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DEPARTMENT OF NUCLEAR SAFETY AND SECURITY





REPORT OF THE INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION TO HUNGARY





Integrated Regulatory Review Service

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INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION

TO

HUNGARY

Mission dates:	11 to 22 May 2015
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 Department of Environmental
	Protection and Nature (BCDEPN)
Location:	Budapest, Hungary
Regulated facilities and	Nuclear Power Plants, Interim Spent Fuel Storage Facility, Research
activities in the mission scope:	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 national infrastructure for nuclear and radiation safety. Comparisons of such numbers between IRRS reports from different countries should not be attempted.

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EXECUTIVE SUMMARY

At the request of the Government of Hungary, an international team of senior nuclear safety and radiation safety experts met with representatives of the Government, the Hungarian Atomic Energy Authority (HAEA), the Office of the Chief Medical Officer (OCMO), the Budapest Radiation Hygiene Decentre (RHD), and the Baranya County Government Office Department of Environmental Protection and Nature (BCDEPN) of Hungary from 11 to 22 May 2015 to conduct an Integrated Regulatory Review Service (IRRS) mission. The mission took place at the HAEA Headquarters in Budapest. The purpose of the IRRS mission was to perform a peer review of Hungary's national regulatory framework for nuclear and radiation safety.

The IRRS mission covered all civilian nuclear and radiation source facilities and activities regulated in Hungary. The review compared the Hungarian regulatory framework for safety against IAEA safety standards as the international benchmark for safety. The mission was also used to exchange information and experience between the IRRS team members and the Hungarian counterparts in the areas covered by the IRRS.

The IRRS team consisted of 16 senior regulatory experts from 11 IAEA Member States, 3 IAEA staff members, 1 IAEA administrative assistant and two observers. The IRRS team carried out the review in 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 including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; control of medical exposures, occupational radiation protection, control of radioactive discharges and materials for clearance, public and environmental exposure control, transport, waste management and decommissioning.

The IRRS mission included two policy issue discussions: resources required for the regulatory supervision of the construction of new nuclear power plants (NPPs) and the organization of clinical audits.

The mission included observations of regulatory activities and interviews and discussions with staff of the HAEA, the OCMO, the Budapest RHD, the BCDEPN, representatives from technical support organizations including the National Research Institute for Radiobiology and Radiohygiene (NRIRR). Activities included visits to: Paks NPP; National Institute of Oncology, Budapest Radiation Hygiene Decentre, Budapest Research Reactor, IKI KFT, and the national radioactive waste repository. The IRRS team members observed regulated activities and performance of inspection activities, including discussions with the licensee personnel and management.

In preparation for the IRRS mission Hungary conducted a self-assessment and prepared a preliminary action plan to address weaknesses that were identified. The results of the self-assessment and supporting documentation were provided to the team as advance reference material for the mission. Throughout the mission, the IRRS team was extended full cooperation in the regulatory, technical, and policy issues by all parties in a very open and transparent manner.

The IRRS team observed that all Hungarian counterparts were committed to provide effective oversight of regulatory functions covering its nuclear programmes and a diverse range of activities with radiation sources.

The most significant challenge at the time of the mission was a complex distribution of regulatory responsibilities among several authorities within different ministries. Other challenges identified by the IRRS team include the effective independence of the regulatory body; and the effective coordination of and collaboration between and within, the regulatory authorities.

The Hungarian Parliament recently enacted the 'Project' Act VII of 2015 on the modification of the regulations connecting to the construction of new nuclear power plant units. The Project Act amends the Act on Atomic Energy in several sections. The new provisions will extend the competence of the HAEA over the complete supervision of all uses of radiation and should help address these challenges. In addition, the Project Act will significantly increase the size of the HAEA. This major and long transition creates additional challenges and will place increased importance on effective knowledge transfer and change management.

The IRRS team identified a number of good practices and made recommendations and suggestions that indicate where improvements are necessary or desirable to continue enhancing the effectiveness of regulatory functions in line with IAEA safety standards.

The good practices identified by the IRRS team include:

- The HAEA has established indicators to monitor research reactor and ISFSF safety performance.
- The HAEA has developed an aide to determine the appropriate post event investigations and oversight of corrective actions.
- Hungary has conducted a multi-unit NPP severe accident emergency exercise.
- The regulatory body has developed an effective database "Hungarian Nuclear Knowledge Data Base" to preserve and update knowledge gained during the use of atomic energy in Hungary.

The IRRS team identified certain issues warranting attention or in need of improvement and believes that consideration of these would enhance the overall performance of the regulatory system:

- The Government:
 - should implement appropriate provisions to ensure the effective independence of the regulatory body from the facilities and activities that it regulates
 - should ensure that all regulatory authorities have sufficient staffing and resources and timely approvals to use them to enable the proper discharge of their assigned responsibilities
 - 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 repositories and for radiation sources
- The regulatory body:
 - \circ should ensure that its structure and organisation enable effective fulfilment of its statutory obligations.
 - $\circ\,$ should develop a long term human resource plan to ensure that competences and skills are maintained.
 - should take appropriate measures to ensure that the regulatory control of all facilities and activities remain as stable as possible during the phases of transferring regulatory responsibilities.
 - should enhance its management systems and develop procedures to promote and support a strong safety culture.

The IRRS team findings are summarized in Appendix V.

An IAEA press release was issued at the end of the IRRS Mission.

I. INTRODUCTION

At the request of the Government of Hungary, an international team of senior safety experts met representatives of the Government, the Hungarian Atomic Energy Authority (HAEA), The Office of the Chief Medical Officier (OCMO), the Budapest Radiation Hygiene Decentre (RHD), and the Baranya County Government Office Department of Environmental Protection and Nature (BCDEPN) of Hungary from 11 to 22 May 2015 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of the peer review was to review the Hungarian governmental, legal and regulatory framework for nuclear and radiation safety. The review mission was formally requested by the Government of Hungary in January 2012. A preparatory mission was conducted from 1 to 2 October 2014 at the HAEA Headquarters in Budapest, Hungary to discuss the purpose, objectives, scope and detailed preparations of the review in connection with the facilities and activities regulated in Hungary. The HAEA was ensuring national coordination in the preparation and conduct of the IRRS Mission.

The IRRS team consisted of 16 senior regulatory experts from 11 IAEA Member States, 3 IAEA staff members, 1 IAEA administrative assistant and 2 observers. The IRRS team carried out the review in 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 including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; occupational radiation protection; control of medical exposures occupational radiation protection; public and environmental exposure control; transport, waste management and decommissioning.

In addition, two policy issues were discussed in connection to the resources required for the regulatory supervision of the construction of new nuclear power plants (NPPs) and the organization of clinical audits.

The HAEA, the OCMO and the BCDEPN conducted a self-assessment in preparation for the mission and the HAEA and the BCDEPN prepared a preliminary action plan. The results of the self-assessment and supporting documentation were provided to the team as advance reference material for the mission. During the mission the IRRS team performed a systematic review of all topics by reviewing the advance reference material, conducting interviews with management and staff from the HAEA, the OCMO, the RHD of Budapest, the BCDEPN and their technical support organization, the National Research Institute for Radiobiology and Radiohygiene (NRIRR) and performed direct observation of their working practices during inspections. Meetings with representatives of the Ministry for National Development, Ministry of Human Capacities, and Ministry of Agriculture, were also organized.

All through the mission the IRRS team received excellent support and cooperation from all Hungarian Counterparts.

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to conduct a review of the Hungary's radiation and nuclear safety regulatory framework and activities to review its effectiveness 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 safety and its good practices.

The key objectives of this mission were to enhance nuclear and radiation safety, emergency preparedness and response:

- Providing Hungary and the HAEA, the OCMO, the RHDs and the BCDEPN, through completion of the IRRS questionnaire, with an opportunity for self-assessment of its activities against IAEA safety standards;
- Providing Hungary and the HAEA, the OCMO, the RHDs and the BCDEPN with a review of its regulatory programme and policy issues relating to nuclear and radiation safety, and emergency preparedness;
- Providing Hungary and the HAEA, the OCMO, the RHDs and the BCDEPN with an objective evaluation of its nuclear safety, and emergency preparedness and response regulatory activities with respect to IAEA safety standards;
- Contributing to the harmonization of regulatory approaches among IAEA Member States;
- Promoting the sharing of experience and exchange of lessons learned;
- Providing reviewers from IAEA Member States and the IAEA staff with opportunities to broaden their experience and knowledge of their own fields;
- Providing key HAEA, OCMO, RHD and BCDEPN staff with an opportunity to discuss their practices with reviewers who have experience with different practices in the same field;
- Providing Hungary and the HAEA, the OCMO, the RHDs and the BCDEPN with recommendations and suggestions for improvement; and
- Providing other States with information regarding good practices identified in the course of the review.

III. BASIS FOR THE 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) was conducted from 1 to 2 of October 2014. The preparatory meeting was carried out by the appointed Team Leader Mr Michael Johnson, Deputy Team Leader Mr Mika Markkanen and the IRRS IAEA Team representatives, Mr Tim Kobetz, Mr Hilaire Mansoux and Mr Rodrigo Salinas.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of the HAEA represented by Mr Kristóf Horvath, General Nuclear Deputy Director General, other senior management and staff of the HAEA and representatives of the OCMO, the STRENCI and the NRIRR. The discussions resulted in agreement that the regulatory functions covering the following facilities and activities were to be reviewed by the IRRS mission:

- Nuclear power plant;
- 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.

Representatives from the HAEA, the OCMO and the BCDEPN made presentations on the national context for nuclear and radiation regulatory framework and the self-assessment results to date.

The IAEA staff presented the IRRS principles, process and methodology. This was followed by a discussion on the tentative work plan for the implementation of the IRRS in Hungary in May 2015.

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

The Hungarian Liaison Officer for the preparatory meeting and the IRRS mission was Mr Dániel Nyisztor. The HAEA was ensuring national coordination in the preparation and conduct of the IRRS mission.

The HAEA provided the IAEA (and the review team) with the advance reference material for the review in April 2015, including the self-assessment results. 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 prior to the commencement of the IRRS mission.

The advance reference material included a reference to the newly passed Act VII of 2015 called the Project Act, which amends the Act on Atomic Energy in several section, including the transfer of

responsibilities to the HAEA for the complete supervision of radioactive materials and radiation protection by 1st of January 2016. However, since the IRRS mission took place before the transition takes place, the IRRS mission only reviewed the regulatory framework that was in place at the time of the mission.

B) REFERENCES 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 the reference for this mission is given in Appendix VII.

C) CONDUCT OF THE REVIEW

The initial IRRS team meeting was conducted on Sunday, 10 May 2015 in Budapest, Hungary 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, context 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. In addition, the Team Leader and IAEA staff provided refresher training to the IRRS team to ensure a common understanding of the IRRS process, methodology, report preparation.

The Liaison Officer was present at the opening IRRS team meeting, in accordance with the IRRS guidelines, and presented logistical arrangements planned for the mission.

The reviewers also reported their first impressions of the advance reference material.

The IRRS entrance meeting was held on Monday, 11 May 2015, with the participation of HAEA, OCMO, RHD, BCDEPN, NRIRR senior management and staff. Opening remarks were made by Mr Michael Johnson, IRRS Team Leader, Mr Gyula Fichtinger, Director General of the HAEA, Ms Andrea Kádár, Deputy State Secretary of the Ministry of National Development, Mr Géza Sáfrány, Deputy Director General of the National Public Health Centre and Mr Tibor Schwarcz, Director of the BCDEPN. Mr Gyula Fichtinger, Mr Géza Sáfrány and Mr Tibor Schwarcz gave an overview of the Hungarian context, the roles and responsabilities of the HAEA, the OCMO and the BCDEPN.

During the mission, a review was conducted for all the review areas with the objective of providing Hungary with recommendations and suggestions for improvement as well as identifying good practices. The review was conducted through meetings, interviews and discussions, visits to facilities and direct observations regarding the national practices and activities.

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

The IRRS exit meeting was held on Friday, 22 May, 2015. The opening remarks at the exit meeting were presented by Mr Gyula Fichtinger, Director General of the HAEA, and were followed by the presentation of the results of the mission by the IRRS Team Leader Mr Michael Johnson. Closing remarks were made by Mr Grzegorz Rzentkowski, IAEA Director, Division of Nuclear Installation Safety.

A joint IAEA and HAEA press conference took place at the end of the mission during which an IAEA press release was issued.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

Hungary is a country with a long-standing and mature radiation and nuclear safety legal system. It reemphasised Hungary's commitment to safety in a National Security and Safety Strategy statement, which was approved by Government Resolution in 2012. The Strategy declares Hungary's support for the continuous improvement of nuclear safety, and that it supports international efforts for strengthening the global safety frameworks.

The Act CXVI of 1996 on Atomic Energy sets the framework from which Hungary's comprehensive regulatory legislation has been developed – and upon which the legislation and authorizations are based. Since its first adoption, the Act has been regularly amended to take account of developments in nuclear and radiation safety.

The Act on Atomic Energy reflects Hungary's long-term commitment to safety and it states the priority of safety; identifies the responsibilities for nuclear and radiation safety and for its supervision; prescribes the regular review of the safety regulation; and prescribes the responsibility for preparation of long-term safety related strategies (including decommissioning and waste disposal).

The Act on Atomic Energy further defines the responsibilities of the users of nuclear facilities; waste management facilities; radiation sources facilities and activities; and related regulatory control activities. A graded approach is applied in addressing the type of facilities and activities, and the associated risks. The Act authorises the development of detailed regulations and the associated inspection system proportional to the risk.

Hungary has welcomed numerous peer reviews over the years and has used the feedback in developing their nuclear and radiation safety infrastructure. This has led to the current set of arrangements that strive to, and largely, meet the IAEA safety standards.

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The Act on Atomic Energy provides the basis for the legally binding framework of nuclear and radiation safety in Hungary. Subsequent governmental decrees, issued in accordance with the Act, provide allocation of responsibilities to ensure the governmental, legal and regulatory framework for nuclear and radiation safety is effective. All types of nuclear facilities; waste management facilities; and radiation sources facilities and activities; are covered by the Act.

The IRRS team noted that the rule making process to amend legislation on the nuclear and radiation safety requirements can take a very long time to progress through the government procedures. As an example, the rule making process to develop Governmental Decree 118/2011 Korm. (on the nuclear safety requirements of nuclear facilities and on related regulatory activities) together with its associated Annexes, was started in 2005; drafts were available for the law making process during 2008; but, due in part to the delayed response from the Ministry of National Development, it wasn't published until 2011. The IRRS team noted that the Government needs to consider ensuring that the legislative proposals submitted by the regulatory body are processed in a timely manner, consistent with a graded approach, within the Ministry responsible for the regulatory body.

Also, in accordance with the Act, except for the defence sector, the regulation of licensing and inspection relating to activities with radioactive materials and equipment generating ionizing radiation lies within the scope of competence of the Minister responsible for health. Ministerial Decree 16/2000. EüM includes arrangements for licensing and inspection; it regulates the scope of competence of both the OCMO and

the RHDs. The scope of radiation sources which are not under the Act on Atomic Energy are regulated by Governmental Decree 124/1997. Korm. The exempt activity concentrations and exempt activities of radionuclides are regulated by Ministerial Decree 23/1997. NM.

In accordance with the Act, Ministerial Decree 16/2000. EüM requires each licensee to establish a radiation protection service. The decree regulates the functions of the radiation protection service.

Environmental impact assessment and authorization is carried out by the BCDEPN based on the prescriptions of the Governmental Decree 314/2005. Korm. Ministerial Decree 15/2001. KöM. on the control of radioactive emissions to air and water specifies the environmental radiological tasks.

The legal and financial provisions for the management of spent fuel and radioactive waste are addressed in Section 1.7.

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

The national regulatory body comprises several organisations including the HAEA, the BCDEPN, the OCMO and the RHDs. Their roles and responsibilities are outlined below.

The HAEA is a government office with its resources provided by the Government and most of the funding is provided by fees paid by the licensee of nuclear facilities. The independence of the HAEA for its professional and regulatory decision making is provided for in the Act on Atomic Energy. The HAEA is supervised by the Minister of National Development.

The HAEA was established and empowered by the Act on Atomic Energy as the nuclear safety authority and was delegated the competence to perform regulatory tasks including: licensing, approving, inspecting, accounting, assessing, identifying and reviewing, and conducting enforcement procedures.

Within the Ministry of National Development, the State Minister for energy affairs has responsibility for both the Paks NPP and the HAEA. Although the Minister's responsibility for the HAEA is solely 'supervisory', the Ministry may face conflicting considerations when progressing the development of legislative provisions submitted by the HAEA. Similarly, the Ministry may face conflicting considerations when reviewing HAEA resource and organizational change submissions. The IRRS team noted that the Director General of the HAEA does not currently have prompt and unconstrained access to the highest level of the Ministry of National Development to address issues of regulatory concern. The Director General of the HAEA needs approval on the HAEA's 'Organisational and Operational Rules'. The current approved version is dated 2007 which does not reflect the current organization and operation of the HAEA. Additionally, the Director General of the HAEA does not have the authority to spend certain budgeted resources without prior approval from the Ministry of National Development. Examples include the purchase of information technology equipment; office furnishing; and office space (buildings). The IRRS team noted that applications for approval for such resources have not been acted on in a timely manner, which has had an effect on the ability of the HAEA to fulfil its regulatory functions. All of these matters raise concerns regarding the independence of the regulatory body.

The IRRS team noted that the Hungarian legal provisions, established in Governmental Decree 118/2011. Korm. (and its Annexes) under the Act, prescribe time limits for the regulatory body to complete various authorization processes. Similarly, for the OCMO and the RHDs, the Act CXL/2004 (KET) also prescribes time limits which may lead to undue pressure on the regulatory body to complete its decision making process and thus compromise safety. This issue is also discussed in Section 5.1.

All authorities in Hungary are required to conduct their procedures according to the general rules of the KET, which also ensures independent decision making. Conflicts of interest are resolved in accordance with the Act CXCIX of 2011 on civil servants. The HAEA's independent decision-making is assured by separate Acts of Parliament, including Act XLIII of 2010 and the Act on Atomic Energy. However, where

issues arise of shared competence legally defined 'co-authorities' must be involved under the KET rules of procedure. The co-authorities for the HAEA are defined in Governmental Decree 112/2011. Korm.

Section 20 of the Act on Atomic Energy prescribes the regulatory functions of the Minister responsible for health. In accordance with the Act on Atomic Energy the Ministerial Decree 16/2000. EüM regulates the scope of competence of the the RHDs and the OCMO as the radiation safety authority. The resources of the OCMO and the RHDs are paid from the central government budget. Most roles of the OCMO and the RHDs regarding radiation safety will be transferred to the HAEA under the provisions of the 'Project' Act VII of 2015.

The Act on Atomic Energy provides for the independence of the OCMO and the RHDs from any other organs or organizations interested in promotion and development of facilities or activities including those involving power generation, use of radiation sources, management of spent fuel and radioactive waste management.

A potential area where independence might be compromised is in the use of radiation in health care as both medical and radiation safety aspects are supervised by the Minister responsible for Health. The RHDs have belonged to the Governmental Office (under the supervision of Ministry of Public Administration), since 2011, and since 2014 belongs to the Prime Minister's Office.

The RHDs operate as part of the Public Health Administration Department of seven County Local Government Offices. The scope of competence of the RHDs is established by Governmental Decree 323/2010. Korm.. The OCMO, according to Government Decree 323/2010. Korm., exercises professional control of the RHDs.

The environmental protection arm of the regulatory body is the BCDEPN which establishes discharge limits for different types of nuclear and radiological facilities and provides environmental regulatory supervision. Their legal authority is derived from Government Decree 71/2015 on the designation of environmental and nature protection authorities and administrative bodies; and Ministerial Decree 15/2001. KöM. on the control of radioactive emissions to air and water.

The Hungarian Parliament has recently accepted the 'Project' Act VII of 2015 on the modification of the regulations involving the construction of new nuclear power plant units. The Project Act amended the Act on Atomic Energy in several sections. The new provisions (inter alia):

- extend the competence of the HAEA over the supervision of uses of radiation, and authorize the Government to establish the relevant decrees;
- define the terminology associated with radioactive waste repositories and extend the nuclear facility specific regulations over them;
- establish individual salaries for the government officers of the HAEA; and
- guarantee that the revenues of the HAEA can only be used for regulatory purpose.

In addition, the Project Act extends the authority of the HAEA over the construction of general civil structures and buildings of nuclear facilities and radioactive waste repositories.

In terms of allocation of sufficient human and financial resources, from the Advance Reference Material and the discussions held during the mission, the IRRS team came to the conclusion that with the exceptions noted in Sections 3.1 and 7.5, the resources allocated to the HAEA seems to be adequate. There is a well-recognized lack of resources for the OCMO, the RHDs and the BCDEPN (see Sections 3.1 and 7.5 for more details).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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 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."

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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.

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."

(1)

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.

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

(1) 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."

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.

1.4. COMPLIANCE WITH REGULATIONS AND RESPONSIBILITY FOR SAFETY

The person or organization having prime responsibility for the safety of nuclear and radiation facilities and activities is identified in the Act on Atomic Energy. The scope of this responsibility is defined in the Act and in Governmental Decree 118/2011. Korm. The Act prescribes that the responsibility for safe operation of facilities, and for compliance with and for enforcement of the safety requirements, rests with the licensee throughout the whole life cycle of the facility. There are only two methods to terminate the responsibility for nuclear safety:

• if the responsibility for safety is transferred to a new licensee; or

• if the provisions of the Act no longer apply (i.e. the site no longer meets the definition of a facility under the Act), the responsibility no longer applies.

The Act states that compliance with the provisions of the Act does not exempt the licensee from the responsibility for safety. Governmental Decree 118/2011. Korm. also strengthens this by stating that regulatory requirements and inspections do not exempt the licensee from their responsibilities. The Act also provides the regulatory authority with the powers to require the demonstration of the licensees' compliance with safety requirements.

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

The Act on Atomic Energy provides a list of authorities responsible for inspecting the safety of facilities and activities and identifies their related tasks. Each of these tasks is detailed in implementation decrees relating to different fields. The decrees also define the designated 'co-authorities' which have to be consulted in a number of circumstances in particular when legislation is proposed or amended.

In the Hungarian legal system, authority cooperation is primarily realized by a system of 'co-authority' contributions codified in Hungary's Administrative law (specifically the KET). Cooperation between authorities may be further amplified in memoranda of understanding. While the KET generally prescribes the methodology for harmonizing authority functions, the Act on Atomic Energy gives precedence to the HAEA in the event of nuclear safety disputes.

To avoid overlaps and gaps in the scope of competence, administrative consultation of draft legislation is carried out by governmental bodies with relevant areas of responsibility. Additionally, the memoranda of understanding between authorities ensure that there is no undue duplication in the regulatory proceedings. Where appropriate this can lead, in some cases, to authorities carrying out joint inspections. When the requirements on licensees appear contradictory the situation is resolved by coordination, or ultimately by judicial decision.

To provide for the effective coordination between the co-authorities, they may enter, inter alia, into memoranda of understanding, or conduct joint inspections. The HAEA has memoranda of understanding with the co-authorities designated in Governmental Decree 112/2011. Korm, and periodically organizes co-authority forums. Similarly, cooperation between the 'co-authority' responsible for fire protection and the HAEA is addressed in Ministerial Decree 19/2007. ÖTM.

In the current realignment of regulatory responsibilities proposed by the Project Act, some specific responsibilities, like regulatory oversight of exposures due to Radon, have not yet been allocated.

The responsibilities and functions of the OCMO and the BCDEPN are specified in the legislation. The establishment of the OCMO is provided for in Ministerial Decree 16/2000. EüM and the scope of its mandate is defined in Governmental Decree 323/2010. Korm. The BCDEPN was established within the Baranya County Government Office in March 2015 under Governmental Decrees 66/2015. Korm. and 71/2015. Korm.

In Hungary, legal provisions exist to enable effective communication, consultation and coordination between and within the regulatory authorities which comprise the regulatory body and with other organizations. The IRRS team noted that the complexity of the regulatory regime for the control of radiation sources, and the complex arrangements for communication, consultation and coordination between the authorities involved, hinders effective information exchange. Similar issues have been identified regarding the communication between regulatory authorities during the transfer of responsibilities for safety oversight of the radioactive waste repositories. This is of concern in view of the planned redistribution of regulatory functions between the regulatory authorities to avoid future inconsistencies, gaps and overlaps in the regulatory oversight. These specific examples are further explained, and other examples identified, in Sections 4.4, 5.4, 7.5 and 11.1.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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.

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."
 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

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

radiation sources.

Governmental Decree 17/1996. Korm. states the actions to be taken in connection with found or seized radioactive or nuclear materials. It describes how the regulatory body should respond to the issue of 'sources of artificial origin' being out of regulatory control. In the event of such a source being found, the process for taking it into regulatory control is identified and the NRIRR, together with the HAEA, have the facilities and expertise to achieve control.

For existing situations in Hungary, the uranium mining facility at Mecsek being a prime example, the strategy for managing radiation and nuclear safety (including remediation and environmental protection) is addressed in specific legislation.

Responsibilities for protective actions to reduce existing or unregulated radiation risks are allocated to the individual elements of the regulatory body (the HAEA, the OCMO and the BCDEPN) in the Act on Atomic Energy and amplified in specific legislation for each authority. This is the case for dealing with both sources outside of regulatory control and any associated emergency arrangements.

In an emergency caused by radioactive or natural source being out of regulatory control the national disaster management organization is responsible for taking protective actions to protect the environment and the population. Technical input to assist in its decision making processes is provided by the HAEA, the NRIRR or the BCDEPN as appropriate. However, the national legislative and regulatory framework does not include comprehensive responsibilities and actions to be performed in order to recover orphan radioactive sources outside the authorised facility.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES 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.

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

The Act on Atomic Energy specifies that the ultimate responsibility for decommissioning and the management of spent fuel and radioactive waste generated in Hungary is the responsibility of the Hungarian state. However, in 1996 the Act also stated that radioactive waste management facilities (e.g. repositories) were not considered to be nuclear facilities which, initially, led to a divided authority and regulatory system. This was resolved in an amendment to the Act in 2013 which addressed the safety requirements for facilities for storage and disposal of radioactive wastes. The amendment, and subsequent implementation legislation, modified the safety regulatory system of radioactive waste repositories to mirror that of the facilities and for the HAEA to be the main licensing and oversight authority.

Since the modification of the Act on Atomic Energy in 2013 the Parliament, in 2015, approved a national policy on management of spent fuel and radioactive waste. The national policy applies to all radioactive waste and nuclear spent fuel generated in Hungary, from origin until final disposal, including the decommissioning of nuclear facilities.

