS).

**Providing information and issuing instructions**

There were no findings in this area in the original IRRS mission.

**Assessing the initial phase**

There were no findings in this area in the original IRRS mission.

**Managing the medical response**

There were no findings in this area in the original IRRS mission.

**Protecting emergency workers**

There were no findings in this area in the original IRRS mission.

**Other activities in emergency preparedness**

There were no findings in this area in the original IRRS mission.

## 10.3. REGULATORY REQUIREMENTS FOR INFRASTRUCTURE

**Authority**

There were no findings in this area in the original IRRS mission.

**Organization**

There were no findings in this area in the original IRRS mission.

**Coordination of emergency response**

There were no findings in this area in the original IRRS mission.

**Plans and procedures**

There were no findings in this area in the original IRRS mission.

**Logistical support and facilities**

There were no findings in this area in the original IRRS mission.

**Training, drills and exercises**

There were no findings in this area in the original IRRS mission.

**Quality assurance programme**

| **Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES** | |
|---|---|
| **Observation:** The operator's emergency plans and procedures are not developed and evaluated in a comprehensive manner taking into account relevant acts, regulations and ordinances in EPR and the hazards associated with their facilities and activities. | |
| **(1)** | **BASIS: GS-R-2 para. 3.2 states that** *"The arrangements for emergency response actions both within and outside facilities, if applicable, or elsewhere under the control of the operator, are dealt with through the regulatory process."* |
| **(2)** | **GS-R-2 para. 3.9 states that** *"In fulfilling its statutory obligations, the regulatory body… shall establish, promote or adopt regulations and guides upon which its regulatory actions are based;… shall provide for issuing, amending, suspending or revoking authorizations, subject to any necessary conditions, that are clear and unambiguous and which shall specify (unless elsewhere specified):… the requirements for incident reporting;…and emergency preparedness arrangements."* |
| **R21** | **Recommendation: SORNS should develop a regulatory guide to facilitate systematic development of on-site emergency arrangements by operators and an internal process to facilitate its systematic review and assessment of the operator's emergency plan and programme.** |

**Changes since the original IRRS mission**

**Recommendation R21:** The CPD plans to develop a guide for the systematic review and assessment of the operator's emergency plan and programme, once the full EPR legislation and regulation is developed. A procedure for internal process to facilitate its systematic review and assessment of the operator's emergency plan and programme has not been approved yet.

**Status of the finding in the initial mission**

**Recommendation R21 remains open,** as internal procedures for evaluation of the licensees' emergency plan and program are available only in a draft form, awaiting approval and the relevant guides are still to be prepared.

## 10.4. ROLE OF REGULATORY BODY DURING RESPONSE

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** The 2013 Act 141/13(39/15) and Regulation 102/12 assign the roles of SORNS in emergency response which include assessment of the situation, provision of technical advice and public information, early notification, organization of environmental monitoring and efficiency control of decontamination. SORNS does not have its emergency plan and procedures necessary to fulfil these roles effectively in an emergency response as required in IAEA Safety Standards (GS-R-2, GS-G-2.1). Currently, SORNS relies on support from authorized TSOs and external experts in nuclear safety without any formal arrangements or protocols being made to ensure availability and reliability of this support when needed. | |
| **(1)** | **BASIS: GS-R-2 para. 5.14 states that** "*Each response organization "shall prepare a general plan or plans for coordinating and [performing their assigned functions as specified in Section 4] .....*" |
| | In addition, the following paragraphs provide basis for this recommendation: **GS-R-2, paras. 5.7, 5.8, 5.9, 5.10, 5.11, 5.14, 5.21, 5.22, 5.25, 5.31, 5.33, 5.37, 5.39** |
| **R22** | **Recommendation: SORNS should develop its own emergency arrangements consistently with IAEA Safety Standards to fulfill its roles in emergency response.** |

### Changes since the original IRRS mission

**Recommendation R22:** Additional emergency arrangements have been drafted specifically instructions for duty officer actions in various emergencies. The duty officers are in key position in activating the emergency response from the side of the CPD. Other positions are also defined and internal procedures for duty officers are in place but in a draft form. To fully develop emergency arrangements, the Plan must be enacted, so that the CPD plans and procedures can be in line with it.

### Status of the finding in the initial mission

**Recommendation R22 remains open,** as the CPD is waiting for the completion of the new national Plan for the development of internal arrangements that will be consistent with the Plan.

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** The roles of SORNS to organize and supervise environmental monitoring and to coordinate and direct the efficiency control of decontamination carried out by authorized TSOs in an emergency may result in a conflict of interest. Namely, the authorized TSOs act at the same time as support to SORNS and/or to an operator and as a response organization as well. This may diminish the roles of other response organizations (such as the Ministry of Environment or Protection and Rescue Directorate). | |
| **(1)** | **BASIS: GS-R-2 para.5.10 states that** "*In planning for, and in the event of [a nuclear or radiological emergency], the regulatory body shall act as an adviser to the government and [response organizations] in respect of nuclear safety and radiation protection.*" |

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| | **BASIS: GSR Part 1 para 2.22 states that***"The government shall designate competent authorities that will have the responsibilities and resources necessary to make preparations and arrangements for dealing with the consequences of incidents in facilities and activities that affect, or that might affect, the public and the environment."*<br><br>**BASIS: GSR Part 1: 2.9 states that** "*No responsibilities shall be assigned to the regulatory body that might compromise or conflict with its discharging of its responsibility for regulating the safety of facilities and activities."* |
| **S16** | **Suggestion: The Government should consider reviewing and revising the roles and responsibilities assigned to SORNS in emergency response in order to avoid compromising SORNS regulatory responsibilities and taking into account IAEA Safety Standards as well as the responsibilities of other State bodies and organizations.** |

## Changes since the original IRRS mission

**Suggestion: S16:** The new Regulation (OG 24/18) clarifies the roles and makes sure of the prime responsibility of the licensee in the response and defines that the regulator provides only expert support (advisory role) in emergencies. The Plan further clarifies the roles and responsibilities of the CPD, as a response organization, in the case of an emergency. The regulatory function of the CPD is not compromised.

Article 25, requires that, in case of an emergency in a facility in EPC I, II or V, the Commander of the Civil Protection Operational Headquarters of the Republic of Croatia shall receive expert support in the management of the emergency response by the experts of the CPD, in cooperation with the National Meteorological and Hydrological Service. Article 26 requires that, in case of an emergency in category III facility and category IV activities, the CPD shall provide the expert support to the licensee, i.e. on-site coordinator.

## Status of the finding in the initial mission

**Suggestion S16 is closed,** as Regulation (OG 24/18) clarifies the roles in respect of the emergency response and makes sure the prime responsibility of the licensee so that the regulatory function of the CPD is not compromised.

# 11.ADDITIONAL AREAS

## 11.1. CONTROL OF MEDICAL EXPOSURES

**Responsibilities of the government and of the regulatory body specific to medical exposure:**

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** The existing legislation does not clearly assign the responsibilities for justification of radiological procedures. As a result, there is no evidence that only justified practices are authorized.<br>Cooperation between SORNS, the Ministry of Health and the professional bodies is not optimal and the consultation process with professional bodies is not formalized.<br>Furthermore, some guidelines, such as those regarding patient release or referral criteria, which should be established by the Ministry of Health, are not yet available. | |
| **(1)** | **BASIS: GSR Part 3 Requirement 34, para. 3.147 states that** *"The government, in accordance with paras 2.13–2.28, shall ensure with regard to medical exposures that, as a result of consultation between the health authority, relevant professional bodies and the regulatory body, the relevant parties identified in paras 2.40 and 2.41 are authorized to assume their roles and responsibilities, and shall ensure that they are notified of their duties in relation to protection and safety for individuals undergoing medical exposures."* |
| **(2)** | **BASIS: GSR Part 3 Requirement 10, para. 3.16 states that** "*The government or the regulatory body, as appropriate, shall ensure that provision is made for the justification of any type of practice and for review of the justification, as necessary, and shall ensure that only justified practices are authorized."* |
| **(3)** | **BASIS: GSR Part 3 Requirement 36, para. 3.151 states that** *"Registrants and licensees shall ensure that no patient, whether symptomatic or asymptomatic, undergoes a medical exposure unless:*<br>*(a) It is a radiological procedure that has been requested by a referring medical practitioner and information on the clinical context has been provided, or it is part of an approved health screening programme;*<br>*(b) The medical exposure has been justified by means of consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate, or it is part of an approved health screening programme;*<br>*(...)."* |
| **(4)** | **BASIS: GSR Part 3 Requirement 37, para. 3.156 states that** *"Generic justification of a radiological procedure shall be carried out by the health authority in conjunction with appropriate professional bodies, and shall be reviewed from time to time, with account taken of advances in knowledge and technological developments."* |
| **(5)** | **BASIS: GSR Part 3 Requirement 37, para. 3.158 states that** "*Relevant national or international referral guidelines shall be taken into account for the justification of the medical exposure of an individual patient in a radiological procedure."* |

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **(6)** | **BASIS: GSR Part 3 Requirement 34, para. 3.149 states that** *"The government shall ensure that, as a result of consultation between the health authority, relevant professional bodies and the regulatory body, the following are established:*<br>*(b) Criteria and guidelines for the release of patients who have undergone therapeutic radiological procedures using unsealed sources or patients who still retain implanted sealed sources." (...)"* |
| **R23** | **Recommendation: SORNS, in coordination with the Ministry of Health, should initiate arrangements for assigning responsibilities for justification. SORNS should also ensure that only justified practices are authorized.** |
| **R24** | **Recommendation: The Ministry of Health and SORNS should issue the necessary guidelines, in cooperation with the relevant professional and scientific bodies, in accordance with the requirement of GSR Part 3.** |

**Changes since the original IRRS mission**

**Recommendation R23:** The control of medical exposures is mainly regulated in the Ordinance on Conditions for use of Ionizing Radiation Sources for Medical and Non-medical Imaging Purposes (Ordinance on Medical) (OG 42/18). The Ordinance is given together with the Ministry of Health, which confirms that regulations were given as a result of a consultation.

