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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

FOLLOW-UP MISSION

TO

Hungary

Budapest, Hungary

24 September to 1 October 2018

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

IAEA Integrated Regulatory Review Service IRRS

Hungarian Atomic Energy Authority

Emberi Erőforrások Minisztériuma

Baranya Megyei Kormányhivatal

Integrated
Regulatory
Review Service

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Mission dates:	*24 September to 1 October 2018*
Regulatory body visited:	*Hungarian Atomic Energy Authority (HAEA), Office of the Chief Medical Officer (OCMO), Budapest Capital Government Office Public Health Administration Department Radiation Hygiene Decenter (RHD), Baranya County Government Office (BCGO)*
Location:	*Budapest, Hungary*
Regulated facilities and activities in the mission scope:	*Nuclear Power Plants, Interim Spent Fuel Storage Facility, Research Reactors, Radioactive Waste Facilities, Decommissioning, Radiation Sources, Transport, Emergency Preparedness and Response, Medical Exposure, Occupational Radiation Protection, Control of Radioactive Discharges, Materials for Clearance, and Existing Exposures Situations; Environmental Monitoring for Public Radiation Protection*
Organized by:	*International Atomic Energy Agency (IAEA)*

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The number of recommendations, suggestions and good practices is in no way a measure of the status of the regulatory body. 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 Hungary, an international team of senior safety experts met with representatives of the Government, the Hungarian Atomic Energy Authority (HAEA), The Office of the Chief Medical Officer (OCMO), the National Public Health Institute (NPHI), and the Baranya County Government Office (BCGO) of Hungary from 24 September to 01 October 2018 to conduct an Integrated Regulatory Review Service (IRRS) follow-up mission. The purpose of the IRRS follow-up mission was to review Hungary's progress against the recommendations and suggestions identified in the initial IRRS mission (which was carried out from 11 to 22 May 2015). The mission took place at the HAEA Headquarters in Budapest. The scope of the IRRS- follow-up mission was the same as the scope of the 2015 mission.

The IRRS review team consisted of eight senior regulatory experts from seven IAEA Member States, two IAEA staff members and one IAEA administrative assistant.

The IRRS team carried out a review of the progress made on each recommendation and suggestion that is documented in the 2015 IRRS mission report. These recommendations and suggestions cover the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body for the control of all facilities and activities in Hungary, including authorization, review and assessment, inspection, enforcement and the development and content of regulations and guides; emergency preparedness and response; occupational exposure control, patient protection and public protection. To assess progress, the IRRS team reviewed the advance reference material provided by HAEA, OCMO and BCGO and conducted a series of interviews and discussions with staff from HAEA, OCMO and BCGO.

Since 2015, the Government and the regulatory body went through a significant transition of the distribution of regulatory roles and responsibilities, and transposed the recent European Directives into national legislation. Hungary has been successful in addressing the associated challenges and has taken positive steps to:

- ensure the effective independence of the regulatory body;
- simplify the distribution of roles and responsibilities of the different regulatory authorities;
- maintain regulatory stability and ensure effective knowledge transfer, throughout the transfer of regulatory responsibilities;
- improve coordination and collaboration between and within regulatory authorities;
- update regulations, guidance and procedures;

Following this transition, work needs to continue to fully implement the new regulatory framework, by

- implementing all the new requirements established in the new legislation and regulations, such as those related to medical exposure;
- formalizing the coordination and collaboration arrangements between the authorities;
- establishing or enhancing the management systems;

Overall, the IRRS team concluded that Hungary, through the HAEA, OCMO and BCGO, has been responsive to the recommendations and suggestions made in 2015, and continues to place appropriate focus on implementing a framework that provides for effective protection of public health and safety. The IRRS team determined that 21 of the 32 recommendations and 9 of the 10

suggestions made by the 2015 IRRS mission had been effectively addressed and therefore could be considered closed. This is a significant achievement in a period of three years. The team offered one new recommendation and two new suggestions for Hungary's consideration.

The IRRS team concluded that HAEA, OCMO and BCGO management and staff are dedicated to continuous improvement and they clearly recognize the importance of their mission towards the safety and protection of the Hungarian public.

An IAEA press release was issued following the mission.

Throughout the mission, the IRRS team received full cooperation from all parties involved. In particular, HAEA, OCMO and BCGO staff was very open in the discussions and provided the best practicable assistance.

I. INTRODUCTION

At the request of the Government of Hungary, an international team of senior safety experts met representatives of HAEA, OCMO and BCGO from 24 October to 1 October 2018 to conduct an Integrated Regulatory Review Service (IRRS) follow-up mission. The purpose of the follow-up mission was to review the implementation of the recommendations and suggestions given to the Government of Hungary during the IRRS Mission in May 2015. The follow-up mission was formally requested by the Government of Hungary in September 2016. A preparatory meeting was conducted on 2 February 2018 at the HAEA's Headquarters in Budapest to discuss the purpose, objectives and detailed preparations of the review in connection with regulated facilities and activities in Hungary and their related safety aspects.

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

Hungary prepared a national follow-up report addressing the findings of the initial mission. The follow-up report and supporting documentation were provided to the IRRS team as advance reference material (ARM) for the mission. During the mission the IRRS 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 HAEA, OCMO and BCGO.

All through the mission the IRRS team received excellent support and cooperation from HAEA, OCMO and BCGO.

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 Hungary during the IRRS Mission in May 2015 and to exchange information and experience in the areas covered by the IRRS. The IRRS review scope included all facilities and activities regulated in Hungary under the Act on Atomic Energy. The review was carried out by comparison of existing arrangements against the IAEA safety standards.

It is expected that the IRRS mission will facilitate regulatory improvements in Hungary and other Member States from the knowledge gained and experiences shared between Hungarian Counterparts and IRRS reviewers and through the evaluation of the effectiveness of the Hungary's regulatory framework for nuclear and radiation safety.

III. BASIS FOR REVIEW

A) Preparatory work and IAEA Review Team

At the request of the Government of Hungary, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) Follow-Up mission was conducted at HAEA's Headquarters in Budapest, Hungary, on 2 February 2018. The preparatory meeting was carried out by the appointed Team Leader Michael Johnson, the Deputy Team Leader Mika Markkanen, IAEA representatives Mr Tim Kobetz and Mr Hilaire Mansoux.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of HAEA represented by Mr Fichtinger, Director General of HAEA, other senior management and staff of HAEA and representatives of OCMO and BCGO. 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:

- Nuclear power plants;
- Research Reactors;
- Waste facilities;
- Radiation sources facilities and activities;
- Decommissioning;
- Transport;
- Patient protection;
- Occupational radiation protection;
- Control of radioactive discharges, materials for clearance, Environmental monitoring for public radiation protection, and existing exposure situations;
- Selected policy issues.

Presentations were made on the national context, the current status of the regulatory body and the progress made since the initial mission of May 2015.

IAEA staff presented the IRRS principles, process and methodology of conducting a follow-up IRRS mission. This was followed by a discussion on the tentative work plan for the implementation of the follow-up mission in Hungary in September and October 2018.

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 review team was tentatively confirmed. Logistics including meeting and work space, counterparts and Liaison Officer identification, lodging and transport arrangements were also addressed.

The Hungarian Liaison Officer for the preparatory meeting and the IRRS follow-up mission was Mr Daniel Nyisztor from HAEA.

Hungary provided the IAEA and the review team with the advance reference material for the review in July 2018. In preparation for the mission, the IAEA review team members conducted a review of the advance reference material and provided their initial review comments to the IAEA Team Coordinator and Team Leader prior to the follow-up mission.

B) Reference for the review

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

C) Conduct of the review

An initial IRRS review team meeting was conducted on Sunday 23 September, in Budapest by the IRRS Team Leader and the IRRS IAEA Team Coordinator to discuss the general overview, the focus areas and 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 and the evaluation among all reviewers. They also presented the agenda for the mission.

The Liaison Officer Mr Daniel Nyisztor was present at the initial IRRS review 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 24 September 2018, with the participation of HAEA, OCMO and BCGO senior management and staff. Opening remarks were made by Mr Fichtinger, Director General of HAEA, Mr Michael Johnson, IRRS Team Leader and Ms Kadar, Deputy State Secretary of the Ministry of National Development.

During the mission, a review was conducted for all the mission scope areas with the objective of reviewing the Hungarian response to the recommendations and suggestions identified during the original mission. 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 II.

The IRRS exit meeting was held on Monday, 1 October 2018, where the IRRS Team Leader Mr. Michael Johnson presented the results of the follow-up mission highlighting the main findings. This was followed by a statement by Mr Fichtinger in response to the Team Leader’s presentation. Closing remarks were made by Grzegorz Rzentkowski IAEA Director, Division of Nuclear Installation Safety.

An IAEA press release was issued at the end of the mission.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY

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

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

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

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *Governmental Decree 118/2011 Korm. stipulates specific time frames for authorization processes, which may lead to undue pressure on the regulatory body to complete its decision making process and thus compromise safety. For the OCMO and the RHDs the KET, while for the BCDEPN the Environmental Act also stipulates specific time frames, which may lead to undue pressure.*	
(1)	**BASIS: GSR Part 1 Requirement 4, para. 2.7 states that** *"…the government shall ensure that the regulatory body is able to make decisions under its statutory obligation for the regulatory control of facilities and activities, and that it is able to perform its functions without undue pressure or constraint."*
(2)	**BASIS: GSR Part 1 para. 4.40 states that** *"The regulatory body shall review and assess the particular facility or activity in accordance with the stage in the regulatory process (initial review, subsequent reviews, reviews of changes to safety related aspects of the facility or activity, reviews of operating experience, or reviews for long term operation, life extension, decommissioning or release from regulatory control). The depth and scope of the review and assessment of the facility or activity by the regulatory body shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach."*
R1	**Recommendation:** The Government should provide additional flexibility to extend the time limits prescribed for the completion of a safety review prior to the granting of an authorization for a facility or activity, to ensure safety is not compromised.
Observation: *Within the Ministry of National Development, one State Minister has responsibility for both the Paks NPP and the HAEA. Similarly, the Ministry of Health has responsibility for the OCMO and the health sector using radiation. This duplication of responsibility within Ministerial Departments for the regulatory body and the facilities or activities they regulate potentially has adverse implications for the independence of the regulatory body.*	
(1)	**BASIS: GSR Part 1 Requirement 4 states that** *"The government shall ensure that the regulatory body is effectively independent in its safety related decision making and that it has functional separation from entities having responsibilities or interests that could unduly influence its decision making."*
(2)	**BASIS: GSR Part 1 para. 2.7 states that** *"An independent regulatory body will not be entirely separate from other governmental bodies. The government has the ultimate responsibility for involving those with legitimate and recognized interests*

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
	in its decision making. However, the government shall ensure that the regulatory body is able to make decisions under its statutory obligation for the regulatory control of facilities and activities, and that it is able to perform its functions without undue pressure or constraint."
(3)	**BASIS: GSR Part 1 para. 2.8 states that** *"To be effectively independent, the regulatory body shall have sufficient authority and sufficient staffing and shall have access to sufficient financial resources for the proper discharge of its assigned responsibilities. The regulatory body shall be able to make independent regulatory judgements and decisions, free from any undue influences that might compromise safety, such as pressures associated with changing political circumstances or economic conditions, or pressures from government departments or from other organizations. Furthermore, the regulatory body shall be able to give independent advice to government departments and governmental bodies on matters relating to the safety of facilities and activities."*
R2	**Recommendation:** The Government should implement appropriate provisions to ensure the effective independence of the regulatory body from the facilities and activities that it regulates.
Observation: *The Director General of the HAEA does not have the full ability to spend the authorized budget in a timely manner which has an effect on the ability of the HAEA to fulfil its regulatory functions. Proposals submitted to the Ministry of National Development by the HAEA to revise its Organizational and Operational Rules have not been approved since 2007.*	
(1)	**BASIS: GSR Part 1 para. 2.8 states that** *"To be effectively independent, the regulatory body shall have sufficient authority and sufficient staffing and shall have access to sufficient financial resources for the proper discharge of its assigned responsibilities. The regulatory body shall be able to make independent regulatory judgements and decisions, free from any undue influences that might compromise safety, such as pressures associated with changing political circumstances or economic conditions, or pressures from government departments or from other organizations. Furthermore, the regulatory body shall be able to give independent advice to government departments and governmental bodies on matters relating to the safety of facilities and activities."*
R3	**Recommendation:** The Government should ensure that the authority to spend the resources approved for and to reorganize or restructure the regulatory body to enable it to discharge its assigned responsibilities is within the direct control of the regulatory body.
Observation: *The resources allocated to the HAEA seem to be adequate; however, there is a well-recognized lack of resources for the OCMO, the RHDs and the BCDEPN.*	
(1)	**BASIS: GSR Part 1 para. 2.8 states that** *"To be effectively independent, the regulatory body shall have sufficient authority and sufficient staffing and shall have access to sufficient financial resources for the proper discharge of its assigned*

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
	responsibilities. The regulatory body shall be able to make independent regulatory judgements and decisions, free from any undue influences that might compromise safety, such as pressures associated with changing political circumstances or economic conditions, or pressures from government departments or from other organizations. Furthermore, the regulatory body shall be able to give independent advice to government departments and governmental bodies on matters relating to the safety of facilities and activities."
R4	**Recommendation:** The Government should ensure that all regulatory authorities that comprise the regulatory body have sufficient staffing and access to sufficient financial resources for the proper discharge of their assigned responsibilities.

Changes since the initial IRRS mission

Recommendation 1: At the time of the initial mission, Government Decree 118/2011 and Government Decree 155/2014 stipulated specific time frames for authorizations processes.

The Public Administration Act (Act L. of 2017) and the Act on General Public Administration Procedures (Act CL of 2016), (modified by Act CLXXIX of 2017) introduced several changes having impact on the Act on Atomic Energy and on the nuclear safety regulatory procedures. The General Public Administration Procedures set new time limits for the administrative activities of the Regulatory Body. In accordance with the Act, longer time limits may be set by law. HAEA's current administrative time limits are stipulated in the Act CXVI on Atomic Energy.

The General Public Administration Procedures Act generally lengthened time limits established for the completion of review of submittals and issuance of authorizations compared to the respective values in the previous Act CXL of 2004 that were in effect at the time of the IRRS mission in 2015. However, the General Public Administration Procedures Act eliminated the possibility of extensions of time limits for specific reasons. Actual time limits may only be extended by the time required to rectify submittals (e.g., obtain additional information) and the time taken by the co-authorities above the 30-day legal limit. In addition, unlike the former regulation, the General Public Administration Procedures Act contains no time limit for rectification of submittals, however, it specifies that rectification may only be requested once in a process. It was recognized that since the complexity of cases processed by HAEA may require multiple rectifications, this possibility was provided in the Act on Atomic Energy.

Regarding time limits, in accordance with provision of the Act on Atomic Energy, HAEA has participated in the drafting legislation and proposed suggestions to provide greater flexibility, including providing increased available time limits for regulatory activities and to providing the possibility to conduct multiple rectifications, as needed. The proposed law is currently in intergovernmental consultation and is expected to be completed in mid-2019.

Regarding environmental reviews, the Baranya County Governmental Office has indicated that regulatory procedures as well as co-authority procedures related to the application of nuclear energy can be completed within the time limits set by the General Public Administration Procedures Act.

On 1 January 2016, the roles and responsibilities of OCMO and the Governmental Offices, as the health authority regarding ionizing radiation, were decreased to covering solely the patient oriented regulatory supervision of medical facilities and certain aspects of radiation safety in special

facilities, without any independent authorization responsibility. Additional tasks of OCMO and the Governmental Offices are described in the Act on Atomic Energy, Annex II. As a part of this transfer of tasks, the majority of responsibilities for regulatory oversight of radiation protection and the related staff moved to HAEA. The remaining regulatory procedures and co-authority procedures can be completed within the time limits set by the General Public Administration Procedures Act.

Recommendation 2: The roles and responsibilities of the members of the Government are detailed at the Government Decree level of the legislative framework. At the time of the 2015 IRRS mission, the relevant Government Decree in effect was 152/2014 (VI.6.), which stated that the Minister of National Development was responsible among others, for issues related to the supervision of national assets, regulation of national asset management as well as the development of energy policy.

Figure 1 below shows a diagram of the functional separation of the above mentioned structure that was valid in 2015, with the state secretariat for energy affairs (led by the state secretary) being responsible for energy policy development and acting as a legal supervisor for the HAEA as a government office, while the state secretariat for state properties (led by the state secretary) was responsible for exercising ownership rights over the Hungarian National Asset Management Inc., a state owned company established to exercise the ownership rights over state assets (including MVM Paks NPP ltd.).

While the ultimate responsibility related to energy policy development, and national asset management rested with the Minister of National Development, the specific issues were dealt with at different functional state secretariats.

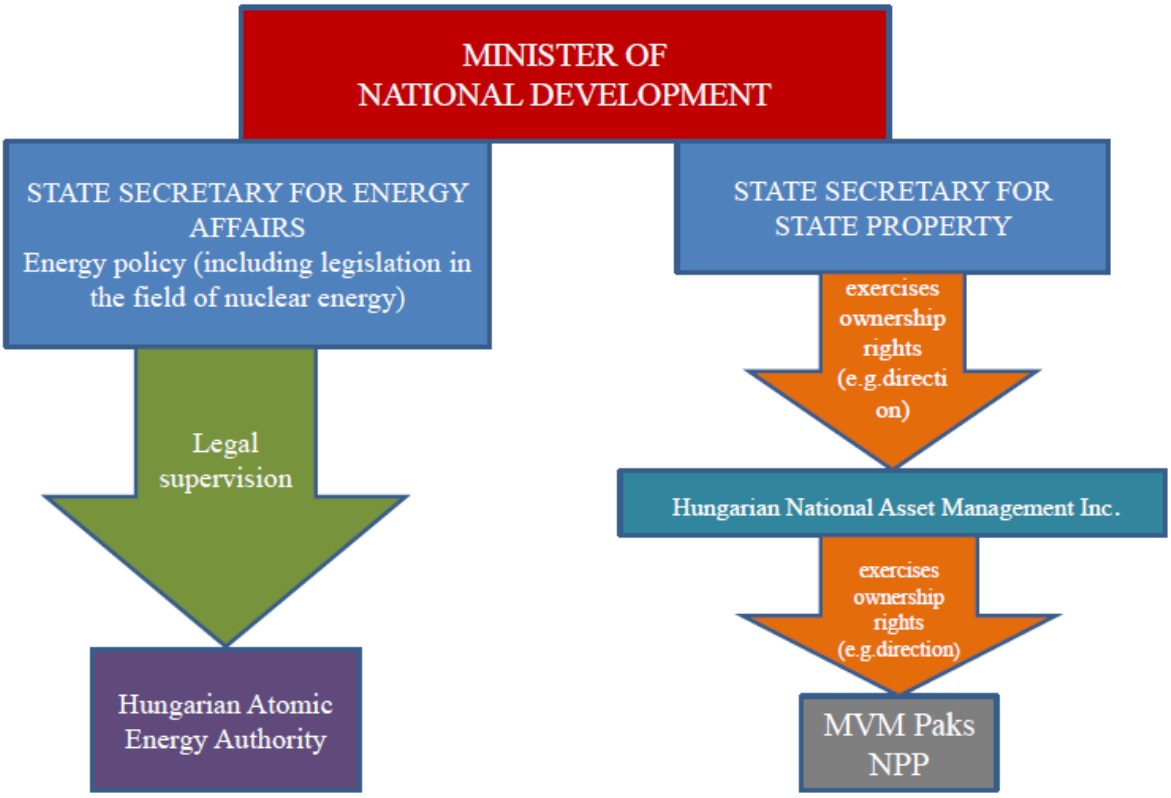

Figure 1: Responsibilities of the Government 2015

Since the IRRS mission, Government Decree 152/2014 was repealed and replaced by Government Decree 94/2018 (V.22.). The changes in the functional roles and responsibilities of the various ministries concerning the field of nuclear energy can be seen below in Figure 2.