A detailed programme to reflect this policy has been developed by Public Limited Company for Radioactive Waste Management (PURAM), designated by the Hungarian Government, under the supervision of the Ministry of National Development together with the HAEA. The programme awaits Government approval, which is required before August 2015 to meet the requirements of the EU Directive on radioactive waste and spent fuel management. The programme includes an estimate of future spent fuel and radioactive waste generation, together with spent fuel and radioactive waste from decommissioning. Additionally, it includes associated targets and dates for the programmes stages, and describes the necessary associated research and development needs. It estimates the costs associated with this programme, which will be reviewed annually and charged to the operators, and the revenue held in a Central Nuclear Financial Fund. The size of such a fund, necessary to cover all stages including decommissioning, storage and final disposal will be difficult to predict and hence the charges to operators will also be a challenge to estimate to ensure that the Fund will be sufficient for the whole programme.

The PURAM is tasked with the development and implementation of the Hungarian programme for radioactive waste and spent fuel management including the final disposal of radioactive waste; interim storage of spent nuclear fuel; and closure of the nuclear fuel cycle and decommissioning and dismantling of nuclear facilities.

The HAEA is the main licensing and oversight authority for spent fuel storage facilities and radioactive waste repositories. This includes, inter alia, licensing; inspection of nuclear safety; licensing and inspection of design, operation and modifications; and approval of emergency response plans.

The OCMO is the licensing authority for radiation protection regulation of the major facilities. The OCMO also participates in the nuclear safety licensing procedures as a co-authority on radiation health questions.

The BCDEPN is the environmental licensing and oversight authority for radioactive waste facilities and spent fuel facilities by Governmental Decree 314/2005. Korm. The BCDEPN also participates in the nuclear safety licensing procedures as a co-authority on environmental matters.

1.8. COMPETENCE FOR SAFETY

The competencies for all parties with nuclear safety responsibilities is addressed in the Act on Atomic Energy which provides for the requirements on ensuring and acquiring adequate general and professional competences, and designates the members of the Government responsible for the general and personnel training.

Regulatory staff, as Government employees, are required to obtain the appropriate basic and professional public administration qualifications for their position. Subsequent professional training is provided by the regulatory body through workshops and further education.

In addition, in accordance with the Ministerial Decree 16/2000. EüM, persons performing regulatory inspection of radiation safety are required to have comprehensive radiation protection qualifications.

Governmental Decree 323/2010. Korm. provides detailed regulatory requirements for medical officers working in government offices. In particular, medical officers working for the RHDs are required to have or obtain the professional qualification on radiation health within five years of appointment.

The HAEA has developed a database profiling the available organizational expertise and has used this to determine the shortfall in staffing. After several years of decreasing staffing levels, due to government imposed constraints, higher staffing levels were approved by the government at the end of 2014 and the HAEA has authorisation to increase its staffing level by 76 personnel.

The HAEA coordinates the national nuclear safety research and development programme, as required under the Act on Atomic Energy. The HAEA receives funding from the Government for this task and ensures that the needs of the regulatory body are addressed. The HAEA then allocates the remaining resources for research and development as requested by the technical institutes and support organisations.

In Hungary, in the area of radiation safety, there are competent experts in many specialisms including medical physics, radiation protection, occupational health, and quality assurance. Some of them are involved in the authorization process. However, there is no formal recognition of medical physicists and no unified formal recognition of qualified experts for radiation protection in accordance with the requirements of GSR Part 3.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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.

1.9. PROVISION OF TECHNICAL SERVICES

Technical services such as personal dosimetry, environmental monitoring are provided by the NRIRR which has laboratory facilities and also provides technical advice to other organisations including licensees, among other authorised organisations. Any issues of potential conflicts of interest are addressed by a Memorandum of Understanding and contract

1.10. SUMMARY

Hungary is a country with a long-standing and mature nuclear radiation and safety legal system. The Act CXVI of 1996 on Atomic Energy sets the framework from which the comprehensive regulatory legislation has been developed. Since its adoption, the Act has been regularly amended to take account of developments in nuclear and radiation safety. The Act reflects Hungary's high level long-term commitment to safety and Hungary has re-emphasised its commitment to radiation and nuclear safety in a National Security and Safety Strategy statement. The Strategy states Hungary's support for the continuous improvement of radiation and nuclear safety; and that it supports international efforts for strengthening the global safety and security frameworks. Currently, the national regulatory body comprises several organisations including the HAEA, the BCDEPN, the OCMO and the RHDs.

Areas of improvement identified by the IRRS team to be addressed:

- The time frames for authorization processes and its pressure on the regulatory body to complete its decision making process.
- The potential conflicts of interest within the Ministry of National Development, and within the Ministry of Health, and the implications for the effective independence of the regulatory body from the facilities and activities that it regulates.
- The lack of the full ability of the Director General of the HAEA to spend the authorised budget to obtain necessary resources, which has an effect on the ability of the HAEA to fulfil its regulatory functions.
- The lack of sufficient qualified staffing and access to sufficient financial resources for all of the regulatory authorities to enable them to discharge their assigned responsibilities.
- The poor communication and cooperation between and within the regulatory authorities comprise the regulatory body, which appears to hamper the quality and effectiveness of the regulatory activities.
- The lack of a comprehensive national strategy establishing the responsibilities and actions to be performed to recover orphan sources.
- The lack of formal recognition for medical physicists and for the unified formal recognition of qualified experts for radiation protection.

2. THE GLOBAL SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

The Act on Atomic Energy provides for cooperation through international conventions and for regular revision, and for updating Hungary's nuclear safety requirements taking into account scientific results and international experiences.

In practice, this legislative initiative is progressed by the HAEA. Hungary is linked to the international system of radiation and nuclear safety. In addition, Hungary is a party to all international conventions and organizations relevant in these fields, and participates in many initiatives to increase the safety of nuclear and radiation facilities and activities in Hungary and abroad.

As such, Hungary actively contributes to the activities of the IAEA, and numerous other international fora including the OECD NEA, WENRA, ESARDA and ENSRA.

Hungary has also signed numerous Government bilateral agreements, and the HAEA is party to international networks, which are dedicated to share news and events relating to nuclear safety (INES-NEWS, IRS, FINAS, etc.).

International conventions

Hungary has joined all conventions related to safety and security of peaceful use of atomic energy and the HAEA performs coordination of the tasks originating from the conventions including the reporting obligations.

Codes of conduct

The HAEA has reviewed the recommendations described in the Code of Conduct for Research Reactors and confirmed that these are covered by Hungarian legislation. The HAEA has expressed its political support to the Code of Conduct on the Safety and Security of Radioactive Sources, however, Hungary has not yet 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.

Internationally agreed IAEA safety standards

To fulfil the obligation of the Act on Atomic Energy for revision of the nuclear safety requirements, the HAEA reviews the Nuclear Safety Codes every five years and prepares amendments taking account of changes to IAEA safety standards, new European legislation and WENRA reference levels. The HAEA also regularly provides experts to participate in the development of the safety standards.

International peer reviews

Hungary regularly makes use of the safety peer review services provided by different international organizations. In return HAEA experts also regularly participate in various international safety reviews.

Multilateral and bilateral cooperation

The Hungarian Government has committed to the strategic aim of providing support to countries introducing nuclear programs in the field of establishment and development of nuclear authority regimes. This is achieved in part by an initiative through the Ministry of National Development to provide structured training programmes within Hungary supported by Institutions and the HAEA. It is also reflected in the work being progressed by the HAEA through the EU INSC to support the authorities in Egypt and Brazil; through the IAEA to support Iran; and through a bi-lateral agreement with Vietnam to train nuclear safety regulators.

Hungary is a party to a large number of multilateral and intergovernmental conventions in the field of radiation and nuclear safety. The HAEA has regulatory authority cooperation agreements with the US NRC, and the Czech, Finnish, Slovak, Slovenian, Romania, Russian and Turkish regulatory authorities to exchange experiences in relation to particular issues and, where appropriate, to incorporate the findings into the national practice. The representatives of these authorities meet regularly in bilateral or multilateral meetings.

The OCMO does not directly participate in international cooperation arrangements. This function is provided by the technical staff of the NRIRR.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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."
	BASIS: GSR Part 1 Requirement 14, para. 3.2(b) states that <i>"The features of the global safety regime include:</i> "
(2)	(b) Codes of conduct that promote the adoption of good practices in the relevant facilities and activities."
S 3	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.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

The HAEA has a comprehensive system in place to ensure the reporting of operating and regulatory experience. This system is described in HAEA Guidance 4.7, "Utilising operating experience."

The HAEA representatives participate regularly and actively in the committee meetings of the IAEA and the OECD NEA and its working groups. Because of the planned construction of new NPP units, it was recently identified as increasingly important that Hungary participates in the Multinational Design Evaluation Program (MDEP). Hungary's application to OECD-NEA in 2014, to join MDEP (specifically the VVER working group) to support Hungary's new build programme, was deferred for further consideration in 2015 by the MDEP Policy Group.

Representatives of the HAEA participate at several committee levels in the European Community including the Council Working Group on Atomic Questions; ENSREG and its working groups; the Commission on the Instrument for Nuclear Safety Co-operation; and the expert working groups established for several EURATOM Treaty Articles.

Representatives of the HAEA also actively participate in WENRA and its working groups; the European Safeguards Research and Development Association (ESARDA); the European Nuclear Security Regulators' Association (ENSRA); and the VVER Regulator's Forum.

Hungary participates in the following international networks: IAEA/NEA Incident Reporting System; IAEA Incident Reporting System for Research Reactors; OECD NEA Fuel Incident Notification and Analysis System; NEA Working Group on Operating Experience; European Clearinghouse; ITDB, and the IAEA International Nuclear Event Scale.

The HAEA has established procedures for addressing issues arising through the information exchange process by notifying the licensee, addressing the issue during routine regulatory inspection, or, in due course, amending the Nuclear Safety Codes. The HAEA has, for the third three-years-period, won the RESPEC (Radiological Emergency Support Project for the European Commission) tender. As a result, Hungary provides assessment and technical assistance to the European Commission in the case of a radiological or nuclear accident either potentially or actually affecting the territory of the European Union. Additionally, the HAEA has won a tender for 3 years for annual EPR fundamentals training for EU members and candidate countries. Hungary is also a party to the European Community Urgent Radiological Information Exchange system.

The OCMO receives an annual report on radiation protection activities from the special facilities. The NRIRR processes and evaluates the report and provides a decision to the OCMO regarding the appropriate actions. NRIRR staff participate in the work of numerous international working groups and organizations, in forums and trainings. The NRIRR disseminates good radiation protection practice guidelines and publishes them on its website, which the OCMO and the RHDs take into account during its licensing and inspection work.

The NRIRR shares its professional experiences during annual workshops of the employees of the health authority and at quarterly meetings of RHDs managers. The IRRS team noted that there does not appear to be a structured operational experience feedback programme in the areas of radiation safety and radiation protection. In addition, there does not appear to be any structured feedback to the facilities, nor is the information analysed and reported publicly. These are aspects that the HAEA would be advised to address when it absorbs the OCMO responsibilities in January 2016.

The BCDEPN also receives an annual report on radiation protection activities from the facilities and the HAEA. The BCDEPN also assesses the reports and takes them into account in its licensing and inspection activities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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

	RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	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.	

2.3. SUMMARY

Hungary is strongly linked to the international nuclear safety network. In addition, Hungary is a party to all international conventions and organizations relevant in this field, and participates in many initiatives to increase the safety of its nuclear facilities. The IRRS team concluded that Hungary has a high level of international cooperation and positively contributes to the global nuclear safety regime.

Hungary has applied to join the MDEP VVER working group to support its new build programme and awaits a response.

The HAEA has a comprehensive system in place to ensure the sharing of operating and regulatory experience.

Areas of improvement identified by the IRRS team to be addressed:

- Hungary has not notified the IAEA of its intention to act in accordance with the IAEA Guidance on the Import and Export of Radiation Sources.
- There is not a comprehensive operating experience and regulatory experience feedback programme for radiation safety and radiation protection.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

The regulatory body consists of several authorities, mainly the HAEA, the OCMO, the RHDs, and the BCDEPN. For about a year the regulatory body has entered into a transition phase that is not yet finished. At least four ministries are involved directly, the Minister of National Development, the Minister of Human Capacity, the Minister of Agriculture, and the Prime-Minister Office. For specific aspects several other ministers might be involved in addition e.g. in case of a nuclear emergency.

The budgets of these regulatory authorities are partly coming from the state budget and partly from levies paid by the licensees (especially in the case of the HAEA).

The HAEA is responsible for the regulation of nuclear installations. Since 1 July 2014, the HAEA is also responsible for the regulation of radioactive waste management facilities and activities. As of 1 January 2016, it will also regulate the safety of radioactive sources, associated facilities and activities.

Associated with the expansion of the Hungarian nuclear power programme, the HAEA is getting 76 new staff. Recruitment is underway (see module 3.3). An additional 10 new positions will be given for the regulation of radiation source facilities and activities. This will double the current staffing level of the HAEA. The HAEA has drafted a new organizational chart which has been submitted to the responsible Minister for approval and is in the process of acquiring additional space for its headquarters.

Until end of 2015, the OCMO and the RHDs are responsible for regulating radiation source facilities and activities. The OCMO has approximately 4 full time staff. The seven RHDs use approximately 45 full time staff, about 30 of them with regulatory duties.

Since April 2015, the RHDs are administratively directed by County Government Offices under the Prime-Minister but also receive technical and professional instructions by the OCMO (under Ministry of Health) through the official channels.

Since April 2015, the Baranya Country Government Office Department of Environmental Protection and Nature Conservation (BCDEPN) has replaced the South Transdanubian Environmental and Nature Conservation Inspectorate for regulating environmental protection. The new formed authority has 2 full time staff involved in regulatory functions. The BCDEPN has 4 full time staff for all environmental radiological issues (2 experts for licensing, 2 employees for laboratory works) for nuclear facilities. The BCDEPN is within the County Government Office under the Prime-Minister's office. The BCDEPN intends to cover the impact of the foreseen workload associated to the planned Paks II units by relieving the 2 full staff involved in regulatory nuclear functions from all other duties. The number of staff that will finally be available is still uncertain.

The current organizational structure of the regulatory body is given in Appendix VIII.

The regulatory body's obligations are defined by law. The overall organizational structure of the regulatory body is in transition and the IRRS team noted that all organizations may face significant challenges associated to these organizational changes. The current organizational structure of the HAEA is waiting for approval.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES		
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.	

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY ACTIVITIES

The legal provisions for the independence of the regulatory body are described in section 1.3. Legal provisions in the KET establish a well-developed integrity policy and prevent conflicts of interests for civil servants, including staff of the regulatory body. The "Safety policy and the regulatory Code of Conduct" of the HAEA gives detailed behavioural rules for HAEA staff in case of a conflict of interest. In addition, an integrity adviser has been designated to the director general of the HAEA to assess integrity and corruption risks. The regulatory body is independent in making decisions on nuclear and radiation safety.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

With regards to regulatory oversight of waste management facilities, a large set of competencies is needed to assess activities and interconnected processes that occur inside a facility, in the geosphere and the environment. Depending on the different phases of the lifetime of radioactive waste disposal facilities, competencies in areas such as radiochemistry, engineering, ventilation, handling of materials, hydrogeology, geology, geochemistry, geomechanics, and computer modelling are needed by the regulatory body. For some of these expertizes the Hungarian Mining Authority and the regional mining authorities (belonging since April of 2015 to the County Government Offices) might supply the knowledge needed. The IRRS team was informed that the HAEA assigns two specific staff to regulate RWM and plans to raise the number to four by the end of 2015 and that some of the needed skills are available at the HAEA.

The HAEA had developed a database profiling the available organisational expertise and in the light of the Government's plans to build the Paks-2 new units, it has used this to determine the shortfall in staffing. The HAEA made a detailed calculation of the necessary capacity and expertise related to the new tasks up to the year 2038. The HAEA projects that its staffing needs will increase by an additional 40 staff by 2017 and another 40 in 2021. Due to the on-going recruitment of new staff and loss of senior staff to retirement, training and knowledge sharing will be of utmost importance for the HAEA.

Regarding the future additional responsibility for radiation safety, the HAEA will have to recruit and retain sufficient staff with adequate competences such as radiochemistry, dosimetry, medical physics, radiation physics, and in-depth knowledge of applied technologies. In addition, the IRRS team noted that also support from TSOs is likely to be needed. The IRRS team was informed through the ARM and during interviews that in the current oversight of radiation source facilities and activities, the lack of qualified staff is of concern.

The HAEA has had difficulty attracting and retaining qualified staff due to salary levels that are not competitive with industry, suppliers and some TSOs. Through the Project Act, the Government

authorized the increase of HAEA salaries to enable the HAEA to counteract the exodus to the TSO's and the industry. These issues were identified by the HAEA in its self-assessment and considered in its action plan. The HAEA has started recruiting new staff, and needs to educate and train them, especially those coming directly from university.

The HAEA had developed a knowledge database as part of the quality system several years ago. However, this database has not been updated with the fields of expertise. In light of the new functions assigned to the HAEA, the database needs to be updated and maintained.

The HAEA has a systematic approach to training. However, the HAEA identified in its self-assessment that the transfer of the existing institutional and personal knowledge and information to the new staff is not effective and identified actions to improve the situation. The IRRS team noted that this is especially valid for waste management.

Regarding other regulatory authorities (the OCMO, the RHDs and the BCDEPN), the IRRS team noted that none have developed appropriate human resources plans with the number of staff needed and the competences necessary for them to perform their regulatory obligations.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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.

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

In its safety related activity, the HAEA can rely on its Scientific Advisory Committee (HAEA SAC), whose scope of work is defined by Subsection (7) of Section 8 of the Act on Atomic Energy. Based on the Act on Atomic Energy (Paragraph (a) of Section 67) the designation and withdrawal of the members, and the organization and operation of the advisory committee is regulated in Govt. Decree 112/2011. Korm. (Section 6). The necessary independence is ensured, together with what said above, by the operational rules of the HAEA SAC, including the rights and responsibilities of the members, and the order of meetings and decision-making.

The HAEA has a systematic approach for obtaining the services of TSOs. There is a database with available expertise at the TSO's. The HAEA has a policy for technical support activities, to be reviewed every 3 to 4 years with objectives, technical areas and with an estimation of financial needs, as well as with attention for the issue of conflicting interests. The implementation of the policy is regulated by an HAEA procedure.

Experts who give their independent opinion about an issue, have to be on a register as an expert. The register specifies the requirements for each speciality which is: the expertise, a further detailed description of the expertise, necessary graduation of the experts, and necessary experience of the expert. The HAEA

has members on Hungarian Chamber of Engineers' relevant subcommittees. The subcommittees approve experts listed in the register. The register is maintained by the Hungarian Chamber of Engineers; however, the Parliament recently decided that maintaining the register shall be a task of the HAEA. There are no specifications for what experts should do to keep their knowledge 'state of the art'. The IRRS team noted that not having requirements to maintain the proficiency of experts in the register makes the knowledge infrastructure vulnerable.

An expert is not allowed to work for the regulatory body and a licensee on the same issues. TSO experts working on projects assigned by the HAEA provide a statement that they are not also working on the same subject for a licensee. The licensee of a nuclear facility shall reveal the name of the expert working on a project, and on request of the HAEA, the TSO shall provide information about the activities of the expert.

According to the KET, in some situations an expert may be appointed by the HAEA. The HAEA can prepare "an experts contract" or "a TSO agreement". Before advising the HAEA experts have to declare their independence for the appointment.

However, provided the activities are different, a TSO expert is allowed to work on different subjects for the regulatory body, a licensee, or a licensee's supplier simultaneously. The ability to work simultaneous tasks could lead to a conflict of interest. In addition, the TSO might work for the regulatory body, a licensee, or the licensee's supplier with different experts with the same technical expertise on the same subject. Both scenarios potentially challenge the independence and objectivity of TSO's and experts.

NRIRR is the dedicated TSO of the OCMO and the RHDs and collaborates with them according to Ministerial Decree 16/2000 EüM. The opinion of experts who are certified by some organizations (e.g., Health Registry and Training Centre and Hungarian Cabinet of Engineers Association) is also taken into account. The KET also applies to the health authorities. For other experts no specific provisions to cover a conflict of interest are available.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

The regulatory body uses various means to inform authorized parties including official communications, publications, website, and official and informal meetings. The HAEA holds meetings with the licensees before application submission and during the licensing process, as appropriate. The management of the HAEA regularly holds meetings with the management of authorized parties.

The regulatory body uses formal and informal communication to build up a constructive relation with licensees.

Regarding resolutions and their justification, the HAEA strives for a formulation as simple and clear as possible, and by referring to legislative prescriptions in support of them.

The public hearings of the regulatory body give an opportunity for interested parties to provide comments. This issue of inspectors' objectivity is addressed in Suggestion 6 in Section 7.2.3.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

The overall legal and regulatory framework is well established. Guidelines for its implementation by licensees are established and made publicly available. In addition, the HAEA has a formal process in the management system to ensure stability in regulatory control and prevent subjectivity. Regulatory decisions are made in accordance with established procedures and must be countersigned by at least two officials including the (deputy) director-general.

However, the on-going and anticipated redistribution of regulatory responsibilities will pose challenges in ensuring stability and consistency of regulatory control.

The IRRS team noted that, due to the on-going and anticipated redistribution of regulatory responsibilities, the HAEA faces challenges in maintaining the stability and consistency of regulatory control. In some instances the responsibilities of the individual co-authorities are still uncertain or unclear as discussed in chapter 1.5, 4.4 and 5.4. Therefore, it is important for the HAEA to focus on ensuring the stability and consistency of conducting the regulatory oversight of all regulated facilities and activities during the transition.

The IRRS team calls the attention of the HAEA to INSAG 18, para. 30 which states that "In times of change, there is significant pressure on the approach to safety and on the safety culture of both, organizations and individuals. The key mission for the leaders of an organization should therefore be to hold as their top priority the need to remain focused on maintaining and enhancing the overall safety culture of the organization. An appreciation of the key elements which support a strong safety culture and, in particular, the need to visibly reinforce the corporate commitment to safety in a way which is credible to the workforce and to continue to communicate honestly and openly about safety matters is vital. The effect of change on the individual's commitment and the impact that this can have on the maintenance of a good safety culture must be recognized. Thus, all actions taken by the leaders in planning and implementing change are to be tested in terms of the effect they will have on the perceptions of individuals about these key elements as beacons of stability within periods of inevitable uncertainty."

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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.

(1)	BASIS: GSR Part 1 Requirement 22 states that <i>"The regulatory authority shall ensure that regulatory control is stable and consistent."</i>
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.

3.7. SAFETY RELATED RECORDS

According to the Ministerial Decree 11/2010. KHEM, for the users of radioactive materials, the licence holder is obliged to manage a local register, which is regularly verified by the HAEA and compared with the physical inventory. Based on the information given by the licensees, the HAEA has established a central register. A guideline established by the HAEA supports the clients on the registration to the central register of radioactive materials and on the operation of local registers. All sources exceeding the exemption level are included in the register. The sources whose owner is not known are registered under the code name "Orphanage". The NRIRR maintains a register with records of occupational doses.

The HAEA requires regular and event reports from the licensee of every nuclear facility on nuclear safety, physical protection and safeguards areas.

The HAEA takes care of managing records and their verification in Procedure ME-0-0-3 (Management of records) and Procedure ME-2-1-6 (Keeping the central register of the radioactive material and oversight of the local registers).

The licensee of the nuclear power plant is obliged to inform the public at least monthly about environmental monitoring results. The IRRS team noted that it is a requirement for the licence holder to record all information relevant for safety and for decommissioning purposes in a digital format.

The HAEA utilizes the data of the radioactive material register during its physical protection tasks. The HAEA has established a comprehensive and up-to-date register of radiation sources, including radioactive waste. The HAEA operates the national register and inspects the local registers to supervise the peaceful use of radioactive materials.

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

The HAEA has a statutory obligation to inform the public on: the safety of the use of atomic energy, its own activities, important decisions, and safety requirements. The HAEA has developed a Public Information Policy and Strategy (ST-2). A mechanism has been established to obtain feedback from selected interested parties. According to the ST-2 the HAEA collects expectations of interested parties through different communications channels, such as, law makers, international organizations, independent review organizations, co-authorities, journalists, etc. All comments from stakeholders are discussed at management review meetings. The managers designated by the Director-General are responsible for evaluation of the comments, internal investigation if necessary, and taking corrective and/or preventive actions. The HAEA does not assess satisfaction of interested parties. The HAEA answers questions and informs the public about international conventions, tasks, decisions and their justification. The public hearings provide an opportunity to comment and influence the regulatory decisions. In addition, there are periodic educational conferences, an annual Open Day, press conferences, and press releases. The HAEA noted in the ARM that additional information could be provided (action plan 43). Communication with external stakeholders and other interested parties takes place by information shared through the website, holding of media conferences, organization of open days and programs like the conference, "About atomic energy to all."

The HAEA operates a website (http://www.oah.hu/web/v3/HAEAPortal.nsf/web?openagent). The website provides news on all important events connected to its work, and publishes the main parameters and statements of HAEA resolutions. Interested parties can sign-up to a digital newsletter.

The HAEA builds structurally on long term relationships with students and journalists. At universities, 3 to 4 times a year, the HAEA organizes public days for students with lectures and small exhibitions about issues of potential interest. The HAEA also sponsors activities to inform journalists specialized in technical aspects by organizing visits to nuclear installations in Hungary, neighbouring countries, or to IAEA headquarters.

HAEA public reports include, in part:

- The decision on the periodic safety review reports
- Regulatory decisions
- Inspection plans
- A yearly report with the evaluation of nuclear safety (sent to interested parties)
- A yearly report about the safe of use of atomic energy in Hungary (for Government and Parliament) including all regular and international activities
- Reports to international conventions.

The licensees whose licensed facility or activity could be the source of a release shall inform the public living in their vicinity about: what is happening, what could happen, and what the public must do in case of a potential or actual release. The licensee of the nuclear installation measures and informs the public in the vicinity about concentrations of radioactive material and dose.

To directly involve the interested parties living in the vicinity of facilities the HAEA has contacts with the mayors of the settlements around the facilities, particularly with the leaders of Paks city. Upon request the HAEA has a dialogue with the civil society organizations.