The responsibilities of a referrer and clinically responsible practitioner for justification are stipulated in the Article 6 of the Ordinance on Medical. In the Article 5 of the Ordinance justification of new type of medical or dental procedure involving ionizing radiation sources is required. However, a provision for assigning the responsibility for justifying a new type of a procedure involving medical exposure is not included.

For justified procedures, it is stipulated in the Article 4, that the Ministry of Health shall draw up and review a list of types and classes of medical exposure procedures for which the use of ionizing radiation sources is considered justified.

**Status of the finding in the initial mission**

**Recommendation 23 remains open,** as the regulation does not address who is responsible for justification of new types of procedures involving medical exposures.

**Changes since the original IRRS mission**

**Recommendation R24:** The CPD has drafted specific guidelines for nuclear medicine and radiotherapy. However, these guidelines are not yet approved. As part of an IAEA Technical Cooperation Program, experts from the IAEA are in the process of reviewing the guidelines, after which the CPD intends to seek input from professional bodies and Ministry of Health. The CPD does not have a process for developing guidelines and there is no established protocol regarding broad consultation when developing guidelines. A planned release date for the guidelines was not provided by the CPD.

**Status of the finding in the initial mission**

**Recommendation R24 remains open,** as the CPD has not issued any guidelines on medical exposures to-date. There is no defined process for developing guidelines and during the development of the recently drafted guidelines relevant professional bodies or Ministry of Health were not engaged.

| **Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES** | |
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| **Observation:** There is no specialization in medical physics, and the IRRS team has been informed that there are not enough medical physicists available in Croatia to implement the radioprotection of patients consistent with the requirements of the IAEA. In addition, the responsibilities of medical physicists, as set in GSR Part 3, are not fully defined in the Croatian regulations. | |
| **(1)** | **BASIS: GSR Part 3 Requirement 35, para. 3.147 states that** *"The regulatory body shall require that health professionals with responsibilities for medical exposure are specialized in the appropriate area and that they fulfill the requirements for education, training and competence in the relevant specialty."*<br><br>**BASIS: GSR Part 3 Requirement 35, para. 3.150 states that** "*The regulatory body shall ensure that the authorization for medical exposures to be performed at a particular medical radiation facility allows personnel (…medical physicists, (…) and any other health professionals with specific duties in relation to the radiation protection of patients) to assume the responsibilities specified in these Standards only if they:*<br><br>*(a) Are specialized in the appropriate area;*<br><br>*(b) Meet the respective requirements for education, training and competence in radiation protection, in accordance with para. 2.32;*<br><br>*(c) Are named in a list maintained up to date by the registrant or licensee."* |
| **(2)** | **BASIS: GSR Part 3 Requirement 35, para. 3.164 states that** *"For therapeutic radiological procedures, the radiological medical practitioner, in cooperation with the medical physicist and the medical radiation technologist, shall ensure that for each patient the exposure of volumes other than the planning target volume is kept as low as reasonably achievable consistent with delivery of the prescribed dose to the planning target volume within the required tolerances."* |
| **(3)** | **BASIS: GSR Part 3 Requirement 35, para. 3.165 states that** *"For therapeutic radiological procedures in which radiopharmaceuticals are administered, the radiological medical practitioner, in cooperation with the medical physicist and the medical radiation technologist, (…), shall ensure that for each patient the appropriate radiopharmaceutical with the appropriate activity is selected and administered, so that the radioactivity is primarily localized in the organ(s) of interest, while the radioactivity in the rest of the body is kept as low as reasonably achievable."* |
| **R25** | **Recommendation: The Government should recognize medical physicists as a profession at a national level and develop specialization in medical physics with objective to ensure the radiation protection of patients.** |

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **R26** | **Recommendation: SORNS should review its regulation to supplement the responsibilities of medical physicists so that they are fully integrated in all medical practices in accordance with GSR Part 3.** |

**Changes since the original IRRS mission**

**Recommendation R25:** The Amendment of the Act (OG 130/17), established the definition of the medical physics expert and set out the corresponding responsibilities in the Articles 3 (130) and 27.b respectively. The Ordinance on Radiation Protection (OG 53/18), establishes the definition of the medical physicist in the Article 3 (10) and the Act of Health Care (OG 100/18) recognizes the medical physicist as a health professional in Article 155.

However, the criteria for the qualification of a person as a medical physicist are not addressed in regulation. At the present time there is no educational institution in Croatia offering post-graduate programmes to persons wanting to acquire specialization in medical physics. The IRRS team acknowledges that there is a concerted effort to address this matter and some progress has been made. The IRRS team held a policy discussion on this subject with Croatian counterparts. A summary is provided in Section 11.1 of this report.

**Status of the finding in the initial mission**

**Recommendation R25 remains open,** as the criteria for the qualification of a person as a medical physicist are not addressed in regulation, and the medical physics specialization has not been established in the educational system.

**Changes since the original IRRS mission**

**Recommendation R26:** The amendment of the Act (OG 130/17) introduced in the Article 27.b the responsibilities of the medical physics expert from paragraphs 1 to 6. The requirements to be designated as a medical physics expert are established in Article 21 of the new Ordinance on Medical (OG 42/18).

**Status of the finding in the initial mission**

**Recommendation R26 is closed,** as the responsibilities of the medical physics expert and the criteria for the designation of a person as a medical physics expert have been introduced in the legislative framework.

**Responsibilities for overall protection of the patient and the carers and for information on radiation risks**

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation**: There is no legal obligation for licensees to systematically inform patients, carers and comforters about radiation risks. | |
| **(1)** | **BASIS: GSR Part 3 Requirement 36 para. 3.151 states that** *"Registrants and licensees shall ensure that no patient, whether symptomatic or asymptomatic, undergoes a medical exposure unless:* |

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| | *(d) The patient or the patient's legal authorized representative has been informed as appropriate of the expected diagnostic or therapeutic benefits of the radiological procedure as well as the radiation risks.* |
| **(2)** | **BASIS: GSR Part 3 Requirement 36, para. 3.153 states that** *"Registrants and licensees shall ensure that no individual incurs a medical exposure as a carer or comforter unless he or she has received and has indicated an understanding of relevant information on radiation protection and information on the radiation risks prior to providing care and comfort to an individual undergoing a radiological procedure. (…)"* |
| **(3)** | **BASIS: GSR Part 3 Requirement 39, para. 3.175 states that** *"Registrants and licensees shall ensure that signs in appropriate languages are placed in public places, waiting rooms for patients, cubicles and other appropriate places, and that other means of communication are also used as appropriate, to request female patients who are to undergo a radiological procedure to notify the radiological medical practitioner, medical radiation technologist or other personnel in the event that:*<br>*(a) She is or might be pregnant;*<br>*(b) She is breast-feeding and the scheduled radiological procedure includes the administration of a radiopharmaceutical."* |
| **S17** | **Suggestion: SORNS should consider making provisions for informing carers, comforters and patients, in particular breast feeding women, about the radiation risks, in accordance with GSR Part 3.** |

**Changes since the original IRRS mission**

**Suggestion S17:** Article 31 in the Ordinance on Medical (OG 42/18) establishes provisions for informing carers, comforters, patients and pregnant woman about the radiation benefits and risks for radiodiagnostic, radiotherapeutic and interventional procedures and include a provision that signs in appropriate languages be placed according to GSR Part 3.

**Status of the finding in the initial mission**

**Suggestion S17 is closed,** as the provisions for informing carers, comforters, patients and in particular breast feeding women, has been established in Ordinance on Medical (OG 42/18), in accordance with the IAEA Safety Standard GSR Part 3.

**Optimization**

1. **Calibration**

There were no findings in this area in the original IRRS mission.

2. **Quality Assurance**

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** The regulatory framework regarding optimization, such as calibration, quality assurance and involvement of medical physicists in all medical practices with radiation exposure, is not fully in line with the requirements of GSR Part 3. As a result, patients may be exposed to undue radiation doses**.**<br><br>SORNS does not verify through independent review, assessment or inspection process that all aspects of optimization are implemented**.** | |
| **(1)** | **BASIS: GSR Part 3 Requirement 38, para. 3.167 states that** "*In accordance with para. 3.154(d) and (e), the medical physicist shall ensure that:*<br><br>*(b) Calibrations are carried out at the time of commissioning a unit prior to clinical use, after any maintenance procedure that could affect the dosimetry and at intervals approved by the regulatory body;*<br><br>*(c) Calibrations of radiation therapy units are subject to independent verification prior to clinical use;*<br><br>*(d) Calibration of all dosimeters used for dosimetry of patients and for the calibration of sources is traceable to a standards dosimetry laboratory."* |
| **(2)** | **BASIS: GSR Part 3 Requirement 38, para. 3.170 states that** "*Registrants and licensees, in applying the requirements of these Standards in respect of management systems, shall establish a comprehensive programme of quality assurance for medical exposures with the active participation of medical physicists, radiological medical practitioners, medical radiation technologists and, for complex nuclear medicine facilities, radiopharmacists and radiochemists, and in conjunction with other health professionals as appropriate."* |
| **(3)** | **BASIS: GSR Part 3 Requirement 38, para. 3.171 states that** *"Registrants and licensees shall ensure that programmes of quality assurance for medical exposure include, as appropriate to the medical radiation facility:*<br><br>(a) *Measurements of the physical parameters of medical radiological equipment made by, or under the supervision of, a medical physicist:*<br><br>*(i) At the time of acceptance and commissioning of the equipment prior to its clinical use on patients;*<br><br>*(ii) Periodically thereafter;*<br><br>*(iii) After any major maintenance procedure that could affect protection and safety of patients;*<br><br>*(iv) After any installation of new software or modification of existing software that could affect protection and safety of patients (…)"* |
| **(4)** | **BASIS: GSR Part 3 Requirement 38, para. 3.172 states that** "*Registrants and licensees shall ensure that regular and independent audits are made of the programme of quality assurance for medical exposures, and that their frequency is in accordance with the complexity of the radiological procedures being performed and the associated risks".* |

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **(5)** | **BASIS: GSR Part 3 Requirement 36, para. 3.154 states that** *"Registrants and licensees shall ensure that:(…)*<br>*(f) Any delegation of responsibilities by a principal party is documented."* |
| **R27** | **Recommendation: SORNS should ensure that the existing requirements for optimization are fully implemented in all medical practices and that requirements regarding responsibilities of medical physicists, quality assurance, quality control and calibration are in accordance with the IAEA standards.** |

**Changes since the original IRRS mission**

**Recommendation R27:** Requirements for approval holders to comply with the principles of dose optimization, and to have quality assurance programs are stipulated in the Article 8 of the Ordinance on Medical (OG 42/18). The section about Quality Assurance Program (QAP) and Quality Control is established in the Ordinance on Radiation Protection (OG 53/18) however, there are no provisions establishing that the licensee shall ensure regular and independent audits for the programme of quality assurance. Additionally, the Annex 15 of the same Ordinance establishes what the QAP shall contain, including the persons who shall be involved and it is established that "the head of an institution shall be in charge of the setting up and implementation of the QAP " and the medical physics expert is considered responsible, only if appropriate, to participate in drawing up of the report.