The newly established Ministry of Innovation and Technology is responsible for issues related to energy affairs and climate policy development. In his role, the minister for innovation and technology exercises legal supervision over the HAEA as a government office.

A new Minister without portfolio (functionally separate and independent from other ministries) was appointed, who is responsible for the management of national assets, i.e. exercising the ownership rights of the MVM Paks NPP ltd.

In addition, in 2017 the Minister without portfolio responsible for the planning, construction and commissioning of the two new units at the site of the Paks NPP was appointed.

The below diagram details the separation of the roles and responsibilities of the various institutions at a ministerial level as well as at the organizational level.

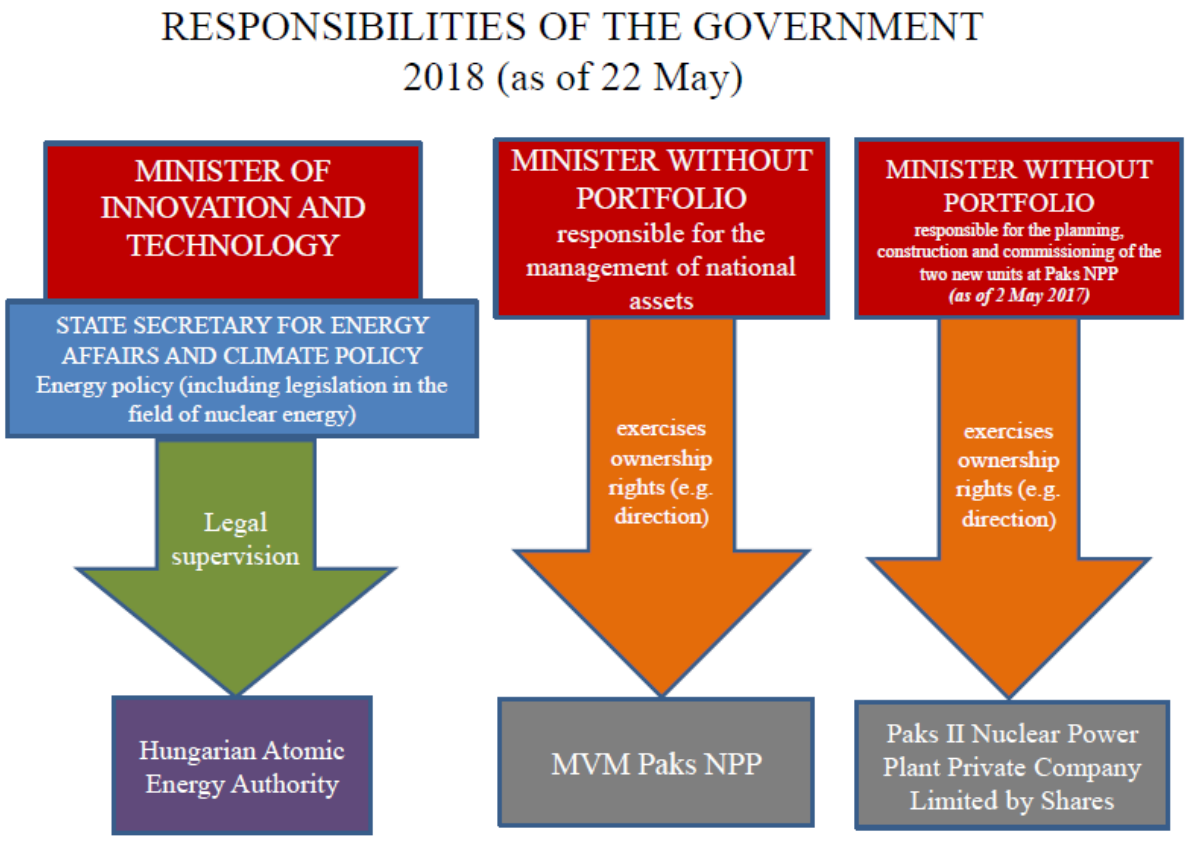

Figure 2: Responsibilities of the Government 2018

This realignment provides independence for HAEA from the nuclear facilities it regulates.

Effective 1 January 2016, the Paks Capacity Maintenance Act was amended to extend the roles and responsibility of HAEA to include oversight of radiation protection. This new role provides independence of HAEA in the oversight of radiation protection in that it is supervised by the

Ministry of Innovation and Technology and separate from any ministry having a promotional role.

Regarding OCMO, at the time of the initial mission, the radiation-healthcare authority consisted on the National Public Health and Medical Officer Service and of seven County/Capital Governmental Offices. Public healthcare departments of the Governmental Offices discharged the regulatory responsibilities. The Minister of State Health had responsibility for OCMO and the health sector using radiation, resulting in concerns regarding the effective independence of the regulatory authority.

Organizational changes within the regulatory body became effective from 1 January 2016 and are mentioned under the text referring to Recommendation 1. In March 2017, the National Public Health and Medical Officer Service was merged into the Ministry of Human Capacities (Deputy State Secretariat of Chief Medical Officer's Affairs), and its staff formed a department in the Ministry. In October 2018, a further reorganization will become effective. Despite these organizational realignments, the Minister of State Health retains responsibility for the regulatory supervision of medical exposures, as well as for the provision of health care services.

Recommendation 3: The Ordinance 24/2017 of the Minister of National Development on the Organizational and Operational Rules of HAEA entered into force on September 5, 2017. Among other changes, it reflects the changes in organizational structure related to the additional regulatory roles and responsibilities of HAEA. At the time of the initial mission, Organizational and Operational Rules had not been approved by the Minister of National Development since 2007. While proposed changes to HAEA organization and operational rules must continue to be "proclaimed" by the Ministry, consistent with Hungarian Law, the issues resulting the long delay for such approval during the Mission seem to have been addressed and have not recurred.

As was true at the time of the initial mission, the Government Resolution No. 1982/2013. (XII 29.) Korm. the Director General of HAEA does not have authority to procure IT equipment, furniture, vehicles and mobile phones. This situation considerably slows down and in certain cases impedes regulatory work. Partial exemption from this prohibition can be requested in highly justified cases from the Minister of the Prime Minister's Office. HAEA has provided a proposal to the Ministry for another Decree to obtain an exemption from the prohibition on procurement. This proposal is in the early stages of intergovernmental discussion.

Recommendation 4: At the time of the initial mission, the IRRS team noted that HAEA had difficulty in attracting and retaining qualified staff due to salary levels that were not competitive with industry, suppliers, and TSOs. This was documented in Section 3.3 of the May 2015 Mission Report. Although this did not result in the identification of a specific observation, it relates to the issue being addressed in Recommendation 4.

Regarding staff salaries, Act VII of 2015 on Paks Capacity Maintenance increased the salaries of HAEA employees to a level higher than other Government employees. Despite this increase, the salaries of the HAEA staff are still less attractive than the salary offered by the nuclear industry. This results in difficulty in recruiting qualified experts and continued staff turnover. As a result, HAEA has provided a proposal to the Ministry to increase salaries further. This proposal is in the early stages of intergovernmental discussion.

On 1 April 2015, the regional environmental protection and nature conservation inspectorates were integrated into the county-wise Governmental offices. Accordingly, the South-Transdanubian Environmental Protection and Nature Conservation Inspectorate became a part of the Baranya

County Governmental Office. The Pecs District Office (within BCGO)is the responsible regulatory authority in environmental issues related to the application of nuclear energy since 1 January 2017.

The radiology Laboratory of the Governmental Office Measurement Centre was transferred to the Laboratory Section of the Public Health Department. The Laboratory of the Governmental Office and the Pecs District Office act together in the environmental regulatory oversight of activities in special facilities using nuclear energy (i.e., nuclear power plant, training reactor, research reactor, SFISF, radioactive waste storage and disposal facilities, uranium mine, and A-level isotope-laboratory).

The head of the Governmental Office is responsible for continuously providing personnel, material and organizational conditions that are needed to fulfil the obligations related to nation-wide radiological measurements, regulatory authority activities, and co-authority activities according to the respective requirements of the Act on Atomic Energy.

At the time of the IRRS mission in 2015, the number of environmental staff available for regulatory functions related to nuclear energy was insufficient, particularly in light of anticipated workload related to the planned Paks II units. Since that time, the environmental review for the Paks unit has been completed. BCGO informed the IRRS team that resources are currently believed to be sufficient.

Organizational changes within the Regulatory Body became effective from 1 January 2016 and are mentioned under the text referring to Recommendation 1. As a part of the transfer of tasks, the majority of responsibilities for regulatory oversight of radiation protection and the related staff moved to HAEA. The staffing of HAEA to accomplish these added responsibilities is sufficient.

The remaining responsibilities in radiation safety were transferred to the Governmental office of Budapest on April 1, 2017. The Governmental offices complemented the staff working in radiation safety in proportion to the remaining responsibilities. Representatives of the health care regulatory authority informed the IRRS team that staffing of their authority is currently sufficient.

The Ministry of Human Capacities, Deputy State Secretariat of Chief Medical Officer's Affairs, successor of OCMO, has kept tasks related to the regulatory supervision of medical exposures. The IRRS team was informed by OCMO counterparts that it is foreseeable that OCMO and NPHI would merge by 1 October 2018 and that staffing will be insufficient to fulfil the delegated tasks.

Status of the finding in the initial mission

Recommendation 1 (R1) is closed on the basis of progress made and confidence in the effective completion as for HAEA, steps have been and are being taken by the Government and the regulatory authority to increase time limits for authorization and to provide flexibility within those time limits. In the case of the environmental and health authorities, time limits are sufficiently broad and do not compromise safety.

Recommendation 2 (R2) is closed as the revised government structure provides independence of the regulatory body from the facilities and activities it regulates.

Recommendation 3 (R3) remains open. Although progress has been made, the prohibition of some procurement relevant to the regulatory functions remains in place.

Recommendation 4 (R4) is closed as the Head of the BCGO has assigned sufficient resources to conduct their established responsibilities. Sufficient staffing has been assigned to ensure that HAEA, the Deputy State Secretariat of Chief Medical Officer's Affairs (successor to OCMO), and the Governmental Office in Budapest can implement their respective roles and responsibilities.

1.4. COMPLIANCE WITH REGULATIONS AND RESPONSIBILITY FOR SAFETY

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

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

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *There is insufficient communication and cooperation between and within the regulatory authorities which comprise the regulatory body that hampers the quality and effectiveness of their regulatory activities.*	
(1)	**BASIS: GSR Part 1 para. 2.18 states that** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the responsibilities and functions of each authority shall be clearly specified in the relevant legislation. The government shall ensure that there is appropriate coordination of and liaison between the various authorities concerned … This coordination and liaison can be achieved by means of memoranda of understanding, appropriate communication and regular meetings. Such coordination assists in achieving consistency and in enabling authorities to benefit from each other's experience."*
S1	**Suggestion:** The Government should consider making provisions to foster the effective coordination of and collaboration between and within the regulatory authorities in particular for those with responsibilities for radioactive waste repositories and for radiation sources.

Changes since the initial IRRS mission

Suggestion 1: An amendment of the Paks Capacity Maintenance Act (c.f. Section I.4.5) entered into force on 1 January 2016, transferring regulatory roles and responsibilities in radiation protection to HAEA. With these changes, the regulatory oversight of radiation sources facilities and activities became the responsibility of HAEA. Alignment within a single organization has provided easier and more effective communications and addressed concerns that existed at the time of the initial mission regarding coordination and collaboration between the regulatory authorities.

In the authorization procedures related to the waste storage and disposal facilities and to handling unsealed radioactive sources, the Baranya County Governmental Office (BCGO) is involved as the environmental co-authority. HAEA and BCGO have recently held joint inspections. For example, in 2017, HAEA and representatives from the Mining Department of the Baranya County Government Office and the Department of Labor and Occupational Safety of the Tolna County Government conducted a complex inspection on the construction works of the National Radioactive Waste Repository in Bátaapáti. In addition, HAEA and BCGO regularly coordinate inspection plans, including potential joint inspections and their details. In addition, to increase the effectiveness and coordination of the authorization process and of joint inspections, HAEA and BCGO have started development of an Agreement on Cooperation.

In the remaining area of common interest with OCMO, the former National Chief Medical Office initiated cooperation in sharing information on the facilities using ionizing radiation in the medical sector. In the framework of this cooperation, HAEA sends a copy of all authorizations related to

the operation of such facilities to the competent County Governmental office. To increase cooperation and coordination, Memoranda of Agreement are under development between the HAEA and the Deputy State Secretariat of Chief Medical Officer's Affairs.

Act CL of 2016 on General Public Administration Procedures was implemented across the Government. This Act introduced electronic administration resulting in faster and more efficient administrative processes between authorities. In addition, a common document management system for use by public administrative bodies (including the government) has been established. In May 2018, the co-ordinating bodies which are important for oversight have been integrated into the system making the sharing of documents more efficient and effective.

Status of the finding in the initial mission

Suggestion 1 (S1) is closed as provisions have been made to foster the effective coordination of and collaboration between and within all regulatory authorities.

1.6. SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE UNREGULATED RADIATION RISKS

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *The national legislative and regulatory framework does not include comprehensive responsibilities and actions to be performed to recover orphan radioactive sources outside the authorised facility.*	
(1)	**BASIS: GSR Part 1 Requirement 9 states that** *"The government shall establish an effective system for protective actions to reduce undue radiation risks associated with unregulated sources … This coordination and liaison can be achieved by means of memoranda of understanding, appropriate communication and regular meetings. Such coordination assists in achieving consistency and in enabling authorities to benefit from each other's experience."*
(2)	**BASIS: CoC on the Safety and Security of Radioactive Sources para. 8 states that** *"Every State should have in place an effective national legislative and regulatory system of control over the management and protection or radioactive sources. Such a system should: (c) include national strategies for gaining or regaining control over orphan sources."*
S2	**Suggestion:** The Government together with the regulatory body should consider revising the national legislative and regulatory framework to include comprehensive provisions for the recovery of orphan sources outside the authorised facility.

Changes since the initial IRRS mission

Suggestion 2: The Government Decree 490/2015 on the reports and interventions regarding missing, found or seized nuclear and other radioactive materials and other actions pertaining to radioactive materials following their report" was established and it entered into force on 1 January 2016. The Decree stipulates measures to be taken after the discovery of an orphan source and assigns responsibilities to the respective competent organizations regarding notifying the event and taking action to recover the source. The Decree stipulates (Section 2, point 2) that after notification, the National Nuclear Emergency Response Plan (OBEIT) shall be implemented.

The IRRS Team was informed that preparations are in their final stages for including measures regarding recovering orphan sources into the National Nuclear Emergency Response Plan (OBEIT). The preparation has involved comprehensive co-operation between various different authorities with an objective to terminate potential overlaps and gaps regarding arrangements for recovering radioactive materials outside authorised facilities. The following organisations were involved: the HAEA, National Police HQ, National Directorate General for Disaster Management, Hungarian Defence Forces, Counter Terrorist Center and the Hungarian MEST Teams. The preparation also included common exercises to gain implementation experience, such as the National TTX exercise to be held in November 2018. The Plan is expected to be approved by the Ministry of Interior and issued as an Annex of the National Nuclear Emergency Response Plan in 2019.

In accordance with Government Decree 490/2015, the HAEA has identified and listed potential facilities which could encounter radioactive material outside authorised facilities. These include e.g. important scrap metal operators and the customs points. The HAEA has drafted the Guide no. SZ-3, "Guidance for radiation portal monitor users for the preparation of action plan in case of detection alarms" to assist the Customs in border monitoring of radioactive materials. The draft has been reviewed and the final editing is to be finished by the end of September 2018. The IRRS team was informed that guidance for the scrap metal operators is also under development.

The HAEA has not initiated any specific campaign to recover radioactive materials from past practices. The IRRS team was informed that such campaigns are not warranted because it would be unlikely to make important findings because radioactive materials have been regulated in Hungary for a long time. For example, records of sealed sources exceeding the exemption level have been maintained by the relevant regulatory authorities since the 1960's.

Status of the finding in the initial mission

Suggestion 2 (S2) is closed on the basis of progress made and confidence in the effective completion as relevant provisions have been incorporated into Government Decree 490/2015 and the process for including measures for recovering orphan sources into the National Nuclear Emergency Response Plan (OBEIT) is at its final stages.

1.7. PROVISIONS FOR DECOMMISSIONING AND MANAGEMENT OF RADIOACTIVE WASTE AND SPENT FUEL

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

1.8. COMPETENCE FOR SAFETY

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *There is no formal recognition of medical physicists and no unified formal recognition of qualified experts for radiation protection.*	
(1)	**BASIS: GSR Part 3 Requirement 2, para. 2.21 states that** *"The government shall ensure that requirements are established for:* *(b) The formal recognition of qualified experts..."*
R5	**Recommendation:** The Government, together with the regulatory body, universities and other professional organizations should establish a process of formal recognition of medical physicists and for the unified formal recognition of qualified experts for radiation protection.

Changes since the initial IRRS mission

Recommendation 5: The Act on Atomic Energy was amended in 2015 by the Act CXCVI of 2015 to include provisions stating that radiation protection experts in the field of application of nuclear energy (which by definition covers also the use of radiation sources) shall be authorized by the HAEA. The professional knowledge necessary for obtaining an authorization is prescribed in the Radiation Protection Decree. The HAEA maintains a register of authorized experts, as required by the Act. The HAEA has also established further guidance on how to prepare the license application for radiation protection experts (SV-8).

Radiation protection experts were earlier authorised by the Healthcare Registration and Training Centre and by the Hungarian Engineering Chamber. The Radiation Protection Decree stipulates that these authorizations are valid until 31 December 2018. After this, an HAEA authorization is always required.

The Radiation Protection Decree requires that medical physicist experts need to have comprehensive level radiation protection qualification. The Ministerial Ordinance 40/2009 defines the professional fields for which authorizations for medical physics experts may be issued (radiation therapy, nuclear medicine, diagnostic radiology). It also defines the general conditions for granting authorizations in the medical field and provides for introducing specific conditions in separate regulations. Specific conditions for medical physics experts have been set in Ordinance 21/2018 of the Minister of Human Capacities. The Governmental Decree 422/2017 defines that authorisations of medical physics experts are issued by the Governmental Office of Budapest.

Status of the finding in the initial mission

Recommendation 5 (R5) is closed as the legislation has been modified to establish processes for formal recognition of medical physicists and for unified formal recognition of qualified experts for radiation protection.