Policy Issues on the construction of new nuclear power plants

On 30 March 2009, The Hungarian Parliament made a decision-in-principle to build new nuclear power plant units. An Intergovernmental agreement of the peaceful use of nuclear energy was signed by Russia and Hungary in January 2014 to build two VVER-1200 type reactors at the Paks II site. This policy discussion with the IRRS team exchanged information on the authorization and supervision required for the approval and construction of a new nuclear power plant. The following issues were discussed:

- The inspection of equipment and components with long lead times
 - Most countries noted that applicants could begin to procure long lead items prior to obtaining a construction permit but they did so at their own risk.
 - Some counties performed inspections at the vendors but most had very little regulatory authority before a construction application was formally submitted.
 - Most counties inspect at foreign vendors
 - When inspections are performed they normally focus on the vendor's quality assurance (QA) programme and how well the vendor is applying it
- Preparatory work or construction activities that take place at the site before granting the construction licence
 - Most countries noted that the construction of support buildings and other infrastructure required for construction activities; and the initial site excavation work could begin prior to receiving a construction authorization
 - One country noted that it was stated in their law that concrete could not be poured for safety related structures until the construction permit was issued by the regulatory body
- Types of construction licences for safety related structures (buildings)
 - Most counties issue only one licence for construction of an NPP; however, in some instances building permits from the local governments are also required
- Inspection hold points used by regulatory bodies

- Only some countries used hold points and normally there were not many
- Some countries relied on having additional site inspectors always available for inspection or being notified of important activities
- Independent expert opinions obtained by the regulatory body before issuing a construction licence
 - Some countries use independent experts from a variety of engineering and scientific fields to review construction applications and provide recommendations or comments on the technical merits of the application
- The role of independent third party reviews
 - The roles were mostly limited to the use of code experts and examiners (e.g., ASME code pressure vessel testing)
- Other issues to consider
 - It is important to ensure that the construction activities do not impact the operation of existing NPPs at the same site.
 - Regulatory bodies should use caution not let construction activities dominate its oversight activities and focus less attention on operating facilities

Regulatory bodies should use international organizations such as the Multi Design Evaluation Programme, the Vendor Inspection Cooperation Working Group as a resource.

3.9. SUMMARY

Hungary's regulatory body comprises several co-authorities, mainly the HAEA, the OCMO, the RHDs, and the BCDEPN. Recent shifts in responsibilities of co-authorities have occurred and new ones have been approved by Parliament. In addition, new build brings additional tasks, especially for the HAEA, together with a doubling of its staff. Areas of improvement identified by the IRRS team to be addressed by the regulatory body are:

- the enabling by its structure and organisation of effective fulfilment of its statutory obligations.
- the development of a long term human resource plan to ensure that competences are maintained.
- the strengthening of the controls governing use of technical support organizations to ensure that there is no conflict of interest.
- the stability of regulatory control of all facilities and activities during the phases of transferring regulatory responsibilities.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

4.1. IMPLEMENTATION AND DOCUMENTATION OF THE MANAGEMENT SYSTEM

The HAEA has developed a comprehensive and well-functioning management system. The management systems of other organizations involved in nuclear and radiological safety in Hungary (i.e. the OCMO, the BCDEPN, the RHDs, and the NRIRR) are only partly established, documented, implemented, assessed and continually improved in accordance with requirements of IAEA safety standard GS-R-3. Safety is an overriding priority within the management system.

OCMO management system considers the Hungarian statutory and regulatory requirements. Operations of the OCMO and the OCMO's processes are prescribed in Organizational and Operational Rules. The operations of the RHDs are prescribed in Organizational and Operational Rules of the Government Office, and Operational Rules and the Operational Procedures of the Public Health Administration Organization. The management of the OCMO is aware that the management is responsible for safety. Management ensures that information is provided to the public. The OCMO has prepared some internal standards and protocols for medical exposure but they are not in force. However, the OCMO and the RHDs do not have internal procedures for authorization of different practices integrated into the management system.

NRIRR laboratories are certified according to the ISO 17025, "General Requirements for the Competence of Testing and Calibration Laboratories."

According to the ARM, the BCDEPN's management system is based on ministerial guidance. The minister responsible for the sector defines the Organizational and Operational Rules. The determination of the organization of authority and the related tasks, the levels and connection of authorities are defined in Organizational and Operational Rules. The BCDEPN management system considers the Hungarian statutory and regulatory requirements. In the ARM, the BCDEPN defined its management system in detail. However, during the interview with the BCDEPN's representative, it became apparent that the management system, as required by IAEA safety standard GS-R-3, has not been established.

In accordance with the Requirement 19 of IAEA Safety Standard GSR Part 1, Governmental, Legal and Regulatory Framework for Safety, all these organizations should have developed an integrated management system considering the IAEA safety standard GS-R-3.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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.

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(1)	BASIS: GSR Part 1 Requirement 19 states that <i>"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".</i>
(2)	BASIS: GSR Part 1 Requirement 22, para. 4.26 states that <i>"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"</i>
(3)	BASIS: GS-R-3 para. 2.6 states that <i>"The application of management system requirements shall be graded"</i>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GS-R-3 para. 2.8 states that <i>"The documentation of the management system shall include the following:</i>
	- The policy statements of the organization;
	- A description of the management system;
(4)	- 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 <i>"The documentation of the management system should be appropriate to the organization and to the work it performs "</i>
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.

The HAEA introduced the management system in 2002, which operates in accordance with the Hungarian standard MSZ EN ISO 9001: 2009. During the development of its quality management system the HAEA has taken into account the requirements of IAEA standard GS-R-3 Management System for Facilities and Activities.

Documentation of the HAEA management system is structured in three levels and consists of:

Level 1 documents:

- Policies: -
- Strategic Plan. _

Level 2 documents:

- Organizational and Operational Rules (OOR);
- Quality Management Manual (QMM);
- **Operational Rules;**
- Regulations.

Level 3 documents

- Procedures:
- Other quality management documents.

The Quality Management Manual is an essential document of the HAEA. The manual describes the HAEA system of management and the activities of its employees. The Quality Management Manual considers all requirements of MSZ EN ISO 9001:2009. Chapter D, Management Declaration of the Quality Management Manual, states that, "the Authority established and operates a quality management system in compliance with the requirements of MSZ EN ISO 9001:2009".

The Quality Management Manual is not upgraded by some additional requirements posed by IAEA safety standard GS-R-3 inter alia promotion of safety culture and graded approach. The IRRS team also noted a need to develop an overall procedure for performing different types of self-assessments, where competences, responsibilities, time periods for conducting individual self-assessment and flow of

activities are defined. Further procedures on enforcement and waste management inspection are not in place.

IAEA safety standard GS-R-3 requires the management system to promote and support a strong safety culture. The safety culture is not defined in the HAEA Quality Management Manual. Safety culture is only addressed in the Safety and Security Policy of the HAEA; however its implementation is not clearly defined.

The HAEA has no internal procedure describing how they will ensure a common understanding of regulatory safety culture. This issue was also identified in the IRRS self-assessment action plan. The HAEA is planning to develop a procedure for facilitating, supporting, developing, and enhancing of safety culture and for the common interpretation of its major aspects.

Graded approach is not explicitly defined in the HAEA Quality Management Manual; however some principles of a graded approach are defined in the Safety and Security Policy (P-0-7). The use of graded approach is defined in HAEA legislation (i.e. Govt. Decree 118/2011 Korm. on the nuclear safety requirements of nuclear facilities and on related regulatory activities. Graded approach is also embedded in some HAEA procedures i.e., ME-2-1-6, "The Central Registers of Radioactive Materials and Control of Local Registers." The graded approach had been narrowly applied to the review of licence amendment requests (the review considers the safety classification; however, other factors did not appear to be considered). In some cases graded approach is defined by expert opinion.

The HAEA did not appear to utilize a graded approach fully consistent with GS-G-3.1 for integrating the performance of safety assessment activities completed by all responsible sections. The HAEA's use of the graded approach did not fully incorporate complexity, significance, hazards and the magnitude of the potential impact (risks), and possible consequences if a product fails or an activity is carried out incorrectly. Further, regarding regulations and guides it was found out that there are about 3200 mandatory NSC requirements in the annexes (volumes 1 thru 10) of the Governmental Decree 118/2011. Korm. The IRRS team noted that during the development of regulatory guides, the HAEA may want to consider transferring some of the NSC requirements to safety guides.

Application of the graded approach across the full spectrum of activities performed by the HAEA is not documented in a systematic manner. The IRRS team noted that application of the graded approach in the Quality Management Manual and in other appropriate management system documents was not defined.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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 <i>"The management system shall be used to promote and support a strong safety culture by:</i> "
	- Ensuring a common understanding of the key aspects of safety culture within the organization:
	- 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 <i>"The application of management system requirements shall be graded so as to deploy appropriate resources on the basis of the consideration of:</i>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	"
(3)	BASIS: GS-R-3 para. 2.7 states that <i>"Grading of the application of management system requirements shall be applied to the products and activities of each process."</i>
	BASIS: GS-R-3 para. 2.8 states that <i>"The documentation of the management system shall include the following:</i>
	- Policy statement
	- A description of the management system;
(4)	- 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.

4.2. MANAGEMENT RESPONSIBILITY

Management commitment to the establishment, implementation, assessment, and continual improvement of the management system is expressed through the Quality Policy of the HAEA.

As defined in the Quality Management Manual, the Director General designates an authorized Quality Manager for the implementation, assessment, and continual development of the quality management system of the HAEA. The quality manager is empowered with the necessary scope of competence and at least once a year prepares a report on the effectiveness of the quality management system. The report documents the reoccurring non-conformances and quality issues, and lists the necessary preventive and corrective actions.

HAEA top management developed the Medium Term Strategic Plan 2015-2017, which defines mission, vision, values, medium term objectives and tasks required for fulfilment of the objectives. One of the HAEA values defined in the medium term strategic plan is the customer friendly approach. The IRRS team noted that the strategic plan did not include a statement that the customer friendly approach should not compromise safety.

The HAEA has prepared a procedure, Working Program for Assessment of the Site Investigation and Evaluation Licence Application, where the map to analyse expected behaviour and potential effect of interested parties on the result of the regulatory process is identified. The procedure defines key interested parties and their expectations, and determines the possible action to handle their expectations. The HAEA intends to extend this pilot procedure to other processes.

Measurement of satisfaction of employees is determined through an employee performance evaluation system. The HAEA management ensures the availability of its policies for the whole staff. In addition to Quality Policy (P-0-1) the HAEA has developed:

- Enforcement Policy (P-0-2);
- Accountancy Policy of the HAEA (P-0-3);

- HAEA Policy on Technical Support Activities 2013-2016 (P-0-5);
- Training Policy of the HAEA (P-0-6) (SAT-based);
- Safety and Security Policy and Authority Code of Conduct of the Hungarian Atomic Energy Authority for the government officers performing authority tasks, (P-0-7).

Senior management has established goals, strategies, plans and objectives. The long term goals are defined in the Quality Policy of the HAEA. On the basis of medium term goals defined in Medium Term Strategy 2015-2017, HAEA medium level management prepares an annual plan which determines the tasks and their deadlines to be performed in the current year. The annual plan is reviewed according to the annual plan deadlines during the management system review.

4.3. **RESOURCE MANAGEMENT**

HAEA management is committed to using and continuously developing the management system and to ensure the necessary resources as defined in Quality Management Manual are maintained. The HAEA has developed the HAEA Training Policy and procedure ME-0-0-8, Training System of the HAEA. From 2014, the HAEA plans its training programs for 4 year periods according to the requirements of Governmental Decree 273/2012. Korm. Training of employees is based on the systematic approach to training.

The HAEA has established several IT data bases for easier managing of information applied to human resources (i.e., Staffing Plan containing the requirements for staff for new build and Knowledge Profile Database for departments (the database has not been updated for the last two years due to the excessive workload).

Due to the legal limitations, the HAEA is only able to employ a new staff member when their predecessor has formally left. Therefore, the transfer of knowledge is limited. So far the new staff members can rely only on the documents left over by the leaving colleagues. As described in the ARM, there is no internal procedure on how to manage this process.

The HAEA developed several databases to capture and preserve knowledge in the organization and transfer knowledge to new staff. The responsible person of these data bases is a retired HAEA employee, now working as a consultant, with extensive past experiences in the nuclear field. The HAEA uses a Flexistore database. The database contains all regulatory decisions together with the applications and justifications document and attachments, which support the employees in drafting regulatory decisions. The HAEA has also developed a database for other reference documents regarding nuclear safety from the construction period of NPP PAKS to date, and a special data base for training materials for new staff.

The HAEA developed an effective database, "Hungarian Nuclear Knowledge Data Base," which involves the entire domestic nuclear industry. The objective of this database is to preserve and keep up-to-date the knowledge gained during the domestic use of atomic energy. The data base is accessible for users on the website. The HAEA, as the operator of the database, has also provided operational rules for the database and it structures all entered data. Fourteen organizations involved in nuclear activities are the part of this system. The usage benefit of the database is that each person uses the same terminology and version of documents. However, the IRRS team noted it would be beneficial if the database included data and the knowledge obtained by the participants at various conferences, workshops and seminars (duty travel records).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The HAEA has developed an effective database, "Hungarian Nuclear Knowledge Data Base", which involves the Hungarian nuclear industry, in order to preserve and keep up to date the knowledge gained during the use of atomic energy in Hungary.

(1)	BASIS: GS-R-3 para. 4.2 states that <i>"The information and knowledge of the organization shall be managed as a resource."</i>
(2)	BASIS: GS-R-3 para. 4.4 states that "Data should be converted into information for the continual development of an organization's knowledge"
GP1	Good Practice: The regulatory body has developed an effective database "Hungarian Nuclear Knowledge Data Base". The benefit of which is to preserve and keep up to date the knowledge gained during the use of atomic energy in Hungary.

As described in ARM, the HAEA professionals participate in various internal and external, domestic and foreign trainings. The evaluation of HAEA trainings includes the collection and assessment of experiences. An internal procedure describes the working methodology of an expert pool and provides the list of experts within the HAEA (ME-3-0-31).

HAEA management ensures appropriate working conditions and work environment. The Work Protection Regulation establishes the obligations and rights of the HAEA and its employees related to safe work performance.

4.4. PROCESS IMPLEMENTATION

HAEA management system is divided into main processes, management processes, and supporting processes. In the Annex 2 of the Quality Management Manual, interaction among the processes of the quality management system is defined. The requirements related to the processes are elaborated in the procedures considering laws (e.g. Act on Atomic Energy, KET.), related standards (ISO 9001) and identified good practices.

The responsibilities of process owners are defined in the one of the Annexes of the Quality Management Manual and in procedure ME 0-0-2, Handling of Management System Documents.

The IRRS team noted that the HAEA Quality Management System consists of large number of rules and procedures, which should be structured in more transparent manner in order to be clear which documents pertains to single process and its sub-processes.

The IRRS team noted that the HAEA should consider finding out which processes are not documented.

The IRRS team noted that when documenting processes additional requirements of IAEA safety standard GS-R-3 para.5.4 should be considered. The description of the processes, in some cases, is only in the form of a textual explanation (without flowcharts). To meet the requirements from the IRRS self-assessment action plan, the IRRS team noted that the HAEA should supplement the textual part of the processes with flowchart process inputs and outputs.

The HAEA has developed internal procedures for development and review of safety guides. The IRRS team noted that the HAEA does not include revision management (traceability) in its internal procedure, which could lead to problems in the future.

The HAEA is currently planning to develop and document a process for managing organizational change. In accordance with the Project Act, significant forthcoming organizational changes in the HAEA are due in early 2016. Therefore, the procedure should be issued before the due date defined in the IRRS selfassessment action plan (30 June 2016). This issue is addressed in Recommendation 11 and also relates to Recommendation 7 and 9.

The HAEA developed a set of performance indicators for measuring the effectiveness and efficiency of processes and other quality management system related activities. The system of indicators was upgraded last year.

4.5. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

The HAEA has developed a system for measurement, assessment and improvements of processes and activities which includes self-assessments, independent assessments and management system reviews. Activities are conducted on the basis of management system documents.

According to the ARM and Quality Management Manual, HAEA management implements several processes to improve the quality management system. These include: the determination of quality policy, process monitoring, measurement of customer satisfaction, implementation of internal audits, management reviews, corrective actions, preventive actions, etc...

HAEA management carries out a number of self-assessments at all levels of the organization in the framework of internal and external audits, management reviews and the IAEA IRRS mission. As addressed in chapter 4.1, the IRRS team noted that an overall procedure for self-assessment is not in place.

The HAEA regularly performs internal audits according to procedure ME-0-0-4, Internal Audits. Internal audits are conducted by appropriately qualified auditors. A main aim of internal audits is to assess whether the quality management system is effective and operates as planned. The Director General and management of the HAEA actively take part in entrance and exit meetings. The internal audits are planned by the quality manager using an ISOFFICE data base. According to the audit plan, at least once a year an internal audit should be conducted for each area in the framework of HAEA activities. Results of the audits are submitted to the director general and on the intranet, so the results are accessible to all employees.

The HAEA is also yearly audited by an external organization and the HAEA has acquired the MSZ EN ISO 9001: 2009 certificate for the quality management system.

The Director General, with the contribution of management, regularly reviews the effectiveness of the quality management system, the fulfilment of quality policy, and quality objectives based on the information provided by the quality manager.

At the management system review meetings the collected information from the following areas are discussed: audit results, customers' feedback, revision of quality management procedures and implementation of necessary modifications, status of preventive and corrective actions, activities from the management reviews, process performance indicators, changes which may affect management system and recommendations on improvement. The HAEA developed a procedure for lessons-learned from other organizations. The IRRS team noted that lessons-learned from other organizations are not the subject of the management system review meeting.

All information connected to the measurement, assessment and monitoring activities are gathered and documented in ISOFFICE. The HAEA has defined in the Chapter 4.2 of the Quality Management Manual, "Management of a non-compliant product," that it is a task of each HAEA employee to timely detect deviations and non-conformances and to report them to the manager authorized to act. The deviations and non-conformances are documented in the corrective action database.

4.6. SUMMARY

The regulatory body in Hungary comprises several organizations that are competent for control of nuclear and radiation safety. Apart from the HAEA, who has developed and implemented a comprehensive management system, other organizations involved in nuclear and radiological safety in Hungary (i.e. the OCMO, the BCDEPN, the RHDs, and the NRIRR) have not established a management system in accordance with IAEA safety standards related to the management systems. The Management system of the organizations should consider the size of organization and complexity of performed activities.

The HAEA's management system has evolved over time. In 2002 the HAEA introduced the quality management system in accordance with ISO 9001. Currently the HAEA operates a quality management system which is process orientated and considers the requirements of Hungarian standard MSZ EN ISO 9001: 2009, and IAEA safety standard GS-R-3 "Management System for Facilities and Activities."

The IRRS team noted there were some observations concerning the comprehensiveness of the current management system regarding IAEA safety standard GS-R-3. There are areas where improvements can be made, inter alia, to update the HAEA Quality Management Manual. Specifically, taking into account all requirements of IAEA safety standards related to the management system, to develop and implement the processes which have not yet been documented but could influence the management system (graded approach, safety culture, managing organization change), and to ensure the management system promotes a strong safety culture. Given the forthcoming significant changes in HAEA organization, the process for implementing management of organizational changes should be promptly established.

5. AUTHORIZATION

5.1. GENERIC ISSUES

The HAEA is the competent regulatory authority for licensing of nuclear facilities. Currently, the HAEA is regulating Paks NPP (operating four VVER-440/V-213 nuclear reactors), Spent Fuel Interim Storage Facility, two Research Reactors and two Radioactive Waste Treatment and Disposal Facilities. The Government has designated various authorities as co-authorities in the regulatory proceedings of the HAEA and they provide their inputs on areas of their responsibilities during various stages of the licensing process as prescribed in the Governmental Decree 112/2011. Korm. The cooperation and interface arrangements with the co-authorities are available in documented form. In case of a difference of opinion with the co-authorities, the issue is resolved through discussion, however, the views of the HAEA have priority in case of disagreement.

BCDEPN is the competent authority for issuing environmental protection licences which is a prerequisite for any further licensing of a nuclear facility by the HAEA. The BCDEPN is also a co-authority in different HAEA procedures.

The Hungarian system of authorization of radiation sources and facilities is based on divided regulatory regime. The OCMO and the seven RHDs issue authorisations. For specific practices, authorization is also issued by the Trade Licensing Office, the HAEA, the BCDEPN and NTA. The OCMO also participates in the nuclear safety licensing procedures as a co-authority in radiation health issues.

The licensing stages for facilities and activities are prescribed in the Act on Atomic Energy and Governmental Decrees. The nuclear safety code prescribes requirements for the contents of licensing applications (document submission requirements) to demonstrate safety arrangements. The authorization/licensing stages for nuclear facilities include site characterization and assessment, determination of site parameters and suitability, construction, commissioning, operation, extension of service life, modification, final shutdown and decommissioning, restart after main outage in case of NPP units, and construction, demolition and commissioning of buildings and building structures and elevators. Further activities bound to nuclear safety licensing include fabrication, purchase, installation, operation of systems, structures and response plan, modification of certain technical, organization and management system. Assembly, realization technology, measurement, calculation, application of technical inspection and evaluation methods related to safety class 1 and 2 components that are not included in the documents submitted for substantiation of regulatory licensing procedures, but influencing nuclear safety shall only take place after preliminary approval by the nuclear safety authority.

Licences issued during various stages have different validity periods. Site survey and assessment licence remains valid for 5 years or until the site licence is issued. The validity may be extended by five years. The site licence is valid until the construction licence becomes valid or for a maximum of 5 years. The validity of the licence can be extended up to two times for a period of 5 years on each occasion. The construction licence is effective until the commissioning licence becomes final or a maximum of 10 years from its date of issue. The duration of the licence may be extended for 5 years. The validity of the operating licence may not extend beyond the designed service life of the nuclear facility which is subject to periodic safety review every ten years. In case of NPP, operation beyond the designed service life requires a new licence. The licence modification undergoes a formal process for issuance of new licence.

The regulatory decision making process at each licensing stage follows a review and assessment process of the safety demonstration submitted by the applicant to verify compliance with the legal requirements and nuclear safety codes issued under a Governmental Decree. The evaluations made by the HAEA and the basis for regulatory decision making are documented. According to the KET the opportunity of appeal is excluded if the decision is made by a minister, by an autonomous state administration organ, independent regulatory organ or leader of a government office. However, in these cases the decision may be subject to judicial review. An appeal mechanism existed earlier within the regulatory framework, however, after the amendment in the Act regarding exclusion of appeal, the mechanism was put to an end.

The review and assessment process of licensing applications utilizes TSOs. However, since a limited number of TSOs are available in the country, they provide services to both the licensees and the regulatory body. Accordingly, the issue of independence was discussed with the HAEA who explained that it is ensured through specific arrangement with the TSOs that the experts providing services to the regulatory body are different from those providing services to the licensee to avoid conflict of interest and to maintain effective independence. This issue is addressed in Suggestion 4 in section 3.4.

The modifications to the existing safety analysis, for example design, management system, emergency preparedness arrangements, undergo a licensing modification process. Documentation substantiating the operation following a modification and the summary of the documentation, also take into consideration the supervisory plan submitted by the licensee and is checked by the HAEA. If during the review of a submitted document or subsequent inspection, the HAEA finds a non-compliance which has the potential to endanger safe operation, the modification licence can be withdrawn or conditions of the licence changed by amending the licence.

Grading is applied in modification licensing by categorizing as 1, 2 or 3. Specific deadlines have been established in the Governmental Decree for completion of modification licensing. Category 1 and 2 are safety related modifications which require approval of the HAEA. Category 3 modifications are non-safety related and do not require approval of the HAEA, but are subjected to a regulatory overview plan (e.g. inspection of specific test/activity, submission of supporting documents,). The management procedures do not address application of graded approach during the assessment of licence modifications process as recommended in IAEA safety standards. This issue is addressed in Recommendation 11 in section 4.1.

According to the legal provisions of the Act on Atomic Energy, the oversight organizations are required to hold public hearings before making a licensing decision for a nuclear facility or a radioactive waste repository facility. The HAEA holds public hearing in every licensing procedure connected to the lifecycle stages of nuclear facilities and radioactive waste repositories, except modifications. A procedure has recently been developed by the HAEA for organizing such public hearing.

The contents of the application and the evaluation made by the HAEA are made available at the HAEA office for public access. In addition, the public may also request specific information by e-mails.

The legal provisions, established in Governmental Decree under the Act, set deadlines for the regulatory body for completion of various authorization processes. Accordingly, category 2 modifications are to be completed within two months with a provision of extending up to one additional month. Category 1 modifications have to be completed within six months and can be extended up for a period of three months. Similarly, time frames have been stipulated for completion of the authorization process for other stages (e.g., construction licence.). The Decree also has provisions to halt the time if a request for additional information is sent to the applicant by the approving regulatory body until receipt of the information. The IRRS team considers the time frame challenging particularly for new plant licensing or modifications of complex nature, causing undue pressure on the staff of the regulatory body. This issue is addressed in Recommendation 1 in section 1.3.

The licences issued by various authorities can be revoked under the law. Revoking of licence by the HAEA has been described. However, the process for revoking the environment protection licence and its impact on the operating licence of the facilities is not defined. No environmental licence for nuclear facilities has so far been revoked.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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.

5.2. AUTHORIZATION OF NUCLEAR POWER PLANTS

The licensing applications are evaluated against the Act, Governmental Decree, Nuclear Safety Codes and guidelines during licensing process. These nuclear safety codes were issued in 2011 based on WENRA recommendations and IAEA safety standards. Incorporation of new IAEA safety standards such as SSR-2/1, SSR-2/2 in the safety codes is expected in the next revisions. The licensing stages (described in section 5.1 of the report) comply with SSG-12 covering all stages from siting through to decommissioning and removal from regulatory control.

The list of safety-critical work positions for nuclear power plants is required to be defined by the designer in the safety analysis report. The list is reviewed and approved by the HAEA during the authorization stage of construction licence. In addition, the HAEA approves the training and qualification program during the licensing of the facility. Written and simulator examination of operating personnel are conducted, upon completion of the training program, by the licensee. A member of the HAEA is part of the team that conducts an oral examination at the completion of the program. The HAEA representative has veto power in the final decision of the issuance of a licence. These safety-critical work positions are required to be filled only by individuals holding a licence issued by the nuclear safety authority upon successfully completing the licensing examination.

SSG-12, Paragraph 2.35, states that safety significant modifications should be submitted to the regulatory body for review and approval. HAEA Procedure ME 3-0-20 for handling licence applications requires that the HAEA add a licence condition requiring the licensee to provide the dates for the installation and testing of modifications and the submittal of test data for Category 1 safety class modifications. Although not required by procedure, the HAEA frequently adds a similar licence condition for Category 2 safety class modifications. The information is used by both inspection and licensing staff to independently validate the appropriateness of facility modifications.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The HAEA adds licence conditions requiring the licensee to provide the dates for the installation and testing of modifications and the submittal of test data for Category 1 safety class modifications. Although not required by procedure, HAEA frequently adds a similar licence condition for Category 2 safety class modifications.

(1)	BASIS: SSG-12 Paragraph 2.35 states that " modifications that are significant to safety should be submitted to the RB for review and approval."
GP2	Good Practice: The HAEA developed and implemented procedures for Category 1 safety modifications that add a condition to an approved licence amendment requiring the licensee to notify the HAEA of installation and testing dates for modifications and

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

the submittal of test data. The information is used by both inspectors for planning subsequent inspections and licensing staff to independently validate the appropriateness of facility modifications.