The amendment of Act (OG 130/17) establishes in the Article 21 that the licensee shall ensure regular calibration of measuring instruments independently on the medical area. However, according to the Ordinance on Radiation Protection (OG 53/18) only devices used for measuring activities or assessing radiation dose for radiodiagnostic and therapeutic procedures in nuclear medicine shall be calibrated in a accredited calibration laboratory (Article 92). Furthermore, the Article 110 of the Ordinance on Radiation Protection (OG 53/18) regarding the calibration of the useful beam is incomplete as it only considers devices with remotely operated sealed radioactive sources.

The IRRS team was informed that in the license application review process, there is no assessment of the applicant's QAP.

**Status of the finding in the initial mission**

**Recommendation R27 remains open,** as there are still gaps in the regulation regarding responsibilities of medical physicists, quality assurance, quality control and calibration.

**Reviews and records**

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES |
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| **Observation:** The IRRS team notices that there is no requirement for:<br>• periodical assessment of patients' doses with regard to diagnostic reference levels;<br>• review when doses are substantially below the relevant diagnostic reference level and the exposures do not provide useful diagnostic information or do not yield the expected medical benefit to the patient;<br>• internal radiological review of the radiation protection practices by licensees.<br>As a result, patients may not be adequately protected**.** |

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| Some records to be kept are not specified in the legislation, especially those regarding the formalization of delegation of responsibilities and certain calibration and exposure records. | |
| **(1)** | **BASIS: GSR Part 3 Requirement 42, states that** *"Registrants and licensees shall ensure that radiological reviews are performed periodically at medical radiation facilities and that records are maintained.(…). The radiological review shall include an investigation and critical review of the current practical application of the radiation protection."* |
| **(2)** | ***BASIS: GSR Part 3 Requirement 38, para. 3.169*** **states that** *"Registrants and licensees shall ensure that:*<br>*(a) Local assessments, on the basis of the measurements required in para. 3.168, are made at approved intervals for those radiological procedures for which diagnostic reference levels have been established (para. 3.148).*<br>*(b) A review is conducted to determine whether the optimization of protection and safety for patients is adequate, or whether corrective action is required if, for a given radiological procedure:*<br>*(…)*<br>*(ii) Typical doses or activities fall substantially below the relevant diagnostic reference level and the exposures do not provide useful diagnostic information or do not yield the expected medical benefit to the patient."* |
| **(3)** | **BASIS: GSR Part 3 Requirement 42, para. 3.183 states that** *"Registrants and licensees shall maintain for a period as specified by the regulatory body and shall make available, as required, the following personnel records:*<br>*(a) Records of any delegation of responsibilities by a principal party (as required in para. 3.154(f));*<br>*(…)."* |
| **(4)** | **BASIS: GSR Part 3 Requirement 42, para. 3.184 states that** *"Registrants and licensees shall maintain for a period as specified by the regulatory body and shall make available, as required, the following records of calibration, dosimetry and quality assurance:*<br>*(a) Records of the results of the calibrations and periodic checks of the relevant physical and clinical parameters selected during treatment of patients;*<br>*(d) Records associated with the quality assurance programme, as required in para. 3.171(d)."* |
| **(5)** | **BASIS: GSR Part 3 Requirement 42, para. 3.185 states that "***Registrants and licensees shall maintain for a period as specified by the regulatory body and shall make available, as required, the following records for medical exposure:*<br>*(a) For diagnostic radiology, information necessary for retrospective assessment of doses, including the number of exposures and the duration of fluoroscopic radiological procedures;* |

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| | *(b) For image guided interventional procedures, information necessary for retrospective assessment of doses, including the duration of the fluoroscopic component and the number of images acquired;*<br>*(...)*<br>*(e) Exposure records for volunteers subject to medical exposure as part of a programme of biomedical research."* |
| **R28** | **Recommendation: SORNS should ensure that the existing requirements for reviews and records related to medical exposure are implemented in all medical practices and supplement its Ordinances to improve assessment and recording of patient doses in accordance with GSR Part 3.** |

**Changes since the original IRRS mission**

**Recommendation R28:** Article 23 of the Ordinance on Medical (OG 42/18) contains a list of exposure parameters to be maintained for each patient who receives medical radiation. The list contained in the Ordinance is not entirely in line with the GSR Part 3 requirement 42 para 3.185. In particular requirements on such issues as, number of exposures, number of images acquired and a description of the planning target volume, are missing.

The Amendment of the Act (OG 130/17) does not empower any relevant party to establish the DRLs, however, DRLs are established in the Ordinance on medical (OG 42/18). The Article 9 paragraph 4 in the same Ordinance determines "Diagnostic reference levels are not mandatory values for radiodiagnostic or interventional radiology procedure and they should be considered as guidelines pertaining to a typical adult patient". This contradiction denotes that even the DRLs are established in the Ordinance they cannot be required in the licensing process or during an inspection.

**Status of the finding in the initial mission**

**Recommendation R28 remains open,** as the Ordinance is not fully aligned with the GSR Part 3 to ensure that the existing requirements for reviews and records related to medical exposure are implemented in all medical practices.

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** Ordinance 89/13 does not cover some of the requirements of GSR Part 3 regarding unintended and accidental medical exposure.<br>Furthermore, SORNS has not developed a procedure for notification by the licensees, and the IRRS team has been informed that SORNS has not received unintended exposure notification to date. Moreover, unintended exposure records are not checked during inspections. | |
| **(1)** | **BASIS: GSR Part 3 Requirement 41, para. 3.180. states that** *"Registrants and licensees shall promptly investigate any of the following unintended or accidental medical exposures:*<br>*(f) Any failure of medical radiological equipment, failure of software or system failure, or accident, error, mishap or other unusual occurrence with the potential for subjecting the patient to a medical exposure that is substantially different from what was intended."* |

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **(2)** | **BASIS: GSR Part 3 Requirement 41, para. 3.181 states that** "*Licensees shall, with regard to any unintended or accidental medical exposures investigated as required in para. 3.180:*<br>*(b) Indicate the corrective actions required to prevent the recurrence of such an unintended or accidental medical exposure;*<br>*(d) Produce and keep, as soon as possible after the investigation or as otherwise required by the regulatory body, a written record that states the cause of the unintended or accidental medical exposure and includes the information specified in (a)–(c) above, as relevant, and any other information as required by the regulatory body; and for significant unintended or accidental medical exposures or as otherwise required by the regulatory body, submit this written record, as soon as possible, to the regulatory body, and to the relevant health authority if appropriate."* |
| **R29** | **Recommendation: SORNS should ensure that all requirements related to unintended and accidental medical exposure are implemented in compliance with the requirement of GSR Part 3.** |
| **S18** | **Suggestion: Since SORNS has not received any unintended or accidental exposure reports to date, SORNS should consider supporting this notification process through developing guidelines or/and training of medical staff and medical physicists.** |

**Changes since the original IRRS mission**

**Recommendation R29:** The Ordinance on Medical (OG 42/18) in the section IX Accidental Unintended Exposure addresses all requirements related to unintended and accidental medical exposure in line with the requirements of the GSR Part 3. No reports on unintended or accidental exposure were received.

**Status of the finding in the initial mission**

**Recommendation R29 is closed,** as the regulation addresses all requirements related to unintended and accidental medical exposure and is fully in line with the requirements of the GSR Part 3.

**Changes since the original IRRS mission**

**Suggestion S18:** Article 34 of the Ordinance on Medical (OG 42/18) contains requirements and criteria for recording, analyzing and reporting "significant events" to the CPD and to the Ministry competent for Health. The CPD has drafted specific guidelines for nuclear medicine and radiotherapy, which contains requirements for reporting real or potential accidental or unintended medical exposures. The guidelines have not been approved.

**Status of the finding in the initial mission**

**Suggestion S18 remains open,** as the guidelines have not been issued for use to licence holders.

**POLICY ISSUE 2**

**Certification of Medical Physicists**

Since the IRRS mission in 2015, there has been considerable progress in the recognition of Medical Physicists as a professional group within the health care sector.

While there is currently no specialized training program to qualify professionals who practice this speciality, Croatia has taken important steps towards addressing this gap. An initiative to introduce specialist training for medical physicists at the postgraduate (Master's) level which will incorporate a practical residency program as well as didactic training is under development. The statutory requirements will undergo amendments once the training programs are in place. In Croatia, University programs undergo an accreditation process to ensure the standard of training is appropriate. There is no final decision on what will be included in the curriculum, but the European qualification framework for medical physics professionals is intended to be used as a reference standard, and it is the expectation of counterparts that the medical physicists will meet the EFOMP (European Federation of Organization for Medical Physicists) recommendations. The counterparts recognized the urgency of the situation and expect that these changes will be in place in two years.

The IRRS team notes the significant steps already taken in this important area, the plans to address the remaining gaps, and the engagement and commitment from the highest levels of government in addressing the situation.