1.9. PROVISION OF TECHNICAL SERVICES

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

2. GLOBAL NUCLEAR SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *Hungary has not notified the IAEA of its intention to act in accordance with the IAEA Guidance on the Import and Export of Radioactive Sources as prescribed in General Conference Resolution GC(48)/RES/10.D.*	
(1)	**BASIS: GSR Part 1 Requirement 14 states that** *"The government shall fulfil its respective international obligations, participate in the relevant international arrangements, including international peer reviews, and promote international cooperation to enhance safety globally."*
(2)	**BASIS: GSR Part 1 Requirement 14, para. 3.2(b) states that** *"The features of the global safety regime include:* *(b) Codes of conduct that promote the adoption of good practices in the relevant facilities and activities."*
S3	**Suggestion:** The Government should consider notifying the IAEA of its intention to act in accordance with the IAEA Guidance on the Import and Export of Radioactive Sources.

Changes since the initial IRRS mission

Suggestion 3: The Director General of HAEA sent a letter on 13 January 2016 to the Director General of the IAEA expressing that Hungary is working towards following the IAEA Guidance on the Import and Export of Radioactive Sources. The IAEA has acknowledged receiving the letter by updating Hungary's status on its related status list: http://www-ns.iaea.org/downloads/rw/imp-export/status-list.pdf.

The IRRS team informed Hungary that a new supplementary guidance to the code of conduct on the management of disused radioactive sources was adopted by the IAEA General Conference in 2017 and published in 2018. Similarly to the import/export Guidance, Member States are invited to express their political commitment to implement this new guidance, by sending a letter to the IAEA, as indicated in the General Conference Resolution GC(61)/RES/8.2.

Status of the finding in the initial mission

Suggestion 3 (S3) is closed as a letter was sent to the Director General of the IAEA expressing that Hungary is working towards following the IAEA Guidance on the Import and Export of Radioactive Sources.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *Currently the OCMO does not have a comprehensive operating experience or regulatory experience feedback programme in the areas of radiation safety and radiation protection. Similarly, there is also no structured feedback to authorized parties, nor is the information analysed and reported publicly.*	
(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."*
(2)	**BASIS: GSR Part 1 Requirement 15, para. 3.4 states that** *"The regulatory body shall establish and maintain a means for receiving information from other States and from authorized parties, as well as a means for making available to others lessons learned from operating experience and regulatory experience. The regulatory body shall require appropriate corrective actions to be carried out to prevent the recurrence of safety significant events. This process involves acquisition of the necessary information and its analysis to facilitate the effective utilization of international networks for learning from operating experience and regulatory experience."*
(3)	**BASIS: GSR Part 1 Requirement 15, para. 3.5 states that** *"To enhance the safety of facilities and activities globally, feedback shall be provided on measures that have been taken in response to information received via national and international knowledge and reporting networks. Such measures could comprise promulgating new regulatory requirements or making safety enhancing modifications to operating practices or to equipment in authorized facilities and activities. Such feedback provided in response to information received via international networks also covers descriptions of good practices that have been adopted to reduce radiation risks."*
R6	**Recommendation:** The regulatory body should ensure that arrangements for operating experience and regulatory experience feedback include radiation safety and radiation protection. This should provide structured arrangements to analyse and disseminate the information both nationally and internationally.

Changes since the initial IRRS mission

Recommendation 6: Since 2016, after taking over regulatory responsibilities in radiation safety and radiation protection, the HAEA has collected and evaluated events related to radiation safety in which the regulatory body requested the licensees to initiate investigations, or conducted its own investigations. The experiences and conclusions are annually presented at the largest domestic professional forum, the Radiation Protection Training Course organized by Loránd Eötvös Physical Society Health Physics Section (member of IRPA). The presentations are made available online. Summaries of the events and conclusions are also incorporated into the HAEA's annual report to the Parliament.

The Radiation Protection Decree (Section 65 §) introduced a requirement for the HAEA to publish the conclusions drawn and experience gained from significant events reported according to Section 57 of the Decree and the subsequent investigations. The Decree also requires the HAEA to notify the IAEA the events according to the INES scale. Only very few such events have occurred so far.

The HAEA has started a project for establishing an electronic tool and related internal processes (similar to the one used for nuclear facilities) for the systematic collection, follow-up and evaluation of events related to radiation safety and radiation protection and to provide for feedback to different regulatory processes and stakeholders. The project is foreseen to be finalized within the first half of 2019.

As part of implementing the related binding requirements of the Council Directive 2013/59/Euratom regarding accidental and unintended medical exposures, the Ministerial Ordinance 21/2018 of the Minister of Human Capacities establishes requirements for the systematic recording, reporting, collection and analyzing of such events, as well as investigations on the systematic exceed of diagnostic reference levels (DRL) and major events as defined in this Ordinance. The operators have an obligation to record, investigate and to report the events to a reporting system operated by the Chief Medical Officer. The National Public Health Institute (NPHI) has an obligation to analyze the events with the view of preparing annually summary reports for the Chief Medical Officer for publishing them on its website. The IRRS was informed that the electronic reporting system and the website of the Chief Medical Officer are currently under reconstruction but are foreseen to be fully operational the first half of 2019.

Status of the finding in the initial mission

Recommendation 6 (R6) is closed on the basis of progress made and confidence in the effective completion as provisions have been introduced in the legislation which, once fully implemented, sufficiently address the recommendation. There are on-going projects at the OCMO and the HAEA for establishing appropriate electronic systems for reporting, collecting and analysing events.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *The HAEA is currently reorganizing its structure to cope with its recent and future additional regulatory functions. The BCDEPN and the RHDs just went under an administrative governmental reorganization. The overall organizational structure of the regulatory body is in transition. This issue is addressed in Section 1.5, specific examples are identified in Sections 4.4, 5.4, 7.5 and 11.1.*	
(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."*
R7	**Recommendation:** Due to the on-going significant organizational changes, the regulatory body should ensure that its structure and organization enable effective fulfilment of its statutory obligations during and after the transition.

Changes since the initial IRRS mission

Recommendation 7: As a result of the organizational changes in the roles and responsibilities of regulatory authorities in Hungary, the scope of HAEA regulatory activities have been expanded to include two major areas namely the regulatory oversight of radiation protection and general oversight of buildings serving the application of nuclear energy.

In the field of radiation protection regulatory supervision of radioactive materials and of equipment producing ionizing radiation, all responsibilities, except for health care and protection of persons undergoing ionizing radiation health services (i.e. medical exposure oversight), are assigned to HAEA. Accordingly, HAEA is now also responsible for:

- authorisation and supervision of all radiation hazardous practices (in industry, healthcare and research);
- authorisation and supervision of the transport of radioactive materials.

To ensure smooth transition, the authorizations issued by the Office of the Chief Medical Officer of National Public Health and Medical Officer Service (OCMO) and by the County (Capital) Governmental Offices were kept in force until the expiration dates set in the existing authorizations, with the additional condition that if several authorizations relate to the same practice, all shall expire at the earliest expiration date among these authorizations. The licensees were also required to fulfil their reporting and data supply obligations to HAEA.

The transfer of register and the underlying documentation of the previous authorizations to HAEA had been completed. The documents received in hardcopy form were digitized and stored in a dedicated database.

Regulatory oversight of non-nuclear specific authorization of buildings within the safety zones of nuclear installations has been assigned to the HAEA since January 2017. Subsequently, HAEA has established an Architecture Working Group and recruited and trained further civil engineering

staff in order to provide resources for completion of the increased workload and responsibility. Relevant documents produced in the previous building authority activities have been transferred to HAEA.

With the increase in roles and responsibilities of HAEA, the number of staff has increased. The planned final number of HAEA staff is 206 (the present number of staff is 178). Besides, the organization and functioning of the Authority has also been revised.

HAEA has identified and assessed the safety relevant risk factors related to its organization and management system and established procedures to manage organizational changes and functioning of project management system.

Based on an agreement between HAEA and OCMO, the transfer of authorities and activities from RHDs and the Governmental Offices to HAEA has been performed in an organized, scheduled and documented way, ensuring a continuous regulatory supervision. Continuity of serving the customers was preserved at all times. The handover followed a number of general rules:

1. The authorizations in force and their underlying documents have been transferred in their original forms.
2. The handover was performed at the premises of OCMO.
3. OCMO has prepared a detailed full list of documents to hand over. The handover was performed according to this list and was acknowledged in Handover Minutes.
4. In case the documents were available in electronic forms, these forms were handed over with appropriate documentations.

Both HAEA and OCMO have assigned contact persons in issues related to the handover. Transfer of responsibilities and authorities and handover of the related documents have been successfully completed without any interference with the regulatory supervisory activities.

In case of BCGO, the Head of the Governmental Office that took over the role of the environmental authority declared that in order to protect the interests and ensure the goals of the environmental and nuclear safety supervision, the Governmental Office shall continuously provide all personal and material conditions required from the Office by the relevant legislation (such as the Environmental Authorization Decree and the Atomic Act, respectively).

Status of the finding in the initial mission

Recommendation 7 (R7) is closed as the regulatory body has effectively managed the transition phase to ensure that its structure and organization enable effective fulfilment of its statutory obligations during and after the transition.

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY ACTIVITIES

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

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *The number of competent staff of the OCMO, the RHDs and the BCDEPN is not sufficient and there is no human resource plan.*	
(1)	**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."*
(2)	**BASIS: GSR Part 1 Requirement 18, para. 4.11 states that** *"… A human resources plan shall be developed that states the number of staff necessary and the essential knowledge, skills and abilities for them to perform all the necessary regulatory functions."*
R8	**Recommendation:** The regulatory body should develop or update if applicable, and maintain a long term human resource plan to ensure that competences and skills are maintained.

Changes since the initial IRRS mission

Recommendation 8: Following the changes in roles and responsibilities of regulatory authorities, the regulatory responsibilities in radiation safety of both the OCMO and of their successors in the Governmental Offices have been substantially decreased. For the current responsibilities and tasks both the Governmental Offices and the Ministry of Human Capacities, Deputy State Secretariat of Chief Medical Officer's Affairs are of the view that they have sufficient staffing. The Ministry of Human Capacities and the Governmental Offices have not established long term human resource plan, but they adjust their human capacities to their actual responsibilities and tasks. The counterpart informed the IRRS team that organizational setup at Government level has changed repeatedly over the last few years, and as a result it is difficult to establish a long-term human resource development plan.

The Organizational and Operational Rules of MHC CMOA state that the numbers of staff members in a self-standing operational unit and in the departments therein are decided by the senior manager supervising the head of the self-standing unit, within the limit determined by the Rules.

BCGO has undertaken the official obligation that in the interest of nuclear safety and protection of environment, for activities related to the application of nuclear energy it shall continually provide the personal, material and organizational conditions that are needed to fulfil its obligations. A statement issued by BCGO mentions that for the sake of completion of its tasks related to the application of nuclear energy and to continuously provide the competencies necessary for that, BCGO shall elaborate a long term human resource development plan. However, no time frame has been provided.

Status of the finding in the initial mission

Recommendation 8 (R8) remains open as OCMO and BCGO have not established long term human resource plans.

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *The regulatory body has not developed sufficient procedural controls to ensure that all potential conflicts of interest are avoided and the independence and objectivity of experts are maintained.*	
(1)	**BASIS: GSR Part 1 Requirement 20, para. 4.20 states that** *"Arrangements shall be made to ensure that there is no conflict of interest for those organizations that provide the regulatory body with advice or services."*
(2)	**BASIS: GSR Part 1 Requirement 20, para. 4.21 states that** *"If the advice or assistance can be obtained only from organizations whose interests potentially conflict with those of the RB, the seeking of the advice or assistance shall be monitored, and the advice given shall be carefully assessed for conflicts of interest."*
S4	**Suggestion:** The regulatory body should consider strengthening the control governing use of technical support organization and experts to ensure that there is no conflict of interest.

Changes since the initial IRRS mission

Suggestion 4: HAEA has updated its standard template for contracting TSO services to include a statement from the TSO providing services to HAEA that it has no contractual agreement in the same subject with organizations other than HAEA. HAEA modified the template to add a stipulation that the TSO may involve subcontractors, subject to prior written notice to HAEA. The subcontractors assume all responsibilities for their work, while they must not invite further subcontractors.

In addition, HAEA requires from the TSO an explicit statement separate from the contract, where the TSO expressly states that it has no working relationship whatsoever in the given subject with organizations other than HAEA. Furthermore, when the work is completed, the TSO has to declare that no conflict of interest arose during completion. Procedure ME-0-0-48 on the TSO activity of HAEA is being revised to include the above requirements.

Status of the finding in the initial mission

Suggestion 4 (S4) is closed as HAEA has strengthened the control governing use of technical support organizations and experts to ensure that there is no conflict of interest.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

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

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

2015 MISSION RECOMMENDATIONS, SUGGESTIONS
Observation: *Recently there have been significant changes regarding the regulatory responsibilities for the oversight of waste management facilities. Additional changes are due to occur at the beginning of 2016 for the regulatory oversight of radiation sources facilities and activities.*

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
(1)	**BASIS: GSR Part 1 Requirement 22 states that** *"The regulatory authority shall ensure that regulatory control is stable and consistent."*
R9	**Recommendation:** The regulatory body should take appropriate measures to ensure that the regulatory control of all facilities and activities remains as stable as possible during the phases of transferring regulatory responsibilities.

Changes since the initial IRRS mission

Recommendation 9: In January 2016 the Radiation Protection Decree entered into force. The Decree stipulates that authorizations issued by the former regulatory authorities remain effective till the time defined in the authorizations with the provision that the licensees have to fulfil their reporting and data provision obligations to HAEA.

The documentation forming the basis of the authorizations in force were also handed over to HAEA to ensure continuity in the regulatory control. The documentation that existed in paper form has since been digitised and stored in a dedicated database.

For the sake of stable regulatory oversight HAEA sends copies of the authorizations of facilities and activities to the concerned Governmental Offices responsible for radiation safety of the county (or Budapest). Similarly, copies of authorizations related to application of unsealed radioactive sources are sent to the BCGO (responsible for environmental regulatory tasks).

Status of the finding in the initial mission

Recommendation 9 (R9) is closed as the regulatory body has taken appropriate measures to ensure that the regulatory control of all facilities and activities remains stable during the phases of transferring regulatory responsibilities.

3.7. SAFETY RELATED RECORDS

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

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

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

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

4.1. IMPLEMENTATION AND DOCUMENTATION OF THE MANAGEMENT SYSTEM

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *Apart from the HAEA, the management systems of other organizations involved in nuclear and radiation safety have not been developed in a systematic way, i.e. the OCMO, the RHDs and the BCDEPN do not have internal procedures for authorization of different practices integrated into the management system.*	
(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 achievements".*
(2)	**BASIS: GSR Part 1 Requirement 22, para. 4.26 states that** *"The regulatory process shall be a formal process that is based on specified policies, principles and associated criteria, and that follows specified procedures as established in the management system…"*
(3)	**BASIS: GS-R-3 para. 2.6 states that** *"The application of management system requirements shall be graded …"*
(4)	**BASIS: GS-R-3 para. 2.8 states that** *"The documentation of the management system shall include the following:* - *The policy statements of the organization;* - *A description of the management system;* - *A description of the structure of the organization;* - *A description of the functional responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work;* *A description of the processes and supporting information that explain how work is to be prepared, reviewed, carried out, recorded, assessed and improved."*
(5)	**BASIS: GS-G-3.1 para. 2.46 states that** *"The documentation of the management system should be appropriate to the organization and to the work it performs …"*
R10	**Recommendation:** The OCMO, the RHDs and the BCDEPN should establish and implement a management system based on IAEA safety standards, including internal procedures for all regulatory functions, safety culture and graded approach.
Observation: *The HAEA Quality Management Manual addresses the requirements of MSZ EN ISO 9001:2009 however, it does not cover all "general requirements" for the management system defined in GS-R-3.*	
(1)	**BASIS: GS-R-3 para. 2.5 states that** *"The management system shall be used to promote and support a strong safety culture by:* - *Ensuring a common understanding of the key aspects of safety culture within the organization:*

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
	- *Providing the means by which the organization supports individuals and teams in carrying out their tasks safely and successfully, taking into account the interaction between individuals, technology and the organization;* - *Reinforcing a learning a questioning attitude at all levels of the organization;* *Providing the means by which the organization continually seeks to develop and improve its safety culture."*
(2)	**BASIS: GS-R-3 para. 2.6 states that** *"The application of management system requirements shall be graded so as to deploy appropriate resources on the basis of the consideration of:* *- ...."*
(3)	**BASIS: GS-R-3 para. 2.7 states that** *"Grading of the application of management system requirements shall be applied to the products and activities of each process."*
(4)	**BASIS: GS-R-3 para. 2.8 states that** *"The documentation of the management system shall include the following:* - *Policy statement* - *A description of the management system;* - *A description of the structure of the organization;* - *A description of the functional responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work;* *A description of the processes and supporting information that explain how work is to be prepared, reviewed, carried out, recorded, assessed and improved."*
R11	**Recommendation:** The HAEA should further develop the management system to implement all the requirements of relevant IAEA safety standards including promoting and supporting a strong safety culture, managing organizational change and providing for a systematic graded approach for products and activities of each process in a documented manner.

Changes since the initial IRRS mission

Recommendation 10: The changes related to regulatory functions of the health authority are described in text referring to Recommendation 1.

In accordance with Ordinance 33/2014 of the Minister of Human Capacities, the existing management system includes the following:

a) Organizational structure
b) Tasks and functions of organization and organizational units
c) Definition of responsibilities and authorities
d) Documentation control measures
e) Human resource matters (hiring and firing rules)

f) Rules for handling confidential information
g) Rules for publishing/sharing public information

The Minister has also established following rules for office management:

a) Rules of operational management
b) Rules for document management
c) Manual of internal audit (covering technical and financial aspects of the organizations)
d) Rules for risk management
e) Rules for management of offences
f) Oversight of financial activities
g) Rules for corruption risk management (anticorruption procedure)

List of internal rules for office management are also made available on intranet such as rules for participation in conferences and EU meetings, rules for personnel assessment, rules for inventory management, rules for use of vehicles, etc.

Departmental procedures have been developed under the rules and submitted to the State Secretary.

The Minister also issues national inspection plan which sets out requirements for inspections of specialized areas. Accordingly, the departments have to develop and implement their own inspection plans.

OCMO confirmed the statement from the ARM that development of an integrated management system would require disproportionate effort, and the Governmental Office would not likely establish a specific management system for a minor, special activity.

Territorial institutions of the central government for radiation environmental protection have also undergone a major overhaul. District Office of Pécs (DOP) of the BCGO is the national environmental authority in authorization procedures and inspection of special nuclear facilities (such as nuclear power plants, research reactors, radioactive waste disposal facilities, A-level isotope laboratories, etc.) and a co-authority in procedures of HAEA regarding the application of nuclear energy and unsealed radioactive sources. The BCGO has a number of internal guidance documents to help unify the workflows. The organizational structure and rules of operations are defined in Ordinance 39/2016 of the Minister of Human Capacities and includes

a) Business of Order comprising tasks and responsibilities of organizational units and its workforce (three levels – officials with University degrees, officials without University degrees and support staff), rules for working hours and hiring/firing rules; and
b) Organizational and Operation rules describing staffing levels and detailed organization charts for various offices.