In June 2012 a Governmental Resolution approved the construction of new reactors at the Paks NPP site. Subsequently, in 2014 a contract was signed for the construction of Russian AES 2006 type reactors. The HAEA approved the site investigation program for the new reactors in November 2014. The HAEA needs to develop plans and procedures for the assessment of licensing applications for new reactors since licensing applications for the next stages (site characterization and evaluation of suitability and construction) are expected in coming years. PSAR is also required as part of the licensing application for a construction licence. The deterministic analysis is required to be complemented with probabilistic analysis in the design of the nuclear power plant according to the nuclear safety code. However, a PSA report is not required as part of licence application submission. A guideline prescribing the format and contents for safety analysis report for new NPPs is available (on the website of the HAEA) in draft form and needs to be finalized. The issue of development and finalization of guidelines is addressed in Recommendation 21 in Section 9.1. As part of its preparation for licensing of new reactors, the HAEA has begun recruiting and training new staff.

5.3. AUTHORIZATION OF RESEARCH REACTORS

Two research reactors are operated: the Budapest Research Reactor (BRR) and the Training Reactor (TR). There is no project for a new research reactor. However, the design requirements are given in the volume 5 of the NSC.

As the operating licence covers a large range of operations, the reactor licensee does not need additional licences for each operation/experiment (usually less than 10/year).

According to the graded approach, three types of modifications are defined. Depending on the type of authorization, a modification of the operation licence is necessary, or a formal authorization by the HAEA inspector in charge of the facility. For the third type, the licensee carries out the safety analysis and the process is inspected. The FSAR gives the classification for all the equipment participating in a safety function. This safety classification is the main input for defining the modification types.

The BCDEPN can modify the environmental protection licence through the specific resolution issued during the closing phase of the PSR. Technical difficulties appear during the comprehensive professional evaluation of submission provided during licensing procedures and PSR process, as identified in ARM. The BCDEPN does not possess the necessary software tools, for the verification of the adequacy of the model calculations described in the applications. The results of calculations are necessary to define the release limits. The modification of the environment protection licence is addressed in detail in chapter 6.

The environment protection licence can be revoked as referenced in ARM. The process for revoking the environment protection licence is not defined. The implications for the revocation of an environmental protection licence on the status of the facility are not clear.

The regulatory body strives for formulating guideline for licence application in relation to all licensing procedures.

The following topics have been discussed through interviews, and no observation was identified:

- Operation
- Staffing of the operating organization

- Operational limits and conditions
- Qualification and training of personnel
- Operating procedures
- Experimental devices and experiments
- Existence of safety committees / advisory groups that is independent of the reactor manager.
- Maintenance and updating of licensing documentation

5.4. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

Hungary operates two radioactive waste disposal facilities: the Radioactive Waste Treatment and Disposal Facility (RWTDF) located at Püspökszilágy and the National Radioactive Waste Repository (NRWR) located at Bátaapáti. The RHDs under the supervision of the OCMO were the regulatory authority of the radioactive waste repositories until 30th of June 2014. From this date, regulatory competence was transferred to the HAEA. During the mission, the IRRS team was informed that transfer of knowledge and information between the two authorities did not take place. A storage facility for spent fuel is operated since 1993. Licensing procedures related to interim spent fuel storage fall under regulation of the HAEA.

The Interim Spent Fuel Storage Facility (ISFSF)

The ISFSF is a modular dry storage facility located in the immediate vicinity of Paks NPP. Currently the facility contains 20 modules. The facility is capable of being extended to accommodate with the assemblies for a period of 50 years that should cover the extended lifetime of Paks NPP. But the storage of the spent fuel that would be generated by the new reactors fuel won't be possible because of limitations including proximity to the Danube River. Different plans are under consideration by Hungary in order to deal with this point.

The Radioactive Waste Treatment and Disposal Facility (RWTDF)

The RWTDF was commissioned by the predecessor of the OCMO in 1976 as the repository for institutional low and intermediate level radioactive waste, and in particular disused sources. The repository is a typical near-surface facility, composed of concrete trenches (vaults) and shallow wells for spent sealed sources. Although the RWTDF was initially planned to dispose institutional waste, almost 2500 m3 of low-level, solid waste originating from the Paks NPP has been disposed of. An interim storage for long lived waste is also operated at the facility.

The National Radioactive Waste Repository (NRWR)

The NRWR is a geological repository under operation since 2012 in the vicinity of Bátaapáti to dispose of the LLW/ILW waste originated by the Paks NPP during its operation and decommissioning. The underground facility consists of two inclined access shafts from the surface down to a depth of 250m into the host rock and two disposal chambers, and two further chambers are being excavated.

The deep geological disposal program

In 1995 a programme was launched for the disposal of high level and long lived radioactive wastes. This programme focused on the in-situ site investigations carried out by the Mecsek Ore Mining Company with the help of the Canadian AECL in the area of the Boda Claystone Formation at 1100 m depth (accessible from the former uranium mine). The next steps of the programme concern in particular the implementation of detailed site investigations and the establishment of a preliminary safety assessment of the repository. The construction of an underground research laboratory is foreseen by 2038.

Current situation

Governmental Decree 155/2014. Korm. specifies the general requirements for the safety of storage and disposal facilities. Requirements include conditions to accept waste in the facilities, the responsibilities of the licensee for the different activities such as site survey and site assessment, construction, operation, closure and institutional control, and the obligations of the authority to review and authorize the activities of the disposal facility along its lifecycle. Article 12. of the Governmental Decree, Licensing, Section 26, states that "The atomic energy oversight organization shall apply graded regulatory procedures considering the impact on safety during the site survey and assessment, siting, construction, operation, modification, closure and transition to active and passive institutional control".

The RWTD facility's licence for operation of the treatment workshop was suspended by the RHD of Budapest, after the contamination incident in 2013. PURAM applied for a modification to reconstruct the ventilation system. According to the HAEA, discussion between the interested parties is on-going about the opportunity to withdraw current licences and group them into a new single licence related to the operation of the facility as a whole (treatment workshop, routine operation of disposal, and storage of long lived radioactive waste). According to the HAEA, the refurbishment licence is not in line with the decree and should be renewed as well.

Since December 2012, the first of the two underground chambers at the NRWR have been accepting concrete containers. (each container contains nine drums and gaps are injected with non-active concrete). The construction of two additional chambers started in parallel with the operation of the first chamber. Section 61 of Governmental Decree 155/2014. Korm. addresses in particular a requirement related to overlapping of construction/operation in the case of construction performed in several phases, the achievability of operation and construction of the storage or disposal facility shall be demonstrated simultaneously and it shall be described how the storage or disposal facility can be safely operated". In parallel with the operation/construction of the NRWR, PURAM has started an in-situ experimental program in a special chamber drilled in the underground facility in order to test closure concepts. The HAEA considers, it is unclear how the long term safety issues have been considered up to now in the approval of the current research program. Since the initial authorization for operation, PURAM has changed its concept in order to optimise (increase) the quantity of radioactivity disposed with a new steel container (with active concrete inside in the gaps). PURAM is going to submit for approval new waste acceptance criteria for the new waste packages to be disposed in the second disposal chamber. The IRRS team is of the opinion that the safety of the facility should be re-assessed in order to verify that the process to design the closure concept, to construct new chambers, and to operate the NRWR complies with the requirements stated by the new Decree. The counterpart has informed the IRRS team that a selfassessment process performed by the licensee was ongoing with the view to identifying the areas where, considering the new Decree, updated safety demonstration is required.

During 2012-2013 PURAM prepared the continuation of the research program on deep geological disposal by developing a geological survey plan for the next stage of the investigation of the Boda Claystone Formation (initial phase of investigation was approved by the Pécs Mining District Authority). The objective of the present investigation stage, which is planned to be implemented between 2014 and 2018, is the general qualification of the host formation and the provision of geological data and information required for the safety assessment. According to the provisions of Article 12 of the Governmental Decree 155/2014. Korm., the HAEA will have to assess whether siting survey and characterization results acquired by PURAM provide sufficient and adequate knowledge and data for the safety assessment of the suitability of the rock with regard to the containment and isolation of radionuclides.

Regarding the environmental protection licensing process, the BCDEPN cooperates as co-authority in nuclear safety licensing procedures of the facilities based on Section 5 of the Governmental Decree 112/2011. Korm. as support of the HAEA.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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.

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.
(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."
(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."
(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."
(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".
(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."

5.5. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

The Hungarian system of authorization of radiation sources and facilities is based on divided regulatory regime. The OCMO and the seven RHDs are issuing authorisation for the use of radiation sources. For specific practices authorization is also issued by the Trade Licensing Office, the HAEA, the BCDEPN and NTA. The import and export of radioactive sources is a well-established process. The authorization system is based on a categorization of sources according to a graded approach.

The IRRS team noted insufficient communication, cooperation and information exchange among regulatory authorities as well as among other parties involved in controlling radiation sources facilities

and activities throughout the full life cycle. The regulatory regime is currently under revision; in particular the functions of the OCMO and the RHDs, and major changes in the authorization process are foreseen.

The HAEA has established a very comprehensive and up to date register of radiation sources, including radioactive waste.

In some cases, the OCMO and the RHDs consult the NRIRR for expert opinion of justification of practices involving radiation sources. However, they haven't developed procedures to assure that during the authorization process only justified practices are licensed. In addition the review of justification is not incorporated in the regulations. There are some provisions for optimization in the Act on Atomic Energy; however, they haven't been developed in the Ministerial Decree 16/2000. EüM. Dose constraints are established in the Ministerial Decree 16/2000. EüM.; however, they are not implemented during the regulatory process, dose constraints are only implemented in the case of special facilities.

The Ministerial Decree 16/2000. EüM. establishes the documentation to be submitted by the applicants in support of the application for authorization. However, the OCMO and the RHDs haven't developed guidance for applicants on the content and format of this documentation. This issue is addressed in Recommendation 26 in Section 9.5.

The OCMO and the RHDs haven't developed procedures to address principles and associated criteria for authorization of different practices integrated in the management system to ensure stability and consistency of regulatory control and prevent subjectivity in decision making by individual members of the regulatory body. This issue is addressed in Recommendation 10 in Section 4.1.

The licensing process incorporates a graded approach. The regulatory body is required to issue the licence 21 days post application submission, according to general rules of administrative procedures, regardless of the complexity of the application. This issue is addressed in Recommendation 1 in Section 1.3.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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.

R14	Recommendation: The regulatory body should establish requirements and procedures for justification of practices and optimization of radiation protection in the facilities and activities.
(2)	(a) Shall establish and enforce requirements for the optimization of protection and safety;(b) Shall require documentation addressing the optimization of protection and safety;
	BASIS: GSR Part 3 Requirement 11, para. 3.22 states that "The government or the regulatory body:
(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."

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."

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

R15 Recommendation: The regulatory body should establish requirements for safety assessment to be submitted by the applicants.

5.6. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

General regulatory requirements for decommissioning of nuclear installations are developed in Volume 8 NSC. The decommissioning requirements for storage and disposal facilities are included in Annex 2 of the Repository Safety Code Volume 2 of the Govt. Decree 155/2014. Korm.

When the nuclear power plants started, no specific decommissioning requirement existed. During the operation (1993) the regulatory body requested to develop a dedicated study of decommissioning options. A new version was prepared in 1997 covering the 4 units under operation and the ISFS facility (the last as part of its FSAR). The first preliminary decommissioning plan was issued for the ISFSF in 2003, revised in 2008 to include several options for the Paks NPP. In 2009, the HAEA requested completion of the preliminary decommissioning activities comprises periodic regulatory reviews of the progress of the preliminary decommissioning plan until the final decommissioning plan. Volume of decommissioning waste and decommissioning costs are integrated in the plan. The waste management strategy and decommissioning. The structure of the decommissioning data base and the database for Paks were established by PURAM in 2004 and reviewed by the IAEA in 2005 upon request of the HAEA.

The research reactor of Budapest University of Technology and Economics (the "training reactor") is planned to be decommissioned after 2027. Decommissioning studies for the research reactor of Center for Energy Research are ongoing. A preliminary decommissioning plan for both research reactors has been already developed by the licensees and accepted by the HAEA.

The Atomic Act mandates PURAM as the acting organization for the implementation of decommissioning activities and management of radioactive waste. For that purpose, PURAM implements an annually revised overall Medium and Long Term Plan in order to anticipate staff management, funding and schedule of activities in the scope of radioactive waste management and decommissioning. In that context, good coordination between the NPP and PURAM is necessary in order to ensure that the options for decommissioning and the overall planning for the funding, availability of competencies and foreseen schedule are consistent.

Regarding the future activity of PURAM in decommissioning, the HAEA expressed the opinion that provision must be made by PURAM and the NPP to ensure that key staff is retained and that institutional knowledge about the facility is maintained and is accessible. The HAEA required that PURAM develops a staff management program commensurate with the future needs for decommissioning activities.

The HAEA informed the team that guidance on the establishment of the safety demonstration of decommissioning activities is under preparation.

5.7. AUTHORIZATION OF TRANSPORT

The implementation of the international modal transport agreements which are transpositions of the IAEA transport regulations for each mode of transport (air, sea, road, railway and inner waterways) demonstrates that all provisions in the TS-R-1 Regulations for the Safe Transport of Radioactive Material (and nearly all in the later version SSR-6) are addressed in the authorization process (e.g. shipment, special arrangement, package design, radioactive material in special form). The full implementation of

SSR-6 in the Hungarian legal system will be effective from 1 July 2015 due to transitional rules in some of the modal transport regulations such as ADR.

The HAEA is responsible under the Atomic Energy Act (in the licensing procedure of nuclear facilities) for the licensing and for the approval of transport package and material designs of radioactive materials including fissile material in accordance with the international modal regulations for the transport of dangerous goods, and for the inspection of packages of radioactive materials. The approval of the transport package and material designs and the notifications are performed by the HAEA, which may include expert support from independent external experts. The authorizations of radioactive materials transports requires with some exemptions a transport licence by the RHDs within their jurisdiction or by the OCMO if more than one RHD – or the RHD itself - is involved. A radioprotection and an emergency preparedness plan are required for transport. Guidance for applicants regarding package design is addressed in Section 9.7. The conclusion is that a functional authorization process for transport of radioactive material is in place.

5.8. SUMMARY

Several authorities (the HAEA, the BCDEPN, the OCMO, the RHDs, the Trade Licensing Office, the STDIPNC and the NTA) along with the support of co-authorities are involved in issuing authorizations to nuclear facilities, radiation sources and facilities, and associated activities during specific stages. The authorization stages and submission requirements are defined in the Act, Decree and NSC. The legal provisions define deadlines for various authorization stages which, on certain cases, may be challenging. A graded approach is only applied during the initial stages of modification licensing of nuclear facilities (while categorizing the modifications). Any authorization decision can be appealed to a court of law. The process for revoking an environmental licence is not described.

The IRRS team identified certain areas where necessary requirements, guidance and management system procedures are needed. Due to limited number of TSOs in the country, the same TSO may be employed by the regulatory body and the licensees for technical support. Such situations must be handled carefully by the regulatory body to avoid any conflict of interest and maintaining objectivity of the TSOs.

Licence condition for category-1 modifications of nuclear installations requires the licensee, to submit to the regulatory body, the dates for the installation and testing of modifications and test data. Information exchange among various authorities involved in the control of radiation sources is not well established nor effective. The principles of justification of practices and optimization of radiation protection are not fully incorporated in the regulatory framework. The regulatory requirements for submission of safety assessment by the licensee of radiation sources have not been established.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

With respect to assessment activities, the HAEA only provides summaries of the results via their homepage. Submittals (e.g. assessment reports, event reports, amendment requests) from the licensee and completed assessments (e.g. quarterly and annual) performed by the regulatory body are not easily accessed via the internet and in mass media, as recommended in SSG-12, Paragraph 2.44. However, the HAEA does allow members of the public access to documents from the HAEA office in Budapest or when specifically requested in writing. The HAEA should consider options to make records related to safety and licensed activities more accessible via the internet.

During the review of HAEA guidelines and procedures, information provided on the HAEA website and ARM, and discussions with HAEA personnel, no significant observations were noted with the following:

- Responsibility for the performance of review and assessment
- Scope of review and assessment: safety assessment has to address all radiation risks for all type of facilities and activities
- Purpose of the safety assessment
- The types and number of documents subject to review and assessment
- Availability of the regulatory body's review and assessment plan including prioritization of various submissions
- Monitoring (tracking) of the review and assessment process and document control system
- Documentation of review process and bases for regulatory decisions, including use of feedback from previous review and assessment
- Quality control of review and assessment processes and documents
- Interface between regulatory bodies involved in review and assessment

Module 3 discusses the adequacy of the following items:

- Use of graded approach in review and assessment
- Regulations and guides related to review and assessment contents of the regulations and guides pertaining to specific review and assessment processes

For waste management facilities geological works are reviewed by different authorities and the interface with the HAEA is unclear. The scope of review, purpose of the safety assessment, documentation of the review process, and bases for regulatory decisions need to be further developed and supported by guidance and internal procedure for waste management facilities.

6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

The HAEA has access to approximately 30 different TSOs from a broad spectrum of technical-scientific professional areas that can assess the safety aspects of nuclear facility operations. The HAEA maintains a database of technical support organizations to facilitate the selection of needed professional staff.

During the review of HAEA guidelines and procedures, information provided on the HAEA website and ARM, and discussions with HAEA personnel, no significant observations were noted with the following:

- Internal manpower and organizational arrangements of the review and assessment
- Staff specific competence and training in the area of review and assessment (waste management facilities are specifically addressed in section 6.4)
- Availability of external independent resources for review and assessment, including TSO and cooperation at international level
- Use of advisory bodies/committees in the area of review and assessment
- Specific regulatory tools for review and assessment (computer codes, experimental facilities) and internal capability for use of the tools (waste management facilities are specifically addressed in section 6.4)

The BCDEPN can modify the licence through a specific resolution issued during the closing phase of the PSR. The technical capabilities of the BCDEPN are challenged by the lack of software tools. In particular, during the comprehensive professional evaluation of licensing actions and the PSR, BCDEPN staff is not fully able to verify the adequacy of model calculations described in the application through the use of qualified software tools. The results from validated calculations are necessary to define the release limits for the licensee. On at least three occasions the BCDEPN has been unsuccessful in their requests to the Ministry of Agriculture for the purchase of software tools.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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.

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.

6.1.3. BASES FOR REVIEW AND ASSESSMENT

During the review of HAEA guidelines and procedures, information provided on the HAEA website and ARM, and discussions with HAEA personnel, no significant observations were noted with the following:

- Availability of relevant regulation/guidance for safety assessment by the licensees
- Availability of specific regulations/guidance on scope and quality of deterministic/probabilistic safety analysis
- Alignment of the regulatory requirements on safety assessment with the IAEA safety standards and with international good practices
- Regulatory access to additional information not directly included in the submission
- Consistency in regulatory requirements on safety assessment in various licensing documents

6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT

The HAEA has developed Procedure ME 3-0-14 to monitor the safety performance of nuclear power plant, research reactors, and ISFSF performance through a set of performance indicators. The indicators

track a wide variety of inputs important to safe facility operation. The performance indicators are independent of the indicators in use by licensees. Expert judgement from a review of past performance was used to initially establish performance thresholds. The thresholds are periodically assessed to ensure regulatory actions can be implemented before performance concerns become significant. Three levels of performance are determined: acceptable (Green), warning (Yellow), and regulatory action required (Red).

During the review of HAEA guidelines and procedures, information provided on the HAEA website and ARM, and discussions with HAEA personnel, no significant observations were noted with the following:

- Methods for verification of comprehensiveness and quality of safety assessment submitted by the licensees (including independent verification by the licensee)
- Verification of the scope and quality of safety analysis, including independent regulatory audits
- Scope of regulatory review and assessment associated with various kinds of authorizations for various facilities and activities
- Communication with the licensees in connection with review and assessment
- Arrangements for interface between review and assessment and inspections

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: HAEA has established a set of performance indicators to aid in the performance assessment of research reactors and ISFSI's. The indicators are used to initiate regulatory actions when action thresholds are exceeded.

(1)	BASIS: GS-G-1.2 para. 3.3 states that <i>"the regulatory body shall prepare its own programme of review and assessment."</i>
GP3	Good Practice: The HAEA has established performance indicators to monitor research reactor and ISFSI safety performance.

6.2. REVIEW AND ASSESSMENT FOR NUCLEAR POWER PLANTS

In addition to PSR that is due every 10 years, the safety performance of the licensee is evaluated via the annual nuclear safety assessment, performance indicators, reports submitted by the licensee, and information collected during regulatory inspections. The NSC establishes the method and scope of reviews, analyses and reports to be made by the licensees for the different stages of the facility. The regulations determine the documents to be submitted by the licensee/applicant to the HAEA for review and assessment depending on the actual life cycle phase of the facility.

Periodic assessments of licensee performance (quarterly, annual, and the 10 year PSR) completed by the HAEA include a comparison of the requirements of the nuclear safety code, recommendations of the various international organizations, and national operating experience. Regulatory guidelines exist for the 10 year PSR. Guidelines include information regarding co-authorities, the areas to be reviewed, and the topics of the PSR. The HAEA procedures exist for the review of the PSR and the performance of the quarterly and annual assessments. The HAEA staff involved in assessment activities is qualified for the assigned tasks.

The HAEA applies a structured approach to the evaluation of plant events, as defined in Procedure ME 3-0-18. The process includes events below the reporting threshold. The process utilizes a numeric scoring system to determine the appropriate level of inspection and oversight provided by the HAEA. The scoring table incorporates a combination of several deterministic inputs and probabilistic insights. Factors included in the scoring system are, in part, the safety classification of equipment, event report scale, Technical Specification entries, probabilistic risk significance, and causal factors. The scoring factors and results of oversight activities are easily retrievable through a database maintained by the HAEA which can be used for performing additional trend analyses of facility performance.

The HAEA performs independent reviews of operating experience sources. Insights from the operating experience reviews are provide to the inspection program, and when warranted, requests are sent to the licensee to supply feedback on corrective actions taken by the facility to address the operating experience. The HAEA includes operating experience from national, international, and a variety of working group sources.

During the review of HAEA guidelines and procedures, information provided on the HAEA website and ARM, and discussions with HAEA personnel; no significant observations were noted with the following:

- Specific review and assessment topics of NPPs, such as those related to
 - $\circ\,$ various types and stages of an authorization, in particular those including Safety Analysis Report
 - periodic safety reviews
 - operational experience feedback
 - lifetime extension
 - o modifications of facilities, including power uprate
 - o competences of operating personnel
- Specific review and assessment methods and tools applied for NPPs

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: HAEA Procedure ME-3-0-18 utilizes a scoring table for nuclear power facilities to aide in the determination of appropriate post event investigations and continued oversight of licensee corrective actions. The process includes events below the reporting threshold. The scoring table incorporates a combination of several deterministic inputs and probabilistic insights.

(1)	BASIS: GS-G-1.2 para. 3.47 states that <i>"the regulatory body should review reports submitted by the operating organization to monitor operational safety performance."</i>
GP4	Good Practice: The HAEA has developed a scoring table for nuclear power facilities to aide in the determination of appropriate post event investigations and oversight of corrective actions.

6.3. REVIEW AND ASSESSMENT FOR RESEARCH REACTORS

The last periodic safety review of the BRR was performed 2 years ago, and the next PSR of the training reactor is planned for next year.

Part of the PSR report is reviewed by the BCDEPN which issues a resolution during the PSR closure step. The resolution that includes the radioactive release limits is considered to be the environmental protection licence. The PSR process ends with the issuance of two resolutions by the HAEA. The PSR closure resolution referring to the BCDEPN resolution gives additional requirements that the licensee will have to fulfil. The resolution for the extension of operation gives the new validity of the licence (up to 2023 for the BRR) and refers to the PSR closure resolution.

The licensees each prepare an annual safety report, which is assessed by the HAEA who issues a letter summarizing their conclusions. In response the licensee submits an action plan to the regulatory body. The regulatory body uses the action plan, in part, to determine future oversight and inspection activities.

The BRR submits preliminary campaign and closure campaign reports to the HAEA. The HAEA does not systematically assess these reports, but does take them into account during the annual assessment.

6.4. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

Since the initial authorization for operation, PURAM has changed its concept in order to optimise (increase) the quantity of radioactivity disposed with a new steel container (4 drums with active concrete in the gaps). PURAM is going to submit for approval new waste acceptance criteria for the new waste packages to be disposed in the second disposal chamber.

During 2012-2013 PURAM prepared the continuation of the research program on deep geological disposal by developing a geological survey plan for the next stage of the investigation of the Boda Claystone Formation. The objective of the present investigation stage, which is planned to be implemented before 2018, is the general qualification of the host formation and the provision of geological data and information required for the safety assessment. In the near future, the HAEA will have to review these activities but no specific internal procedure exists to ensure an appropriate review is completed.

The issue of resources for review and assessment of waste management facilities is addressed in Recommendation 8 in Section 3.3.

The issue of the capabilities of HAES to review and assess waste management facilities is addressed in Recommendation 13 in Section 5.4

6.5. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

In most cases a safety assessment as one of the main parts of the authorization is not required, nor are there any internal procedures on how to carry out the assessment.

The IRRS team observed that radiation protection and radiation safety plans are prepared by certified experts and these plans are evaluated by the NRIRR in the case of facilities involving higher risk (according to Ministerial Decree 16/2000. EüM 17. § (1)). These experts are certified by different bodies e.g. Health Registry and Training Centre and Hungarian Chamber of Engineers.

There is a component of safety assessment as the OCMO and the RHDs take into account the expert opinion of the NRIRR before issuing the authorisation for construction of some specific facilities and activities. Some standards have been developed by the Hungarian Standardization Body and they are used in the authorization process. However, these standards are not regulatory requirements and, as such, they are not binding.

Inspections are performed by the OCMO and the RHDs over the life time for special facilities and category I facilities. This appears to be the only source of assessment information regarding safety in facilities and activities available to them. The BCDEPN performs regular inspections of releases to the environment monitoring capabilities and performance of environmental monitoring.

The IRRS team observed that processes, competencies and resources allocated to review and assessment are limited and could be enhanced, in particular, for the higher risk facilities and activities (e.g. linear accelerators). The OCMO and the RHDs assess the safety of the facilities and activities in the process of authorization.

The IRRS team found that the review and assessment of the safety of radiation sources facilities and activities is incomplete.

The issue of resources is addressed in Recommendation 3 in Section 1.3.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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 <i>"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"</i>
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.