## 11.2. OCCUPATIONAL RADIATION PROTECTION

### Legal and Regulatory Framework

There were no findings in this area in the original IRRS mission.

### General responsibilities of employers, registrants and licensees

There were no findings in this area in the original IRRS mission.

### General responsibilities of workers

There were no findings in this area in the original IRRS mission.

### Requirements for radiation protection programmes

There were no findings in this area in the original IRRS mission.

### Monitoring programmes and technical services

**Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**Observation:** One of the tasks and responsibilities assigned by the Government to SORNS is to authorize and supervise the professional operations of authorized TSO. No post-authorization inspection or assessment of any authorized TSO in Croatia has ever taken place to establish that the authorized TSO still complies with the prescribed requirements of its authorization.

The formal recognition of Qualified Experts is absent.

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **(1)** | **BASIS: GSR Part 1 Requirement 27, states that** "*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."* |
| **R30** | **Recommendation: SORNS should put in place a programme of inspection of authorized TSOs as part of their annual inspection programme to establish that all authorized TSOs are maintaining the prescribed requirements of their authorizations.** |
| **(2)** | **BASIS: GSR Part 3 Requirement 2, para 2.21(b) states that** *"The government shall ensure that requirements are established for the formal recognition of qualified experts."* |
| **R31** | **Recommendation: SORNS should initiate in consultation with the relevant government departments and state agencies the development of a formal recognition for qualified experts and an additional requirement for TSOs to have a qualified expert on their staff should be included in SORNS process for authorizing TSOs.** |

**Changes since the original IRRS mission**

**Recommendation R30:** Due to staff shortages within the *"*Radiological and Nuclear Safety Inspection*"*, the annual inspection programme of the CPD for 2019 does not include any inspections of authorized TSOs. The IRRS team was informed that the annual inspection programme for 2020 may include an inspection of at least one authorized TSO.

**Status of the finding in the initial mission**

**Recommendation R30 remains open,** as insufficient progress has been made in including the inspection of authorized TSOs in the annual inspection programme of the regulatory body.

**Changes since the original IRRS mission**

**Recommendation R31:** The CPD certifies Radiation Protection Experts (RPEs) and the criteria for the issuing or renewal of certificates as a proof of competence for providing advice in relation to ionising radiation protection for a particular area, the periods of validity of the certificates and the manner of renewing the certificates are prescribed fully in the Ordinance on Radiation Protection Experts (OG 36/18).

In addition, the Ordinance on granting authorization to technical services organization for performing tasks pertainning to radiation safety (OG 40/18), specifies that TSOs must employ at least one Radiation Protection Expert (RPE) who is certified by the CPD.

**Status of the finding in the initial mission**

**Recommendation R31 is closed,** as the CPD has developed and implemented a system for the formal recognition by certification of RPEs. In addition, the CPD has included in the authorization process for TSOs a requirement for TSOs to have a RPE on their staff.

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES |
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| **Observation:** Emergency Exposure Situations - There is no documented programme for managing, controlling and recording the occupational doses received by emergency workers in an emergency. |

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| SORNS, in line with the legislation and regulations does not consider an emergency worker under the definition of an exposed worker nor is it defined as to who is to be regarded as an emergency worker. An emergency worker needs to be defined consistently with IAEA safety standards (GSR Part 3). | |
| **(3)** | **BASIS: GSR Part 1 Requirement 45, para. 4.12 states that** *"The government shall establish a programme for managing, controlling and recording the doses received in an emergency by emergency workers, which shall be implemented by response organizations and employers."* |
| **R32** | **Recommendation: The Government should define the concept of an emergency worker taking into account the IAEA safety standards and should establish a programme for managing, controlling and recording the doses received in an emergency by emergency workers. This programme should be implemented by response organizations, licensees and SORNS.** |

**Changes since the original IRRS mission**

**Recommendation R32:** Articles 35, 36 and 45 of the Regulation (OG 24/18) define an Emergency worker and sets down their rights and the requirement to manage, control and record their doses.

In Section D of the Regulation, Article 35 covers the responsibilities of the approval holder and lists the participants in the Emergency Preparedness and Response System.

Article 36 covers the protection of workers involved in the Emergency Response in relation to training; the provision of updated information on health risks associated with their activities and on the precautionary measures to be taken in the event of an emergency; permitted dose limits under normal circumstances and in exceptional situations; dosimetric monitoring of workers and medical examination of workers who have received doses in excess of specified limits and long-term medical surveillance as appropriate.

Article 36 addresses the responsibilities for the dosimetric monitoring of workers involved in the emergency response.

Article 45 covers the recording of radiation doses into the National Dose Register maintained by the CPD.

**Status of the finding in the initial mission**

**Recommendation (R32) is closed,** as the CPD through the Regulation (OG 24/18) has defined Emergency workers and has set down their rights and the requirements to manage, control and record their doses during emergencies.

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES |
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| **Observation:** Existing Exposure Situations – Cosmic Exposure of Aircrew and exposure to radon in work places. The current regulatory system for controlling exposure to cosmic radiation and exposure to radon in work places requires the full implementation of the radiation protection system for practices once exposed workers are identified. |

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **(4)** | **BASIS: GSR Part 3 Requirement 5.24 states that** *"The requirements in respect of occupational exposure in existing exposure situations (paras5.25–5.33) apply to any occupational exposure arising from the situations specified in para. 5.1."* |
| **(5)** | **BASIS: GSR Part 3 Requirement 52, para. 5.29 states that** *"If, despite all reasonable efforts by the employer to reduce radon levels, the activity concentration of 222Rn in the workplace remains above the reference level established in accordance with para. 5.27, the relevant requirements for occupational exposure in planned exposure situations as stated in Section 3 shall apply."* |
| **S19** | **Suggestion: SORNS should consider reviewing and revising its regulatory system for existing exposure situations with a view to implementing only those relevant requirements for occupational exposure of exposed workers.** |

**Changes since the original IRRS mission**

**Suggestion S19:** Article 40 of the Ordinance on Environmental Monitoring of Radioactivity (Ordinance on Environmental Monitoring) (OG 40/18) covers the requirements in relation to aircrew exposure to ionising radiation. This Article covers Assessment of Doses for aircrew, Methods of Assessment, Results of Assessment, Classification of Workers, Conditions for Repeat Assessment and Reporting to the CPD.

Article 39 of this Ordinance covers the requirements in relation to exposure to radon in workplaces. This Article covers Measurement of Radon and Dose Assessment, Results of the Dose Assessment, Reporting to the Regulatory Body and the National Dose Register.

Articles 31 to 38 of this Ordinance covers the requirements in relation to occupational exposure in existing exposure situations.

**Status of the finding in the initial mission**

**Suggestion S19 is closed,** as the CPD has introduced the Ordinance on Environmental Monitoring (OG 40/18) which covers the requirements in relation to aircrew exposure to ionising radiation and in relation to exposure to radon in workplaces. This Ordinance also sets down the relevant requirements that will apply to all exposed workers in these existing exposure situations.

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** There is no requirement in Croatian legislation that in the event of a TLD being lost or damaged, that a dose to an exposed worker should be estimated and that the estimated dose should be recorded in the personal dose record of the worker as an estimated dose. In addition, the absence of a requirement for workplace or area monitoring to be conducted by licensees using calibrated radiation survey meters will makes such dose assessments difficult. | |
| **(6)** | **BASIS: IAEA Safety Series RS-G-1.3 Section 8 para. 8.3 states that** *"If a dose assessment is not available for a period when a radiation worker was (or should have been) monitored — which may happen when a dosimeter has been damaged or lost, or recorded a dose that, on investigation, is declared invalid — the record keeping system should allow the introduction of doses estimated or assessed by an authorized person. These dose estimates* |

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| | *should be marked in such a way that they can be distinguished from official dose measurements made by the approved monitoring service."* |
| **S20** | **Suggestion: SORNS should consider revising Article 23 (3) of the Ordinance on Measurement of Personal Doses, Examination of Ionizing Radiation Sources and Working Conditions and on Reports and Registers (OG 41/12) in accordance with IAEA Safety Guide RS-G-1.3 Section 8.** |

**Changes since the original IRRS mission**

**Suggestion S20:** A new Ordinance on Dose Limits, Dose Constraints and Assessment of Personal Doses (OG 38/18) entered into force in 2018.

Article 30 of this Ordinance requires the undertaking to engage a radiation protection expert or an authorized TSO when estimating a dose to an exposed worker, in the event of a personal dosimeter being lost or damaged or not returned.

The estimate of the dose should be carried out not later than 90 days after the end of the relevant measurement period, and the estimated dose must be recorded in the personal dose record of the worker as an "estimated dose".

If the approval holder (licensee or undertaking) does not provide an estimated dose within the 90-day period he shall enter the value of $1/12^{th}$ of the appropriate protective quantity into the personal dose record of the exposed worker.

**Status of the finding in the initial mission**

**Suggestion S20 is closed,** as the Regulatory Body has introduced a new Ordinance on Dose Limits, Dose Constraints and Assessment of Personal Doses (Ordinance on Personal Doses) (OG 38/18) which sets down the requirements that in the event of a personal dosimeter being lost or damaged, the dose to an exposed worker shall be estimated and that the estimated dose shall be recorded in the personal dose record of the worker as an estimated dose. This is in line with the IAEA safety standards.

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** Currently only *Hp*(10) is being measured in Croatia as no TSO is authorized to measure *Hp*(0.07) or conduct internal dosimetry. With the introduction of the new dose limit for the lens of the eye in 2018, a national capability will be required to assess *Hp*(0.07) and *Hp*(3). The development of the radwaste management programme will also require a capability for internal dosimetry. | |
| **(7)** | **BASIS: IAEA Safety Series RS-G-1.3 Section 3.10 states that** *"An individual monitoring service approved by the regulatory authority should be used. The regulatory authority should require such a service to supply dosimeters capable of measuring Hp(10) and Hp(0.07) with adequate accuracy for all relevant radiation type."* |
| **S21** | **Suggestion: SORNS, in light of the introduction of the new dose limit for the lens of the eye and the development of the radwaste management programme, should consider introducing arrangements so that a national capability for extremity dose assessment *Hp*(0.07) and *Hp*(3) together with a national capability for internal dosimetry is** |

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| | **available. The relevant ordinance on Measurement of Personal Doses, Examination of Ionizing Radiation Sources and Working Conditions and on Reports and Registers (OG 41/12) should be revised in accordance with IAEA Safety Guides.** |

**Changes since the original IRRS mission**

**Suggestion S21:** The Ordinance on Personal Doses (OG 38/18) introduced significant changes in the implementation of personal dosimetry and the monitoring of exposed workers.