BCGO has established similar rules and procedures (document management, risk management, financial activities, issue of documents anticorruption procedure, internal audit, public service, data protection, communication, etc) as Ministry of Human Capacities whereas an annual inspection plan has also been established which sets out requirements for inspections of specialized areas, including unannounced inspections.

BCGO informed the IRRS team that based on their analysis of the actual status, development of a unified, integrated management system is not foreseen because it would require disproportionate effort.

Recommendation 11: The advance reference materials provide information and refer to various documents which address promoting and supporting a strong safety culture, managing organizational changes and application of graded approach.

HAEA has elaborated its procedure on the survey and evaluation of its safety culture. Based on the procedure HAEA has performed the survey of its safety culture level and the report (in Hungarian language) was shown during the follow-up mission.

Another procedure for management of organizational changes in HAEA has been developed to ensure that organizational changes are performed under effective control, within accepted limits and that the records are maintained in a retrievable manner.

Functional Principles of the Integrated Management System Manual, Edition 10 of HAEA has been supplemented with the principle of graded approach and is applied in regulatory functions of HAEA.

The Enforcement Policy of HAEA has also been supplemented by the principle of graded approach. An enforcement procedure has been developed which includes the application of graded approach in enforcement process.

The Quality Policy of HAEA has been supplemented with general objectives of risk management. Integrated risk management has been introduced according to the requirements by the Risk Management Policy SZ-14. The purpose of the policy is to define the procedures and the tasks, responsibilities and competences, and to regulate the uniform handling of risk factors for the integrated risk management system of HAEA.

Status of the finding in the initial mission

Recommendation 10 (R10) remains open as OCMO, governmental offices and BCGO have not established management systems and procedures for the regulatory functions within their domain as required by IAEA safety standards.

Recommendation 11 (R11) is closed as HAEA has implemented the requirements of relevant IAEA safety standards related to promoting and supporting a strong safety culture, managing organizational changes and application of graded approach in its management system.

New observation from the follow-up mission

A new finding was identified regarding the management systems of OCMO and BCGO. As described in Modules 7 and 8 of this report, these organizations did not fully address Suggestion 5 and Recommendation 20 from the initial mission. Specifically, OCMO and BCGO have not developed and implemented sufficiently detailed procedures to plan and conduct unannounced inspections and guidance to implement their enforcement policies.

FOLLOW UP MISSION RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: *The OCMO and the BCGO do not have formal procedures to implement their enforcement policies. In addition, these agencies do not have formal detailed procedures to implement unannounced inspections.*

FOLLOW UP MISSION RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 2, Requirement 6, para 4.11 states that** *"The organizational structure, processes, responsibilities, accountabilities, levels of authority and interfaces within the organization and with external organizations shall be clearly specified in the management system."*
(2)	**BASIS: GSR Part 1 Requirement 28, para. 4.50 states that** *"The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspections including unannounced inspections and shall stipulate the frequency of the inspections and the areas and programmes to be inspected, in accordance with a graded approach."*
(3)	**BASIS: GS-G-1.3, para. 3.3, states in part that** *"Inspection by the regulatory body, both announced and unannounced, shall be a continuing activity."*
(4)	**BASIS: GS-G-1.3, para. 5.14, states in part that** *"The regulatory body should adapt clear administrative procedures and guidelines governing the use and implementation of enforcement actions. All inspectors and other staff of the regulatory body should be trained in and should be knowledgeable about the procedures and guidelines. The procedures and guidelines should state the policy of the regulatory body for the use of regulatory and enforcement measures and the associated authority delegated to the inspectors and other regulatory staff."*
SF1	**Suggestion: The OCMO and BCGO should consider developing procedures to implement their enforcement policies and developing or enhancing their procedures for planning and conducting unannounced inspections.**

4.2. MANAGEMENT RESPONSIBILITY

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

4.3. RESOURCE MANAGEMENT

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

4.4. PROCESS IMPLEMENTATION

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

4.5. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

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

5. AUTHORIZATION

5.1. GENERIC ISSUES

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *The process for revoking the environment protection licence is not defined within the current regulatory framework.*	
(1)	**BASIS: GSR Part 1 Requirement 23, para. 4.37 states that** *"Any subsequent amendment, renewal, suspension or revocation of the authorization for a facility or an activity shall be undertaken in accordance with a clearly specified and established procedure, and shall make provision for the timely submission of applications for the renewal or amendment of the authorization."*
R12	**Recommendation:** The regulatory body should define the process for revoking the environment protection licence.

Changes since the initial IRRS mission

Recommendation 12: The Act on the General Rules of Environmental Protection and the Government Decree on Environmental Impact Assessment include provisions for revoking an environmental protection authorization. A flow diagram was shown and explained on how the authorization revocation process is implemented. However, it was observed that the flow diagram is not part of any official documentation neither any plan to include the flow diagram in management system documentation was confirmed.

Status of the finding in the initial mission

Recommendation 12 (R12) remains open as revocation process for the environmental authorization is not defined in the management system documentation of the BCGO.

5.2. AUTHORIZATION OF NUCLEAR POWER PLANTS

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

5.3. AUTHORIZATION OF RESEARCH REACTORS

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

5.4. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

2015 MISSION RECOMMENDATIONS, SUGGESTIONS
Observation: *The Governmental Decree 155/2014. Korm. establishes obligation of the regulatory body to review and authorize the activities of the disposal facilities along their lifecycle. The current situation of the existing radioactive waste disposal facilities and the activities developed for deep geological disposal will soon bring challenging responsibilities for the HAEA. In that perspective, the regulatory body has not yet put in place an integrated approach in order to tackle with various interconnected safety issues to be handled with to ensure it can fulfil its obligations. This integrated approach comprises in particular the availability of the different competencies (as mentioned in module 7.4 for inspection), the development of guidance (as mentioned in module 9) and procedure and the transfer of knowledge .*

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
(1)	**BASIS: GSR Part 5 Requirement 3 states that** *"The regulatory body shall also set conditions for the 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."*
(2)	**BASIS: SSR-5 Requirement 2 states that** *"The regulatory body shall establish the requirements for the development of radioactive waste management facilities and activities and shall set out procedures for meeting the requirements for the various stages of the licensing process. The regulatory body shall review and assess the safety case …".*
(3)	**BASIS: SSR-5 Requirement 2, para. 3.9 states that** *"[The regulatory body] has to maintain competent staff, to acquire capabilities for independent assessment and to undertake international cooperation, as necessary, to fulfil its regulatory functions."*
(4)	**BASIS: SSR-5 Requirement 2, para. 3.10 states that** *"The regulatory body has to document the procedures that it uses to evaluate the safety of each type of disposal facility, the procedures that operators are expected to follow in the context of licensing, important decisions prior to licensing and licence applications. It also has to document the procedures that it follows in reviewing submissions from operators to assess compliance with regulatory requirements."*
(5)	**BASIS: SSR-5 Requirement 2, para. 3.11 states that** *"Similarly, in respect of each individual disposal facility, the regulatory body has to set out the procedures that an operator is expected to follow in demonstrating compliance with the conditions for the development and operation of the facility. The regulatory body also has to set out the procedures that it follows to assess compliance with the conditions throughout all stages of the development, operation and closure of the facility"*
R13	**Recommendation:** The regulatory body should ensure it has all necessary capacities to implement its functions assigned by the decree for the licensing of waste management facilities.

Changes since the initial IRRS mission

Recommendation 13: The organization of HAEA has been modified: a specific Radioactive Waste and Spent Fuel Management Facilities (RW&SF) department has been created under the Deputy Director General of HAEA. The department deals with licensing, review and assessment, inspection and enforcement for spent fuel and radioactive waste management activities and facilities. In addition, the department is responsible for the oversight of transboundary movement and radiation protection for the HAEA. The regulatory activities for deep geological programme are also managed by this new department.

Staffing in the new department has been significantly increased, with individuals who possess technical skills in areas such as nuclear physics, natural sciences, and radiation protection. There are still a few positions to be filled.

Cooperation with other departments (Nuclear Reactors; Structures, Systems and Components; Radioactive Sources, Safeguards, Security; on site Inspectorate) is a key aspect of the capacity building because review of radioactive waste programme requires interactions with specialists from other fields. HAEA developed internal specific procedures to manage these relationships. Staff from other departments is assigned to support the RW&SF department. In return, people from RW&SF department are early involved in the licensing of facilities conducted by other departments, ensuring this way the early consideration for radioactive waste management.

A set of new guidance, according to the HAEA annual guideline development update/review plan and amendment to the Government Decree 155/2014. (VI. 30.) have been issued since 2015 (see Recommendation 23).

The importance of the support provided by TSOs is worth being noted. This strategy is relevant to complement internal capacities of HAEA provided that TSOs are able to maintain their own capacities to support the HAEA, avoiding conflict of interest where works is done for licensees (which is particularly difficult to ensure for a small nuclear program). However actions have been taken by HAEA to eliminate the risk of conflict of interest while involving TSOs (see Suggestion S4).

New procedures for regulatory activities of HAEA related to conducting inspections (ME 5-2-0), assessing the performance indicators (ME 3-0-14), licensing (ME 5-1-0), conducting events investigation (ME 3-0-8) and reviewing of periodic reports (ME 3-0-13) have been published from 2015 to 2017. Procedures for enforcement (ME 3-0-15) and for review and assessment (ME 5-3-0) are under approval at DG level. As part of the licensing procedure, elements on the review of the Periodic Safety Report assessment are provided. Specific topics related to radioactive waste management activities and facilities have been included in these internal procedures.

A new procedure referenced ME 0-0-8 has been issued in 2016 in order to guide the identification and follow-up of training needs for the staff of the HAEA. It defines the HAEA training system. For the RW&SF department, the list of training activities has been provided, covering general and specific technical fields. A mentoring system is developed and international activities (ME-0-0-32) are also considered as valuable for sharing experience (ME 3-0-30).

In addition to these new procedures, the new Annex 3 of the Government Decree 155/2014. (VI. 30.) establishes a set of comprehensive requirements for the survey and assessment of the site and for the siting of the planned storage and disposal facility that are useful for the review activity to be undertaken by the HAEA.

All these changes contribute to enhance internal capacities of the HAEA.

Status of the finding in the initial mission

Recommendation 13 (R13) is closed on the basis of progress made and confidence in the effective completion of the internal procedures for reviewing the safety case of the facilities as stated by the quality management system.

5.5. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

2015 MISSION RECOMMENDATIONS, SUGGESTIONS
Observation: *The general principles of justification of practices and optimization of radiation protection are partly addressed in the Act on Atomic Energy, however, their application is not fully incorporated in the regulatory system.*

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
(1)	**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."*
(2)	**BASIS: GSR Part 3 Requirement 11, para. 3.22 states that** *"The government or the regulatory body:* *(a) Shall establish and enforce requirements for the optimization of protection and safety;* *(b) Shall require documentation addressing the optimization of protection and safety;*
R14	**Recommendation:** The regulatory body should establish requirements and procedures for justification of practices and optimization of radiation protection in the facilities and activities.
Observation: *There are limited provisions for safety assessment for any of the practices involving radiation sources.*	
(1)	**BASIS: GSR Part 1 Requirement 22, para. 4.33 states that** *"Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment, which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures."*
R15	**Recommendation:** The regulatory body should establish requirements for safety assessment to be submitted by the applicants.

Changes since the initial IRRS mission

Recommendation 14: As described in Module 1, the regulatory framework underwent significant changes.

The Government Decree 487/2015 (XII. 30.) in its last amendment, which became effective on 01.03.2018, introduced requirements for justification and optimisation in line with the requirements given in the EU COUNCIL DIRECTIVE 2013/59/EURATOM. Specifically, Article 5 of that document requires prior justification of new types of practices as well as revision of justification. This Article addresses occupational, public and medical exposures. In particular, as stated in Annex 7 of the Govt. Decree 487/2015 (XII. 30.) in an application for a license a "justification of the radiation hazardous practice" should be part of the licensing documentation. A list of activities which require only notification but not a license is given in Govt. Decree 487/2015 (XII. 30.). In case of medical exposure, a part of the licensing documentation submitted to the HAEA is a document justifying a new type of medical application of radiation sources, which is issued by National Chief Medical Officer as stated in Ordinance 21/2018. (VII.9.) of the Minister of Human Capacities. In that legislation detailed provisions related to justification of medical exposure are also given.

Requirements related to optimisation of protection of workers and members of the public are defined in Arts. 7 and 8 of the Govt. Decree 487/2015 (XII. 30.). In addition, Article 8 requires the

use of dose constraints for Category A workers. The same article requires implementation of dose constraints for members of the public in relation to practices of category I and II. According to the Article 54 licensing documentation should include description of optimisation. Annex 8 requires incorporation of the optimisation into the Workplace Radiation Protection Rules.

Regarding optimisation related to medical exposure requirements are given in the Ordinance 21/2018. (VII.9.) of the Minister of Human Capacities. However, there are no requirements related to submission of documentation to the regulatory body, addressing the optimization of protection and safety in the case of medical exposure.

Recommendation 15: The Govt. Decree 487/2015 (XII. 30.). establishes in Article 54 and Annex 7 detailed requirements on the documentation to be submitted as part of a license application. Annex 7 describes the content of the Radiation Protection Description that should be sent as part of this documentation. An integral part of the Radiation Protection Description is a safety assessment. Safety assessment should be prepared or reviewed by a qualified radiation protection expert before being submitted to the regulatory authority. Safety assessment is reviewed and assessed by the regulatory body, namely the HAEA and BCGO when appropriate. HAEA inspectors also perform inspection including measurements before granting the license in line with new regulatory tasks of the HAEA.

Status of the finding in the initial mission

Recommendation 14 (R14) remains open as there are no provisions in place requiring the applicant to submit documentation concerning optimization of medical exposure to the regulatory body.

Recommendation 15 (R15) is closed as the applicant is required to send the safety assessment as a part of the authorization documentation to the regulatory body.

5.6. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

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

5.7. AUTHORIZATION OF TRANSPORT

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

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

6.1.1 MANAGEMENT OF REVIEW AND ASSESSMENT

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

6.1.2 ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *The BCDEPN does not possess the necessary software tools, which are needed for the verification of the adequacy of the model calculations described in the applications.*	
(1)	**BASIS: GSR Part 1 Requirement 25 states that** *"The regulatory body shall review and assess relevant information … to determine whether facilities and activities comply with regulatory requirements …"*
R16	**Recommendation:** The BCDEPN should ensure it has access to technical capabilities to review and assess model calculations submitted by applicants.

Changes since the initial IRRS mission

Recommendation 16: The Governmental Office has contacted the Hungarian Academy of Sciences Centre for Energy Research to seek assistance in obtaining software suitable for the purpose. After several technical consultations the Centre for Energy Research offered to develop the specific software that is potentially suitable for regulatory purposes and may satisfy the needs of the Governmental Office. Further consultations will be necessary in order to define the boundary conditions and requirements regarding the software and then to select and apply a software fully capable to model the environmental regulatory functions. A senior manager level discussion is being organized on the related financial arrangements. The action seems at a very preliminary stage whereas no time frame has been defined for the development of software or for human competence development on the software.

Status of the finding in the initial mission

Recommendation 16 (R16) remains open as only initial steps have been taken towards the software development and considerable amount of work is yet to be undertaken.

6.1.3 ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

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

6.1.4 PERFORMANCE OF REVIEW AND ASSESSMENT

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

6.2. REVIEW AND ASSESSMENT FOR NUCLEAR POWER PLANTS

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

6.3. REVIEW AND ASSESSMENT FOR RESEARCH REACTORS

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

6.4. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

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

6.5. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *Review and assessment of facilities and activities by the OCMO, the RHDs and the BCDEPN over the lifetime is very limited.*	
(1)	**BASIS: GSR Part 1 Requirement 25 states that** *"This review and assessment of information shall be performed prior to authorization and again over the lifetime of the facility or the duration of the activity…"*
R17	**Recommendation:** The regulatory body should strengthen the review and assessment to determine whether facilities and activities comply with regulatory requirements and to ensure appropriate regulatory oversight of their safety throughout their lifetime.

Changes since the initial IRRS mission

Recommendation 17: As described in Module 1, the regulatory framework underwent significant changes, which include the review and assessment of information prior to authorization and again over the lifetime of the facility or the duration of the activity.

The Govt. Decree 487/2015 (XII. 30.) prescribes detailed review and assessment of information by the HAEA prior granting a license. A list of requirements required to obtain a license is given in Govt. Decree 487/2015 (XII. 30.). As a part of the licensing procedure, the HAEA inspectors performs inspections including measurements. The HAEA receives reports on occupational exposure regularly as well as dose investigations reports. The HAEA is also informed in case of an incident and accident. Regular inspections based on an Annual Program which applies a graded approach are conducted by the HAEA inspectors, e.g. once per year at special facilities and facilities of Category I. Measurements are a part of the inspection procedure.

Regarding review and assessment performed by the Ministry of Human Capacities, the IRRS team was informed that, in cases when the Budapest Capital Governmental Office is co-authority to HAEA, the review and assessment of occupational and public radiation protection is performed by this office before issuing the consent, but not again afterwards through the lifetime of the facility or activity.

According to Act VII. on Paks Capacity Maintenance from 2015 medical exposures are subject to control of the Ministry of Human Capacity. Review and assessment related to medical exposure over the lifetime of facility or activity is based only on inspections conducted by Governmental Offices of the seven counties and on reporting of major events.

No changes related to BCGO review and assessment are noted.

Status of the finding in the initial mission

Recommendation 17 (R17) remains open as review and assessment over the lifetime of the facility or the duration of the activity by OCMO and BCGO continues to be very limited.

6.6. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

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

6.7. REVIEW AND ASSESSMENT FOR TRANSPORT

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

7. INSPECTION

7.1. GENERIC ISSUES

7.1.1 INSPECTION PROGRAMME

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

7.2. INSPECTION OF NUCLEAR POWER PLANTS

7.2.1 INSPECTION PROGRAMME

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *The HAEA and the OCMO and the RHDs do not have specific guidance regarding when to conduct unannounced inspections.*	
(1)	**BASIS: GSR Part 1 Requirement 28, para. 4.50 states that** *"The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspections including unannounced inspections and shall stipulate the frequency of the inspections and the areas and programmes to be inspected, in accordance with a graded approach."*
S5	**Suggestion:** The regulatory body should consider revising its inspection programme for unannounced inspections to include a variety of safety related activities.
Observation: *The HAEA develops its annual inspection plan based on input from managers and inspectors in accordance with the past year's performance by the NPP. The inspection plans differ for each unit and do not contain any inspections that are conducted at all four units. This could result in inspections that do not cover all areas recommended by IAEA Safety Standards.*	
(1)	**BASIS: GSR Part 1 Requirement 29, para 4.53 states that** *"In conducting inspections, the regulatory body shall consider a number of aspects including:* - *Structures, Systems, components and materials important to safety:* - *Management systems:* - *Operational activities and procedures* - *Records of operational activities and results of monitoring:* - *Liaison with contractors and other service providers:* - *Competence of staff:* - *Safety culture:* *Liaison with relevant organization for joint inspections, where necessary."*
R18	**Recommendation:** The regulatory body should revise its inspection planning process to ensure that all inspection areas stated in GSR Part 1 are covered in accordance with the graded approach and involve other authorities, as necessary.