6.6. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

During the review of HAEA guidelines and procedures, information provided on the HAEA website and ARM, and discussions with HAEA personnel; no significant observations were noted with the following:

- Review and assessment of the various decommissioning strategies and plans
- Periodicity of the review of the decommissioning plans
- Review and assessment of novel decommissioning methods
- Review and assessment of decommissioning reports
- Human resources of the regulatory body for review and assessment of decommissioning activities

6.7. REVIEW AND ASSESSMENT FOR TRANSPORT

The international modal transport regulations (e.g. ADR) are legally binding in Hungary. As mentioned in Section 5.7, TS-R-1 2009 (SSR-6) is fully implemented in the modal transport codes, so they are addressed in the review and assessments process. Since safety during transport of radioactive material is primarily ensured by the design of the package, review and assessment of applications for transport licences is achieved by evaluating the technical aspects of a package and the source specifications, such as special form material or low dispersible material. The design review aspects include mechanical properties, thermodynamics, criticality, and radiation protection. The HAEA has experts in the field of criticality safety with access to validated software.

In order to judge the compliance with the relevant licensing requirements, the HAEA may involve independent technical experts. Requirements for these experts are set in Section 19 A-D of the Act on Atomic Energy.

Package design and handling of packages is a crucial part of the transport process for radioactive materials of all categories. Radiation protection is mainly handled through requirements in the international modal requirements for transport, such as the need for transport index and for certain cases criticality safety index. Procedures for review and assessment verify that requirements for transport in the implementation of SSR-6 are fulfilled. The HAEA has a guide for applicants discussed in Section 9.7.

6.8. SUMMARY

The HAEA has implemented an appropriate level of regulatory oversight for review and assessment activities associated with nuclear power facilities and research reactors.

The HAEA has developed an event follow-up scoring system that incorporates a mixture of deterministic and probabilistic attributes to aid in the determination of appropriate regulatory actions. Additionally, the

HAEA uses a comprehensive set of performance indicators to aid in the assessment of nuclear power, research, and ISFSF facilities.

The BCDEPN should ensure it has access to technical capabilities to review and assess model calculations submitted by applicants.

The IRRS team observed that processes, competencies and resources allocated to review and assessment associated with the use of radioactive sources are limited and could be enhanced, in particular, for the higher risk facilities and activities.

7. INSPECTION

7.1. GENERIC ISSUES

7.1.1. INSPECTION PROGRAMME

In Hungary, nuclear and radiological regulatory activities are carried out by different regulatory bodies. The HAEA has the responsibility to inspect all phases of the life-cycle of all nuclear facilities. During the inspections HAEA inspectors identify and document both non-compliances and good practices. The OCMO and the RHDs have inspection responsibilities for medical and industrial uses of radioactive materials. The BCDEPN has the inspection responsibilities for environmental and emission monitoring.

The execution of the various inspection programmes are discussed in Sections 7.2 through 7.7.

7.2. INSPECTION OF NUCLEAR POWER PLANTS

7.2.1. INSPECTION PROGRAMME

The IRRS team found HAEA inspection staff to be very dedicated, well trained and knowledgeable of the Paks I NPPs. The HAEA rarely uses TSOs to supplement inspection activities. The inspection programme has previsions for both announced and unannounced inspections. Unannounced inspections were normally used during plant outage activities and for the oversight of maintenance staff including contractors. During normal operation, inspections are mostly conducted during regular HAEA working hours. The IRRS team noted that the HAEA could better utilize unannounced inspections during backshifts and outside normal hours to obtain a complete evaluation of plant operations. The IRRS team also identified a similar issue regarding the OCMO/RHDs in Section 7.5.

The HAEA implements its annual inspection plan for each unit by performing inspections using three types of inspections. Ad-hoc inspections are conducted of plant operations by observing activities in the control room and evaluations of plant areas and equipment; revealing inspections are conducted of specific maintenance, surveillance, and other activities; and annual comprehensive team inspections of issues selected by senior HAEA management that require additional regulatory oversight. The HAEA is developing a procedure to inspect and evaluate safety culture, and seeking input from affected interested parties. The IRRS team encourages the HAEA to develop and implement the procedure. In addition, as noted in Section 7.5, the OCMO does not have inspection procedures for the assessment of management systems and safety culture and should also develop and implement procedures to cover these areas. This issue is addressed in Recommendation 10 and 11 in Section 4.1.

The HAEA has established an inspection programme and stated in the ARM that the program was implemented using a graded approach. However, the IRRS Team could not find any internal procedure which shows how the HAEA uses the graded approach.

The HAEA develops annual inspection plans for each Paks I unit using input based on the previous year's experiences. This results in an inspection plan that is tailored specifically for each unit. The IRRS team agrees that the use of past performance and operating experience are important components in creating an inspection plan and recommends that the HAEA enhance its inspection planning to ensure that all inspection areas addressed in GSR Part 1, and GS-G-1.3 as applicable, be considered during inspection planning. The inspection planning and implementation should include coordination with other authorities as necessary.

The HAEA inspection staff stated that in some cases it performs joint inspections with other regulators (e.g. environmental monitoring and fire protection) and shares all of their inspection results with other related regulators.

The inspection programme interfaces with authorization, review and assessment and enforcement as needed. Inspectors confirm statements for licensing actions as necessary.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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."
	Suggestion. The regulatory hady should consider revising its inspection programme for

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 <i>"In conducting inspections, the regulatory body shall consider a number of aspects including:</i>
	- 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.

7.2.2. INSPECTION PROCESS AND PRACTICE

HAEA Guideline 1.43, "Regulatory inspection of nuclear facilities," addresses the process, conditions and documentation of regulatory inspections to be carried out at nuclear facilities during construction, commissioning, operation, and decommissioning of the facility. The objective of the guideline is to provide recommendations for the licensee to support the efficient and effective regulatory inspection to ensure the safety of the facility. This guidance provides inspection methods and techniques and how the results of an inspection should be documented.

The HAEA performs ad-hoc inspections using licensee check-lists and procedures to perform an independent assessment of activities such as plant maintenance and operations. For revealing inspections,

the inspectors create their own inspection plan of the areas they intend to cover. The IRRS team noted that, while the inspectors did use inspection procedures, there was no procedure for the development of new inspection procedures or plans. The HAEA has begun developing such procedure and the IRRS team recommends that the procedure include information to ensure that all applicable regulatory requirements and licence conditions are covered during inspections. This issue is addressed in Recommendation 11 in Section 4.1.

The HAEA has initiated a performance indicator programme to evaluate the effectiveness of its inspection programme. The IRRS team suggests that the HAEA implement the programme as soon as practicable and include the enforcement programme. One of the goals of the performance indicator programme would be to periodically update and improve both the inspection and enforcement programmes. The issue of the self-assessment of the inspection and enforcement programmes is addressed in Recommendation 11 in Section 4.1.

7.2.3. INSPECTORS

The HAEA has an inspector training programme that lasts between 2 to 3 years based on the individuals' previous experience. The programme includes training to become a public servant, in-house technical training, training at the Paks NPP Training Centre on operation of the Paks NPP, and on-the-job training. At the conclusion of the training the individual must pass a written exam and oral board to become a certified inspector. Annual refresher training, tailored to an individual's needs, also takes place. Currently, six staff members are undergoing training to become resident inspectors and other 22 future inspectors are being trained to work at the HAEA headquarters for the construction phase of the Paks II NPP.

Through the use of up to 8 resident inspectors, the HAEA has a good inspector presence on site. The inspectors have unlimited access to the facilities and the authority to issue on the spot enforcement actions. However, this authority has never been exercised. The HAEA management is involved with all enforcement actions.

The HAEA does not have a formal process to evaluate the objectivity of resident inspectors. Once inspectors are assigned for Paks I, they are allowed to remain at the site indefinitely. The IRRS team noted that the HAEA should consider implementing a process to evaluate the site inspector's objectivity.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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 <i>"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."</i>
(2)	BASIS: GS-G-1.3 para. 6.1 states that <i>"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."</i>
S 6	Suggestion: The regulatory body should consider developing guidance to ensure the objectivity of inspectors.

7.2.4. INSPECTION OF FACILITIES

The IRRS team visited the Paks I NPP, accompanied with an HAEA inspector on a plant safety inspection and met with senior managers for the facility. There are currently 8 resident inspectors assigned to Paks. The role of the resident inspection staff is to complete most of the annual inspection plan for each unit and

they also have some licensing duties. The resident staff is supplemented by inspectors from the HAEA. The total of trained inspectors is approximately 40. The site inspectors stated that they had sufficient staff to implement the inspection programme.

The IRRS team observed an inspection of the general condition of one of the emergency core cooling systems pump rooms in Unit 1. These observations included the inspector's detailed walk-down of the high pressure and low pressure ECCS. The IRRS team noted that the inspector was knowledgeable of the plant systems and interacted professionally with the licensee staff.

The IRRS team met with Chief Executive Officer (CEO) for Paks NPP to obtain feedback on HAEA inspections. The CEO indicated that they conduct periodic informal calls with HAEA management and hold a formal annual meeting to discuss items of mutual interest and noted that the HAEA was a firm but reasonable regulator. The CEO noted that the inspection staff was competent but expressed a concern whether the HAEA would be able to recruit sufficient and competent staff to oversee activities at both Paks I operating NPPs and, in the future, Paks II new build NPPs.

The day after the observed inspection the inspector sent the inspection report to the licensee.

7.3. INSPECTION OF RESEARCH REACTORS

The IRRS team observed an inspection by HAEA inspectors of a modification to the emission monitoring system of the BRR and met with the reactor manager, a user and the general manager. During the inspection the inspectors were very professional in interactions with the licensee. At the conclusion of the inspection the inspectors presented the licensee the observed facts as noted in the inspection record. The lead inspector and a representative of BRR signed the inspection record. The prescriptions and specifications of tasks will be sent to BRR within 30 days.

The HAEA plans approximately 10 inspections at both of the two research reactors it regulates. The IRRS team found that the HAEA inspects in accordance with GSR part 1, requirement 29 para. 4.53. Inspection topics specific to research reactors such as experimental devices important to safety, and experimenters' management are considered. The research reactors seldom subcontract activities and try to choose suppliers from among a list of nuclear qualified companies.

During the inspection, neither the BCDEPN nor a TSO expert in metrology were invited to participate even though the emission monitoring system could have an influence on the quality of the environmental measurements used by the organizations. The IRRS team found that there were no joint inspections with the BCDEPN on common topics. However, the content of the inspection plan is shared for comment with other authorities, as appropriate. The HAEA should consider further enhancement of its inspections to include joint inspections and is addressed in Recommendation 18 in Section 7.2.1.

The HAEA has one inspector specialized in research reactors. Three others inspectors were currently receiving on-the-job-training for research reactor inspections.

The IRRS team identified that the HAEA procedures ME-3-2-7 and ME-3-2-8 for inspection of the research reactors does not include drafting and issuing inspection reports. Procedures should be developed for documenting inspections. The issue of the development of inspection procedures for research reactors is addressed in Recommendation 10 in Section 4.1.

The inspection team met with one of the users of BRR who stated that the users of the reactor and experimental devices never interfere with the safety of the reactor, the licensee has the prime responsibility for safety.

During the visit the BRR manager and the general manager of the Energy Research Centre were complimentary of their relationship with the HAEA; especially with the management staff and inspectors who demonstrate a strong understanding of the problems and difficulties specific to research reactors.

They noted that the regulatory administrative burden is becoming too prescriptive and limits the creativity of the researchers and licensees.

7.4. INSPECTION OF WASTE MANAGEMENT FACILITIES

The HAEA performs periodic inspection of radioactive disposal facilities. Most of the methods stated in IAEA GS-G-1.3 are utilized. A guideline on the Inspection of radioactive waste storage and disposal facility is under development at the HAEA. Its purpose is to state the required actions to be taken by the licensee to prepare HAEA inspections. As mentioned in Section 3.3, a radioactive waste disposal, depending on its nature and lifetime, may require a large set of competencies to implement an inspection process able to cover activities that are over the common routine of waste handling (ie overlap of construction/operation, tests of closure systems, conduct of experimental programme, ...). The HAEA does not have a formal procedure to assist staff in the preparation and the performance of inspections for waste management facilities that would in particular allow to organize such competencies.

The operators of the radioactive waste disposal facilities are responsible for developing relevant quality assurance system in order to ensure that waste packages comply with the waste acceptance criteria. The HAEA controls, through regular inspection, the documentation related to the implementation of the quality assurance system. To provide a high level of confidence that operators are in compliance with the safety objectives prescribed or approved by the regulatory body, the HAEA does not conduct independent verification of compliance of waste packages. The IRRS team observed an inspection by the HAEA at Bátaapáti NRWR of the transfer of one concrete container from the storage building to the underground disposal chamber. During the handling of the container one corner was damaged. The inspector and facility manager discussed the damage and how the same damage had occurred at least once in the past. At that time, the HAEA requested PURAM to perform a study to evaluate any safety concerns. That study was still in progress at the time of the inspection. During the inspection the inspector was very professional with the licensee. The inspector conducted a meeting to discuss the observed facts and signed the inspection record.

	RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES		
Observa	Observation: The HAEA does not conduct independent verification of the nature of the waste package.		
(1)	BASIS: GSR-Part 1 Requirement 27 states that <i>"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."</i>		
(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.		

7.5. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

The OCMO and the RHDs conduct inspections in accordance with Ministerial Decree 16/2000. EüM. The inspection frequencies are prescribed in the Annex 7 of this Ministerial Decree and are performed using a graded approach. There are no detailed (including dates and facilities, non-announced inspections), annual inspection plans available. However, both authorities perform inspections of high risk facilities and activities. The self-assessment performed for the IRRS mission identified that the regulatory bodies had an insufficient number of qualified inspectors to fully carry out its inspection duties. While observing an inspection, the IRRS team found that, due to the insufficient number of inspectors, all the facilities and activities, except for inspections of Category I. or special facilities are not inspected with the frequency established in the Ministerial Decree 16/2000. EüM. This issue is addressed in Recommendation 4 in Section 1.3.

The IRRS team noted lack of mutual understanding of regulatory processes which are taking place in different regulatory bodies and inappropriate communication and cooperation among regulatory authorities and other parties taking part in radiation safety, e.g. the RHDs' staff has no direct communication with the NRIRR regarding occupational doses received by a licensee, except in case of an emergency or exposures above the investigation level (6mSv) so the efficiency of an inspection is limited. The OCMO and the RHDs do not have immediate access to the HAEA inventory of sources.

Planned and reactive inspections are performed. There are provisions for unannounced inspections, however, only announced inspections have been performed, however only the time of inspection is arranged for announced inspections, but not its scope. The issue of lack of unannounced inspections is addressed in Suggestion 5 in Section 7.2.1. There are no procedures or checklists specific for inspecting the use of radiation sources. The inspection techniques usually include a review of documentation, site visits, radiological measurements and communication with the licensee. Reports are prepared at the end of the inspections do not include the assessment of management systems or safety culture. The issue of development of assessment management systems and safety culture for radiation sources facilities and activities is addressed in Recommendation 10 in Section 4.1.

The IRRS team noted that due to the insufficient number of qualified inspectors a comprehensive inspection may be a challenge. The IRRS team was informed that the regulatory body is archiving files related to the inspections so that the information is maintained; however, feedback from inspections is not used in the authorisation process.

The IRRS team also observed an inspection at a nuclear medicine (therapy and diagnostic) facility in Budapest. The issue of insufficient resources is addressed in Recommendation 4 in Section 1.3.

7.6. INSPECTION OF DECOMMISSIONING ACTIVITIES

The regulatory body has the authority to carry out inspections of decommissioning activities of nuclear facilities in accordance with Subsection 22 (1) of Govt. Decree 118/2011. Korm. In addition, the HAEA can inspect the actual implementation of the decommissioning based on the Final Decommissioning Plan, Decommissioning Safety Report and decommissioning licence, updates to the Decommissioning Safety Report, and preparation of radioactive wastes for final disposal or clearance.

There are currently no facilities undergoing decommissioning in Hungary and no decommissioning inspections are being performed or are planned in the near future.

7.7. INSPECTION OF TRANSPORT

The HAEA has the authority to conduct inspections of radioactive transport packages. The inspection of a shipment is performed by the police, the National Transport Authority (NTA), the competent RHD and

the national disaster management organization. By law, the organizations must inform each other of their inspections. Inspections are conducted as determined in Section VI "Authority inspection" of the KET. Inspections performed by the HAEA are approved within the quality management system of the authority and comply with the requirements of KET. The inspection frequency of transport activities by the HAEA is one to two inspections per year per licensee.

Radiation protection inspections for transport packages are conducted by the OCMO and the RHDs. Transports are regarded as Category II and the OCMO and the RHDs determine the frequency of inspections of the facilities using a graded approach which designates the inspection frequency of Category II every 3 years.

The IRRS Team observed an HAEA inspection at the Isotope Institute Ltd. The inspection was performed by two HAEA inspectors of the production of special form sealed sources and the associated quality control system. The inspection included a review of the documentation of the control of sources produced over the past year. The inspection also included a visit to the hot cells where leak testing was performed.

The inspectors conducted the inspection in professional manner. A draft inspection report which documented the observed facts was agreed upon by both the inspectors and the facility operator and issued on the spot. There were no findings; however, the IRRS team was told that if there had been findings they would have been handled separately. The HAEA inspector has the authority in such cases to sign and issue the report. Normally inspections are performed by only one inspector. One to two transport inspections are performed by the HAEA of each licensee. The manager of the plant confirmed during a private discussion that the cooperation with the HAEA was working very well.

7.8. SUMMARY

The regulatory body inspection staff is well trained and knowledgeable. However, some human resource issues need to be addressed. The IRRS team found that the regulatory body should:

- 1. Consider enhancing the use of unannounced inspections.
- 2. Develop a procedure to inspect and evaluate safety culture, and as necessary, management systems.
- 3. Enhance inspection planning to ensure that all inspection areas addressed in GSR Part 1 and GS-G-1.3 are covered and to coordinate and implement the plan with other authorities as necessary.
- 4. Develop guidance for developing inspection procedures to include information to ensure that all applicable regulatory requirements and licence conditions are covered during inspections.
- 5. Consider implementing a process to evaluate NPP resident inspectors' objectivity.
- 6. Ensure sufficient resources are available to adequately implement the inspection programme.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESS

The regulatory framework in Hungary provides the necessary authority to the various regulatory bodies associated with radiation, nuclear facilities and activities. The Act of Atomic Energy and the KET along with various governmental and ministerial decrees are in place and used by the appropriate authorities to initiate enforcement action when required. Regarding actions arising that would be considered criminal in nature, enforcement under Act C of 2012 of the Penal Code would be applied.

The various tools to be used for enforcement purposes have been well established and are described as part of the regulatory framework. The principle of a graded approach is applied when an enforcement action is to be taken. These enforcement tools are:

- written notices, corrective actions by a deadline;
- prescription of conditions;
- limitation and termination of an activity;
- revocation of a licence; and
- imposition of an administrative penalty.

In situations when an administrative penalty is the enforcement action, circumstances need to be taken into consideration in arriving at a determination. In particular,

- whether an extraordinary event, nuclear emergency or a nuclear damage has occurred;
- the significance of the violation of requirements and prescriptions;
- whether a recurring violation has occurred;
- whether a behaviour causing the violation or omission can be identified; and
- whether the legal person violating the requirements or omitting the obligations has behaved in a way that supported measures implemented for the termination or mitigation of the consequences.

The Governmental Decree 112/2011. Korm. specifies the range of the administrative penalty that could be applied in the case of a non-compliance.

Administration penalties are issued to only licensees not individuals and the HAEA has the capacity to publish the decisions regarding the issuance of an administrative penalty on their website. The request for review of enforcement actions can be addressed to the HAEA as well as the Budapest-Capital Administrative and Labour Court. The administrative review procedure of an enforcement action is described in the KET Sections 3, 81/A, 81/B, and 114. Concerning the court procedure the rules of the Code of Civil Procedure (Act III of 1952) shall be applied.

Enforcement Policy and Processes

Enforcement policy

The enforcement strategy of the HAEA for nuclear facilities is based upon Enforcement Policy P-0-2, implemented in 2001 and revised as recently as February 2014. This places an unnecessary burden on inspectors when an enforcement action is being contemplated. Updated procedures will assist the inspector in the application of the Enforcement Policy. This will ensure consistency in the selection of enforcement actions when non-compliances are identified. With respect to administration penalties, procedures will provide guidance with respect to the determination, assessment and calculation. The need

to prepare such procedures has been identified in the ARM Action Plan. Up to date enforcement procedures for inspectors will ensure a comprehensive assessment of any non-compliance and the application of consistency when assessing the circumstances specified in the KET, Government Decrees 112/2011. Korm., 118/2011. Korm. and 155/2014. Korm.

The OCMO and the RHDs have no enforcement policy for radiation sources to guide inspectors when faced with the need to take enforcement action.

Graded approach

A graded approach to enforcement is applied to non-compliances identified during inspections, event investigations, and reports provided by the licensee. The Section 94/A of KET, Sections 2-3 of Governmental Decree 112/2011. Korm., describes the provisions for the application of a graded approach by the HAEA, and the criteria to apply to a non-compliance when considering the imposition of an administrative penalty. The graded approach is only applicable to nuclear facilities and radioactive waste repositories and not for the other authorized activities associated with radioactive sources and other radioactive materials. The safety significance of the non-compliance and the response of the licensee are taken into consideration when applying any enforcement measure.

Environmental protection

The BCDEPN is the responsible authority for all aspects of environmental compliance and enforcement related to nuclear facilities and nuclear materials in Hungary. The ARM and interviews conducted by the IRRS team confirmed that with respect to facilities and activities that require environmental impact assessment, enforcement actions are covered under Governmental Decree 314/2005. Korm. Where no environmental impact assessment has been performed, there is no legal basis for taking enforcement action. The BCDEPN is taking action to resolve this gap.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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 <i>"The regulatory body shall establish and implement an enforcement policy within the legal frameworkspecified in the authorization."</i>
(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	

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	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 <i>"the regulatory body should enforce the applicable regulations and the authorization, including suspension, modification or revocation of the authorization".</i>
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.

8.2. ENFORCEMENT IMPLEMENTATIONS

The enforcement measures taken by HAEA inspectors in the event of non-compliances are commensurate with the safety significance and a graded approach is applied. For example, non-compliance administrative in nature or of low safety significance could result in a warning issued by the HAEA. A significant non-compliance could result in a limitation of the operating licence, termination of an activity, an administrative penalty or a combination of these. Enforcement measures are systematically reviewed with all site HAEA inspectors, technical staff and management prior to being issued. The IRRS team confirmed a lack of procedures to document key elements of this process and the application of an administrative penalty. A similar issue was noted in the ARM and action plan.

The HAEA uses trends and indicators arising from enforcement actions and observations of HAEA inspectors and technical experts to confirm the effectiveness of their enforcement measures. The HAEA management system currently does not require a formal systematic review of the effectiveness of this approach. This issue is addressed in Recommendation 11 in Section 4.1.

In Hungary there is one research and one training reactor. The IRRS team identified that there are no enforcement procedures in place for inspectors regulating activities at these facilities. The ARM has recognized the lack of procedures and is addressing this in the Action Plan. The current approach taken by the HAEA with respect to any non-compliances identified was described as a "soft" enforcement approach. The licensee has responded in a timely fashion to any warnings or written notices that have been issued based on inspection findings, authorizations, or safety reviews. Should more forceful measures be required, inspectors would implement the provisions of Governmental Decree 112/2011. Korm. and Governmental Decree 118/2011. Korm. With respect to the environment, the IRRS team confirmed that the BCDEPN has no policy or procedures for inspectors with respect to the initiation of enforcement actions.

Radiation Sources

The OCMO is the regulatory body responsible for ensuring compliance with the regulatory requirements for the safe use of radiation sources. There are provisions for enforcement and for revoking of a licence and or suspension of a licence in Ministerial Decree 16/2000. EüM., and for imposing health and administrative fines in line with the Health Act and the KET respectively.

The OCMO and the RHDs have applied some enforcement actions, e.g. the IRRS team was told that an RHD has started enforcement actions regarding an accident involving contamination with Am-241 where three workers were affected. The OCMO and the RHDs have the necessary management and legal

support within their organizations to carry out enforcement actions including the issuance of administrative penalties. The licensee can appeal to the RHDs, exercise a second appeal to the OCMO, and finally to Budapest-Capital Administrative and Labour Court.

Regulatory authorities responsible for the enforcement of non-compliances all have the necessary legal instruments to take the appropriate action.

The HAEA along with the NTA oversees the transportation of nuclear materials in Hungary. The authority to take regulatory action in the event of non-compliance is identified in ARM. As a result of the review of information supplied in the ARM, interviews and the transport inspection observed by the IRRS team, it was confirmed that enforcement measures are in place and that actions such as notices and fines have been issued.

8.3. SUMMARY

The HAEA has an enforcement policy, P-0-2 in place that applies to all activities regulated by the authority. The IRRS team observed that inspectors use a graded approach to enforcement actions and that procedures are being developed to comply with the current policy. A range of enforcement actions are identified within the regulatory framework describing the various enforcement measures that can be taken based on the safety significance and other pertinent considerations. Execution of enforcement actions is taken seriously involving extensive internal consultation prior to a final decision by the HAEA.

With respect to the OCMO, the RHDs, and the BCDEPN, enforcement actions are taken commensurate with the safety significance. The IRRS team confirmed that these authorities do not have enforcement policies nor procedures to guide inspectors when enforcement actions are necessary. The need has been identified for the BCDEPN to enhance their ability to take environmental action when required.

9. **REGULATIONS AND GUIDES**

9.1. GENERIC ISSUES

The Act CXVI of 1996 on Atomic Energy covers peaceful use of atomic energy, the related rights and obligations and the protection of people and the living and lifeless environment against harmful effects of ionizing radiation of natural and artificial origin. The Government and the concerned ministers issued decrees in the various fields for a detailed regulation of the principles laid down in the act. The Act also determines the HAEA mandate and tasks in the field of law-making. The HAEA has an obligation to initiate the establishment, amendment of laws and to participate in the public administration coordination of them.

The HAEA, under its mandate, develops a draft proposal of legislation. According to HAEA procedure (ME-0-0-25) it sends draft proposals to the Ministry of National Development. According to the Act the requirements for using atomic energy shall be regularly reviewed and updated, taking into account the results of science and international experiences. According to Governmental Decree 118/2011 Korm. taking into consideration the scientific results, and national and international experience, the Nuclear Safety Code shall be reviewed at least every five years and updated as required. The guidelines shall be reviewed periodically.

In 2005 the HAEA started the renewal process of mandatory safety requirements by drafting the Governmental Decree of Nuclear Safety (later issued as Govt. Decree 118/2011. Korm.) and its annexes, the volumes (1...10) of the Nuclear Safety Code (NSC), to determine the provisions on nuclear safety requirements for nuclear facilities and the corresponding regulatory authorizations. Compliance with the nuclear safety requirements and provisions are mandatory for all those, who are under continuous regulatory supervision according to the Act. In addition to the nuclear safety requirements and provisions the requirements involve individual authority prescriptions, conditions and obligations, what the HAEA is authorized to determine as a nuclear safety authority in a resolution made for nuclear safety of a nuclear facility.