The Ordinance introduced the obligatory categorisation of exposed workers into the system of monitoring and control of exposed workers. Undertakings must ensure systematic monitoring of Category A workers, based on individual measurements, performed by approved dosimetry services and Category B workers must be monitored either by individual measurements or other means (estimation based on the workplace monitoring etc.) according to the advice of an RPE in order to demonstrate that they are correctly classified.

Individual measurements with personal dosimeters are conducted monthly, and individual measurements must be performed by Dosimetry Services, authorized by the CPD. Data on the exposure of workers, i.e. on received doses, are kept in the National Dose Register maintained by the CPD.

All authorized TSOs currently supply various types of dosimeters that are capable of measuring Hp(10), Hp(0,07) and Hp(3) (whole body, extremity and eye lens).

The IRRS team was informed by the Head of the Department of Nuclear Medicine and Radiation Protection, at the University Hospital Centre Zagreb that the Centre is equipped with competent and trained staff, and with instrumentation for personal counting and internal dosimetry for gamma radiation.

**Status of the finding in the initial mission**

**Suggestion S21 is closed,** as a national capability now exists for extremity dose assessment *Hp*(0.07) together with lens of the eye dose assessment *Hp*(3) and whole-body dose assessment *Hp*(10). There is also a capability for internal dosimetry for gamma radiation available at the University Hospital Centre, Zagreb.

## 11.3. CONTROL OF RADIOACTIVE DISCHARGES, MATERIALS FOR CLEARANCE, AND EXISTING EXPOSURES; ENVIRONMENTAL MONITORING FOR PUBLIC RADIATION PROTECTION

### 11.3.1. CONTROL OR RADIOACTIVE DISCHARGES AND MATERIALS FOR CLEARANCE

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** Regulation 44/08 does not address limits for liquid and gaseous radioactive discharges in accordance with IAEA standards. As a result, radioactive discharge limits are not imposed on licences and protection of the public cannot be verified. There is also no procedure for establishing dose constraints to be used in the optimization of protection and safety for public exposure, which is required to derive discharge limits. | |
| **(1)** | **BASIS: GSR Part 3 Requirement 11, para. 3.22 states that** *"The government or the regulatory body:* |

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| | *(a) Shall establish and enforce requirements for the optimization of protection and safety;*<br>*(b) Shall require documentation addressing the optimization of protection and safety;*<br>*(c) Shall establish or approve constraints on dose and on risk, as appropriate, or shall establish or approve a process for establishing such constraints, to be used in the optimization of protection and safety."*<br>**BASIS: GSR Part 3 Requirement 11, para. 3.122 states that** *"Before authorization of a new or modified practice, the regulatory body shall require the submission of, and shall review, the safety assessments (paras 3.29–3.36) and other design related documents from the responsible parties that address the optimization of protection and safety, the design criteria and the design features relating to the assessment of exposure and potential exposure of members of the public."* |
| **(2)** | **BASIS: GSR Part 3 Requirement 14, para. 3.37 states that** "*The regulatory body shall establish requirements that monitoring and measurements be performed to verify compliance with the requirements for protection and safety. The regulatory body shall be responsible for review and approval of the monitoring and measurement programmes of registrants and licensees."* |
| **(3)** | **BASIS: GSR Part 3 Requirement 29, para. 3.123 states that** "*The regulatory body shall establish or approve operational limits and conditions relating to public exposure, including authorized limits for discharges."* |
| **(4)** | **BASIS: GSR Part 3 Requirement 31, states that** *"Relevant parties shall ensure that radioactive waste and discharges of radioactive material to the environment are managed in accordance with the authorization."* |
| **R33** | **Recommendation: SORNS should review their regulatory framework with regards to liquid and gaseous radioactive discharges and ensure the optimization of protection and safety is achieved and discharge limits imposed on licences that cover such discharges.** |

**Changes since the original IRRS mission**

**Recommendation R33:** The requirements in relation to liquid and gaseous radioactive discharges are now regulated through the Ordinance on Waste (OG 12/18). Under Article 21 liquid and gaseous radioactive waste from a site may be discharged to the environment only if the requirements pertaining to the activity and quantity of radioactive waste are complied with. The activity and quantity of radioactive waste to be discharged ie the site discharge limits shall be established for each site taking into consideration the following:

- transport routes and radionuclide behaviour in the natural environment;
- results of optimisation of radiation protection and;
- good operating practices in similar facilities.

In addition, when discharging liquid and gaseous radioactive waste, it is also necessary to take into consideration the outcome of the generic study assessment based on internationally recognised scientific

guidelines that demonstrates the compliance with the environmental protection requirements for long-term protection of human health.

As part of the authorization process, the undertaking must submit to the CPD an environmental risk assessment and estimate the doses to representative persons from the discharges to the environment. The environmental risk assessments are conducted by TSOs on behalf of the undertakings. The results of the risk assessment shall then inform the undertaking whether Facility Monitoring and/or Facility Environmental Monitoring will be required.

At the site level, the undertaking is required to supervise the release into the environment and should monitor the discharge prior to release. In addition, the undertaking is required to prepare a report on the supervision of the concerned release into the environment and submit it to the CPD.

The IRRS team noted that due to a shortage of competent staff the implementation of the regulatory requirements by the CPD is not being supported by an appropriate annual inspection programme to cover the relevant licensees (operators or approval holders).

**Status of the finding in the initial mission**

**Recommendation R33 is closed,** as the Regulatory Body has reviewed their regulatory framework with regards to liquid and gaseous radioactive discharges which is now regulated through the Ordinance on Waste (OG 12/18) which impose discharge limits on licensees.

### 11.3.2. ENVIRONMENTAL MONITORING

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** The Ordinance 121/13 does not differentiate between types of authorized users or types of monitoring. SORNS also does not enforce operators to carry out monitoring programmes in accordance with its Ordinance. As a result operators have not developed nor implemented monitoring programmes.<br>The existing calibration programme developed by SORNS is not being implemented due to the lack of financial resources. This affects the credibility/reliability of the results that are used in the decision-making process. | |
| **(1)** | **BASIS: GSR Part 3 Requirement 14, para. 3.37states that** *"The regulatory body shall establish requirements that monitoring and measurements be performed to verify compliance with the requirements for protection and safety. The regulatory body shall be responsible for review and approval of the monitoring and measurement programmes of registrants and licensees."* |
| **(2)** | **BASIS: GSR Part 3 Requirement 32, states that** *"The regulatory body and relevant parties shall ensure that programmes for source monitoring and environmental monitoring are in place and that the results from the monitoring are recorded and are made available."* |
| **(3)** | **BASIS: RS-G-1.8 para.3.4 states that** *"In relation to the control of discharge practices, the regulatory body has the following general responsibilities:*<br>*(b) Ensuring that the operator complies with the appropriate regulations and regulatory requirements, including those in respect of carrying out such source and environmental monitoring as may be necessary;* |

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| | *(c) Providing assurance that judgements concerning the safety of the public are based upon valid information and sound methods."* |
| **R34** | **Recommendation: SORNS should ensure that monitoring programmes are developed and implemented in accordance with IAEA standards and supported by its regulatory framework.** |
| **S22** | **Suggestion: SORNS should consider implementing a calibration programme for all of its monitoring and measuring instruments.** |

**Recommendation R34:** The Ordinance on Environmental Monitoring (OG 40/18) sets out in detail the requirements on approval holders for conducting monitoring and measurement programmes to verify compliance with the requirements for radiation protection and safety.

The Ordinance covers:

- Aim and principles of environmental monitoring;
- Risk appropriate frequency of sampling and measuring;
- Methodology for collection, preparation and testing of samples;
- Calibration of Equipment and devices used for testing of samples;
- Data collection required for interpretation of the results and assessing the exposure of members of the public (quantity of precipitation, river flows, quantity of distributed drinking water, etc.);
- Preparation of Results for analysis;
- Requirements for Facility Monitoring and Facility Environmental Monitoring during facility operation;
- Monitoring Programme approval by the responsible Authority;
- Responsibility of the user of the facility to ensure implementation of monitoring programme;
- Obligation of the holder of the approval to keep records and provide access to all stakeholders in relation to the measurement of external exposure and contamination, assessment of radionuclide intake and results of the exposure assessment of the representative person.

The IRRS team noted that a shortage of competent staff is preventing the CPD from exercising an appropriate annual inspection programme to cover the relevant licensees.

The IRRS team was informed that currently there is no licensed facility required to perform environmental monitoring in accordance with Article 24 of this Ordinance.

**Status of the finding in the initial mission**

**Recommendation (R34) is closed,** as the Regulatory Body through the Ordinance on Environmental Monitoring (OG 40/18) sets out in detail the requirements on approval holders for conducting monitoring and measurement programmes to verify compliance with the requirements for radiation protection and safety.

**Changes since the original IRRS mission**

**Suggestion S22:** The CPD has implemented a full calibration programme for its continuous environmental monitoring stations (CEWS). The programme operates on a four-year cycle, which is deemed to be adequate to ensure good working order of all the probes, as well as reasonable financial implications.

Frequently used hand-held monitoring instruments were calibrated in 2018 and will be calibrated on 2-4 yearly basis, depending on their expected use.

**Status of the finding in the initial mission**

**Suggestion (S22) is closed,** as the CPD has implemented a calibration programme for all of its continuous environmental monitoring stations (CEWS) and its frequently used hand-held monitoring instruments.