Changes since the initial IRRS mission

Suggestion 5: In Hungary, Act CL of 2016 on General Public Administration Procedures, Section 102, provides Hungarian regulatory authorities with the legal basis to conduct inspections without prior notification (unannounced).

Following the initial IRRS mission, HAEA initiated the revision of its inspection program. This revision was part of a series of modifications by HAEA to improve its oversight of NPPs. Implementation of the modifications through revision of the relevant procedures is ongoing. The yearly planning process is described in draft procedure NBI-ME-3-0-28, "Preparing of Annual Inspection Plan", and is to be published by October 2018.

HAEA has reviewed its practice regarding unannounced inspections and, as a result, such inspections have been added to the annual inspection plan. While in the past HAEA conducted unannounced inspections of onsite activities, a graded approach has been instituted to better focus the unannounced inspections on systems, structures and components, and activities with higher safety significance. The IRRS team was told that approximately 50 percent of security related inspections for nuclear installations are unannounced and include state law enforcement agencies.

Following the initial IRRS mission a new Act CL of 2016 was entered into force which promotes the execution of unannounced inspections by governmental offices (including OCMO). OCMO has incorporated a condition for conducting unannounced inspections into The Rules of Procedure of the Department of Environmental Nutrition for Health; however, the procedure does not stipulate the periodic or routine use of unannounced inspections.

BCGO informed the IRRS team that it strives to conduct unannounced inspections beyond the inspections required by the regulations. BCGO stated that when there is potential that advance notification could jeopardise the success of an inspection, the regulatory inspections are unannounced. Notwithstanding, the BCGO does not have a documented procedure for planning and conducting unannounced inspections under the authority of Act CL of 2016. Most inspections are announced to ensure the facility and staff are available for inspection.

Recommendation 18: As noted above, HAEA has updated procedure NBI-ME-3-0-28 for the development of the annual inspection plans. The Annex of the procedure includes comparison of the inspection areas recommended by GSR Part 1 and suggested by GS-G-1.3. HAEA intends to issue the final guide in October 2018.

HAEA also has developed an IT tool to promote the systematic inspection planning process. It covers the entire inspection planning process and produces a filterable database with statistical datasets in accordance with the Guide. HAEA has been using the tool for approximately two years and intends to complete its development in early 2019.

The revisions to the inspection programme also facilitate the involvement of other governmental co-authorities into the inspections. HAEA plans and performs joint inspections with OCMO and other relevant authorities in the common areas.

Status of the finding in the initial mission

Suggestion 5 (S5) is closed, since HAEA has revised its inspection programmes and procedures to include unannounced inspections for a variety of safety related activities. A new Suggestion SF1 has been identified regarding the development and implementation of procedures for planning and conducting unannounced inspections by OCMO and BCGO.

Recommendation 18 (R18) is closed on the basis of progress made and in confidence of effective completion, since the HAEA has revised its inspection planning process to ensure that all inspection areas stated in GSR Part 1 are covered in accordance with the graded approach. The related guide is expected to be finalized by the end of 2018.

7.2.2 INSPECTION PROCESS AND PRACTICE

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

7.2.3 INSPECTORS

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *Once a resident inspector has been assigned to the Paks site, the inspector may continue in this position indefinitely. The HAEA does not have a formal process for periodically evaluating the objectivity of the inspectors.*	
(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 in the authorization."*
(2)	**BASIS: GS-G-1.3 para. 6.1 states that** *"The regulatory body should have a system to audit, review and monitor all aspects of its inspection and enforcement activities to ensure that they are being carried out in a suitable and effective manner."*
S6	**Suggestion:** The regulatory body should consider developing guidance to ensure the objectivity of inspectors.

Changes since the initial IRRS mission

Suggestion 6: HAEA operates a resident inspectorate on-site at Paks. The inspectors live in the neighbouring villages, far from Budapest, therefore the Paks office is their permanent workplace. HAEA does not have a rotation policy for the resident inspectors and they can remain at the site indefinitely.

Since the initial IRRS mission the HAEA inspection programme has been updated to include several 'checks and balances' to monitor inspector objectivity. For example, draft procedure ME-3-0-28 discusses the professionalism, conduct and objectivity of inspectors. In addition, the IRRS team was told that (while it is not explicitly stated in the procedure) all inspections are performed with two or more inspectors and often include inspectors from HAEA headquarters in Budapest office. The IT tool directs inspection results to be independently evaluated by specialists. In addition, the resident inspectors have daily conference calls with HAEA management and other staff to discuss plant performance and inspection findings in accordance with ME-5-2-3, Regulatory Supervision on Suppliers' Activity.

HAEA management informed the IRRS team that it is their practice to meet annually with the NPP operator to discuss plant performance, receive feedback on the inspection and oversight of the facility and discuss any concerns the operator may have with inspection results and inspector conduct.

In addition, all staff of the regulatory body are bound to conduct their work in accordance with the Code of Ethics for Government employees and HAEA also has its own Code of Ethics (SZ-15) and staff cannot have financial relationships with the personnel of the licensees. The inspectors must routinely assess their potential incompatibilities and conflicts of interest in their work and they should make regular statements on this assessment. The inspectors make a declaration of wealth at specified intervals.

Through the processes above HAEA has not identified that the objectivity of the resident inspectors has been compromised.

Status of the finding in the initial mission

Suggestion 6 (S6) is closed, since the regulatory body has implemented additional measures to monitor inspector objectivity.

7.2.4 INSPECTION OF FACILITIES

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

7.3. INSPECTION OF RESEARCH REACTORS

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

7.4. INSPECTION OF WASTE MANAGEMENT FACILITIES

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *The HAEA does not conduct independent verification of the nature of the waste package.*	
(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: GS-G-1.3 para. 2.2 states that** *"The principal objectives of regulatory inspection and enforcement are to provide a high level of assurance that all activities performed by the operator at all stages of the authorization process (see the Appendix in Ref. [4]) and all stages during the lifetime of a nuclear facility (siting, design, construction, commissioning, operation and decommissioning or closure) have been executed safely and meet the safety objectives and licence conditions".*
(3)	**BASIS: GS-G-1.3 para. 2.3 states that** *"The regulatory inspection is performed to make an independent check on the operator and the state of the facility, and to provide a high level of confidence that operators are in compliance with the safety objectives prescribed or approved by the regulatory body."*
S7	**Suggestion:** The HAEA should consider conducting or contracting the independent verification of the compliance of waste packages.

Changes since the initial IRRS mission

Suggestion 7: HAEA contracted a TSO (TS ENERCON) to propose an approach and to assess technical feasibility of non-destructive and destructive methods to analyse compliance of waste packages with acceptance criteria. The study was issued in June 2018.

The TSO studied the waste management activities performed at the radioactive waste facilities and the related waste management criteria. It also examined the Hungarian and international best practices for radioactive waste package quality control, the HAEA's measurement tools and the potential independent laboratories' capabilities. Inspection methods were suggested for assessing the compliance of each waste package with acceptance criteria. Two inspections are planned in 2018 using non-destructive methods.

HAEA indicated during the IRRS follow-up mission that its intention is to comply with TSO recommendations. In that perspective, a first action has been launched with the development of a new internal procedure (referenced ME 5-2-5, under approval at DG level) for radiation protection measurements, including radioactive waste measurements to be performed by HAEA during inspections.

The commitment of laboratories in support to HAEA's internal capabilities will be further explored by HAEA on the basis of the feedback from the first inspections.

Status of the finding in the initial mission

Suggestion 7 (S7) is closed as practical actions (assessment of measurement tools, development of a specific procedure and planning of dedicated inspections) have been undertaken to perform an independent verification of the compliance of waste packages.

7.5. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

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

7.6. INSPECTION OF DECOMMISSIONING ACTIVITIES

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

7.7. INSPECTION OF TRANSPORT

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

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESSES

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *The OCMO and the RHDs have no enforcement policy for radiation sources to guide inspectors when faced with the need to take enforcement action. The BCDEPN has no enforcement policy to guide inspectors (except the legal regulations of Governmental Decree 314/2005. Korm.) when faced with the need to take enforcement action. The HAEA has a policy for Enforcement (P-0-2) that applies to all nuclear facilities and radioactive waste repositories. Currently, this policy does not include a clear statement that any enforcement action is to be taken in a graded manner, based on risk and safety significance of the non-compliance.*	
(1)	**BASIS: GSR Part 1 Requirement 30 states that** *"The regulatory body shall establish and implement an enforcement policy within the legal framework……specified in the authorization."*
(2)	**BASIS: GSR Part 1 Requirement 31, para. 4.54 states that** *"The response of the regulatory body ….. shall be commensurate with the significance for safety of the non-compliance in accordance with a graded approach."*
R19	**Recommendation:** The regulatory body should prepare or revise its enforcement policy to ensure that the policy covers all facilities and activities using a graded approach.
Observation: *The HAEA has a policy for Enforcement (P-0-2) but the procedures to describe the assessment, preparation, approval, documentation, implementation of an enforcement measure are outdated. The BCDEPN, the OCMO and the RHDs do not have procedures to guide their inspectors.*	
(1)	**BASIS: GSR Part 1 Requirement 31, para. 4.54 states that** *"The response of the regulatory body … shall be commensurate with the significance for safety of the non-compliance in accordance with a graded approach."*
(2)	**BASIS: GS-R-3 para. 5.28 states that** *"… the documentation of the management system shall include the following ... a description of the processes and supporting information that explains how the work is to be prepared, reviewed, carried out, recorded, assessed and improved"*
(3)	**BASIS: NS-R-4 para. 3.16 states that** *"the regulatory body shall require the operating organization to curtail its activities and to take any further actions necessary to restore an adequate level of safety."*
(4)	**BASIS: CoC on the Safety of Research Reactors para. 19(c) states that** *"the regulatory body should enforce the applicable regulations and the authorization, including suspension, modification or revocation of the authorization".*
R20	**Recommendation:** The regulatory body should prepare or revise the procedures to implement the enforcement policy and ensure that the necessary procedures remain up to date.

Changes since the initial IRRS mission

Recommendation 19: HAEA enhanced its enforcement policy to include the application of a graded approach by considering the safety significance and risks of the issues addressed in the enforcement process. The revised policy was entered into force by the Director General of HAEA in September 2016. This includes use of a graded approach for the additional regulated activities that HAEA has received since the initial IRRS mission (e.g., radioactive sources).

Act XI of 1991 provides the legal obligations and authorities of enforcement activities for OCMO including the use of a graded approach in applying sanctions of regarding their regulated activities as described in Ordinance 21/2018 of the Minister of Human Capacities on the rules for the protection of the health of persons exposed to ionising radiation during the provision of health services outside their work duties, in force since July 2018. The IRRS team concluded that the provisions of Act XI of 1991 contain sufficient detail to meet the GSR Part 1 (Rev. 1) requirements for an enforcement policy.

Since the initial IRRS mission, BCGO has implemented an Enforcement Policy (Registration Number 1258-6/2017 dated October 27, 2017) which discusses its legal obligations and authorities. The policy discusses the use of a graded approach to applying enforcement.

Recommendation 20: In March 2018 a draft enforcement procedure (ME-3-0-15) was incorporated into the HAEA management system. The draft is scheduled for final approval by the Director General before the end of October 2018. The draft procedure considers the safety significance of the violation or non-conformance using a graded approach. The procedure takes into account the rules set by the *General Public Administration Act* and the *Public Sanctioning Act* with special emphasis on the authority's right to free deliberation.

OCMO does not have enforcement procedures in place. OMCO informed the IRRS team that it is considering the development of a procedure to implement enforcement in accordance with its authorities in Ordinance 21/2018 of the Minister of Human Capacities and Act XI of 1991.

BCGO does not have any procedures to provide guidance on the implementation of the enforcement policy.

Status of the finding in the initial mission

Recommendation 19 (R19) is closed, since all regulatory authorities have implemented or enhanced their enforcement policy which includes a graded approach to applying enforcement.

Recommendation 20 (R20) is closed on the basis of progress made and in confidence of effective completion, as the enforcement procedure has been developed by HAEA and is expected to be issued by the Director General in October 2018. A new Suggestion SF1 has been identified regarding the development and implementation of procedures for the OCMO and BCGO enforcement programmes.

8.2. ENFORCEMENT IMPLEMENTATIONS

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

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *The HAEA has not published the full set of safety guidelines to complement the mandatory safety requirements according to the Nuclear Safety Codes (NSC), Governmental Decree 118/2011. and Governmental Decrees issued from 2005 to 2011. The OCMO, the RHDs and the BCDEPN have not published guidelines with respect to their regulatory requirements.*	
(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."*
R21	**Recommendation:** The regulatory body should complete development of the safety guidelines in a timely manner.
Observation: *The HAEA consulted with licensees, but not with the public or other interested parties within the process to develop and review the regulatory safety guides.*	
(1)	**BASIS: GSR Part 1 Requirement 34, para. 4.61 states that** *"… These processes shall involve consultation with interested parties…"*
R22	**Recommendation:** The regulatory body should include provisions for consultation with the public and interested parties in the development of the safety guides.

Changes since the initial IRRS mission

Recommendation 21: HAEA has since initial mission created an annual guideline development and update/review plan (action plan) to address the development of the guidelines defined/referred in the Nuclear Safety Code and other Regulations. HAEA has a 5-year-periodical review of Nuclear Safety Code. Since initial mission, HAEA have issued nine guidelines in 2015, six in 2016 and one in 2017 under the Nuclear Safety Code. The annual plan for 2018 contains the issuance of the four remaining guidelines referred to in the Nuclear Safety Code.

HAEA has started to create a software based requirement management system to enable managing regulatory requirements and guides. Each requirement is linked to relevant source or origin of requirements and enables HAEA to trace the relationship between the different levels of requirements, including national and international sources (e.g. IAEA, WENRA, etc.). The requirement management system development is ongoing activity within HAEA.

The regulatory tasks of the HAEA were substantially expanded from 2014 to 2016, e.g. all facilities and activities using radiation sources became a subject of a regulatory control of the HAEA. The HAEA is responsible for authorization and inspection of all types of practices with ionizing radiation expect when a practice or a source is exempted from all requirements. The HAEA informed the IRRS team that a plan of specific radiation safety guidelines, which are needed to be developed to cover all practices mentioned. The plan of developing new guidance includes among other guideline for radiotherapy, industrial radiography and use of x-ray machine in dental medicine. In particular, the HAEA identified a need to prepare a specific guidance for justification

and optimisation. The IRRS noted that HAEA guide titled "Complying with the requirements of justification and optimization in preparation of authorization submittals" is under development."

NPHI has issued a methodological guide entitled "Assessment of radiohygiene cases in co-authority proceedings". The objective of the methodological guide is to summarize the radiation-healthcare aspects and requirements, as well as, the domestic and international experience to be taken into account by the radiation safety authority when acting as a co-authority in the regulatory procedures of HAEA.

HAEA and NPHI informed the IRRS team that contracts will be signed among them for the development of the methodological guide for the conditions for diagnostic radiology equipment conformity described in Section 11 of the Ordinance 21/2018 (VII. 9.) of the Minister of Human Capacities. Contracts will also be signed with the Budapest University of Technology and Economics for the development of the radiotherapy related methodological guide.

The IRRS team was informed by HAEA that initial discussions have been started for the development of the nuclear medicine related methodological guide or the technical guideline for justified radiological procedures foreseen to be prepared by the Health Care Professional Association in Section 6 of the Ordinance 21/2018 (VII. 9.) of the Minister of Human Capacities. Also, there is a stipulation in Ministerial Ordinance 21/2018 (VII. 9.) EMMI that Health Care Professional Association shall prepare a methodological guide for setting criteria related to the implementation of clinical audits. The guide shall be annually updated. During the follow-up mission it was found, that there is no guidance yet available for Ordinance 21/2018 (VII. 9.) of the Minister of Human Capacities, nor a written plan or procedure on guidance development.

The BCGO develops and annually revises its standing orders related to the regulatory requirements for environmental permitting. These standing orders play the role of guidelines in the sense that they assist the users of environment and other applicants in complying with the technical and legal requirements pertaining to their submittals. The standing orders for environmental permitting are available from the official website of the Office among other environmental permitting guidance.

BCGO manages the guidance process in a high level internal guidance document. Internal guidance document defines annual review plan of environmental permitting guides with process description, responsible unit persons. BCGO claim that they carry out an annual gap analysis to newly revised IAEA safety standards. BCGO will issue change request to the Ministry, if seen that change should be taken into account in regulations. Changes to the guidance documentation is done internally within BCGO. The main environmental regulation document is "Government Decree on environmental impact assessment and integrated environmental licensing procedure 314/2005. (XII.25)".

Recommendation 22: HAEA has revised its procedure ME-0-0-36 "Development, issuing and revision of guidelines in the scope of the Nuclear Safety Code, Waste Storage Safety Code and in the authority of HAEA." The procedure has been extended to also include the consultation process with the public. The revised procedure assigns the responsibility of publication of a draft on the HAEA website by the competent organizational units.

In June 2017 HAEA extended their website to publish draft guidelines. HAEA noted, that to date feedback has not been received via this communication process. HAEA may consider enhancing awareness of this offer.

Status of the finding in the initial mission

Recommendation 21 (R21) remains open as HAEA, OCMO, BCGO and NPHI have not completed the full set of safety guidelines.

Recommendation 22 (R22) is closed as the HAEA has established a consultation process with the public and interested parties.

9.2. REGULATIONS AND GUIDES FOR NUCLEAR POWER PLANTS

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *No systematic gap analysis was conducted between the new IAEA requirements and the Hungarian legislative framework.*	
(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."*
S8	**Suggestion:** The regulatory body should consider establishing a formalized procedure to undertake a gap analysis between new IAEA requirements and the Hungarian legislative framework in order to ensure that the framework is up to date.

Changes since the initial IRRS mission

Suggestion 8: HAEA is a member in IAEA safety standards committees and working groups as NUSSC, RASSC, WASSC, etc. One of the Hungarian committee and working group delegates´ task is to inform the management of HAEA on the changes being prepared to the safety standards. The drafts are reviewed jointly by HAEA and its licensees and necessary modifications in the Hungarian regulations are initiated. HAEA experts are assigned to the various safety standards with a responsibility to follow-up modifications and to make proposals to the necessary domestic modifications. This formalization and harmonization of the transposition of the IAEA safety standard requirements into the Hungarian legislation and regulation process is included in HAEA procedure ME-0-0-73.

HAEA has updated procedure ME-0-0-25 "Quality Assurance Plan of review and issuance of nuclear safety codes" to include a process to address instances where IAEA safety requirements were found missing from legislation or regulations or they need to be updated.

It is also worth mentioning that a requirement management software based system is under development that will be able to aid gap-analysis of IAEA and WENRA safety requirements with those in the Hungarian legislation. HAEA is among few regulatory bodies, which have started to manage regulatory requirements with designated software tools used for requirement management in other complex and safety critical industries.

Regarding the tasks remained in the responsibility of the OCMO the basis for the respective legislation is the transposition of the EC Directives. At the request letter by the Ministry of Human Capacities Deputy State Secretariat of Chief Medical Officer's Affairs (MHC CMOA), the National Public Health Institute follows the changes in the relevant IAEA safety standards and informs MHC CMOA, which takes this information into account in its legislative work.