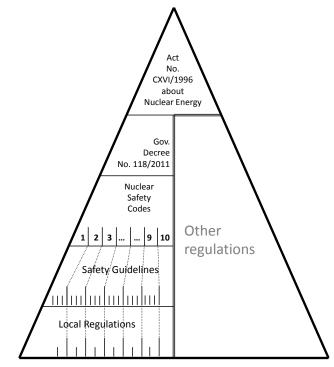


Figure: Hierarchy of Hungarian Regulations and Guidance of Nuclear Safety

NSC covers all nuclear facilities throughout their lifecycles including research reactors and spent fuel storage facility. NSC Volume 5 is specific for research reactors design and operation and NSC Volume 6 is specific for design and operation of the interim spent nuclear fuel storage facility. Specific NSC for Decommissioning is Volume 8. There is a separate Volume 10 for terminology.

The HAEA has created an internal procedure (ME-0-0-36) for review of NSC and the development and review of regulatory guidelines. In 2006, the HAEA developed a project plan and Quality Assurance Plan (MÜT) for Nuclear Safety Code and guidance preparation.

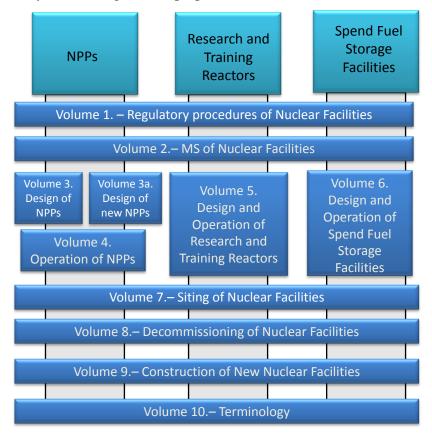


Figure: Present structure of Nuclear Safety Code (NSC)

The original plan was to finalize the draft requirements for all volumes of NSC and relevant guidelines containing recommendations on the compliance with the requirements of the NSC by 2008. The drafting of NSC was finished by 2008 but due to the long consultation process the NSC volumes were published three years later in 2011 and without the complete set of regulatory guidance, which is currently being developed. The HAEA demonstrated to the IRRS mission team that the HAEA has plans in 2015-16 to validate and create guidelines.

The HAEA is using as a reference IAEA requirements and recommendations, WENRA reference levels and safety objectives, European Utility Requirements (EUR) and OECD NEA MDEP position papers as well as the construction experience of new build NPPs from the OECD NEA ConEx-database.

NSC regulations and related safety guides specify the review and assessment topics, as use of Probabilistic Safety Analysis. It also has requirements to carry out the Periodic Safety Reviews (PSR), taking into account e.g. Operating Experience Feedback and Severe Accident Management. In Hungary the regulations related to inspection and enforcement are mainly described in Atomic Energy Act, Governmental Decree 118/2011. Korm and NSC volume 1.

The new Governmental Decree (Govt. Decree 155/2014. Korm.) specifies the general requirements for the safety of radioactive waste storage and disposal facilities. Requirements concern in particular conditions to accept waste in the facilities, the responsibilities of the licensee for the different activities.

The legislative and statutory framework for the control of radiation sources is the Act CXVI of 1996 on Atomic Energy, together with the Ministerial Decree 16/2000. EüM, of the Minister of Health on the implementation of certain provisions of the Act. Other Governmental and Ministerial Decrees, including Governmental Decree 124/1997 Korm., Governmental Decree 17/1996 Korm., Ministerial Decree 23/1997 NM and Ministerial Decree 31/2001 EüM, among others, supplement the framework for radiation safety. The revision of the Ministerial Decree 16/2000 EüM can be initiated by the Ministry of Health, the OCMO or Governmental offices. The draft is sent to the interested parties for comments. The last revision of Ministerial Decree 16/2000. EüM. was initiated in 2014 by the OCMO, with the collaboration of the RHDs and the NRIRR.

The Ministries of Agriculture and Ministry of National Development are responsible to draft the regulatory requirements for environmental legislation including Environmental Impact Assessment (EIA) process. In the environmental law making process the both ministries will ask statements from the relevant institutes and authorities as County Government Offices such as the BCDEPN responsible for environmental protection according to Governmental Resolution 1144/2010. Korm. and Ministerial Resolution issued by the Ministry of Agriculture 3/2014. The EIA is carried out according to the Act LIII/1995 on environmental protection and Governmental Decree 314/2005. Korm. on environmental assessment and unified environmental use licensing procedure. The Ministry of Agriculture is the coordinating authority and conducts international consultations according to Espoo Convention, which sets out the obligations of Parties to assess the environmental impact of certain activities at an early stage of planning. Espoo Convention also lays down obligations to consult on major projects that have a significant adverse environmental impact across boundaries. Ministerial Decree 15/2001. KöM. sets the limits of radiological discharges to the environment under normal operations. County Government Offices as the BCDEPN uses the limits for releases in accident conditions established in NSC Volumes 3 and 3a for NPPs.

Hungary has established the following legislation pertaining amongst others to the safe transport of radioactive material: Act on Atomic Energy, KET, Govt. Decree 112/2011. Korm., Ministerial Decree 51/2013. NFM, Govt. Decree 190/2011. Korm., Govt. Decree 34/2009. Korm., Ministerial Decree 16/2000. EüM and Govt. Decree 263/2006. Korm. the HAEA is the relevant authority to develop and draft requirements for safe transport of radioactive materials and issue any needed guidance.

The HAEA consults with the licensees in the early phase of the review to make proposals to improve and develop the NSC based on operating experience. During the elaboration of the regulations, the HAEA was taking into account the safety hazards of the nuclear facilities and developed the regulation to be commensurate with importance of safety taking into account a graded approach. The HAEA determined that there are about 3200 mandatory Nuclear Safety Requirements (NSC) in the appendices (vol. 1 through 10) of the Governmental Decree 118/2011. Korm. In addition, the NSC, there are special requirements for design on new nuclear power plants (NSC Vol. 3a). Among the NSC Vol 3a requirements, some of the NSC mandatory requirements were found to be very detailed and prescriptive. The graded approach should be taken into account in a more systematic manner when developing the safety requirements and safety guidance. This would allow more effective use of graded approach in HAEA internal processes is addressed in Recommendation 11 in Section 4.1.

To enhance the HAEA regulatory processes and to promote the Nuclear Safety regulatory framework to the interested parties and the public, the HAEA is creating a single web-portal with the Act on Atomic Energy, Governmental Decree 118/2011. Korm. and its appendices, NSC volumes 1 through 10, and

relevant safety guides. By using the web-portal with the build-in links, it will be user friendly for users to see the relationship and the references between different Nuclear Safety requirements and guides.

The following interpretation of safety guides apply in Hungary: If the fulfilment of the obligation takes place according to the safety guidelines with its methods based on Governmental Decree 118/2011. Korm the HAEA considers the selected method to be suitable and the method itself is not examined. If a method other than those in the guidelines is selected, then the HAEA shall examine the correctness, suitability and entirety of the applied method.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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.

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.*

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.

Observation: To enhance the effectiveness of HAEA regulatory processes and promotion of the Nuclear Safety regulatory framework to the interested parties and public, the HAEA is creating a single web-portal covering the Act on Atomic Energy, Governmental Decree 118/2011. Korm. and its appendices, NSC volumes 1 through 10, and safety guides. By using the web-portal with built-in links, the portal will be user friendly and able to show the relationship and references between different Nuclear Safety requirements and guides.

(1) **BASIS: GSR Part 1 Requirement 34 states that** "The regulatory body shall notify interested parties and the public of the principles and associated criteria for safety established in its regulations and guides, and shall make its regulations and guides available."

GP5 Good Practice: The Regulatory Framework Web-portal with links between different levels of requirements and guides is considered a good practice.

9.2. REGULATIONS AND GUIDES FOR NUCLEAR POWER PLANTS

Hungary has a comprehensive set of safety requirements for Nuclear Power Plants in the Government Decree 118/2011. Korm. and its appendices (NSC volumes 1 through 10). The Design of Nuclear Power Plants (NPP) shall be conducted according to mandatory safety requirements set in the Nuclear Safety Code (NSC) volumes 3 and 3a. The NSC volume 1, 2, 7, 8, 9, and 10 sets the requirements effective for all nuclear facilities.

The site assessment of the NPP is based on NSC volume 7 while the construction is based on NSC volume 9. Requirements on commissioning and operation of nuclear power plants are governed by volume NSC 4. Decommissioning of nuclear power plants as well as other nuclear facilities shall fulfil the requirements set in NSC 8.

There is a parliamentary Decision-in-Principle, 30.3.2009, in Hungary to extend the Nuclear Power Program by constructing new Light Water Reactors at the Paks site. Therefore the decision was made to separate the mandatory requirements to two different Nuclear Safety Codes. NSC Volume 3 is for operating Nuclear Power Plants (NPP) and Volume 3a was developed for new builds. The HAEA determined the priority of the guidelines out of those to be issued for the new units after consultation with future licence applicant. Accordingly the site assessment related guidelines have been developed and issued (1.1 Site licensing of nuclear facilities; 7.1 Methodology for site assessment and characterization). The issuance of the design and construction related guidelines are under progress within the HAEA. According to HAEA internal management system procedure (ME-0-0-36), the HAEA shall develop or review the safety guides by using own staff resources or using support from the TSOs to draft the safety guides. The development of safety guides for new NPPs is an important task to accomplish for effective regulatory review and assessment as well as for future inspection actions.

The Fundamental safety functions for operating and new nuclear power plants are described in NSC volume 10 and design requirements for safety functions are set in NSC volumes 3 and 3a and fulfil IAEA SSR-2-1 requirement 4.

The principle application of five levels of Defense-in-Depth (DiD) for all nuclear facilities is described in Governmental Decree 118/2011. Korm. section 7. Supplementary requirements for new NPPs are in NSC volumes 3 and 3a for operating NPPs. The safety requirements for new NPPs in Hungary comply with the IAEA requirements and with the WENRA safety objectives published for new NPPs (2013). According to WENRA, the DiD level 3 has been divided to two sublevels. Sublevel 3a to cope with design basis accidents and sublevel 3b to cope with complex accidents with the postulation of multiple failures. Fourth level in DiD is for Severe Accident Management (SAM).

The requirement for design basis is set in Governmental Decree 118/2011. Korm. section 9 and for NPPs are set in NSC volumes 3 and 3a. The design limits shall be consistent with the nuclear safety requirements and with applicable standards. In order to fulfil the fundamental safety functions, all required safety functions and systems shall be identified for all Operating Conditions by safety or other analysis. In the case of a new nuclear power plant unit Operating Conditions are defined as:

- a) normal operating condition (TA1);
- b) design basis operating conditions;
 - anticipated operational occurrences (TA2);
 - low frequency design basis accidents (TA3); and
 - very low frequency design basis accidents (TA4);
- c) extended beyond design basis operating conditions;
 - complex accidents (TAK1);
 - severe accidents (TAK2)

For the NPP design, all postulated initiating events that may influence the safety of the nuclear power plant shall be identified. The ones of these initiating events to be incorporated into the design basis shall be selected by a deterministic method or the combination of deterministic and probabilistic methods. Design limits shall be specified for the fundamental physical parameters of the systems, structures and components important to nuclear safety. Volumes 3 and 3a present the list of initiating events, which should be considered. Design limits shall be consistent with the nuclear safety requirements and the applied standards.

Descriptions of Plant States and Operation Conditions are presented in NSC volume 10 and further requirements are presented in NSC volumes 3 and 3a. Design extension, as "extended design basis", is

also considered in NSC requirements. Requirements for operation of nuclear power plants including operating procedures and operational limits are set in NSC volume 4, which contain also regulatory requirements on operation, in specific. Safety classification requirements for NPPs are presented in design NSC volumes 3 and 3a. NSC volumes 3 and 3a have reliability requirements for computer based systems and safety classified systems have to tolerate a single failure. Also requirements to monitor safety performance in all operation conditions are included to design requirements.

One of the design principles for safety in new NPPs, is that systems categorized in nuclear safety classes shall be designed so that the nuclear power plant unit need not shut down due to scheduled preventive maintenance or testing. In the case of all systems, structures and components important to nuclear safety, the programme of in-service or regular in-service inspections, reviews and material testing programmes, the mode and frequency of the testing of structural integrity, leak tightness and functions, and the designer specifications for planned preventive maintenance and other maintenance strategies shall be determined. Design requirements include the allowance for future modifications of new NPPs as well as authorization, assessment, review and inspection actions are specified to control plant modifications.

Accident management is defined in NSC volume 10 as "Measures taken by the operator in beyond design basis operating conditions with the aims as follows: a) the prevention of the event being more severe and of its evolution into a severe accident; b) achievement of long-term safe and stable conditions; and c) mitigation of consequences".

Upper level requirement for licensee having comprehensive training policy is set in Governmental Decree 118/2011. Korm. More detailed requirements for training are in NSC volume 2 chapter 2.4 under human resources, which includes also the requirements for management of competencies. Further requirements related to training are included in NSC Vol. 4 Chapter 4.4.1.

Based on the questions in the self-assessment chapter Commissioning and Operation it can be concluded that the HAEA essentially complies with the requirements and recommendations of the IAEA documents.

The HAEA has established a systematic process to check that WENRA 2008 reference levels were recognised in the Governmental Decree 118/2011. Korm. and all its appendices NSC (volumes 1 through 10). Updated systematic process will be also used with WENRA 2014 reference levels elaboration. For systematic coherence check of IAEA requirements fulfilment, the HAEA should use systematic methods.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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 <i>"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."</i>
S 8	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.

9.3. REGULATIONS AND GUIDES FOR RESEARCH REACTORS

Two RRs are operated: the BRR and the TR. Hungary has a comprehensive set of safety requirements for research reactors in the Governmental Decree 118/2011. Korm. and its appendices and NSC Volume 5 which sets the specific requirements for research reactors.

The IRRS team has reviewed this specific volume with the inspectors in charge of the RRs. It includes design requirements that would apply in the eventuality of a new reactor project. The requirements on the operational limits and conditions are detailed. Volume 5 also deals with worker safety, including the users of the reactor who are operating experimental devices as well as the contractors. It emphasises the prime responsibility of the licensee, which has been confirmed during the interviews. The question of training of any person working in the facility is also addressed. Concerning the authorisation classification principles they are described according to a graded approach and cover the new experimental devices.

According to the information provided, three specific guidelines from NSC Volume 1 have been issued. Safety guide 1.51 is under development for RR Periodical Safety Review (PSR). Guideline for modifications for RR is also under development, while the guideline for decommissioning is only planned at this time. The IRRS team noted that the decommissioning of RR is not planned before 2023.

9.4. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

In order to comply with the new Governmental Decree 155/2014. Korm., the HAEA has undertaken the elaboration of guidelines with the support of an external company acting as TSO (SOM System Ltd.) on the following topics: Regular and event reports of radioactive waste storage and disposal facilities, Periodic Safety Review (PSR) for the National Radioactive Waste Repository (NRWR) and for the Radioactive Waste Treatment and Disposal Facility (RWTSF), Pre-construction Safety Analysis Report (PSAR) of radioactive waste storage and disposal facilities and the Operation Supporting Safety Analysis Report (OSAR). Two other guidelines are also under development with internal staff on the Inspection of radioactive waste storage and disposal facility and the Licensing activities of modification in connection with radioactive waste storage and disposal facility.

According to the IAEA standards and international approach, the licence application for the construction of a disposal facility should contain sufficient evidence that a concept for closure adapted to the characteristics of the disposal and of the site will be feasible. The HAEA provided the IRRS team with the documentation submitted by PURAM for the licence of construction of the NRWD. This safety report presented some generic indications of possible concepts for closure based on international practices and modelling calculations using data from the site without any specific in situ demonstration test that would support evidence for closure strategy. Recently, PURAM has started an in-situ experimental programme in a special chamber drilled in the underground facility in order to test sealing concepts. It is unclear how the long term safety issues have been considered with respect to the current research program. The long term safety of this underground facility will rely on the sealing concept of the access galleries and tunnels; the development of a suitable engineered concept shall be driven by specific safety requirements for the post-closure phase. Such specific requirements should be developed by the regulatory body.

At the beginning of 2008 a document entitled "Updated concept of the long term research programme of the Boda Claystone Formation including content, financial and schedule aspects" was prepared. As a draft concept, the study discusses the possible extent, expected costs and scheduling of the preparatory research activities for developing a deep geological disposal for spent nuclear fuel and HLW. During 2012-2013 PURAM prepared its geological survey plan for the next stage of the investigation of the Boda Claystone Formation, which was approved by the competent authority (Pécs Mining District Authority). The objective of the present investigation stage, which is planned to be implemented between 2014 and 2018, is the general qualification of the host formation and the provision of geological data and information required to determine the suitability of the site.

Since the initial authorization for operation, PURAM has changed its disposal concept of NRWR in order to optimize (increase) the quantity of radioactivity disposed with a new steel container (with active

concrete inside the gaps). PURAM is going to submit for approval new waste acceptance criteria for the waste packages to be disposed in the second chamber. Presently there is no guidance on the development of waste acceptance criteria for the disposal facilities under operation or to be develop in the future for HLW and SF.

In NRWD, since December 2012, the first of the two underground chambers at the NRWR at Bátaapáti has been accepting concrete containers (each container contains nine drums and gaps are injected with concrete). The construction of two additional chambers started in parallel with the operation of the first chamber. In order to encompass with the mechanical disturbances caused by the drilling work (excavation is made by explosive technics), the strategy of PURAM is to always remain one empty chamber between the one under filling and the other under construction. International projects (IAEA GEOSAF & GEOSAF2, EURATOM SITEX as example) raised the safety concerns induced by the implementation of construction activities (in the mining zone) and handling and disposing of radioactive waste containers (in the controlled zone) nearby and possibly at same time (co-activity). In that case, a systematic risk based approach must be developed in order to assess possible impact of accidents or unexpected events occurring in the "mining zone" on the safety of the "controlled zone". In return, provisions must be taken in order to allow radiation protection of mining workers in normal operation or in case of incident in the controlled zone. The development of safety guidance would allow the operator/constructor to define and implement a strategy to manage those particular hazards and assess the safety of those activities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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.

(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."

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(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.

9.5. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

Facilities and activities that use radiation sources are regulated by Ministerial Decree 16/2000. EüM, supplemented with other Ministerial and Governmental Decrees. Hungary as a member of the EU has to transpose and implement the EU Directive and any other document on nuclear and radiation safety.

The IRRS team was told that the process of drafting the transposition of the 2013/59/Euratom Directive, largely in line with the GSR Part 3 currently under review. This issue is addressed in Recommendations 26, 28 and 30 in Chapter 11.

The IRRS team also noted that the control of radioactive sources is covered in the regulations; however, there are some aspects of safe management of disused sources that have to be strengthened; i.e. there are no financial provisions for the safe management of disused sources, as stated in the ARM, and there are no provisions for reuse or reprocessing of radioactive sources.

Some documents addressing some specific authorization topics, i.e. nuclear medicine, have been prepared by the NRIRR and are promoted by the OCMO through regular meetings with the RHDs. However, the regulatory body has not prepared guidance on how to fulfil the regulatory requirements and associated criteria for safety, based on regulatory judgements, decisions and actions for all use types. This issue is addressed in Recommendation 21 in Section 9.1.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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 <i>"For radioactive sources and radiation generators the regulatory process shall continue over their entire lifetime".</i>
(2)	BASIS: GSR Part 1 Requirement 17, para. 3.60 states that " <i>Registrants and licensees</i> 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 <i>"Every State should encourage the reuse or recycling of radioactive sources, when</i>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	practicable and consistent with considerations of safety and security."
	BASIS: CoC on the Safety and Security of Radioactive Sources, para. 20(e) states that <i>"Every State should ensure that the regulatory body established by the legislation has the authority to: …</i>
(4)	(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.

9.6. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

General regulatory requirements for decommissioning of nuclear installations are developed in Volume 8 (Nuclear Safety Code) of Annex 8 of Governmental Decree 118/2011. Korm. The decommissioning requirements for radioactive waste storage and disposal facilities are included in Annex 2 (Repository Safety Code Volume 2) of the Govt. Decree 155/2014. Korm.

The objective of NSC Volume 8 regulation is to define nuclear safety requirements applicable during planning and execution of decommissioning a nuclear facility, as well as dismantling of safety important systems, structures and components and demolishment of nuclear facility buildings in order to cease operations and to terminate the supervision of nuclear authority.

There is currently a plan to start the decommissioning of BRR not before 2023.

The HAEA informed in ARM action plan that the guidance on the contents of decommissioning plan is under preparation.

9.7. REGULATIONS AND GUIDES FOR TRANSPORT

Hungary has established the following regulation pertaining amongst others to the safe transport of radioactive material: KET, Govt. decree 112/2011. Korm., Ministerial Decree 51/2013. NFM, Govt. Decree 190/2011. Korm., Govt. Decree 34/2009. Korm., Ministerial Decree 16/2000. EüM, Govt. Decree 263/2006. Korm.

The modal regulations have specific requirements regarding reporting of incidents and accidents with dangerous goods, RAM included. All general provisions of section III of SSR-6 are inter alia addressed in the modal transport regulations. The HAEA, within its scope of authority, shall require the compliance with them. The HAEA has issued Guidelines for transport in 2013:

"Guideline on the compilation of licensing applications in relation to packaging of radioactive materials in case when the approval of the competent nuclear authority is required by the stipulations of laws and international agreements on the transport of dangerous goods" The scope of the guideline is:

"The subject guideline aims at assisting the client requesting the approval of the packaging of transport of radioactive materials in cases that fall under the competence of the competent national authority according to the stipulations of laws and international agreements on the transport of dangerous goods

with the description of the administrative steps of the relating procedure and the minimum content requirements of the licensing documentation to be submitted."

9.8. SUMMARY

Hungarian legal framework is based on the Act CXVI of 1996 on Atomic Energy, from which the comprehensive regulatory legislation has been developed. Since its development, the Act has been amended to take account of developments in nuclear and radiation safety. Under the Act on Atomic Energy a comprehensive safety regulatory framework has been created. After the year 2005 there has been a revision and development of substantial amount of Governmental Decrees, Ministerial Decrees and Ministerial Resolutions. The IRRS team identified following areas of improvement:

The regulatory body should complete regulatory safety guide development in timely manner. The regulatory body should revise the regulations for radiation sources facilities and activities, bring it in line with the requirements of GSR Part 3. The regulatory body should consider initiating changes to the regulations to improve the control of radioactive sources over their entire life, specifically for assuring financial provisions. Using graded approach in a more systematic manner, while creating and revising regulatory requirements and guides. 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 draft revisions to the legislative framework to keep legislation up to date. The HAEA should add interaction between the HAEA and interested parties including public in safety guidance development and review process. The regulatory body should amend the regulations to improve the control of radioactive sources over their entire life.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

10.1. GENERAL EPR REGULATORY REQUIREMENTS

Basic responsibilities

As previously highlighted in this report, regulatory responsibilities for nuclear and radiological aspects are shared between several organizations: the HAEA, the OCMO and the RHDs.

In designating the HAEA as the regulatory authority for nuclear facilities and activities, the Atomic Energy Act (AEA) explicitly includes reference to oversight of EPR arrangements in the definition of fundamental oversight tasks (Sect 17, para 1). In addition, Ministerial Decree 51/2013. NFM. gives the HAEA the mandate for "authorizing" emergency response plans for the transportation of nuclear fuel. The HAEA mandate for EPR oversight is clearly defined in law and regulations.

Responsibilities of licensees, the regulator and others are clearly defined in AEA and the Governmental Decree 167/2000. Korm. The HAEA is responsible for assessing and approving licensees' nuclear emergency response (NER) plans as part of licensing and oversight and ensuring that the licensee's on-site emergency preparedness "could reasonably provide an effective response". The competence of the HAEA extends over all aspects of emergency preparedness of its licensees.

The EPR regulatory requirements for nuclear activities under the HAEA's purview are based on IAEA standards and guides, and also consider EU and WENRA requirements. The requirements for nuclear facility licensees are clearly and comprehensively described in the form of EPR-related chapters within the Nuclear Safety Code, and were last updated in 2014 to extend the design basis to include all potential sources (reactor, spent fuel, radioactive waste treatment facilities), multiple unit NPP accidents and nearby facilities. There is a legal requirement for the Safety Requirements, including EPR aspects, to be reviewed every 5 years for nuclear facilities and every 10 years for radioactive waste facilities. As highlighted in the ARM, there are no formal or documented EPR requirements for transport of nuclear fuel. The HAEA has been using "temporary" requirements extracted from the Hungarian National NER Plan.

Guidance for licensee EPR arrangements is established in HAEA Nuclear Safety Guidelines. The guidelines for nuclear facilities have not been updated to remain aligned with the updated requirements in the Nuclear Safety Code. As identified in the action plan of the ARM, there are no guidelines developed for radioactive waste facilities or nuclear fuel transportation.

All aspects of the radiation sources and practices are under the regulatory oversight of the OCMO and the RHDs as described in Ministerial Decree 16/2000. EüM. In particular, EPR aspects are the responsibility the NRIRR, who act as the TSO to the OCMO and the RHDs.

There is reference to a requirement of a "Workplace EP plans" in Ministerial Decree 16/2000. EüM. and how the plans are to be included in the licensee's radiation protection program. There is also a requirement that the plans should be revised and exercised periodically, but there is no further detail or guidance. As well, there are no documented requirements or guidance for development of emergency plans and emergency preparedness arrangements for radiation activities that may fall within higher threat categories.

Assessment of threats

All facilities in Hungary are categorized in the National NER Plan using the IAEA threat categories.

The HAEA uses threat categories as basis for setting EPR requirements in a graded approach in relation to the risk of the facilities. On-site emergency plans are based on safety analysis developed as part of the

licensing process. In addition, threat categorization is used to guide emergency planning zone sizing, exercise frequency and EPR inspection frequency.

OCMO uses threat categories for licensing and compliance inspections, but there is no use of threat categories in establishing or testing of EPR arrangements for radiation practices. As a result, threat category II facilities such as Isotope Institute Ltd. are dealt with in the same manner as radiation source users.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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 <i>"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"</i>
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.

10.2. FUNCTIONAL REGULATORY REQUIREMENTS

Establishing emergency management and operations

Regulatory requirements in the Nuclear Safety Code include specific requirements for prompt execution of onsite emergency response and its coordination with offsite authorities, while ensuring operational safety is not impaired. The Code requires an authorized person to be onsite at all times to initiate response operations and associated notifications and actions. This is verified at the time of licensing of facility NER plans and during inspections of emergency exercises.