### 11.3.3. EXISTING EXPOSURE SITUATIONS, INCLUDING REMEDIATION OF AREAS CONTAMINATED WITH RESIDUAL RADIOACTIVE MATERIAL

**Radon**

There were no findings in this area in the original IRRS mission.

**Remediation**

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** Ordinance 53/08 does not address remediation of areas contaminated with residual radioactive material. As a result, no remediation process has been established and no limits and criteria exist to initiate remediation. | |
| **(1)** | **BASIS: GSR Part 1 Requirement 3, para. 4.29 states that** *"Different types of authorization shall be obtained for the different stages in the lifetime of a facility or the duration of an activity. The regulatory body shall be able to modify authorizations for safety related purposes. For a facility, the stages in the lifetime usually include: site evaluation, design, construction, commissioning, operation, shutdown and decommissioning (or closure). This includes, as appropriate, the management of radioactive waste and the management of spent fuel, and the remediation of contaminated areas. For radioactive sources and radiation generators, the regulatory process shall continue over their entire lifetime."* |
| **(2)** | **BASIS: GSR Part 3 Requirement 47, Responsibilities of the government specific to existing exposure situations, states that** *"The government shall ensure that existing exposure situations that have been identified are evaluated to determine which occupational exposures and public exposures are of concern from the point of view of radiation protection."* |
| **(3)** | **BASIS: GSR Part 3 Requirement 49, Responsibilities for remediation of areas with residual radioactive material, states that** *"The government shall ensure that provision is made for identifying those persons or organizations responsible for areas with residual radioactive material; for establishing and implementing remediation programmes and post-remediation control measures, if appropriate; and for putting in place an appropriate* |

| Original Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| | *strategy for radioactive waste management."* |
| **(4)** | **BASIS: WS-G-3.1, para. 3.1 states that** *"The overall remediation process shown in Fig. 1 involves four main activities:*<br>*(a) initial site characterization and selection of remediation criteria;*<br>*(b) identification of remediation options and their optimization, followed by subsequent development and approval of the remediation plan;*<br>*(c) implementation of the remediation plan; and*<br>*(d) post-remediation management."* |
| **R35** | **Recommendation: The Government should ensure that existing exposure situations that have been identified are evaluated to determine which occupational exposures and public exposures are of concern from the point of view of radiation protection, in accordance with IAEA standards.** |
| **R36** | **Recommendation: SORNS should revise their Ordinances to address the remediation process of areas contaminated with residual radioactive material in accordance with IAEA standards.** |

## Changes since the original IRRS mission

**Recommendation R35:** Past activities were recognized in the Strategy for Management of Radioactive Waste, Disused Sources and Spent Nuclear Fuel (OG 125/14) including the remediation of sites containing natural radioactive materials.

In 2018, a National Programme for Implementation of the Strategy for Management of Radioactive Waste, Disused Sources and Spent Nuclear Fuel was adopted, and this programme foresees the remediation of previously identified sites that are contaminated with naturally occurring radionuclides.

Other existing exposure situations that may give rise to occupational and public exposures that are of concern from a radiation protection perspective are listed in the Ordinance on Dose Limits, Dose Constraints and Assessment of Personal Doses (OG 38/18).

A Radon Action Plan with the long-term aim of contributing to the reduction of radon exposure in the Republic of Croatia was adopted in 2018 (OG 118/18) and national reference levels were transposed into national legislation in Ordinance on Dose Limits, Dose Constraints and Assessment of Personal Doses (OG 38/18).

## Status of the finding in the initial mission

**Recommendation R35 is closed,** as existing exposure situations have been identified which are deemed to give rise to occupational exposures and public exposures which are of concern from the point of view of radiation protection.

## Changes since the original IRRS mission

**Recommendation R36:** The Ordinance on the Content and Requirements, Criteria and the Authorisation Procedure for the Remediation Plan (Ordinance on Remediation) (OG 38/18) address the remediation process of areas contaminated with residual radioactive material.

The remediation plan for the environment contaminated by radioactive substances shall be made for each site separately, in accordance with the reference levels prescribed in Ordinance on Remediation (OG 38/18) applying the principles of justification and optimisation and taking into account the future use of the site.

Remediation plans must be submitted to the CPD for formal approval and this will ultimately entail the CPD having the necessary competent and trained staff to assess such remediation plans.

## Status of the finding in the initial mission

**Recommendation R36 is closed,** as the regulatory body has issued the Ordinance on Remediation (OG 38/18) which addresses the remediation process of areas contaminated with residual radioactive material.

# APPENDIX I LIST OF PARTICIPANTS

| | | | |
|---|---|---|---|
| **INTERNATIONAL EXPERTS** | | | |
| 1. | **BLY** Ritva | Radiation and Nuclear Safety Authority (STUK)<br>FINLAND, | Ritva.Bly@stuk.fi |
| 2. | **DA SILVA TEIXEIRA** Flavia Cristina | National Nuclear Energy Commission (CNEN)<br>BRAZIL | flavia@cnen.gov.br |
| 3. | **MADDEN** Jack | Environmental Protection Agency | J.Madden@epa.ie |
| 4. | **MURTHY** Kavita | Canadian Nuclear Safety Commission (CNSC)<br>CANADA | kavita.murthy@canada.ca |
| 5. | **SIRC** Igor | Slovenian Nuclear Safety Administration<br>SLOVENIA | Igor.Sirc@gov.si |
| 6. | **SCHNELZER** Lars | Federal Ministry for the Environment, Nature Conservation, and Nuclear Safety<br>GERMANY | lars.schnelzer@bmu.bund.de |
| 7. | **ZOMBORI** Peter | Senior Expert<br>HUNGARY | petezombori@gmail.com |
| **IAEA STAFF MEMBERS** | | | |
| 1. | **PACHECO** Ronald | Division of Radiation, Transport and Waste Safety | R.Pacheco.jimenez@iaea.org |
| 2. | **BOSNJAK** Jovica | Division of Radiation, Transport and Waste Safety | J.Bosnjak@iaea.org |
| 3. | **SWOBODA** Zumi | Division of Radiation, Transport and Waste Safety | Z.Swoboda@iaea.org |
| **LIAISON OFFICERS** | | | |
| 1.<br>2. | **NOVOSEL** Nevenka<br>**TEČIĆ** Zdravka | Liaison Officer | nnovosel3@mup.hr<br>ztecic@mup.hr |

# APPENDIX II LIST OF COUNTERPARTS

| IRRS EXPERTS | COUNTERPART |
|---|---|
| **RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT** | |
| I.Sirc<br>K. Murthy | Z. Tečić |
| **GLOBAL SAFETY REGIME** | |
| I.Sirc<br>K. Murthy | Z. Tečić |
| **RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY** | |
| I.Sirc<br>K. Murthy | Z. Tečić |
| **MANAGEMENT SYSTEM** | |
| Ronald Pacheco | Z. Tečić |
| **AUTHORIZATION** | |
| J. Bošnjak<br>L. Schnelzer | Z. Tečić<br>R. Laknar<br>S. Krča<br>M. Medić |
| **REVIEW AND ASSESSMENT** | |
| J. Bošnjak<br>L. Schnelzer | Z. Tečić<br>R. Laknar<br>S. Krča<br>M. Medić |
| **INSPECTION** | |
| J. Bošnjak<br>L. Schnelzer | R. Laknar<br>Nikola Turkalj |
| **ENFORCEMENT** | |
| J. Bošnjak<br>L. Schnelzer | Z. Tečić<br>R. Laknar<br>S. Krča<br>M. Medić |
| **REGULATIONS AND GUIDES** | |

| IRRS EXPERTS | COUNTERPART |
|---|---|
| J. Bošnjak<br>L. Schnelzer | Z. Tečić<br>R. Laknar<br>S. Krča<br>M. Medić |
| **EMERGENCY PREPAREDESS AND RESPONSE** | |
| P. Zombori | S. Popović |
| **ADDITIONAL AREAS - Medical Exposure** | |
| F. Teixeira<br>R. Bly | Z. Tečić<br>N. Novosel |
| **ADDITIONAL AREAS - Occupational Exposure** | |
| J. Madden | S. Krča<br>R. Laknar<br>S. Popović |
| **ADDITIONAL AREAS - Control of radioactive discharges and materials for clearance, Environmental monitoring associated with authorized practices for public radiation protection purposes<br>Control of chronic exposures** | |
| J. Madden | S. Krča |

# APPENDIX III MISSION PROGRAMME

| IRRS FOLLOW-UP MISSION PROGRAMME | | |
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| **Sunday 20 October** | | |
| **IRRS Initial Team Meeting** | | |
| 14:00 - 17:15 | Opening remarks by the IRRS Team Leader<br>Introduction by IAEA<br>Self-introduction of all attendees<br>IRRS Process and report writing (IAEA)<br>Schedule (TL, IAEA)<br>First impression from team members arising from the Advanced Reference Material (ARM) (all Team members): Presentations<br>Administrative arrangements (MUP Liaison Officers, IAEA): Detailed Mission Programme | Location: Hotel Dubrovnik<br>Participants: IRRS Team, Liaison Officers |
| 17:15 -19:00 | Groups prepare for interviews;<br>Module Leaders prepare TL presentation for the Entrance Meeting (if necessary) | Participants: the IRRS Team |

| **Monday 21 October** | | |
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| **IRRS Entrance Meeting** | | |
| 09:00 –12.00 | 09:00 Arrival, registration<br>09:30 Assistant Minister Damir Trut, PhD – Welcoming Address<br>9:50 Self-introduction of MoI Liaison Officers and counterparts of each module<br>10:20 Opening remarks by IRRS Team Leader. Expectations for the Mission<br>10:35 Self-introduction of IAEA mission members<br>11:00 MUP presentation – Overview of the Croatia regulatory approach since 2015<br>11:30 Photo session | Location: CPD, Meeting Room on the ground floor<br>Participants: High Level Government Official, MoI Management, Liaison Officers and staff, the IRRS Team |
| 12:00 –13:00 | Lunch | |
| 13:00 –17:00 | Interviews and Discussions with Counterparts (parallel discussions) | Location: CPD Counterparts and Offices according the interviews schedule |