Furthermore, the Governmental Offices dealing with radiation issues receive notifications on such changes. During the follow-up mission it was noted that OCMO and NPHI does not have written procedure in place, how and when and by whom the gap analysis will be conducted.

In the BCGO**,** an expert is responsible to check the IAEA safety standards weekly for any alternations in the respective standards. If new requirements are found, the BCGO contacts the Ministry of Agriculture and initiates the necessary further steps.

During the follow-up mission it was noted that BCGO does not have written procedure in place, how and when and by whom the gap analysis will be conducted.

Status of the finding in the initial mission

Suggestion 8 (S8) is closed as the HAEA has established a process and developed a guideline and is developing a software tool to assist its gap analysis between the IAEA safety requirements and the Hungarian legislative framework.

New observation from the follow-up mission

The OCMO, BCGO and NPHI have not conducted systematic and formalised gap analysis between the new IAEA requirements and the Hungarian legislative framework.

FOLLOW UP MISSION RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The OCMO, BCGO and NPHI have not established systematic gap analysis between the new IAEA requirements and the Hungarian legislative framework.*	
(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."*
SF2	**Suggestion: The OCMO, BCGO and NPHI should consider establishing a formalized procedure to undertake a gap analysis between new IAEA requirements and the Hungarian legislative framework in order to ensure that the framework is up to date.**

9.3. REGULATIONS AND GUIDES FOR RESEARCH REACTORS

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

9.4. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

2015 MISSION RECOMMENDATIONS, SUGGESTIONS
Observation: *There are several areas where safety guides have not been developed, including (i) the closure of radioactive waste disposal facilities under operation or under study for the HLW; (ii) site characterisation process that must be conducted by the licensee in order to demonstrate adequacy of the site with respect to the overall safety ; (iii) the development and the update of waste acceptance criteria for the facilities under operation and for the HLW disposal under study, and (iv) safety assessment of overlapping excavation/construction and disposal operation in a radioactive waste disposal.*

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
(1)	**BASIS: GSR Part 1 Requirement 33, para. 4.62 states that** *"The regulation and guides provide the framework for the regulatory requirements and conditions to be incorporated into individual authorizations or applications for authorization. They shall also establish the criteria to be used for assessing compliance…"*
(2)	**BASIS: SSR-5 Requirement 19, para. 4.38 states that** *"The safety of a disposal facility after closure will depend on a number of activities and design features, which can include the backfilling and sealing or capping of the disposal facility. Closure has to be considered in the initial design of the facility, and plans for closure and seal or cap designs have to be updated as the design of the facility is developed. Before construction activities commence, there has to be sufficient evidence that the performance of the backfilling, sealing and capping will function as intended to meet the design requirements."*
(3)	**BASIS: SSR-5 Requirement 15, para. 4.26 states that** *"An understanding of the site for a disposal facility has to be gained in order to present a convincing scientific description of the disposal system on which the more conceptual descriptions that are used in the safety assessment can be based. The focus has to be on features, events and processes relating to the site that could have an impact on safety and that are addressed in the safety case and supporting safety assessment. In particular, this has to demonstrate that there is adequate geological, geomorphological or topographical stability (as appropriate to the type of facility), and features and processes that contribute to safety. It also has to demonstrate that other features, events and processes do not undermine the safety case."*
(4)	**BASIS: SSR-5 Requirement 20 states that** *"Waste packages and unpackaged waste accepted for emplacement in a disposal facility shall conform to criteria that are fully consistent with, and are derived from, the safety case for the disposal facility in operation and after closure."*
(5)	**BASIS: SSR-5 Requirement 17, para. 4.34 states that** *"Excavation and construction of a disposal facility could continue after the commencement of operation of part of the facility and after the emplacement of waste packages. Such overlapping of construction and operational activities has to be planned and carried out so as to ensure safety, both in operation and after closure."*
R23	**Recommendation:** The HAEA should continue developing guidance which covers all relevant areas of radioactive waste management for the different facilities throughout their entire life cycle according to a graded approach.

Changes since the initial IRRS mission

Recommendation 23: The Government Decree 155/2014. (VI. 30.) on the "Safety requirements of interim storage and final disposal facilities of radioactive waste and the related regulatory activities" (entered into force on 30 June 2014) was completed with Annex 3 on "Site survey and assessment of the storage and disposal facility, siting of the storage and disposal facility". This

Safety Code Volume 3 establishes a set of comprehensive requirements for the site survey and assessment of the site and for the siting of the planned storage and disposal facility, in the period from the selection of the formation potentially applicable to host the storage and disposal facility until the submission of the construction license application of the storage and disposal facility.

HAEA has issued new guidance since 2015. The list is provided below:

- T0.1. Regulatory inspection of Radioactive Waste Storage and Disposal Facilities
- T0.2. Event reports of Radioactive Waste Storage and Disposal Facilities
- T0.3. Periodic reports of Radioactive Waste Storage and Disposal Facilities
- T0.4. Periodic Safety Review of the Püspökszilágy Radioactive Waste Treatment and Disposal Facility
- T0.5. Guidance on the content and format of Safety Report for Operation of Radioactive Waste Storage and Disposal Facilities
- T0.6. Guidance on the content and format of Safety Report for Construction of Radioactive Waste Storage and Disposal Facilities
- T1.1. Management systems of Radioactive Waste Storage and Disposal Facilities
- T1.2. Survey of safety culture and utilization of its results for Radioactive Waste Storage and Disposal Facilities
- T2.1. Safety classification of systems, structures and components of the Hungarian Radioactive Waste Storage and Disposal Facilities

In addition, HAEA started the development of further guidance on risks analysis, emergency preparedness, technical modifications, workplace radiation protection rules, monitoring of environmental discharge for storage and disposal facilities.

The HAEA has also launched the development or update of other guidance:

- The closure of a repository: 2 guidance are currently under revision to better reflect HAEA expectations regarding closure procedure at different phases of a repository: one related to the operational phase (T0.5. “Guidance on the content and format of Safety Report for Operation of Radioactive Waste Storage and Disposal Facilities”) with more detailed requirements, the other one related to the construction phase (T0.6. “Guidance on the content and format of Safety Report for Construction of Radioactive Waste Storage and Disposal Facilities”) with less stringent requirements. Some HAEA departments (architecture, mechanics) as well as implementers are involved in the revision. The revised versions are expected to be completed by 2019.

- In order to support the application and review of site survey program for the deep geological repository (DGR), in complement to the Annex 3, a specific detailed guidance is expected to be issued in 2019 to detail the requirements of Annex 3. Specific requirements of the closure at the siting phase will be elaborated in this guidance;

- Guidance for (i) the development and update of waste acceptance criteria for the facilities under operation and for the HLW disposal under study and for (ii) the safety assessment of overlapping excavation/construction and disposal activities in radioactive waste disposal facilities are expected to be issued in 2019 according to the annual guideline development update/review plan. TSOs have been contracted for developing the guidance.

It is worth noting that after the initial IRRS mission, dedicated inspections were organized by HAEA at the Radioactive Waste Treatment and Disposal Facility (RWTDF) and at the National Radioactive Waste Repository (NRWR) to assess the way the operators manage overlapping construction and disposal activities.

Based on the IAEA recommendation of GSG-1, HAEA proposed a new radioactive waste category of Very Low Level Waste into the Hungarian radioactive waste classification system, to support the future needs linked to decommissioning activities. According to the recent (March 2018) amendment of the Government Decree 487/2015 (XII. 30.) the definition of the new class is issued, and since then, the licensees have to classify the waste according to this new, complemented system. In addition to this decree, on the basis of international practices and in coordination with the licensees, HAEA also developed a draft version of a new Government Decree on the safety requirements for very low level radioactive waste disposal and the related regulatory activities (similarly to the existing Government Decree 155/2014 (VI. 30.)). It is currently at ministry level for approval.

Two sets of safety requirements have also been developed related to:

- Waste treatment and conditioning: safety requirements have been developed on the basis of WENRA Safety Reference Levels and approved by HAEA;
- Design: safety requirements for all types of radioactive waste facilities (including DGR) were approved by HAEA;

For both sets, the pending issue at the time of the follow-up IRRS mission is the status to be adopted for their publication (via a decree or a guidance).

Status of the finding in the initial mission

Recommendation 23 (R23) is closed on the basis of progress made and confidence in the effective completion as HAEA has continued developing guidance according to a well-established plan. All relevant guides are expected to be completed by 2019.

9.5. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *The regulations do not cover some aspects of the regulatory control of radioactive sources over their entire life, in particular: financial provisions for the safe management of disused sources and provisions for reuse or reprocessing of radioactive sources.*	
(1)	**BASIS: GSR Part 1 Requirement 24, para. 4.29 states that** *"For radioactive sources and radiation generators the regulatory process shall continue over their entire lifetime".*
(2)	**BASIS: GSR Part 1 Requirement 17, para. 3.60 states that** *"Registrants and licensees shall ensure that arrangements are made promptly for the safe management of and control over radiation generators and radioactive sources, including appropriate financial provision, once it has been decided to take them out of use"*
(3)	**BASIS: CoC on the Safety and Security of Radioactive Sources, para. 14 states that** *"Every State should encourage the reuse or recycling of radioactive sources, when practicable and consistent with considerations of safety and security."*

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
(4)	**BASIS: CoC on the Safety and Security of Radioactive Sources, para. 20(e) states that** *"Every State should ensure that the regulatory body established by the legislation has the authority to:…* *(e)attach clear and unambiguous conditions to the authorizations issued by it, including conditions relating to:…* *(vii) the safe and secure management of disused sources, including, where applicable, agreements regarding the return of disused sources to a supplier;"*
S9	**Suggestion:** The regulatory body should consider initiating changes to the regulations to improve the control of radioactive sources over their entire life, specifically financial provisions for the safe management of disused sources and provisions for reuse or reprocessing of radioactive sources.

Changes since the initial IRRS mission

Suggestion 9: The IRRS team identified two steps toward safe management of disused sources. Namely, the Govt. Decree 487/2015. (XII. 30.) requires that sources of category 1, 2 and 3 can be purchased only if there is a return guarantee of the manufacturer, i.e. Art. 40 (2) says: "A radioactive source belonging to Categories 1-3 of the Physical Protection decree shall only be bought with return guarantee of the manufacturer." The system enabling management of radioactive sources once they are becoming disused is established in the Govt. Degree 490/2015 (XII.30.). It determines HAEA activities when a licensee does not comply with requirements or a licensee is not able to manage a radioactive source due to lack of financial resources. In the latter situation, HAEA has to fund the management of the source and is reimbursed from the state budget.

Status of the finding in the initial mission

Suggestion 9 (S9) is closed as provisions for safe management of disused sources and provisions for reuse or reprocessing of radioactive sources are in place.

9.6. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

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

9.7. REGULATIONS AND GUIDES FOR TRANSPORT

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

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

10.1. GENERAL EPR REGULATORY REQUIREMENTS

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *The OCMO and the RHD regulatory framework for radiation source facilities and activities contains only limited EPR requirements and only within the framework of the licensee's radiation protection program. There are no comprehensive EPR regulatory requirements or guidance based on the risk assessment and threat categories. There are no regulatory requirements and guidelines for fuel transportation EPR. The EPR regulatory guidelines for NPP, RR and ISFS have not been kept up to date and are not aligned with current requirements in the Nuclear Safety Code. There are no EPR guidelines for radioactive waste facilities.*	
(1)	**BASIS: GS-R-2 para. 3.9 states that** *"…the regulatory body shall establish, promote or adopt regulations and guides upon which its regulatory actions are based…"*
(2)	**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 response…"*
R24	**Recommendation:** The regulatory body should develop EPR regulatory requirements and guidance for radiation sources facilities and activities in relation to the threat category, establish EPR regulatory requirements for nuclear fuel transportation and update the EPR regulatory guidelines.

Changes since the initial IRRS mission

Recommendation 24: As explained in Module 1, the HAEA took over in 2016 the regulatory supervision of facilities and activities using ionizing radiation sources. This provides an opportunity for harmonization of the EPR regulatory oversight of operating organizations of the various facilities and activities. HAEA has made progress in strengthening the EPR regulatory requirements (e.g. in the Radiation Protection Decree) for various facilities and activities and on conducting studies to see how overall EPR regulatory framework can be improved and harmonized. However, not all facilities and activities are in the scope of these improvements.

EPR related guidelines for the NPP are yet to be revised and the EPR related guidelines for other facilities and activities, as well as EPR regulatory requirements for nuclear fuel transportation are yet to be developed. Their development is included in the annual guideline development update/review plan (see Module 9).

For the time being, the regulatory assessment of the adequacy of on-site emergency arrangements of operating organization is based on the evaluation of the acceptability of the safety analysis. There is no explicit requirement for operating organizations to conduct a hazard assessment as a basis for establishment of on-site emergency arrangements.

Status of the finding in the initial mission

Recommendation 24 (R24) remains open as work is still needed for the establishment of EPR regulatory requirements and guidance for all facilities and activities that could necessitate emergency response actions in line with GSR Part 7.

10.2. FUNCTIONAL REGULATORY REQUIREMENTS

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *The NSC and EPR guidelines are comprehensive in addressing preparedness and response requirements, however there are no requirements for recovery and transition to recovery.*	
(1)	**BASIS: GS-R-2 para. 4.99 states that** *"…Arrangements shall be established for the transition from emergency phase operations to routine long term recovery operations. This process shall include: the definition of the roles and functions of organizations; methods of transferring information; methods of assessing radiological and non-radiological consequences; and methods of modifying the actions taken to mitigate the radiological and non-radiological consequences of the nuclear or radiological emergency…"*
R25	**Recommendation:** The regulatory body should establish EPR regulatory requirements for recovery and transition to recovery.

Changes since the initial IRRS mission

Recommendation 25: With GS-R-2 being superseded by GSR Part 7, the former concepts of recovery and transition to recovery have been replaced by the concepts of termination of a nuclear or radiological emergency and the transition from an emergency exposure situation to an existing exposure situation or to a planned exposure situation. With the corresponding changes of terminology, Recommendation 25 is still applicable.

The National Nuclear Emergency Response Plan (OBEIT) was recently updated and approved in February 2018. The updates brought it in compliance with the EC Directive 2013/59/EURATOM regarding the provisions for the transition from an emergency exposure situation to an existing exposure situation. Chapter 9 of the plan contains the radiological conditions of termination of an emergency and the decision-making process including the termination of the on-site emergency (to be formerly announced by the operator, which is the starting point for deciding the termination).

However, the Nuclear Safety Decree and the Radioactive Waste Management Decree do not contain detailed provisions requiring the operating organizations to put arrangements in place for enabling to terminate the emergency on-site and to transition to a planned exposure situation. These provisions are required in the IAEA Safety Standards Series No. GSR Part 7 and GSG-11 and recommended by R25 of the initial IRRS mission. The Nuclear Safety Code and the Waste Safety Code contain provisions for the presence on-site of a person with the authority to classify the emergency situation, to declare the emergency and its termination.

The Radiation Protection Decree addresses the transition from an emergency exposure situation to an existing exposure situation, with consideration of the off-site emergency response only. It does, however, include, in annex 8 (point 6.2.2.1.3), the requirement for the operating organization of some facilities (Radiation protection category I and II, and special facilities with the exemption of

nuclear and radioactive waste disposal facilities) to add in its Emergency Preparedness and Response Plan the exact conditions for the termination of an on-site emergency.

HAEA reported that it initiated the development of guidance on termination of an emergency to take into account the recommendations of the IAEA Safety Guide GSG-11. The guidance is still under development, and intends to include provisions for operating organizations for on-site termination of the emergency. However, the extent of the coverage of the EPR regulatory guidance directed to operating organization regarding the on-site termination and transitioning could not be assessed during the follow up mission. Moreover, such provisions for operating organizations should not only be part of the guidance but should also appear in regulations.

Status of the finding in the initial mission

Recommendation 25 (R25) remains open as the regulatory body has not yet established EPR regulatory requirements for termination of a nuclear or radiological emergency on-site for all facilities and activities and for the subsequent transition to a planned exposure situation on-site, in line with GSR Part 7 and taking into account GSG-11.

10.3. REGULATORY REQUIREMENTS FOR INFRASTRUCTURE

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

10.4. ROLE OF REGULATORY BODY DURING RESPONSE

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

11. ADDITIONAL AREAS

11.1. CONTROL OF MEDICAL EXPOSURES

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *The Hungarian legal and regulatory framework addresses medical exposure control but in a manner that it is not fully in accordance with GSR Part 3. In addition, some of the existing regulatory provisions are not implemented.*	
(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".*
(2)	**BASIS: GSR Part 1 Requirement 34 states that** *"The government shall ensure that relevant parties are authorized to assume their roles and responsibilities, and that diagnostic reference levels, dose constraints, and ... are established."*
R26	**Recommendation:** The regulatory body should revise the current legal and regulatory framework to bring it in line with the requirements of GSR Part 3 for strengthening the medical exposure control and should ensure its full implementation.

Changes since the initial IRRS mission

Recommendation 26: As outlined in Module 1, significant changes have been introduced in Hungary, relating to the responsibilities and authorities for radiation safety, since the initial IRRS Mission in 2015. The control of medical exposures remains the responsibility of the Governmental Offices (formerly Radiation Healthcare Decentres – RHD) and the National Public Health Institute (NPHI). The regulatory oversight of medical applications using ionizing radiation with regard to occupational and public exposures is assigned to HAEA.

Ordinance 21/2018 (VII. 9.) of the Minister of Human Capacities, is the primary regulatory document transposing the medical exposures requirements into the national framework. Moreover, the Government Decree 487/2015 (XII. 30.) includes provisions related to the medical applications of ionizing radiation, such as qualification requirements and radiation protection training.

Ordinance 21/2018 (VII. 9.) of the Minister of Human Capacities includes, inter alia, provisions for the justification of new technologies and techniques and their regular review, establishment of diagnostic reference levels (DRLs), quality assurance programmes for medical exposures, pregnant or breast-feeding female patients, reporting of significant unintended or accidental medical exposures, and the conduct of clinical audits procedures.

Following a meeting with the competent authorities for medical exposures earlier this year, participation to the Heads of the European Radiological Protection Competent Authorities (HERCA) campaign for inspecting the justification of radiological procedures was taken and a formal memorandum of understanding for improving cooperation and exchange of information is under preparation by HAEA.

Status of the finding in the initial mission

Recommendation 26 (R26) is closed as the legal and regulatory framework was revised in line with the requirements of GSR Part 3.

New observation from the follow-up mission

Criteria for the release of patients who have undergone therapeutic radiological procedures using unsealed sources or patients who still retain implanted sealed sources are established in Ordinance 21/2018 (VII. 9.) of the Minister of Human Capacities. The existing provision concerning the dose constraints for volunteers participating in biomedical research programmes does not assign responsibility to set dose constraints to any authority, as provided for in GSR Part 3. Moreover, the licensees are required to establish the dose constraints for carers and comforters. National DRLs have not been established, although the Ordinance 21/2018 (VII. 9.) of the Minister of Human Capacities provides for their establishment and review every three years, by the Health Care Professional Association and their publication in the Journal of Public Health on the basis of the national dose survey study conducted by the NPHI.