Identifying, notifying and activating

Reporting obligations of HAEA licensees is described in the Nuclear Safety Code, with specific time targets that are aligned with IAEA standards and guidance: classification must be completed within 15 minutes of incident and offsite notification within 30 minutes of incident. This includes notifying national response organizations, the regulatory body, regional and local authorities as well as mayors within the 30km Urgent Protective Action Planning Zone (UPZ). Monthly alerting drills are conducted. Emergency plans describe activation methods and time objective for onsite emergency response organization activation.

Emergency classification is described in the Hungarian National NER Plan and is associated with threat classifications. The classification method is consistent with the GS-R-2 classification scheme. HAEA regulatory guidelines require licensees to use the national plan emergency classification system. This is verified by the HAEA when licensing nuclear facility NER plans.

Taking mitigatory actions

There are requirements for emergency actions of the facilities in Govt. Decree 118/2011. Korm. and the NSC whereby licensees are required to develop emergency operating procedures, severe accident management guidelines and emergency response procedures. During emergencies, a licensee can take response actions, measures or modifications without obtaining regulatory approval. Where external support is required from offsite first response organizations, there are requirements for coordination in advance, but this coordination is not required to be formally documented. These arrangements are observed in practice during emergency exercises. Requirements for onsite self-sufficiency are established in the NSC, for example NPP is required to be self-sufficient for up to 120 hours.

Govt. Decree 167/2010. Korm. provides for the government coordination committee to order the intervention of the national organizations on-site in support of the actions being taken by the licensee. The use of external resources within the facility would be initiated by the head of the HAEA Emergency Response Organization (ERO), based on a continuous coordination, independent assessment of the nuclear situation or by direct request from the head of the facility ERO.

For radiological emergencies, the licensee's responsibility for response is clearly established in Ministerial Decree 16/2000. EüM. and the NRIRR is mandated as the response organization in case of radiological incidents where no licensee is involved or available.

Taking urgent protective action

Govt. Decree 167/2010. Korm. establishes that regional and local levels shall make protective action decisions based on licensee recommendations until the national governmental coordination body is established. The HAEA has established regulatory requirements in the Nuclear Safety Code to ensure licensees have the tools, capabilities and means to develop and communicate these recommendations. When the national coordination body is established, protective actions recommendations to local authorities are made at the national level, in consideration of analysis made by the HAEA based on information provided by licensee and other national organizations.

Planning zone sizes are defined in the National NER Plan by threat category and are aligned with the most conservative recommendations in IAEA standards and guides. The HAEA chairs the working committee responsible for management of the National plan and is thus directly involved in establishing emergency planning zone sizes.

Decisions related to protective actions are based on the condition of the nuclear power plant and also modelling. Emergency Action Levels are established in the licensee NER plans, which are reviewed and licensed by the HAEA. General emergencies at NPP can be declared based on plant status or radiological measurements, and lead to automatic evacuation of 3km Precautionary Action Zone (PAZ).

Providing information and issuing instructions

The Nuclear Safety Code requires NPP licensees to operate and maintain a public alerting and information system (sirens, auto-messaging) for the 30km planning zone. The licensee is required to assess offsite consequences and provide recommendation to offsite decision makers. Instructions are issued to the public by offsite authorities. These aspects are verified during NER plan approvals and also during emergency exercise inspections.

Protecting emergency workers

The requirement for protection of workers is established in the NSC and OCMO requirements under Ministerial Decree 16/2000. EüM. The dose reference levels are the same for onsite and offsite emergency workers and are based on the scope of emergency response tasks. This is addressed in further detail in chapter 11.2.

Assessing the initial phase

The NSC explicitly requires licensees to have capability of assessing technical and radiological aspects of the emergency situation. There is a requirement that the licensee must classify the emergency and have the ability to advise protective actions to offsite in early phase. Accordingly, the licensee must then be adequately prepared to assess the early phase of the emergency. In addition, all nuclear facilities have near boundary radiation monitoring systems that can be used for assessment of the initial phase by the licensee and offsite authorities. These capabilities are verified during exercises.

Managing the medical response

Medical response to nuclear or radiological emergencies falls under the purview of the Ministry responsible for Health, with support from the NRIRR. Certain national facilities have been designated in annex of Ministerial Decree 16/2000. EüM. for decontamination of persons and medical response.

Other activities in emergency preparedness

Food chain safety regulation and inspection are the responsibility of the Ministry of Agriculture. The HAEA plays an advisory role to decision-makers in assessing environmental monitoring data at centre, primarily in the early phase. Offsite recovery is briefly addressed in the National NER plan and is the responsibility of the National Nuclear Emergency Response System in accordance with national disaster management law. The HAEA regulatory framework contains no requirements or guidance on licensee's transition to recovery and recovery plans.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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.

10.3. REGULATORY REQUIREMENTS FOR INFRASTRUCTURE

Authority

The Atomic Energy Act section 17 (1) clearly establishes the HAEA's authority for regulatory oversight of EPR arrangements for nuclear facilities and nuclear fuel transport. The Ministerial Decrees 16/2000. EüM. and 51/2013. NFM. establish the OCMO, the NRIRR and the RHDs' authority for EPR arrangements of radiation sources, practices and transport.

Organization

Functional regulatory requirements on staffing of licensee's response organization are established in Nuclear Safety Code and are in line with IAEA GS-R-2. The HAEA licenses the onsite NER plans which contain the details of the response organization structure and response time objectives. HAEA inspections include verifying staff qualifications and results of activation drills. Personnel assigned to the facility response are activated from operational staff at the facility. Members of the Operational and Technical

Support Centres of Paks NPP are on call with targeted activation times of 1hr, 2hrs or 5hrs depending on position.

Coordination of emergency response

The requirement for coordination between onsite and offsite organizations is clearly defined in the Nuclear Safety Code. Interactions and support to offsite organizations is verified during HAEA inspections of emergency exercises.

Plans and procedures

Emergency plans are considered part of the licensing basis and any changes must be reviewed and approved by the HAEA. Licensees are required to prepare a NER plan; to provide personnel, material and organizational conditions; to confirm the presence of these regularly; and finally to ensure conditions for external assistance are identified.

Emergency plans are typically licensed for no more than 2 years, ensuring that they are revised on a regular basis and kept up to date. Procedures associated with the emergency response plan do not require HAEA approval, but the verifications of procedures are done during HAEA inspections.

Logistical support and facilities

Volume 3 of the Nuclear Safety Code establishes the functional requirements for NPP emergency response centres. The requirements address robustness, redundancy and functionality of the centres as well as the need for a backup or reserve centre. Response facilities and equipment are verified during EPR inspections.

Training, drills and exercises

The HAEA approves licensees' annual EPR training and exercise plan, and also reviews and assess the licensee's performance report on annual training and exercises. All onsite and offsite exercises are planned and evaluated in accordance with National NER Plan Guide 5.2 developed in accordance with IAEA EPR Exercise 2005.

The evaluation of exercises is done in a systematic fashion, evaluating discrete and overall exercise performance criteria and objectives, with associated corrective actions. For nuclear facilities, the minimum frequency of exercises is clearly defined in the Nuclear Safety Code. In addition, licensees are required to submit an annual training and exercise plan, as well as individual exercise preparation, conduct and evaluation plans, to the HAEA for review and approval. Licensees must also prepare a retrospective report on past year training and exercise performance, with action plan. This report is submitted to the HAEA and is considered in the development of the annual EPR inspection plan.

Quality assurance programme

The Nuclear Safety Code requirements address continuous update of the emergency plan. Exercise results are fed back into planning process to update emergency response plans and future training and exercise plans. Licensees' response plans and procedures are managed within their management system.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The Nuclear Safety Code EPR requirements were promptly updated to explicitly require that multi-unit accidents at the NPP be considered in preparing NER plans. A two-unit severe accident emergency exercise has already been conducted at Paks NPP in March 2015 and was inspected by the HAEA. A site-wide, three-unit NPP severe accident exercise is being planned for 2016 and a four-unit exercise for 2017.

(1) **BASIS: GS-R-2 para. 3.15 states that** "...The nature and extent of emergency arrangements ... shall be commensurate with the potential magnitude and nature of the

	RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	[threat] associated with the facility or activity "	
(2)	BASIS: GS-R-2 para. 5.33 states that " <i>Exercise programmes shall be conducted to ensure that all specified functions required to be performed for emergency responseare tested at suitable intervals</i> "	
GP6	Good Practice: Hungary has promptly incorporated lessons learned from the Fukushima Dai-ichi Nuclear Power Plant Accident by updating EPR requirements for multi-unit accidents and has proactively conducted an evaluated multi-unit NPP severe accident emergency exercise.	

10.4. ROLE OF REGULATORY BODY DURING RESPONSE

The HAEA is responsible for assessment of nuclear safety and radiation protection conditions in a nuclear emergency and gives advice to the government and to competent authorities regarding nuclear safety and radiological aspects of the emergency. The HAEA makes protective action recommendations to the National response system. The HAEA may initiate measures for nuclear safety or to protect life, health, environment and assets.

The Hungarian National NER Plan is managed via the "High Level Working Committee" made up of representatives from a broad cross section of national agencies, regional/county agencies and licensees, including the regulator (HAEA). Nuclear emergency response arrangements are well integrated into the national all-hazard response system

The HAEA has its own NER plan and it is well integrated with licensee and national NER plans. The HAEA establishes an annual training and exercise plan that is coordinated with licensees and national exercise schedules. Core ERO staff are maintained on a duty call system and must remain within one hour of the HAEA for prompt activation. The ERO comprises approximately 18 positions, with several persons trained for each position. Based on the size of the HAEA and amount of subject matter experts in various areas, it would likely be challenging for the HAEA to undertake a prolonged response to an emergency lasting several weeks or more.

The HAEA has a dedicated and well-equipped response centre with appropriate redundancies. The HAEA has a reactor parameter data system, "CERTA VITA", that provides the HAEA with real-time information on key parameters of Paks reactors as well as information on status of the research reactor.

The OCMO, the RHDs and the NRIRR are included in the Hungarian National NER Plan for response to radiation source incidents. The NRIRR has a field response capability to deal with orphan sources or transport incidents if no licensee is available.

10.5. SUMMARY

There is a comprehensive EPR framework in place for nuclear facilities and practices under the HAEA's mandate. The EPR regulatory requirements, in addition, the licensing and compliance practices are well aligned with IAEA safety standards and guides. Some areas for improvement were identified, including the need to develop formal requirements for nuclear fuel transport EPR and to update the EPR guidelines.

The EPR framework for higher risk radiation sources and practices under the OCMO's oversight is very basic and needs to be developed further, in accordance with IAEA standards and guides.

11. ADDITIONAL AREAS

11.1. CONTROL OF MEDICAL EXPOSURES

Regulatory framework and responsibilities

According to Act CXVI of 1996 on Atomic Energy, the Minister of Health is responsible to regulate the medical applications of ionizing radiation. Medical exposure is dealt with in the Ministerial Decree 31/2001. EüM. of Minister of Health. This Decree designates the OCMO, the RHDs and the professional inspector head physician as the competent authority responsible for its implementation. Several entities, namely the OCMO, the RHDs, the NRIRR and professional bodies, have a role in ensuring the safety of patients undergoing medical exposures.

NRIRR is authorized to and performs, upon request by the vendor or the licensee, acceptance tests for the new radiological equipment emitting ionizing radiation. Additionally, the NRIRR seems to be the only accredited organization in the country for the performance of annual or post major maintenance quality control testing of radiological equipment. The aforementioned accreditation is required by the legislation.

The Hungarian Standardization Body has published several standards to be used by the licensees e.g. MSZ 824:1999 Protection against radiation in medical and veterinary work places, MSZ 62-7:2011 for work places using unsealed sources, MSZ 62-4:1999 Protection against ionizing radiation in gamma irradiation facilities and medical linear accelerators. This is further discussed in Chapter 9, Section 9.5.

The IRRS team understood that the OCMO, the RHDs and the professional inspector head physician are designated to check compliance with Ministerial Decree 31/2001. EüM., while the OCMO and the RHDs are designated by Ministerial Decree 16/2000. EüM. to perform inspections in medical facilities. Justification and optimization of medical exposure, availability of paediatric protocols, quality control tests and equipment calibration, preventive actions regarding unintended and accidental medical exposures are not inspected, mainly due to the dispersion of regulatory responsibilities assigned by the afore mentioned Decrees. During the onsite inspection in the National Institute of Oncology in Budapest, the IRRS team noted that, as mentioned in ARM, medical exposure aspects are not included in RHD inspection procedures. The inspection procedures should be updated to include the medical exposure aspects. This issue is addressed in Recommendation 10 in Chapter 4.1.

Responsibilities of registrants and licensees

As reported in ARM, acceptance test for γ cameras, PET scanners, bone densitometers, intraoral x-ray units and radiotherapy equipment are not performed by the NRIRR. IAEA GSR Part 3 requires the licensees to ensure that appropriate techniques and parameters are used to deliver a medical exposure of the patient that is the minimum necessary to fulfil the clinical purpose of the radiological procedure.

The legislation states that the radiological medical practitioner is responsible for any medical radiological procedure and can assign responsibility for the implementation of a procedure or part thereof, to a medical worker with appropriate qualifications. Nevertheless, there is no specific requirement for documentation of the aforementioned responsibility assignment.

As reported in ARM, in medical facilities, apart from radiotherapy and some nuclear medicine work places, equipment necessary for patient dose assessment is rarely available.

These issues are addressed in Recommendation 26 below.

Justification of medical exposure

Regulatory provisions related to justification of medical exposure are in place. With regard to individual medical exposures, the regulation states that all exposures must be justified by both the referring and the radiological medical practitioner. The IRRS team was informed that the professional college of nuclear medicine has developed and made publicly available referral criteria with an indication of administered activities; the professional college of radiology has uploaded some referral criteria in a password protected area of its website, but has not issued methodological letters for referring physicians, as prescribed in the regulation.

Regarding medical scientific research programs, justification by the ethics committee and establishment of dose constraints is required by the regulations. It was mentioned in ARM that no medical scientific research program involving ionizing radiation has been approved in Hungary during the last decade.

There are no specific provisions for the justification of screening programs in the existing legislation. As mentioned in ARM, they are considered as medical exposures and their justification is determined generally, taking into account mortality and morbidity health indicators.

These issues are addressed in Recommendation 26 below.

Optimization of medical exposure

The existing legislation explicitly establishes the principle of optimization and includes provisions on establishing Diagnostic Reference Levels (DRLs), dose constraints and quality assurance programmes. The IRRS team was informed that even though a national survey was conducted in the 90s for the establishment of DRLs, they have not been published. The establishment of dose constraints for carers and comforters, and volunteers subject to exposure as part of a biomedical research programme is also required by the regulation. Nevertheless, dose constraints for carers and comforters have not been established. Information is not available for biomedical research programme dose constraints. The implementation of clinical audits seems to be in a very initial stage, even though the legislation requires that they shall be conducted on a three year base. The clinical audit mechanism should be improved and consideration should be given to the involvement of several professional specialties in the auditing team.

The IRRS team was informed that clinical radiation physicists are employed in the medical sector; physicists with specialization in medical physics hold a university degree, but there is no system in place, for their recognition by the Government as professionals. Ministerial Decree 60/2003. EüM sets, among others, the minimum requirements for medical physicists, but only in relation to radiotherapy, as mentioned in ARM. In practice, it seems that only radiotherapy departments employ them. Inconsistency with IAEA GSR Part 3 requirements was identified, as also reported in ARM, regarding optimization of protection and safety in medical exposures due to the lack of medical physicists. The Government and the regulatory body should establish a process of formal recognition of medical physicists. This issue is addressed in Recommendation 5 in Section 1.8.

Pregnant women and breast feeding women

Requirements regarding the pregnant and breast feeding patients are included in the legislation. As reported in ARM, appropriate signs are in place but only in Hungarian language.

This issue is addressed in Recommendation 26 below.

Release of patients

Patients release criteria have been established in the methodology letter concerning "Uses of unsealed sources in laboratories" published by the NRIRR in 2011. During the on-site inspection in the National Institute of Oncology in Budapest, the IRRS team was informed that the dose rate of 25μ Sv/h measured at

1 m distance from the patient, who has undergone radioiodine ablation therapy, is used as patient release criterion.

Unintended and accidental medical exposures

According to the legislation, the licensee is responsible for taking all necessary preventive actions regarding the occurrence and severity of unintended and accidental medical exposures. The IRRS team was informed that there are no specific requirements for reporting unintended and accidental exposures.

The National Institute of Oncology in Budapest has developed and launched the ROSIS database for registering locally, unintended and accidental exposures in the radiotherapy department.

This issue is addressed in Recommendation 26 below.

Reviews and records

The licensees shall operate a quality management program according to the legislation. In practice, the medical facilities seem to be accredited according to ISO 9001 or the Hungarian Health Supply Standard (MEES). As reported in ARM, compliance with the existing accreditation systems is not included in the inspections performed by the RHDs to medical facilities. There are regulatory provisions for record keeping regarding quality assurance test results and reviews, as well as corrective actions.

The IRRS team was informed that provisions regarding the retention period of all documents produced by the Hungarian State are included in Act LXVI of 1995.

Record keeping and requirements for reporting to the authorities are to be described in WPRPR. The IRRS team observed that additional guidance related to records or data to be registered, is not available. This issue is addressed in Recommendation 21 in Section 9.1.

The IRRS team noted that there are aspects of the GSR Part 3 that are not included in the regulations and/or have not been implemented in Hungary, as for example:

- comprehensive programmes of quality assurance for medical exposures;
- regular and independent audits of the quality assurance programmes for medical exposures;
- diagnostic reference levels;
- dose constraints for carers and comforters, and volunteers participating in biomedical research programmes;
- comprehensive justification for radiological procedures as part of health screening programmes;
- reporting of significant unintended or accidental medical exposures.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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 <i>"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".</i>
(2)	BASIS: GSR Part 1 Requirement 34 states that <i>"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."</i>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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.

Policy issue on clinical audits

The second policy issue session of the IRRS mission was dedicated to the challenges faced by Hungary for the organization of clinical audits. As mentioned above, there are regulatory requirements, related to the periodic conduct of clinical audits since 2001, but they have not been implemented. Given the recent publication of GSR Part 3 and of the EC Directive 59/2013, and the planned realignment, Hungary is seeking advice to improve the situation. From the description of the current situation, it is clear that the absence of clinical audits is not the only weakness in the area of patient protection in Hungary. As clarified by IRRS team members, clinical audits are one tool to contribute to the improvement of quality of health service provided to patients, to the justification of practices and to the optimization of patient exposure; but they cannot be implemented independently of other patient protection aspects, for instance the establishment of Diagnostic Reference Levels (DRLs). For an effective implementation of clinical audits, the regulatory body in charge of patient protection has to play a role, but in close cooperation with the health authorities and the relevant professional associations. It is a multidisciplinary and multi organization effort, for which resources have to be allocated. However, the financial reimbursement of experts conducting clinical audits might not be the best solution.

The IRRS team members suggested that efforts have to be prioritized according to the risks associated to the different practices. One prerequisite is to collect data on the levels of individual doses and frequencies of medical procedures involving ionizing radiation. Establishment of national DRLs, estimation of collective effective dose to the Hungarian population due to medical uses of ionizing radiation and comparison with the relevant data available in the literature, would provide a useful insight to the various medical practices in Hungary. The actions taken since early 2015 by the head inspector medical physician under the initiative of the RHD of Budapest and the OCMO for nuclear medicine (development of a questionnaire, conduct of interviews with nuclear medicine practitioners) is a good initial step. It was recognized that in all countries, the establishment of clinical audits is a long term effort. Hungary may consider getting direct feedback from the regulatory bodies of Finland, France, Ireland, UK. The Head of Radiation Protection Competent Authorities association (HERCA) is also a good forum for Hungary to get other EU Member States experience. Access to the relevant IAEA publications was provided to the Counterparts.

11.2. OCCUPATIONAL RADIATION PROTECTION

Legal and regulatory framework

The legal and regulatory framework in Hungary, regarding occupational exposure comprises of the following:

- Act CXVI of 1996 on Atomic Energy
- Ministerial Decree 16/2000. EüM on the implementation of certain provisions of the Act on Atomic Energy, and
- Ministerial Decree 30/2001. EüM on the occupational radiation protection of external workers.

According to Act CXVI of 1996 on Atomic Energy, the Minister of Health is responsible to regulate the occupational exposure in all uses of atomic energy.

The concepts of "planned, emergency and existing" exposure situations are not yet introduced in the legislation. However, normal situation and emergency and accident intervention levels, as well as the reference levels for workers performing emergency response activity are described.

As mentioned in ARM, no limits have been established regarding emergency workers in the case of an intervention. The following reference levels are in place: for taking part in the intervention the effective dose of 50mSv, for life saving actions the effective dose of 250mSv and for actions to prevent severe consequences to people and environment the effective dose of 100mSv. These reference levels are lower than the guidance values for emergency workers, as defined in Table IV.2 of Schedule IV of IAEA GSR Part 3. There is no explicit requirement, as required by the IAEA GRS Part 3, that response organizations and employers shall ensure that emergency workers who undertake actions in which the doses received might exceed 50mSv, do so voluntarily.

The dose limits (expressed in terms of effective and equivalent doses) for exposed workers, apprentices, students and public are set for a period of a year (12 consecutive months) with the option that the effective dose of the workers can be averaged for a period of five years. Dose limits are consistent with IAEA GSR Part 3, except for the dose limit for the lens of the eye. The regulations define that for the estimation of effective dose, the external and internal dose received from artificial and natural sources as well as materials with activity concentration exceeding exemption levels (e.g. phosphate, minerals, ash) shall be taken into account.

Even though there are regulatory requirements to address the cosmic radiation exposure of aircrew, it was mentioned in ARM that the reference level has not been established.

The protection of workers against radiation exposure due to radon in workplaces is addressed in the regulations. An action level of 1000 Bq/m3 for annual average radon concentration in air in workplaces has been established, for the requirements of the long-term interventions to apply. The IRRS team was informed that enforcement/compliance control actions regarding radon in workplaces are taken by the regional RHDs. As reported in ARM, the identification/evaluation of workplaces due to exposure to radon has not yet been completed.

According to the legislation, the licensee is required to establish a Radiation Protection Service (RPS) whose responsibilities include, the development the Workplace Radiation Protection Rules (WPRPR). As reported in ARM, the WPRPR are reviewed and assessed prior to the authorization of workplaces. The IRRS team observed that additional guidance for the development of WPRPR, based on the complexity of a given facility or practice, is not available. The regulatory body should develop additional guidance for the applicants. This issue is addressed in Recommendation 21 in Section 9.1.

These issues are addressed in Recommendation 28 below.

General responsibilities of registrants, licensees and employers

The licensees and the personal dosimetry service of the NRIRR are requested to maintain the records of personal dosimetry data for 50 years after termination of the work in which the worker was subject to occupational exposure and the dosimetry service shall maintain the records for 50 years after the cessation of worker's monitoring. Consistency with IAEA GSR Part 3 would be achieved, if the 75 years worker's age was included in the regulatory requirements for occupational exposure records retention.

The personal dosimetry monitoring data or the individual dose assessments based on workplace monitoring are made available to the worker concerned, upon his/her request, according to the regulations. There is no explicit requirement, as required by the IAEA GSR Part 3, that such procedures take place on a regular basis.

As reported in ARM, the regulations do not explicitly require the employers and licensees to involve workers, through their representatives where appropriate, in optimization of protection and safety. The

IRRS team was informed that the cooperation of employers and workers regarding labour safety, among other issues, is addressed in the Labour Code.

The necessary radiation protection qualification is obtained in multilevel trainings (basic, extended and comprehensive levels) and in regular retraining. The licensee, via the established work place RPS, is responsible for providing training programmes to workers. Depending on the training level, programmes and trainers approval by the RHDs (for basic level) and the OCMO, based on NRIRR opinion (for higher levels) is described in the regulation.

These issues are addressed in Recommendation 28 below.

General responsibilities of workers

All workers, as well as external workers (i.e. workers engaged in work that involves a source that is not under the control of their employer), are required to comply with relevant regulations, WPRPR and any conditions included in the licences.

According to the regulation, after returning to Hungary, the external worker is required to provide the personal dosimetry data to the national registry and to his/her employer in the country.

Requirements for radiation protection programmes

Licensees are required to designate relevant areas of the workplaces as controlled or supervised and to establish the necessary procedures and infrastructure for controlling exposures. However, the requirement to have a suitable storage area for personal clothing at entrances to controlled areas is not explicitly stated in the regulation.

In the regulation, it is explicitly mentioned that radiation protection expert(s) or board(s) of such experts shall be involved in the classification procedure and in the development of the system of requirements, depending on the decision of the licensee. Considering this regulatory requirement, the lack of process for formal recognition of qualified experts (see Section 1.8, Recommendation 5) and the limited employment of qualified experts in some cases (e.g. medical facilities) as reported in ARM, inconsistency with IAEA GSR Part 3 is identified, with regard to establishment and maintenance of workplace monitoring programmes under the supervision of a radiation protection officer or qualified expert.

The IRRS team understood that the workplace emergency plan (EP), protective actions and requirements, frequency and methodology of external and internal exposure monitoring are described in WPRPR, according to the regulations.

The IRRS team was informed that health surveillance programmes are based on general principles of occupational health and it is designed to assess the initial and continuing fitness of workers. It was reported in ARM that the legislation does not explicitly mention that the licensee and the employer of an external worker, should together determine special arrangements for the external worker's health surveillance.

These issues are addressed in Recommendation 28 below.

The Act XCIII of 1993 on labour safety states that "instead of complying with the requirements for nonhealth-hazardous and safe performance, the employer shall not provide financial or other compensation to the employee." At the same time, the Act XXXIII of 1992 on the legal status of public servants explicitly states that "workers spending at least 3 hours in a workplace subject to radiation exposure shall be annually provided with 5 days extra holidays". Moreover, provisions for "diagnostic extra salary for doctor (i.e. medical physician) working with x-ray" and for "technicians repairing x-ray systems" are included in the Governmental Decree 356/2008. Korm. on the implementation of Act XXXIII of 1992 in medical facilities".

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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

Monitoring programmes and technical services

exposure.

In Hungary, occupational exposure monitoring services are provided, for external and internal dosimetry, biodosimetry and monitoring of natural radioactivity. There are regulatory provisions for the accreditation of these service providers, apart from the natural radioactivity monitoring. The personal dosimetry service of the NRIRR also maintains the national dose registry (external workers are included).

The IRRS team was informed that, according to the Law on Metrology, measuring instruments used for monitoring the radiation exposure of persons and surface contamination monitors shall be calibrated, in terms of conformity test (HE-060-2014 Radiation measuring instruments in radiation protection and medical dosimetry), by the Metrology Authority, at least every 2 years. As mentioned in ARM, the National Accreditation Body is authorized to certify their accredited status and perform audits and annual reviews. The IRRS team could not identify any provisions providing for regular calibration of other measuring instruments e.g. for area or environmental monitoring.