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| 17:00 - 18:00 | Daily IRRS Review Team meeting | Location: Hotel Dubrovnik<br>Participants: the IRRS Team + the LO |
| **Tuesday 22 October** | | |
| **Daily Discussions / Interviews** | | |
| 09:00 –12:00 | Interviews and discussions with counterparts (parallel discussions) | Location: CPD Counterparts and Offices according the interviews schedule |
| 12:00 –13:00 | Lunch | |
| 13:00 –17:00 | Interviews and discussions with counterparts (parallel discussions) | Location: CPD<br>IRRS Team |
| 14:00 –15:00 | Policy issue on waste | Location: Fund NEK |
| 17:00 –18:00 | Daily IRRS Review Team meeting/ Discussion of the preliminary findings (conclusions) | Location: Hotel Dubrovnik<br>Participants: the IRRS Team + the LO |
| 20:00 –24:00 | Report conclusions drafting | IRRS Team |
| **Wednesday 23 October** | | |
| **Daily Discussions / Interviews** | | |
| 09:00 –12:00 | Follow-up Interviews as needed | Location: CPD Counterparts and Offices according the interviews schedule |
| 12:00 –13:00 | Lunch | |
| 13:00 –17:00 | Report preparation | Location: CPD<br>IRRS Team |
| 17:00 | Written preliminary (conclusions) delivery to the Team Leader copied to IAEA Coordinator | IRRS Team |
| 17:00 –18:00 | Daily IRRS Review Team Meeting: conclusions discussions | Location: Hotel Dubrovnik<br>Participants: the IRRS Team + the LO |
| 20:00 –24:00 | Report drafting | IRRS Team |
| **Thursday 24 October** | | |
| **Daily Discussions / Interviews** | | |
| 09:00 –12:00 | Interviews as required<br>Report preparation | Location: CPD Counterparts and Offices according the interviews schedule |
| 09:30 | Policy issue on medical physicists | Location: Ministry of Health |
| 12:00 –13:00 | Lunch | |
| 13:00 –16:00 | Discussion of the interviews with team and revising conclusions (if necessary) | Location: CPD<br>Participants: the IRRS Team |

| | | |
|---|---|---|
| 16:00 –17:00 | Individual discussion of findings with counterparts | Location: CPD Counterparts and Offices according the interviews schedule |
| 17:00 –18:00 | Daily IRRS Review Team Meeting: conclusions discussions, cross reading division among the Team | Location: Hotel Dubrovnik Participants: the IRRS Team + the LO |
| 20:00 –24:00 | Report revision | IRRS Team |
| **Friday 25 October** | | |
| **Daily Discussions/ Interviews (if needed)** | | |
| 09:00 –12:00 | Team members cross reads and discusses report draft | Location: CPD IRRS Team |
| 12:00 –13:00 | Lunch | |
| 14:00 | Meeting with the Assistant Minister | Location: CPD |
| 13:00 –16:00 | Collective reading and revising the draft report | Location: CPD IRRS Team |
| **Saturday 26 October** | | |
| **Daily Discussions** | | |
| 09:00 –12:00 | Final revision of the report | Location: Hotel Dubrovnik IRRS Team |
| 12:00 –13:00 | Lunch | |
| 14:00 | Submission of the report to the Host –MoI for review | TL, TC |
| 13:00 –17:00 | Executive summary and exit presentation finalization<br>Press release draft preparation | TL, TC, and AA |
| 19:00 | Dinner | Restaurant Kaptolska klet |
| **Sunday 27 October** | | |
| | | |
| | Free day | |
| **Monday 28 October** | | |
| **Daily Discussions** | | |
| 09:00 –10:00 | Review of amendments based on MoI's comments | Location: CPD IRRS Team |
| 10:00 –12:00 | Discussion with MoI | Location: CPD IRRS Team and counterparts |
| 12:00 –13:00 | Lunch | |
| 13:00 –17:00 | Report finalization by the Team<br>Press release finalization | Location: CPD IRRS Team |

| Tuesday 29 October | | |
|---|---|---|
| | | |
| 09:00 –11:00 | MoI opening remarks | Location: CPD<br>Participants:<br>MoI Management, LO and staff, the IRRS Team |
| | Main findings of the IRRS mission (Team Leader) | |
| | Remarks by MoI in response to the Mission findings. | |
| | IAEA Official Closing remarks delivery by IAEA Official | |

## APPENDIX IV Recommendations (R) and Suggestions (S) from the 2015 IRRS mission that remain open

| Section | Module | R/S | Recommendations/Suggestions |
|---|---|---|---|
| 1.3 | 1 | R3 | The Government should provide SORNS with human and financial resources enabling SORNS to completely fulfil its statutory obligations for regulatory control. |
| 1.3 | 1 | S1 | The Government should consider organizing training and refresher courses in a way that do not compromise effective independence of SORNS. |
| 1.7 | 1 | R4 | The Government should implement the provisions for the safe management of radioactive waste in particular with the construction and operation of the Central National Storage Facility in compliance with the Strategy for the Management of Radioactive Waste, Disused Sources and Spent Nuclear Fuel. |
| 2.2 | 2 | R5 | SORNS should established and maintain process and procedures for analysing and disseminating the lessons learned from national and international operating experience and regulatory experience to be used by SORNS, other authorities and authorized parties. |
| 3.1 | 3 | R6 | SORNS should have sufficient resources and optimize them in order to discharge its responsibilities and perform its functions in a manner commensurate with the radiation risks associated with facilities and activities. |
| 3.3 | 3 | R7 | SORNS should prepare and implement comprehensive training plans in order to improve knowledge, skills and abilities to perform all the functions and responsibilities. |
| 4.2 | 4 | R8 | SORNS should appoint an individual with the authority to coordinate and develop the integrated management system and to raise issues relating to the management system to the senior management. |
| 4.5 | 4 | R9 | SORNS should develop an integrated management system in line with IAEA safety standard GS-R-3. |

| Section | Module | R/S | Recommendations/Suggestions |
|---|---|---|---|
| 4.5 | 4 | S3 | SORNS should consider revising its strategic plan to expand the requirements on management system from the quality assurance programme to the integrated management system. |
| 4.5 | 4 | S4 | SORNS should consider preparing the plan for establishment, development, and implementation of an integrated management system where the priorities are stressed out such as defining responsibilities for the management system, defining key processes related to inspection, licensing, etc. and defining the interactions among the processes. |
| 6.1.4 | 6 | S6 | SORNS should consider introducing pre-licensing verification of the contents of the documents submitted for review and assessment of an application for authorization to confirm credibility of submitted documents, where appropriate. |
| 7.1.1 | 7 | R13 | SORNS should establish inspection programme that commensurate with the radiation risks associated with the facility or activity in accordance with a graded approach that covers all areas relevant to safety and radiation protection and implement this programme. |
| 7.1.2 | 7 | S7 | SORNS should review its inspection programme and include tests and measurements as a method of inspection. |
| 9.1 | 9 | S10 | SORNS should establish within its regulatory framework processes and procedures for reviewing and revising regulations, taken into account internationally agreed standards and the feedback of relevant experience. |
| 10.1 | 10 | R17 | SORNS should revise and strengthen its regulatory framework in EPR consistently with IAEA Safety Standards to also include inspection, enforcement and evaluation of some of operator's exercises and should implement a graded approach. |
| 10.2 | 10 | S14 | SORNS should consider continuing its efforts to coordinate and harmonize emergency planning zones with their Slovenian counterparts in relation to Krsko NPP in line with relevant IAEA Safety Standards. |

| Section | Module | R/S | Recommendations/Suggestions |
|---|---|---|---|
| 10.3 | 10 | R21 | SORNS should develop a regulatory guide to facilitate systematic development of on-site emergency arrangements by operators and an internal process to facilitate its systematic review and assessment of the operator's emergency plan and programme. |
| 10.4 | 10 | R22 | SORNS should develop its own emergency arrangements consistently with IAEA Safety Standards to fulfill its roles in emergency response. |
| 11.1 | 11 | R23 | SORNS, in coordination with the Ministry of Health, should initiate arrangements for assigning responsibilities for justification. SORNS should also ensure that only justified practices are authorized. |
| 11.1 | 11 | R24 | The Ministry of Health and SORNS should issue the necessary guidelines, in cooperation with the relevant professional and scientific bodies, in accordance with the requirement of GSR Part 3. |
| 11.1 | 11 | R25 | The Government should recognize medical physicists as a profession at a national level and develop specialization in medical physics with objective to ensure the radiation protection of patients. |
| 11.1 | 11 | R27 | SORNS should ensure that the existing requirements for optimization are fully implemented in all medical practices and that requirements regarding responsibilities of medical physicists, quality assurance, quality control and calibration are in accordance with the IAEA standards. |
| 11.1 | 11 | R28 | SORNS should ensure that the existing requirements for reviews and records related to medical exposure are implemented in all medical practices and supplement its Ordinances to improve assessment and recording of patient doses in accordance with GSR Part 3. |
| 11.1 | 11 | S18 | Since SORNS has not received any unintended or accidental exposure reports to date, SORNS should consider supporting this notification process through developing guidelines or/and training of medical staff and medical physicists. |

| Section | Module | R/S | Recommendations/Suggestions |
|---|---|---|---|
| 11.2 | 11 | R30 | SORNS should put in place a programme of inspection of authorized TSOs as part of their annual inspection programme to establish that all authorized TSOs are maintaining the prescribed requirements of their authorizations. |

## Appendix V Recommendations (RF), Suggestions (SF) and good practices (GPF) from the 2019 IRRS Follow-up Mission

| Section | Module | RF/SF/GPF | Recommendations, Suggestions or Good Practices |
|---|---|---|---|
| **4.5** | **4** | RF1 | The CPD should clearly specify the interfaces and exchange of information within the CPD in the integrated management system taking into account sectors and units in performing tasks related to radiation and nuclear safety to be able to fulfil statutory obligations effectively. |