FOLLOW UP MISSION RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Diagnostic reference levels for medical imaging, including image guided interventional procedures and dose constraints for carers and comforters and volunteers participating in a programme of biomedical research have not been established, as required by Ministerial Ordinance 21/2018 (VII. 9.) EMMI.*	
(1)	**BASIS: GSR Part 3, Requirement 34, para. 3.148 states that** *"The government shall ensure, …, that as a result of consultation between the health authority, relevant professional bodies and the regulatory body, a set of diagnostic reference levels is established for medical exposures incurred in medical imaging, including image guided interventional procedures…."*
(2)	**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:* *(a) Dose constraints, to enable the requirements of paras 3.173 and 3.174, respectively, to be fulfilled for:* *(i) Exposures of carers and comforters;* *(ii) Exposures due to diagnostic investigations of volunteers participating in a programme of biomedical research.* *(b)…"*
RF1	**Recommendation: The Government should ensure that diagnostic reference levels for medical exposures incurred in medical imaging, including image guided interventional procedures and dose constraints for carers and comforters and for volunteers participating in biomedical research programmes are established.**

11.2. OCCUPATIONAL RADIATION PROTECTION

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *In Hungary there are legal provisions for compensatory arrangements for workers exposed to ionizing radiation.*	
(1)	**BASIS: GSR Part 3 Requirement 3.111 states that** *"The conditions of service of workers shall be independent of whether they are or could be subject to occupational exposure. Special compensatory arrangements, or preferential consideration with respect to salary, special insurance coverage, working hours, length of vacation, additional holidays or retirement benefits, shall neither be granted nor be used as substitutes for measures for protection and safety in accordance with the requirements of these Standards."*
R27	**Recommendation:** The Government should ensure that the conditions of service of workers shall be independent of whether they are, or could be subject to occupational exposure.
Observation: *The Hungarian legal and regulatory framework addresses occupational exposure control but in a manner that it is not fully in accordance with GSR Part 3. In addition, some of the existing regulatory provisions are not implemented.*	
(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".*
R28	**Recommendation:** The regulatory body should revise the current legal and regulatory framework to bring it in line with the requirements of GSR Part 3 for upgrading the occupational exposure control and should ensure their full implementation.

Changes since the initial IRRS mission

Recommendation 27: In response to Recommendation 27, the State Secretary of the Ministry of Human Capacities responsible for public health clarified that the existing preferential benefits are not offered to workers exposed to ionizing radiation as compensatory arrangements for ionizing radiation hazards; they are solely offered for policy reasons, aiming to make specific professions more attractive. Moreover, formerly existing provisions for the early retirement of workers exposed to ionizing radiation are no longer in force.

Recommendation 28: In response to Recommendation 28, Hungary issued Government Decree 487/2015 (XII. 30.) on the protection against ionizing radiation and the corresponding licensing, reporting (notification) and inspection system. This decree, inter alia, introduces the concepts of "planned, emergency and existing" exposure situations, establishes occupational dose limits, reference levels for radon in workplaces and for aircrew and includes provisions for radiation protection programmes, worker's health surveillance in line with GSR Part 3.

The decree states that external and internal dosimetry data are maintained in the National Personal Dosimetry Registry until the given worker attains or would have attained the age of 75 years, but

at least for 30 years after cessation of the work subject to occupational exposure. There are provisions in place for granting workers access to the results of their own occupational exposure data, as in the Council Directive 2013/59/EURATOM. The IRRS team was informed that activities are undertaken in Hungary for further developing the existing capacity for dose measurements for the eye and extremities. In addition, the IRRS team was informed that the existing provisions for monitoring and registering the aircrew doses have not been implemented, as there are no airline companies registered in Hungary up to date.

The decree further provides, in line with the Council Directive 2013/59/EURATOM, that emergency workers who are liable to undertake actions whereby an effective dose of 100 mSv may be exceeded, undertake these actions voluntarily, while the pertinent value in GSR Part 3 is 50 mSv.

The Government Resolution 1862/2017 (XI. 29.) on measures serving the implementation of the National Radon Action Plan delegates responsibilities to Ministers and establishes deadlines for the implementation of actions as described in the draft National Radon Action Plan prepared by the Ministry of Human Capacities.

According to this Government Decision, the development of the representative national radon survey is anticipated to be completed by the end of 2018. The communication programme to increase the awareness of employers and workers is anticipated to be commenced by the end of 2019.

Status of the finding in the initial mission

Recommendation 27 (R27) is closed as the Government has ensured that the conditions of service for workers are not offered, by any means, as substitutes for measures for protection and safety.

Recommendation 28 (R28) is closed on the basis of progress made and confidence in the effective completion as the legal and regulatory framework was revised in line with the requirements of GSR Part 3 and that the already prepared draft radon action plan will be implemented.

Policy Discussion

A policy issue discussion took place related to the Recommendation 27 of the initial IRRS mission regarding Hungary's legal provisions for compensatory arrangements for workers exposed to ionizing radiation.

Hungary introduced the policy issue by stating the legislative provisions in force since 1983. According to the Labor Safety Act, the employer must not offer financial nor other compensations as a substitute for safe and healthy working conditions. This Act applies to all working environments, whether public or private. HAEA considers this legal provision in compliance with the GSR Part 3 Requirement, para 3.111. However, other legislation (governmental decree for civil servants in the medical area) allows radiation workers to receive benefits. According to HAEA, these benefits do not substitute for safety provisions but enhance the ability for employers to recruit and retain a qualified workforce. An official note sent by the Ministry of Human Capacity to HAEA in March 2018 confirmed HAEA's interpretation. In radiation working environments other than in the medical area (e.g. NPPs) there are also benefits for workers that are not required by legislation but are the result from arrangements between the employers and the workers.

The IRRS team members shared their countries' experience and practices on the matter.

In some countries, there is a history (dating back to the 1960's) of benefits given as compensatory measures because of the perceived increased safety risks to radiation workers. Such mechanisms were clearly stated in the legislation. In more recent times (10 to 20 years ago), the regulatory body determined that these mechanisms may circumvent the establishment of safety measures and managed to remove them from the legislation.

In other countries, although not foreseen by legislation, there are still benefits for radiation workers. However, the IRRS team members made it clear that these benefits are never to replace safety measures. They are meant to attract qualified people in a competitive market. An example was given that an employer is offering different benefits for workers at two separate NPPs in an effort to attract qualified staff to a more remote NPP. Some have also provided benefits based on the increased qualifications, skills and experience of workers, but with no direct link to the risk associated to the work.

Regardless of the existence of benefits, the IRRS team agreed that the regulatory body must play a role to ensure that all safety provisions are in place and not substituted by any kind of special compensatory arrangements.

In conclusion, the IRRS team advised Hungary to work towards amending the civil servant decree to more clearly dissociate the benefits from the radiation work.

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

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *Except for special facilities, there are no requirements, nor guidance for the operators to properly record and control their discharges. The environmental legislation requires only annual report for non-special facilities about their discharges.*	
(1)	**BASIS: GSR Part 3 Requirement 31 states that** *"Relevant parties shall ensure that … discharges of radioactive material to the environment are managed in accordance with the Authorization".*
R29	**Recommendation:** The regulatory body should initiate development of requirements and develop associated guidance for verification of compliance with discharge limits for all facilities.
Observation: *The concepts of clearance and clearance levels in Hungarian regulations are not consistent with GSR Part 3.*	
(1)	**BASIS: GSR Part 3 Requirement 8 para. 3.12 states that** *"The regulatory body shall approve which sources, including materials and objects, within notified or authorized practices may be cleared from regulatory control, using as the basis for such approval the criteria for clearance specified in Schedule I or any clearance levels specified by the regulatory body on the basis of these criteria. By means of this approval, the regulatory body shall ensure that sources that have been cleared from regulatory control do not again become subject to the requirements for notification, registration or licensing unless it so specifies".*

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
(2)	**BASIS: GSR Part 3 Schedule I para. I.12 states that** *"Radioactive material within a notified practice or an authorized practice may be cleared without further consideration provided that:* *(a) The activity concentration of an individual radionuclide of artificial origin in solid form does not exceed the relevant level given in Table I.2 (p. 124); or* *(b) The activity concentrations of radionuclides of natural origin do not exceed the relevant level given in Table I.3 (p. 128); or* *(c) For radionuclides of natural origin in residues that might be recycled into construction materials, or the disposal of which is liable to cause the contamination of drinking water supplies, the activity concentration in the residues does not exceed specific values derived so as to meet a dose criterion of the order of 1mSv in a year, which is commensurate with typical doses due to natural background levels of radiation."*
R30	**Recommendation:** The regulatory body should initiate changes in the regulations regarding the criteria for clearance specified in GSR Part 3 and update accordingly the clearance level values.
Observation: *There are no adequate procedures for recording the process of clearance of materials as an evidence of good performance in the management of cleared materials.*	
(1)	**BASIS: GSR Part 3 Requirement 8 states that** *"The regulatory body shall approve which sources, including materials and objects, within notified practices or authorized practices may be cleared from regulatory control".*
(2)	**BASIS: RS-G-1.7 para. 5.15 states that** *"Verification of the values should be based on a procedure that may include ..... adequate traceability of material, including its origin, or other means that are acceptable to the regulatory body, by prior approval or on application".*
S10	**Suggestion:** The regulatory body should consider requiring the licensees to establish procedures to provide evidence on traceability and the adequate management of materials cleared from the regulatory control.
Observation: *Although studies on radon concentrations carried out in living spaces in Hungary are not exhaustive, some measured values are significant. There are no reference levels for radon with public radiation protection purposes in Hungarian regulations. There are only independent programs on survey of living space radon level.*	
(1)	**BASIS: GSR Part 3 Requirement 50 states that** *"The government shall provide information on levels of radon indoors and the associated health risks and, if appropriate, shall establish and implement an action plan for controlling public exposure due to radon indoors".*
R31	**Recommendation:** The Government should complete the studies related to radon levels and their impact on the public and, if needed, implement an action plan for controlling public exposure due to radon indoors.

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *Hungarian regulations have not established reference levels, or the dose criteria for establishing them, for commodities such as building materials, foodstuffs and water.*	
(1)	**BASIS: GSR Part 3 Requirement 51 states that** *"The regulatory body or other relevant authority shall establish reference levels for exposure due to radionuclides in commodities".*
R32	**Recommendation:** The regulatory body should establish the scope of the commodities to be object of supervision and formulate reference levels for exposure due to radionuclides present in them.

Changes since the initial IRRS mission

Recommendation 29: BCGO clarified for the IRRS team the extent of the information required on an annual basis from non-special facilities. BCGO considers that for these facilities there is sufficient evidence to submit the annual report established by regulations, considering that the amounts of radioactive material authorized to be used, and the very conservative models applied for fixing the discharge limits, ensure that the discharge limits will not be exceeded.

Recommendation 30: In January 2016, Hungary entered into force the Radiation Protection Decree (Government Decree 487/2015). This Decree introduced the criteria for clearance in agreement with GSR Part 3 and established related clearance levels. The Decree also establishes generic procedures for the management of waste to be stored until decay below clearance levels before its release without restrictions.

Suggestion 10: Hungary has made improvement in its regulatory provisions for clearance. Generic procedures for clearance of materials are stated in paragraphs (2) and (3), Section 41 of Government Decree 487/2015. Additionally, the Decree includes some requirements related to the procedures to be submitted by the applicants for a license, in which reference to management of waste to be cleared after decay is made.

Moreover, the Ordinance 11/2010 (III.4.) of Minister of Transport, Telecommunication and Energy on the rules of accountancy for and control of radioactive materials, and on the corresponding data provisions, includes some prescriptions on minimal record keeping and reporting duties including cleared materials and wastes.

However, specifications on adequate content of records to be kept by the licensee, valid to demonstrate the traceability and the adequate management of materials cleared from the regulatory control regulatory body, have not been established.

Recommendation 31: The Government, through Government Resolution 1862/2017 assigned responsibilities for the implementation of a national radon action plan, which is currently in draft version and is expected to be approved by the end of 2018. A reference level of 300 Bq/m^3 of radon average activity concentration in the air for both the workplaces and the residential and public buildings has been established in the Radiation Protection Decree of 2016. Currently there is no definition on what authority will enforce what provisions of the drafted radon action plan and the completion of radon concentrations map of the country is still pending. After completion of this map, required remedial actions are expected to be initiated by 2023.

Recommendation 32: The 2016 Radiation Protection Decree has identified building materials as commodities requiring control and establishes relevant reference levels. Additionally, reference

levels for the control of radionuclides in drinking water have been established in Government Decree 201/2001. Provisions for the control of radioactivity levels in foodstuffs and animal feed, as well as in other environmental objects, including numerical values, have been established in Radiation Monitoring Decree 489/2015.

Status of the finding in the initial mission

Recommendation 29 (R29) is closed as requirements established in Ordinance 15/2001 of the Minister of Environment ensure that radioactive releases to the environment in the case of non-special facilities are in compliance with discharge limits established by regulations.

Recommendation 30 (R30) is closed as criteria for clearance of materials and related clearance levels have been established in accordance with GSR Part 3.

Suggestion 10 (S10) remains open as requirements establishing specific information to be recorded by licensees to evidence compliance with requirements for clearance of materials have not been fully established.

Recommendation 31 (R31) remains open as the studies related to radon levels and their impact on the public have not been completed and the national radon action plan has not been implemented yet.

Recommendation 32 (R32) is closed as regulations have established the scope of commodities to be subject of supervision and have formulated reference levels for exposure due to radionuclides present in them.

IRRS FOLLOW-UP MISSION TEAM

APPENDIX I - LIST OF PARTICIPANTS

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LIAISON OFFICER		
NYISZTOR Dániel	Hungarian Atomic Energy Authority (HAEA)	nyisztor@haea.gov.hu

APPENDIX II - MISSION PROGRAMME

<table>
<tr><th>Time</th><th>Sun
23 Sept</th><th>Mon
24 Sept</th><th>Tue
25 Sept</th><th>Wed
26 Sept</th><th>Thu
27 Sept</th><th>Fri
28 Sept</th><th>Sat
29 Sept</th><th>Sun
30 Sept</th><th>Mon
1 Oct</th></tr>
<tr><td>9:00-10:00</td><td rowspan="3">Team Arrival</td><td rowspan="3">Entrance Meeting</td><td rowspan="3">Interviews</td><td rowspan="3">Interviews</td><td rowspan="3">Discussion of findings/ report by the team</td><td rowspan="8">Individual reading of the report

Discussion of results of cross-reading

Collective reading of the report

Finalise draft Report

Review of the Executive Summary

Submission of Report to IRRS Admin

Submission of the Draft Report to the Host</td><td rowspan="3">Host reads report

TL prepares presentation</td><td rowspan="3">Review of host’s comments</td><td rowspan="3">Exit Meeting</td></tr>
<tr><td>10:00-11:00</td></tr>
<tr><td>11:00-12:00</td></tr>
<tr><td>13:00-14:00</td><td rowspan="5">Initial Team Meeting</td><td rowspan="4">Interviews</td><td rowspan="3">Interviews</td><td rowspan="3">TM finalize findings/
TM write report</td><td rowspan="3">Discussion of findings with counterpart</td><td rowspan="3">Social Event</td><td>Discussion with the Host

Preparation of the press release</td><td rowspan="6">Departures of Team Members</td></tr>
<tr><td>14:00-15:00</td><td rowspan="2"></td></tr>
<tr><td>15:00-16:00</td></tr>
<tr><td>16:00-17:00</td><td>Written preliminary findings delivered</td><td>Final findings with text delivered</td><td>Team revises report based on discussions</td><td rowspan="3">Written comments presented by the Host</td><td>Final Draft to the Host</td></tr>
<tr><td>17:00-18:00</td><td>Daily Team Meeting</td><td>Daily Team Meeting</td><td>Daily Team Meeting</td><td>Daily Team Meeting</td><td rowspan="2">Farewell Dinner</td></tr>
<tr><td>20:00-24:00</td><td></td><td>TM write findings</td><td>Secretariat edits findings
TM write report</td><td>Secretariat edits report
TM Read Draft</td><td>Cross reading
TL drafts Executive Summary</td></tr>
</table>

APPENDIX III - MISSION COUNTERPARTS

	IRRS Experts	Lead Counterpart	Support Staff
1.	**RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT**		
	Michael Johnson	Gyula FICHTINGER (HAEA), Péter MUCK (BCGO), Márta KOVÁCS (OCMO)	Béla András BALCZÓ, Andrea KÁDÁR (Ministry for IT), Árpád VINCZE, István LÁZÁR, Gábor NAGY (HAEA), Hajnalka CSIZMADIA, Henriett BALLABÁSNÉ VASKA-POTHARN (NPHI)
2.	**GLOBAL NUCLEAR SAFETY REGIME**		
	Mika Markkanen	Árpád VINCZE (HAEA), Márta KOVÁCS (OCMO)	Eszter RÉTFALVI, László JUHÁSZ, Zsófia SZEPES (HAEA),), Hajnalka CSIZMADIA, Henriett BALLABÁSNÉ VASKA-POTHARN (NPHI)
3.	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**		
	Faizan Mansoor	Árpád VINCZE (HAEA), Péter MUCK (BCGO), Márta KOVÁCS (OCMO)	Elizabeth BÓDIS, Judit HORVÁTHNÉ PAÁL, Tamás ABOU ABDO, Bánk CZIPPÁN, Béla András BALCZÓ, László CZOTTNER (HAEA), CSIZMADIA, Henriett BALLABÁSNÉ VASKA-POTHARN (NPHI)
4.	**MANAGEMENT SYSTEM OF THE REGULATORY BODY**		
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5.	**AUTHORIZATION**		
	Faizan Mansoor, Helena Janzekovic, Christophe Serres	Árpád VINCZE (HAEA), Péter MUCK (BCGO), Richárd ELEK, (NPHI)	Sándor KAPITÁNY, István LÁZÁR, Gábor NAGY, Péter TOMKA, Tamás GULYÁS (HAEA), László JUHÁSZ (NPHI)

	IRRS Experts	Lead Counterpart	Support Staff
6.	**REVIEW AND ASSESSMENT**		
	Faizan Mansoor, Helena Janzekovic, Christophe Serres	István LÁZÁR (HAEA), Péter MUCK (BCGO)	Gábor NAGY, Péter TOMKA, Tamás GULYÁS (HAEA)
7.	**INSPECTION**		
	Tim Kobetz, Helena Janzekovic, Christophe Serres	Eszter RÉTFALVI (HAEA), Péter MUCK (BCGO), Márta KOVÁCS (NPHI)	Bendegúz PUSKÁS, Zsolt STEFÁNKA, Armand VIPLAK (HAEA), Hajnalka CSIZMADIA, Henriett BALLABÁSNÉ VASKA-POTHARN (NPHI)
8.	**ENFORCEMENT**		
	Tim Kobetz, Helena Janzekovic, Christophe Serres	Eszter RÉTFALVI (HAEA), Péter MUCK (BCGO), Márta KOVÁCS (NPHI)	László CZOTTNER, Gergely BADACSONYI, István OLÁH, Zsotl STEFÁNKA, Viktórai HÓDOSI (HAEA), Hajnalka CSIZMADIA, Henriett BALLABÁSNÉ VASKA-POTHARN (NPHI)
9.	**REGULATIONS AND GUIDES**		
	Janne Nevalainen, Helena Janzekovic, Christophe Serres	János KRUTZLER (HAEA), Péter MUCK (BCGO), László JUHÁSZ (NPHI)	István OlÁH, Tamás GULYÁS (HAEA)
10.	**EMERGENCY PREPAREDNESS AND RESPONSE**		
	Hilaire Mansoux	Márton KERESZTES (HAEA)	Sándor KAPITÁNY, Árpád VINCZE (HAEA)
11.	**ADDITIONAL AREAS**		
	Stavroula Vogiatzi, Juan Tomas Zerquera	Anikó FÖLDI (HAEA), Péter MUCK, (BCGO), László JUHÁSZ (NPHI)	Árpád VINCZE, Sándor KAPITÁNY (HAEA), Richárd ELEK (NPHI)

APPENDIX IV - RECOMMENDATIONS (R) AND SUGGESTIONS (S) FROM THE PREVIOUS IRRS MISSION THAT REMAIN OPEN

Section	Module	R/S	Recommendation/Suggestion
1.3	**1**	**R3**	The Government should ensure that the authority to spend the resources approved for and to reorganize or restructure the regulatory body to enable it to discharge its assigned responsibilities is within the direct control of the regulatory body.
3.3	**3**	**R8**	The regulatory body should develop or update, if applicable, and maintain a long term human resource plan to ensure that competences and skills are maintained.
4.1	**4**	**R10**	The HAEA should further develop the management system to implement all the requirements of relevant IAEA safety standards including promoting and supporting a strong safety culture, managing organizational change and providing for a systematic graded approach for products and activities of each process in a documented manner.
5.1	**5**	**R12**	The regulatory body should define the process for revoking the environment protection licence.
5.5	**5**	**R14**	The regulatory body should establish requirements and procedures for justification of practices and optimization of radiation protection in the facilities and activities.
6.1.2	**6**	**R16**	The BCDEPN should ensure it has access to technical capabilities to review and assess model calculations submitted by applicants.
6.5	**6**	**R17**	The regulatory body should strengthen the review and assessment to determine whether facilities and activities comply with regulatory requirements and to ensure appropriate regulatory oversight of their safety throughout their lifetime.
9.1	**9**	**R21**	The regulatory body should complete development of the safety guidelines in a timely manner.