## APPENDIX VI REFERENCE MATERIAL USED FOR THE REVIEW

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| 1. | Act on Radiological and Nuclear Safety (OG 141/13) |
| 2. | Act on Amendments to the Act on Radiological and Nuclear Safety (OG 39/15) |
| 3. | Act on Amendments to the Act on Radiological and Nuclear Safety (OG 130/17) |
| 4. | Act on Amendments to the Act on Radiological and Nuclear Safety (OG 118/18) |
| 5. | ARMS - IRRS Croatia Follow-Up Mission Report |
| 6. | Industry Radiography-Instruction for future holders |
| 7. | Industry Radiography _ Guide_30.6.2019 |
| 8. | List of Legislation |
| 9. | NORM -Guide_30.6.2019 |
| 10. | Training in the field of nuclear and radiological safety |
| 11. | National Programme for the Implementation of the Strategy for Management of Radioactive Waste, Disused Sources and Spent Nuclear Fuel (OG 100/18) |
| 12. | Nuclear Medicine-Guide 30.6.2019 |
| 13. | Nuclear Medicine-Guidelines for future holders |
| 14. | Upute za pregled i ocjenu zahtjeva za obavljanje djelatnosti s izvorima ionizirajućeg zračenja (Guide for Review and Assessment of Application for Practices with Radiation Sources) |
| 15. | Uputa za izradu propisa iz područja radiološke i nuklearne sigurnosti (Gude for Development of Regulations in the Field of Radiological and Nuclear Safety – document needs to be revised) |
| 16. | Ordinance on Conditions and Measures of Ionising Radiation Protection for Performing Activities Involving Ionising Radiation Sources (OG 53/18) |
| 17. | Ordinance on Content Application for Approval for Commencement or Termination of Operation or Decommissioning of a Nuclear Installations (OG 47/17) |
| 18. | Ordinance on Granting Authorisation to Professional Technical Services For Performing Tasks Pertaining To Radiological Safety (OG 40/18) |
| 19. | Ordinance on Training required for Handling Ionising Radiation Sources, Application of Measures for Radiological Safety and Managing Technical Processes in Nuclear Installations (OG 42/18) |
| 20. | Ordinance on Conditions and Procedure for Issuing and Withdrawing the Approval for Packaging Used for Transport of Radioactive and Nuclear Materials (OG 42/13 and 19/17) |
| 21. | Ordinance on Health Requirements of Exposed Workers and Persons Undergoing Training to Work with Ionising Radiation Sources (OG 66/18) |
| 22. | Ordinance on Scope and Content of the Plan and Programme of Measures in the Event |

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| | of an Emergency and Informing Public and Competent Bodies (OG 123/12) |
| 23. | Ordinance on the Supervision During Import or Export of Material for which there is Justified Suspicion of Contamination by Radionuclides or of Containing Radioactive Sources (OG 114/07) |
| 24. | Ordinance on Authorised Nuclear Safety Expert Organizations (OG 29/17) |
| 25. | Ordinance on Conditions for Use of Ionising Radiation Sources for Medical and Non-Medical Irradiation (OG 42/18) |
| 26. | Ordinance on Dose Limits, Dose Constraints and Assessment of Personal Doses (OG 38/18) |
| 27. | Ordinance on Environmental Monitoring (OG 40/18) |
| 28. | Ordinance on Management of Radioactive Waste and Disused Sources (OG 12/18) |
| 29. | Ordinance on Notification, Registration, Approval and Placing on the Market of Sources of Ionising Radiation (OG 54/18) |
| 30. | Ordinance on Nuclear Safety Requirements for Issuing the Consent on Construction of a Nuclear Installation (OG 36/16 and 79/16) |
| 31. | Ordinance on Nuclear Security (OG 38/18) |
| 32. | Ordinance on Radiation Protection Experts (OG 36/18) |
| 33. | Ordinance on Site Evaluation for Nuclear Installations (OG 38/17) |
| 34. | Ordinance on the Content of the Application for the Nuclear Facility Commissioning Licence (OG 29/17) |
| 35. | Ordinance on the Content, Requirements, Criteria and Authorisation Procedure for the Remediation Plan (OG 38/18) |
| 36. | Ordinance on the Content, Scope, Method and Frequency of Reporting on the Operation of Nuclear Installations (OG 94/17) |
| 37. | Ordinance on the Establishment of a Quality Assurance Programme for the Management of Nuclear Facilities (OG 29/17) |
| 38. | Ordinance on the Frequency, Content, Scope and Method for Carrying out Periodic Safety Reviews of Nuclear Installations (OG 94/17) |
| 39. | Ordinance on the List and Content of Documents Required for Nuclear Activity Licensing (29/17) |
| 40. | Ordinance on the Official Identity Card and Badge of The Radiological and Nuclear Safety Inspector (OG 125/15) |
| 41. | Ordinance on the Safety Analysis Report for Nuclear Installations (OG 29/17) |
| 42. | Ordinance on the Supervision and Control of Transboundary Shipments of Radioactive Waste and Spent Fuel (OG 11/13) |
| 43. | Radiological and Nuclear Safety Strategy (OG 65/17) |
| 44. | Radiology-Dental X-ray-Instruction for Future Holders of Licence |

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| 45. | Radiotherapy Guide 30.6.2019 |
| 46. | Radiotherapy-Instruction for Future Holders of Licence |
| 47. | Radon Action Plan (OG 118/18) |
| 48. | Regulation on Measures for Protection Against Ionising Radiation and Interventions in Case of Emergency (OG 24/18) |
| 49. | Regulation on Internal Organization of the Ministry of the Interior (in Croatian) (OG 24/19) |
| 50. | Strategy for the Management of Radioactive Waste, Disused Sources and Spent Nuclear Fuel (OG 125/14) |
| 51. | Croatian Radiological or Nuclear Emergency Preparedness and Response Plan (draft) |
| 52. | Priručnik postupanja inspekcije za radiološku i nuklearnu sigurnost |
| 53. | Godišnji plan inspekcijskih nadzora za 2019. |
| 54. | Act on Health Care (OG 100/18) |

# APPENDIX VII IAEA REFERENCE MATERIAL USED FOR THE REVIEW


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[2] INTERNATIONAL ATOMIC ENERGY AGENCY, Governmental, Legal and Regulatory Framework for Safety, IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), IAEA, Vienna (2016).

[3] INTERNATIONAL ATOMIC ENERGY AGENCY, Leadership and Management for Safety, IAEA Safety Standards Series No. GSR Part 2, IAEA, Vienna (2016).

[4] INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014).

[5] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety Assessment for Facilities and Activities, IAEA Safety Standards Series No. GSR Part 4 (Rev. 1), IAEA, Vienna (2016).

[6] INTERNATIONAL ATOMIC ENERGY AGENCY, Predisposal Management of Radioactive Waste, IAEA Safety Standards Series No. GSR Part 5, IAEA, Vienna (2009).

[7] INTERNATIONAL ATOMIC ENERGY AGENCY, Decommissioning of Facilities, IAEA Safety Standards Series No. GSR Part 6, IAEA, Vienna (2014).

[8] INTERNATIONAL ATOMIC ENERGY AGENCY, Preparedness and Response for a Nuclear or Radiological Emergency, IAEA Safety Standards Series No. GSR Part 7, IAEA, Vienna (2015).

[9] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety of Research Reactor, IAEA Safety Standards Series No. SSR-3, IAEA, Vienna (2016).

[10] INTERNATIONAL ATOMIC ENERGY AGENCY, Disposal of Radioactive Waste, IAEA Safety Standards Series No. SSR-5, IAEA, Vienna (2011).

[11] INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR OFFICE, Criteria for Use in Preparedness and Response for a Nuclear or Radiological Emergency, IAEA Safety Standards Series No. GSG-2, IAEA, Vienna (2011).

[12] INTERNATIONAL ATOMIC ENERGY AGENCY, Communication and Consultation with Interested Parties by the Regulatory Body, IAEA Safety Standards Series No. GSG-6, IAEA, Vienna (2017)

[13] INTERNATIONAL ATOMIC ENERGY AGENCY, Organization, Management and Staffing of the Regulatory Body for Safety, IAEA Safety Standards Series No. GSG-12, IAEA, Vienna (2018)

[14] INTERNATIONAL ATOMIC ENERGY AGENCY, Functions and Processes of the Regulatory Body for Safety, IAEA Safety Standards Series No. GSG-13, IAEA, Vienna (2018).

[15] INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR OFFICE, Arrangements for Preparedness for a Nuclear or Radiological Emergency, IAEA Safety Standards Series No. GS-G-2.1, IAEA, Vienna (2007).

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[17] INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR OFFICE, Occupational Radiation Protection, IAEA Safety Standards Series No. GSG-7, IAEA, Vienna (2018).

[18] INTERNATIONAL ATOMIC ENERGY AGENCY, Establishing the Infrastructure for Radiation Safety, IAEA Safety Standards Series No. SSG-44, IAEA, Vienna (2018)

[19] INTERNATIONAL ATOMIC ENERGY AGENCY, WORLD HEALTH ORGANIZATION, PAN AMERICAN HEALTH ORGANIZATION AND INTERNATIONAL LABOUR OFFICE, Radiation Protection and Safety in Medical Uses of Ionizing Radiation, IAEA Safety Standards Series No. SSG-46, IAEA, Vienna (2018)

[20] INTERNATIONAL ATOMIC ENERGY AGENCY, Environmental and Source Monitoring for Purposes of Radiation Protection, IAEA Safety Standards Series RS-G-1.8, IAEA, Vienna (2005)

[21] INTERNATIONAL ATOMIC ENERGY AGENCY, Categorization of Radioactive Sources, IAEA Safety Standards Series No. RS-G-1.9, IAEA, Vienna (2005)

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[32] INTERNATIONAL ATOMIC ENERGY AGENCY, IRIS Guidelines, IAEA Services Series No. 28, IAEA, Vienna (20

# APPENDIX VIII ORGANIZATION CHART