Section	Module	R/S	Recommendation/Suggestion
10.1	**10**	**R24**	The regulatory body should develop EPR regulatory requirements and guidance for radiation sources facilities and activities in relation to the threat category, establish EPR regulatory requirements for nuclear fuel transportation and update the EPR regulatory guidelines.
10.2	**10**	**R25**	The regulatory body should establish EPR regulatory requirements for recovery and transition to recovery.
11.3	**11**	**S10**	The regulatory body should consider requiring the licensees to establish procedures to provide evidence on traceability and the adequate management of materials cleared from the regulatory control.
11.3	**11**	**R31**	The Government should complete the studies related to radon levels and their impact on the public and, if needed, implement an action plan for controlling public exposure due to radon indoors.

APPENDIX V - RECOMMENDATIONS (RF), SUGGESTIONS (SF) AND GOOD PRACTICES (GPF) FROM THE 2018 IRRS FOLLOW UP MISSION

Section	Module	RF/SF/GPF	Recommendation, Suggestion or Good Practice
4.1	**4**	**SF1**	The OCMO and BCGO should consider developing procedures to implement their enforcement policies and developing or enhancing their procedures for planning and conducting unannounced inspections.
9.2	**9**	**SF2**	The OCMO, BCGO and NPHI should consider establishing a formalized procedure to undertake a gap analysis between new IAEA requirements and the Hungarian legislative framework in order to ensure that the framework is up to date.
11.1	**11**	**RF1**	The Government should ensure that diagnostic reference levels for medical exposures incurred in medical imaging, including image guided interventional procedures and dose constraints for carers and comforters and for volunteers participating in biomedical research programmes are established.

APPENDIX VI - REFERENCE MATERIAL PROVIDED BY HAEA

[1]	

HAEA

Governmental Decree 112/2011. (VII. 4.) Korm. on the scope of authority of the Hungarian Atomic Energy Authority in relation to European Union obligations and international obligations in connection with atomic energy, on the designation of co-authorities contributing to the regulatory proceeding of the Hungarian Atomic Energy Authority, and on the scientific council assisting the work of the Hungarian Atomic Energy Authority

Governmental Decree 118/2011. (VII. 11.) Korm.on the nuclear safety requirements of nuclear facilities and on related regulatory activities

Annex 1 to Governmental Decree 118/2011. (VII. 11.) Korm. Nuclear Safety Code, Volume 1 – Nuclear safety authority procedures of nuclear facilities

Annex 2 to Governmental Decree 118/2011. (VII. 11.) Korm. Nuclear Safety Code, Volume 2 – Management systems of nuclear facilities

Annex 3 to Governmental Decree 118/2011. (VII. 11.) Korm. Nuclear Safety Code, Volume 3 – Design requirements for nuclear power plants

Annex 4 to Governmental Decree 118/2011. (VII. 11.) Korm. Nuclear Safety Code, Volume 4 – Operation of nuclear power plants

Annex 5 to Governmental Decree 118/2011. (VII. 11.) Korm. Nuclear Safety Code, Volume 5 – Design and operation of research reactors

Annex 6 to Governmental Decree 118/2011. (VII. 11.) Korm. Nuclear Safety Code, Volume 6 – Interim storage of spent nuclear fuel

Annex 7 to Governmental Decree 118/2011. (VII. 11.) Korm. Nuclear Safety Code, Volume 7 – Site survey and assessment of nuclear facilities

Annex 8 to Governmental Decree 118/2011. (VII. 11.) Korm. Nuclear Safety Code, Volume 8 – Decommissioning of nuclear facilities

Annex 9 to Governmental Decree 118/2011. (VII. 11.) Korm. Nuclear Safety Code, Volume 9 – Requirements for the construction of a new nuclear installation

Annex 10 to Governmental Decree 118/2011. (VII. 11.) Korm. Nuclear Safety Code, Volume 10 – Nuclear Safety Code definitions

Governmental Decree 155/2014. (VI. 30.) Korm. on the safety requirements for facilities ensuring interim storage or final disposal of radioactive wastes and the corresponding authority activities. Effective: from 01.07.2014.

Annex 3 to Govt. decree 155/2014. (VI. 30.) Korm. – Safety Code

Government Decree 190/2011. (IX. 19.) Korm. on physical protection requirements for various applications of atomic energy and the corresponding system of licensing, reporting and inspection

Governmental Decree 246/2011. (XI. 24.) Korm. on safety area of nuclear facilities and radioactive waste repositories

Govt. decree 487/2015. (XII. 30.) Korm. on the protection against ionizing radiation and the corresponding licensing, reporting (notification) and inspection system

Ministerial Decree 51/2013. (IX. 6.) NFM on shipping, carrying and packaging of radioactive materials

Government Decree 490/2015 (XII. 30.) on the reports and interventions regarding missing, found or seized nuclear and other radioactive materials and other actions pertaining to radioactive materials following their report

Act CXVI of 1996 on Atomic Energy

Act CL of 2016 on General Public Administration Procedures

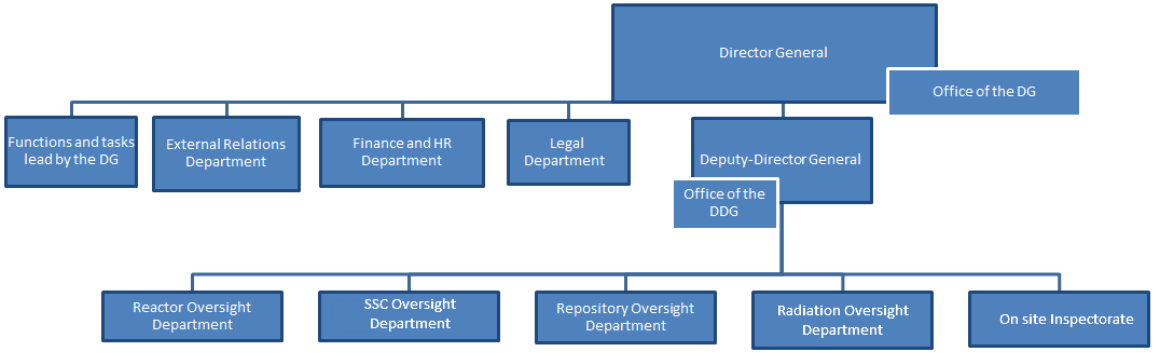
Guidelines, internal documents *P-0-2 – Enforcement Policy of the HAEA* *Annex 1 of P-0-2 –Enforcement policy of the HAEA* *ME-3-0-15 – Enforcement procedure of HAEA* *ME-3-0-28 – Annual planning of inspection activities related to nuclear facilities and radioactive waste repositories*
[2]
BCGO *Statements of the leader of BCGO* *Training policy* *Quality management policy* *Strategy and information policy* *Procedures and guides on different procedures/actions of BCGO* *Inspection plan of BCGO*
[3]
OCMO *Act XI of 1996 on pubic health regulatory actions* *EMMI Decree No. 21/2018 (VII. 9.) on the rules for the protection of the health of persons exposed to ionizing radiation during the provision of health services outside their work duties* *Government Decree No. 1862/2017 (XI. 29.) on measures serving the implementation of the National Radon Action Plan* *NATIONAL RADON ACTION PLAN to reduce natural radiation exposure originating from radon and building materials, 2018-2023.*

APPENDIX VII - IAEA REFERENCE MATERIAL USED FOR THE REVIEW

1.	**IAEA SAFETY STANDARDS SERIES No. SF-1** - Fundamental Safety Principles
2.	**IAEA SAFETY STANDARDS SERIES No. GSR PART 1** - Governmental, Legal and Regulatory Framework for Safety
3.	**IAEA SAFETY STANDARDS SERIES No. GSR PART 3** - Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards
4.	**IAEA SAFETY STANDARDS SERIES No. GS-R-2** - Preparedness and Response for a Nuclear or Radiological Emergency
5.	**IAEA SAFETY STANDARDS SERIES No. GS-R-3** - The Management System for Facilities and Activities
6.	**IAEA SAFETY STANDARDS SERIES No. NS-R-1** – Safety of Nuclear Power Plants: Design
7.	**IAEA SAFETY STANDARDS SERIES No. NS-R-2** – Safety of Nuclear Power Plants: Operation
8.	**IAEA SAFETY STANDARDS SERIES No. NS-R-4** - Safety of Research Reactors
9.	**IAEA SAFETY STANDARDS SERIES No. GS-G-1.1-** Organization and Staffing of the Regulatory Body for Nuclear Facilities
10.	**IAEA SAFETY STANDARDS SERIES No. GS-G-1.2** - Review and Assessment of Nuclear Facilities by the Regulatory Body
11.	**IAEA SAFETY STANDARDS SERIES No. GS-G-1.3-** Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body
12.	**IAEA SAFETY STANDARDS SERIES No. GS-G-1.4** - Documentation for Use in Regulatory Nuclear Facilities
13.	**IAEA SAFETY STANDARDS SERIES No. GS-G-2.1** - Arrangements for Preparedness for a Nuclear or Radiological Emergency
14.	**IAEA SAFETY STANDARDS SERIES No.GS-G-3.1** - Application of the Management System for Facilities and Activities
15.	**IAEA SAFETY STANDARDS SERIES No. GS-G-3.2** - The Management System for Technical Services in Radiation Safety
16.	**IAEA SAFETY STANDARDS SERIES No. RS-G-1.3** - Assessment of Occupational Exposure Due to External Sources of Radiation
17.	**IAEA SAFETY STANDARDS SERIES No. RS-G-1.4** - Building Competence in Radiation Protection and the Safe Use of Radiation Sources
18.	**IAEA SAFETY STANDARDS SERIES No. NS-G-2.10** - Periodic Safety Review of Nuclear Power Plants Safety Guide
19.	**IAEA SAFETY STANDARDS SERIES No. NS-G-211** - A System for the Feedback of Experience from Events in Nuclear Installations Safety Guide
20.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Convention on Early Notification of a Nuclear Accident (1986) and Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency (1987), Legal Series No. 14, Vienna (1987).

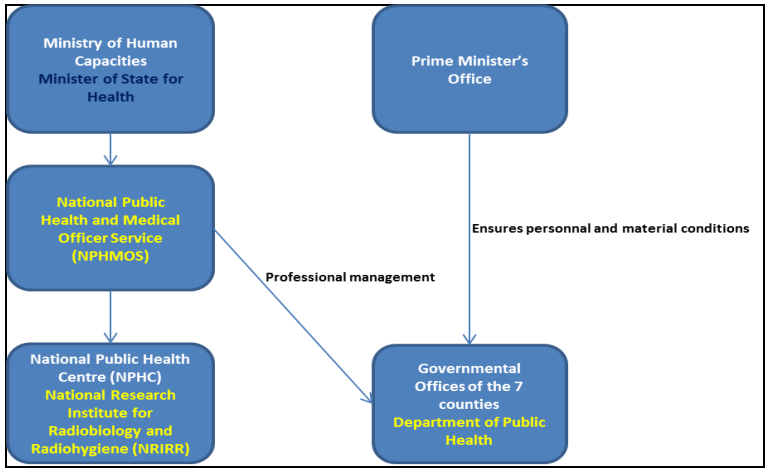
APPENDIX VIII - ORGANIZATIONAL CHARTS

HAEA

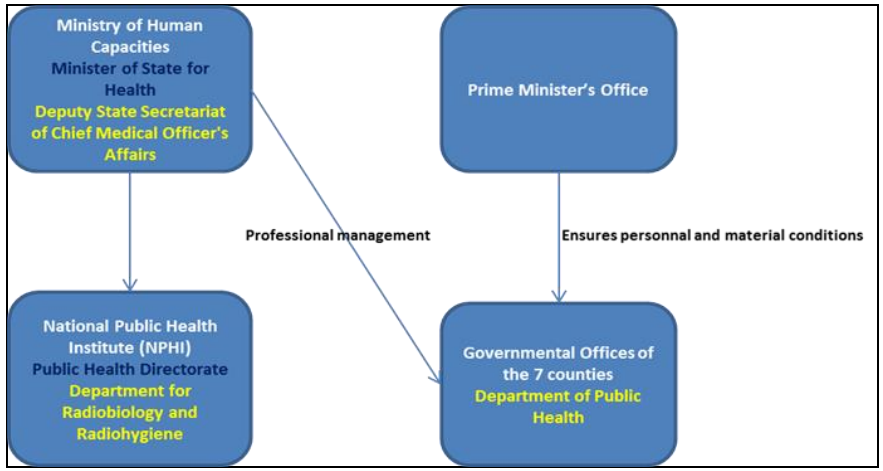


OCMO

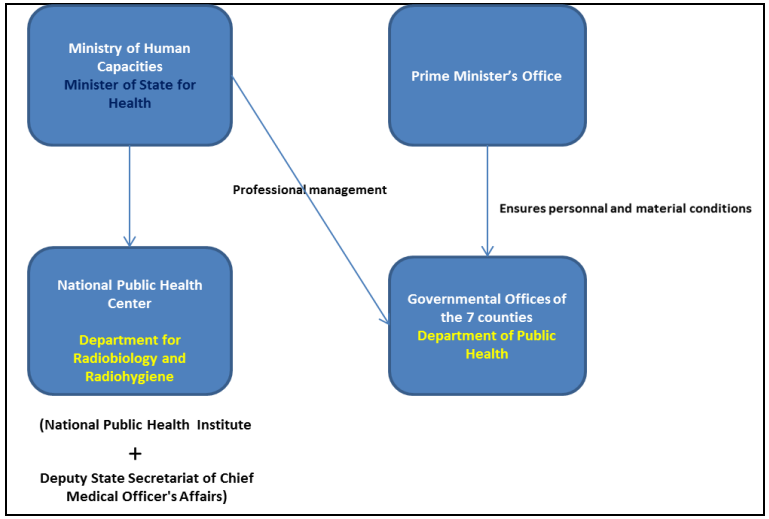
until 31 March 2017



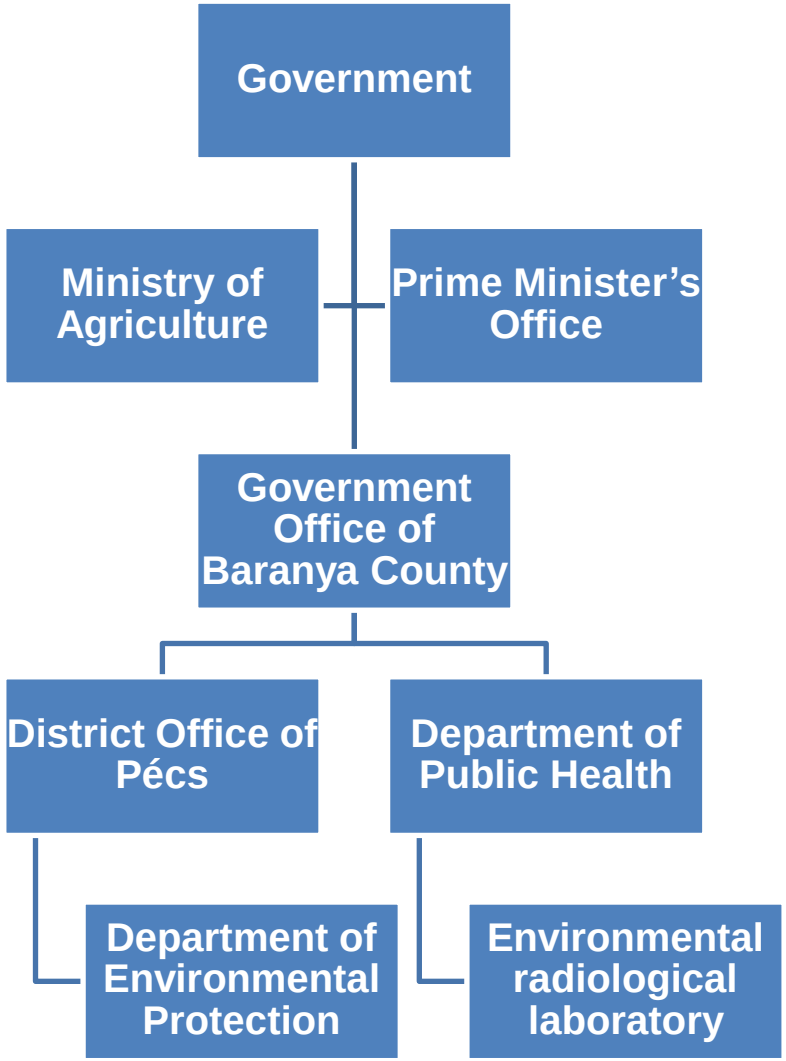
from 1 April 2017 until 30 September 2018



from 1 October 2018



BCGO


Government
Ministry of Agriculture
Prime Minister's Office
Government Office of Baranya County
District Office of Pécs
Department of Public Health
Department of Environmental Protection
Environmental radiological laboratory