The IRRS team noted that there are aspects of the GSR Part 3 that are not included in the regulations and/or have not been implemented in Hungary, as for example:

- dose limit for the lens of the eye;
- additional requirements for occupational exposure records retention;
- personal dosimetry monitoring data and individual dose assessments based on workplace monitoring to be made available to the worker concerned on a regular basis;
- workplace monitoring programmes established and maintained, under the supervision of a radiation protection officer or qualified expert;
- emergency workers who undertake actions in which the doses received might exceed 50mSv, do so voluntarily;
- evaluation of workplaces where radon is present to be completed;
- establishment of reference level for aircrew personnel;
- monitoring/registering of aircrew doses.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The Hungarian legal and regulatory framework addresses ooccupational 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.

	RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(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.	

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

Control of radioactive discharges

In Hungarian regulations requirements for discharges of radioactive materials differentiate two types of facilities: special facilities (a nuclear power plant, training and research nuclear reactor, uranium mine, storage and disposal facility for radioactive waste, A-level isotope laboratory, and interim storage facility for spent fuel) and other facilities. According to Ministerial Decree 15/2001. KöM. of the Minister for Environment, for the case of special facilities as part of the licensing process the applicant should propose the discharge limits values on the basis of specific dose constraint values for the public established by the Office of Chief Medical Officer (OCMO) and using a methodology described in the Decree. The proposal prepared on this basis should be sent to the BCDEPN for approval as part of the licensing process. The environmental licence contains the discharge limits. The discharge limits values are referred to in the licence issued by the HAEA and compliance is verified through the periodic reports on monitoring results produced by the licensee and a parallel monitoring program carried out by the BCDEPN. For the case of other facilities, the mentioned Decree establishes fixed discharge limits values for each radionuclide, derived from a trivial dose constraint of 30 µSv/y. Although these discharge limit values are derived on a very conservative basis, during the visit to the nuclear medicine department of the National Institute of Oncology in Budapest it was observed and confirmed in the discussion followed afterwards, that for the case of "other facilities" there are no clear procedures for verifying compliance with the established discharge limits.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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".

Recommendation: The regulatory body should initiate development of requirements
 and develop associated guidance for verification of compliance with discharge limits for all facilities.

Clearance of materials

The concept of clearance is not explicitly defined in Hungarian regulations. Ministerial Decree 23/1997. NM. establishes exemption levels in terms of activities and activity concentrations, and these values are used as clearance levels as well. Ministerial Decree 47/2003. ESzCsM. provides a definition of clearance

level which involves not only materials, but also activities and is not in compliance with the definition in GSR Part 3. Although values for clearance levels exist in Hungarian regulations, clearance criteria are not fully compliant with GSR Part 3, complicating the decision making process, in particular when deciding on conditional clearance of materials containing radionuclides of natural origin, e.g. for their use as building materials.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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".
	BASIS: GSR Part 3 Schedule I para. I.12 states that <i>"Radioactive material within a notified practice or an authorized practice may be cleared without further consideration provided that:</i>
	(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
(2)	(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.

Regarding the implementation of the clearance process it was observed that in the case of "other facilities", as is the case of the visited nuclear medicine department of the National Institute of Oncology in Budapest, the process of releasing materials from regulatory control is carried out without recording the actions taken. Therefore there is no evidence on the adequate management of these materials, demonstrating compliance.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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.

	BASIS: GSR Part 3 Requirement 8 states that "The regulatory body shall approve which
(1)	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

	RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
	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.

Environmental monitoring for public radiation protection

According to Ministerial Decree 15/2001. KöM., facilities and activities releasing radioactive material to the environment are required to design and propose an environmental monitoring program as part of the licensing process. This program is submitted to the BCDEPN for approval and should be implemented afterwards. These monitoring programs are complemented with monitoring programs carried out by the environmental authority (BCDEPN or County Government Offices) in order to verify compliance with the authorized discharge limits and the adequacy of the measurements reported by the licensee. Any further modification to be introduced in the approved monitoring program should be approved previously by the BCDEPN. Licensees are also required to notify in writing the environmental authority immediately when the results of the measurements indicate a potential deviation from normal operation.

The results of environmental monitoring programs carried out by the licensee are sent to the environmental authority on a quarterly and a yearly basis. This information, together with the information on the results of monitoring programs carried out by the environmental authority in each territory is sent to the NRIRR, which collects all this information and put it in a data basis and produces an annual report, which is available for the public, too (www.okser.hu).

Existing exposure

In Hungary independent programs for surveying radon levels in public buildings and dwellings have been carried out. The NRIRR has reported radon concentrations values in the range 10-1900Bq/m3, which suggests the existence of significant radon exposure scenarios. The ARM stated that, a new open consortium is being organized for performing a parallel survey of internal and soil gas radon concentration and to establish a new database, in line with 2013/59/EURATOM directive. A radon action plan is also being established simultaneously. At the present there are no radon reference levels for public radiation protection purposes in Hungarian regulations.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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.

Currently existing exposure situations due to the presence of radionuclides in commodities have not been identified in Hungary. Commodities that should be subject to control has not been defined and specific reference levels for exposure due to radionuclides in commodities such as construction materials, food and feed, and in drinking water have not been established in Hungarian regulations.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: Hungarian regulations have not established reference levels, or the dose criteria for establishing them, for commodities such as building materials, foodstuffs and water.

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.

11.4. SUMMARY

The Hungarian legal and regulatory framework addresses medical and occupational exposure control, but in a manner that it is not in full compliance with GSR Part 3. In addition, some of the existing regulatory provisions are not implemented. The identified discrepancies should be resolved during the transposition of the EC Directive 59/2013 in the national legislation. Diagnostic reference levels, formal recognition of qualified experts, comprehensive quality assurance programmes, reporting of accidental/unintended medical exposures, identification/evaluation of workplaces where radon is present, aircrew exposure are some of the areas where improvements should still be done. The contradicting legal provisions for compensatory arrangements for workers exposed to ionizing radiation need to be resolved.

Discharge limits in regulations are derived on the basis of established dose constraints for public exposures. For facilities other than special facilities, it was observed that there are no procedures for verification of compliance with discharge limits. The concepts of clearance and clearance levels in Hungarian regulations are not consistent with GSR Part 3 and 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. Requirements for environmental monitoring with radiation protection purposes of the public are in line with GSR Part 3. There are no reference levels for radon with public radiation protection purposes in regulations. Currently existing exposure situations due to the presence of radionuclides in commodities have not been identified and reference levels for them have not been established.

APPENDIX I – LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS:			
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GROUP PHOTO



APPENDIX II – MISSION PROGRAMME

	Sunday, 10 May 2015	Venue
09:00 - 17:00	IRRS Refresher Training, Initial Team meeting	HAEA, Budapest
09.00 - 17.00	Presentation of mission agenda (Liaison officer, Dániel Nyisztor)	HAEA, Dudapest

	Monday, 11 May 2015	
09:30 - 11:00	 Entrance meeting Opening remarks – Team leader, HAEA DG, Ministry representative, Environmental protection & health sector representatives Presentation of HAEA DG, Environmental protection & health sector representatives Hungarian Reg. body structure, Present situation. Self-introduction of the IRRS Team members and the Hungarian Counterparts Group photo 	HAEA, Budapest
13:00 - 17:00	IRRS Team Experts: Interviews and Discussions with Counterparts Mr Michael Johnson, Mr Mika Markkanen, Mr Tim Kobetz and Mr Hilaire Mansoux: Interview with the deputy director general of National Public Health Centre	HAEA, Budapest
17:00 - 18:00	Daily IRRS Team meeting	HAEA, Budapest

	Tuesday, 12 May 2015	
09:00 - 12:00	 Ms Maria Cristobal, Ms Helena Janzekovic, Ms Starvoula Vogiatzi, Ms Olga Lugovskaya: observation of inspection in the National Institute of Oncology, interview with the top management. 	Hospital, Budapest
09:30 - 16:00	 Mr Henry Rabsky, Mr Tim Kobetz, Mr Mark Hulsmans: observation of NPP inspection, interview with the management. 	Paks NPP
13:00 - 15:00	Mr Michael Johnson, Mr Mika Markkanen, Mr Hilaire Mansoux: interview with the state secretary in the Ministry for National Development	Ministry, Budapest
14:00 - 16:00	Ms Maria Cristobal, Ms Helena Janzekovic, Ms Starvoula Vogiatzi, Ms Olga Lugovskaya: visit radiation health Decentre in Budapest	Decenter, Budapest
09:00 - 12:30	IRRS Team Experts: Interviews and Discussions with Counterparts	HAEA, Budapest
14:00 - 17:00	IRRS Team Experts: Interviews and Discussions with Counterparts	HAEA, Budapest
17:00 - 18:00	Daily IRRS Team meeting	HAEA, Budapest

	Wednesday, 13 May 2015	
08:00 - 15:00	Mr Luc Sigouin, Mr Mark Hulsmans: observation of inspection regarding emergency preparedness in Paks NPP	Paks NPP
09:00 - 12:30	IRRS Team Experts: Interviews and Discussions with Counterparts	
09:00 - 15:00	 Mr Christophe Serres, Mr Juan Thomas Zerquera: interview with the site manager of National Radioactive Waste Repository, observation of inspection in the National Radioactive Waste Repository, interview with the top manager of South Trans Danubian Environmental Protection Inspectorate. 	Bátaapáti
09:00 - 14:00	 Mr Helmuth Zika: observation of inspection in IKI Kft interview with the manager of IKI Kft. 	IKI Kft, Budapest
09:00 - 14:00	 Ms Helene Vacelet: observation of inspection in the Budapest Research Reactor, interview with the top manager of Budapest Research Reactor. 	Budapest Research Reactor
14:00 - 17:00	IRRS Team Experts: Interviews and Discussions with Counterparts	HAEA, Budapest
15:00 - 16:30	Mr Michael Johnson, Mr Mika Markkanen, Mr Tim Kobetz and Mr Hilaire Mansoux: Interview with the state secretary in the Ministry of Human Capacities	Ministry, Budapest
17:00 -	Daily IRRS Team meeting	HAEA, Budapest

	Thursday, 14 May 2015	
09:00 - 12:30	IRRS Team Experts: Interviews and Discussions with Counterparts	HAEA, Budapest
12:00 - 13:30	Mr Michael Johnson, Mr Mika Markkanen, Mr Hilaire Mansoux: Interview with the state secretary	Ministry,
12:00 - 15:50	in the Ministry of Agriculture	Budapest
14:00 - 17:00	IRRS Team Experts: Interviews and Discussions with Counterparts	HAEA, Budapest
17:00 - 18:00	Daily IRRS Team meeting	HAEA, Budapest

	Friday, 15 May 2015	
09:00 - 10:00	Policy discussion: building new units	HAEA, Budapest
10:00 - 12:30	IRRS Team Experts: Interviews and Discussions with Counterparts.	HAEA, Budapest
14:00 - 17:00	Report writing.	HAEA, Budapest
17:00 - 18:00	Daily IRRS Team meeting	HAEA, Budapest

	Saturday, 16 May 2015	
09:00 - 12:30	IRRS team: Report writing, discussion about report.	HAEA, Budapest
14:00 - 17:00	IRRS team: Report writing, discussion about report.	HAEA, Budapest

	Sunday, 17 May 2015	
09:00 - 15:00	Social event, guided bus tour in Budapest.	
16:00 -	IRRS team: report editing.	HAEA, Budapest

	Monday, 18 May 2015	
09:00 - 10:30	Policy discussion: clinical audit.	HAEA, Budapest
10:30 - 12:30	Discussion of Recommendations, Suggestions and Good Practices with counterparts.	HAEA, Budapest
14:00 - 17:00	Discussion of Recommendations, Suggestions and Good Practices with counterparts.	HAEA, Budapest
17:00 - 18:00	Daily IRRS Team meeting.	HAEA, Budapest

	Tuesday, 19 May 2015	
09:00 - 12:30	Discussion of open questions with counterparts, finalization of report.	HAEA, Budapest
14:00 - 18:00	Discussion of open questions with counterparts, finalization of report.	HAEA, Budapest
18:00 -	Finalization and submission of draft report to the HAEA.	

	Wednesday, 20 May 2015	
09:00 - 18:00	Host reading Draft report.	HAEA, Budapest
10:00 - 14:00	IRRS Team Lead: finalization of Executive Summary, preparation of Exit Meeting and press release.	HAEA, Budapest

	Thursday, 21 May 2015	
08:30 - 13:30	IRRS Team discuss the comments of Host.	HAEA, Budapest
13:30 - 14:30	Plenary – IRRS Team + Host – to discuss Host comments and finalize the report.	HAEA, Budapest
14:30 -	IRRS team finalize report, submit final report.	HAEA, Budapest
18:30 - 22:00	Farewell dinner	Budapest

	Friday, 22 May 2015	
09:30 - 10:30	Exit meeting Acknowledgements – HAEA DG, representative of Minister for National Development, Team leader presents the results of the IRRS Mission, IAEA Director officially close the Hungarian IRRS mission.	Hotel Acquincum, Budapest
11:30 - 12:30	International press conference	HAEA, Budapest
12:30 -	IRRS team members departure	

APPENDIX III – SITE VISITS

Paks Nuclear Power Plan National Institute of Oncology, Budapest Radiation Health Decentre, Budapest Budapest Research Reactor National Radioactive Waste Repository, Bátaapáti IKI Kft., Budapest

APPENDIX IV – LIST OF COUNTERPARTS

	IRRS EXPERTS	Lead Counterpart	Support Staff			
1.	LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES					
	Peter Addison	Gábor PETŐFI (HAEA), Péter MUCK (BCDEPN), Márta KOVÁCS (OCMO)	Zoltán LENGYEL (HAEA), Hajnalka CSIZMADIA (OCMO)			
2.	GLOBAL NUCLEAR SAFETY RI	EGIME				
	Peter Addison	Zoltán LENGYEL (HAEA), Péter MUCK (BCDEPN), László JUHÁSZ (OCMO)	Gábor PETŐFI (HAEA), Hajnalka CSIZMADIA (OCMO)			
3.	RESPONSIBILITIES AND FUNC	TIONS OF THE REGULATORY BODY				
	Aad Sedee	István LÁZÁR (HAEA), Péter MUCK (BCDEPN), Márta KOVÁCS (OCMO)	Ferenc LÓRÁND (HAEA), Hajnalka CSIZMADIA (OCMO)			
4.	MANAGEMENT SYSTEM OF TH	IE REGULATORY BODY				
	Darja Slokan-Dusic	Elizabeth BÓDIS (HAEA), Péter MUCK (BCDEPN), Márta KOVÁCS (OCMO)	Mihály LEHOTA (HAEA), Hajnalka CSIZMADIA (OCMO)			
5.	AUTHORIZATION					
	Faizan Mansoor, Helmuth Zika, Helen Vacelet, Christoph Serres	István MÉSZÁROS, Eszter RÉTFALVI, István LÁZÁR (HAEA), Péter MUCK (BCDEPN)	Attila SÁGI, Marianna PAPP, Zoltán PÁZMÁNDI, Zsuzsanna HAUSZMANN (HAEA)			
6.	REVIEW AND ASSESSMENT					
	Faizan Mansoor, Helmuth Zika, Helen Vacelet, Christoph Serres	László JUHÁSZ, Eszter RÉTFALVI, István LÁZÁR (HAEA), Péter MUCK (BCDEPN)	Sándor SZIRMAI, Zoltán PÁZMÁNDI, Zsuzsanna HAUSZMANN (HAEA)			
7.	INSPECTION					
	Tim Kobetz, Helmuth Zika, Helen Vacelet, Christoph Serres	Péter FARKAS, Eszter RÉTFALVI, István LÁZÁR (HAEA), Péter MUCK (BCDEPN), Márta KOVÁCS (OCMO)	Bendegúz PUSKÁS, Zoltán PÁZMÁNDI, Zsuzsanna HAUSZMANN (HAEA), Hajnalka CSIZMADIA (OCMO)			

	IRRS EXPERTS	Lead Counterpart	Support Staff	
8.	ENFORCEMENT			
	Henry Rabski, Helen Vacelet, Christoph Serres	Judit SILYE, Eszter RÉTFALVI, István LÁZÁR (HAEA), Péter MUCK (BCDEPN), Márta KOVÁCS (OCMO)	Zoltán PÁZMÁNDI, Zsuzsanna HAUSZMANN (HAEA), Hajnalka CSIZMADIA (OCMO)	
9.	REGULATIONS AND GUIDES			
	Janne Nevalainen, Helmuth Zika, Helen Vacelet, Christoph Serres	Mihály LEHOTA, Eszter RÉTFALVI, István LÁZÁR (HAEA), Péter MUCK (BCDEPN), Márta KOVÁCS (OCMO)	Zoltán PÁZMÁNDI, Zsuzsanna HAUSZMANN (HAEA)Hajnalka CSIZMADIA (OCMO)	
10.	D. EMERGENCY PREPAREDNESS AND RESPONSE			
	Luc Sigouin	Géza MACSUGA (HAEA), Péter MUCK (BCDEPN), Nándor FÜLÖP (NRIRR)	András KÁRMÁN, Márton KERESZTES (HAEA), Attila POLGÁR (OCMO)	
11.	ADDITIONAL AREAS			
	Stavroula Vogiatzi, Juan Tomas Zerquera, Helmuth Zika	József SÁFÁR, Árpád VINCZE (HAEA), Péter MUCK (BCDEPN), Nándor FÜLÖP, Richárd ELEK, László JUHÁSZ (NRIRR), Károly ÓDRY, Netti BABÁRI (OCMO)	Zsófia SZEPES (HAEA), Zsolt DÉRI, Ferenc CZELBA, Gábor WINDISCH, Zsuzsanna NAGY (OCMO)	

APPENDIX V – RECOMMENDATIONS (R), SUGGESTIONS (S) AND GOOD PRACTICES (GP)

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	R1	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.
	R2	The Government should implement appropriate provisions to ensure the effective independence of the regulatory body from the facilities and activities that it regulates.
1. LEGISLATIVE AND	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.
GOVERNMENTAL RESPONSIBILITIES	R4	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.
	S1	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.
	S2	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.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	R5	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.
	\$3	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.
2. THE GLOBAL SAFETY REGIME	R6	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.
	R7	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.
3. RESPONSIBILITIES AND	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.
FUNCTIONS OF THE REGULATORY BODY	S4	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.
	R9	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.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	R10	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.
4. MANAGEMENT SYSTEM OF THE REGULATORY BODY	R11	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.
	GP1	The regulatory body has developed an effective database "Hungarian Nuclear Knowledge Data Base". The benefit of which is to preserve and keep up to date the knowledge gained during the use of atomic energy in Hungary.
	R12	The regulatory body should define the process for revoking the environment protection licence.
5. AUTHORIZATION	GP2	The HAEA developed and implemented procedures for Category 1 safety modifications that add a condition to an approved licence amendment requiring the licensee to notify the HAEA of installation and testing dates for modifications and the submittal of test data. The information is used by both inspectors for planning subsequent inspections and licensing staff to independently validate the appropriateness of facility modifications.
	R13	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.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	R14	The regulatory body should establish requirements and procedures for justification of practices and optimization of radiation protection in the facilities and activities.
	R15	The regulatory body should establish requirements for safety assessment to be submitted by the applicants.
	R16	The BCDEPN should ensure it has access to technical capabilities to review and assess model calculations submitted by applicants.
	GP3	The HAEA has established performance indicators to monitor research reactor and ISFSI safety performance.
6. REVIEW AND ASSESSMENT	GP4	The HAEA has developed a scoring table for nuclear power facilities to aide in the determination of appropriate post event investigations and oversight of corrective actions.
	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.
	85	The regulatory body should consider revising its inspection programme for unannounced inspections to include a variety of safety related activities.
7. INSPECTION	R18	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.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	S 6	The regulatory body should consider developing guidance to ensure the objectivity of inspectors.
	87	The HAEA should consider conducting or contracting the independent verification of the compliance of waste packages.
8. ENFORCEMENT	R19	The regulatory body should prepare or revise its enforcement policy to ensure that the policy covers all facilities and activities using a graded approach.
6. ENFORCEMENT	R20	The regulatory body should prepare or revise the procedures to implement the enforcement policy and ensure that the necessary procedures remain up to date.
	R21	The regulatory body should complete development of the safety guidelines in a timely manner.
	R22	The regulatory body should include provisions for consultation with the public and interested parties in the development of the safety guides.
9. REGULATIONS AND	GP5	The Regulatory Framework Web-portal with links between different levels of requirements and guides is considered a good practice.
9. REGULATIONS AND GUIDES	S 8	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.
	R23	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.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	S 9	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.
10. EMERGENCY	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.
PREPAREDNESS AND RESPONSE –	R25	The regulatory body should establish EPR regulatory requirements for recovery and transition to recovery.
REGULATORY ASPECTS	GP6	Hungary has promptly incorporated lessons learned from the Fukushima Dai-ichi Nuclear Power Plant Accident by updating EPR requirements for multi-unit accidents and has proactively conducted an evaluated multi-unit NPP severe accident emergency exercise.
	R26	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.
11. ADDITIONAL AREAS	R27	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.
	R28	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.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	R29	The regulatory body should initiate development of requirements and develop associated guidance for verification of compliance with discharge limits for all facilities.
	R30	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.
	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.
	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.
	R32	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.

APPENDIX VI – COUNTERPART'S REFERENCE MATERIAL USED FOR THE REVIEW

Legislation
Extract from Governmental Resolution 1035/2012. Korm. Hungary's National Security and Safety
Strategy
Ministerial Decree 11/2010. (III. 4.) KHEM issued by the Minister of transport, telecommunication and
energy on the rules of accountancy for and control of radioactive materials, and on the corresponding
data provisions
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 Resolution 1150/2012. (V. 15.) Korm. on the establishment of Inter-ministry Disaster
Management Coordination Committee and on its the organization and operation
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 124/1997. (VII. 18.) Korm. on radioactive materials and equipment generating
ionizing radiation not falling under the scope of the Act CXVI of 1996 on atomic energy
Ministerial Decree 15/2001. (VI. 6.) KöM of the Minister for Environment on radioactive discharges to
the atmosphere and into waters during the use of atomic energy and on monitoring of the discharge
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.
Ministerial Decree 16/2000 (VI. 8.) EüM of the Minister of Health on the Implementation of Certain
Provisions of the Act CXVI of 1996 on Atomic Energy
Governmental Decree 165/2003. (X. 18.) Korm. on the rules of public communication in nuclear or

radiological emergency

Governmental Decree 167/2010. (V. 11.) Korm. on national nuclear emergency preparedness and response

Governmental Decree 17/1996. (I. 31.) Korm. on actions in connection with the found or seized radioactive or nuclear materials

Ministerial Decree 23/1997. (VII. 18.) NM of Minister of Social Welfare on determination of exemption levels of activity concentrations and exemption activities of radioisotopes

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

Governmental Decree 275/2002. (XII. 21.) Korm. on the monitoring of the environmental radiation situation and levels of radioactivity in Hungary

Ministerial Decree 30/2001. (X. 3.) EüM of Minister of Health on workplace radiation protection of external employees

Ministerial Decree 31/2001. (X. 3.) EüM of Minister of Health on the health protection of persons exposed to ionizing radiation during provision of health services

Ministerial Decree 47/2003. (VIII. 8.) ESZCSM of the Minister of Health, Social and Family Affairs on certain issues of interim storage and final disposal of radioactive wastes, and on certain radiohygiene issues of naturally occurring radioactive materials concentrating during industrial activity

Ministerial Decree 51/2013. (IX. 6.) NFM on shipping, carrying and packaging of radioactive materials Governmental Decree 72/2000. (V. 19.) Korm. on the special conditions of acquiring the possession rights of certain materials, equipment and facilities belonging to the scope of use of atomic energy, as well as on the procedure for reporting their possession and operation

Ministerial Decree 8/2002. (III. 12.) EüM of Minister of Health on the operation and structure of the radiological monitoring and data acquisition network of the health sector

Act CXVI of 1996 on Atomic Energy

(as being effective from January 1, 2016)

Act C of 2012 On the Criminal Code

Misappropriation of Radioactive Materials - Extract

Guidelines, internal documents

Guideline 1.25, Event reports of the nuclear power plant

Guideline 1.43, Regulatory inspection of nuclear facilities

Guideline 1.49, Regular reports of research reactors

Guideline 1.50, Event reports of research reactors

Guideline to support the clients on the registration to the central register of radioactive materials and on the operation of local registers

Guideline on the compilation of licensing applications in relation to packaging of radioactive materials in case when the approval of the competent nuclear authority is required by the stipulations of laws and international agreements on the transport of dangerous goods

Deed of Foundation of the Hungarian Atomic Energy Authority (in a unified structure consolidating all modifications)

Instruction/2014.(.....) NFM of the Minster of National Development on the Organizational and Operational Rules of the Hungarian Atomic Energy Authority – HAEA OOR

Appendix 1 of HAEA OOR – Organizational chart

Appendix 2 of HAEA OOR– Tasks of organizational units of the Hungarian Atomic Energy Authority

Appendix 3of HAEA OOR – Organizational units of the Hungarian Atomic Energy Authority and the distribution of the number of employee status

Appendix 4 of HAEA OOR- Job posts (task posts) obliged to make declaration of property
Operational Rules of the Hungarian Atomic Energy Authority
Annex 1of HAEA OR – Detailed description of the rules of signature in connection with the activity
of the HAEA
Annex 2of HAEA OR – Types of Authority Documents
P-0-1 – Quality policy of the HAEA
P-0-2 – Enforcement Policy
Annex 2 of P-0-2 – Legislations to be considered during the implementation of the enforcement policy of the HAEA
P-0-5 – HAEA Policy on Technical Support Activities 2013-2016
P-0-6 – Training policy
P-0-7 – Safety and security policy and authority code of conduct of the Hungarian Atomic Energy
Authority
ST-1 – Public information policy and strategy of the HAEA
SZ-0-8 – Security Regulation of the Hungarian Atomic Energy Authority for the protection of classified
information
Quality management manual
ME-3-0-12 Comprehensive inspection system of nuclear facilities – procedure
ME-3-0-12 Completiensive inspection system of indefeat facilities procedure ME-3-0-13 -Assessment of event reports – procedure
ME-3-0-13 -Assessment of event reports – procedure ME-3-0-28 Planning of inspection activities of Nuclear Safety Directorate – procedure
ME-3-2-7 Inspection of Budapest Research Reactor – procedure
ME-3-2-7 Inspection of Budapest Research Reactor – procedure ME-3-2-8 Inspection of Budapest Training Reactor – procedure
National Nuclear Emergency Response Plan
Nuclear Emergency Response Plan of the HAEA – HAEA NERP Annex 1 of HAEA NERP – Action And Intervention Levels
Annex 2 of HAEA NERP – Maps
Annex 3 of HAEA NERP – Public Information Plan Of The HAEA ERO for Management of Nuclear
Emergencies Annex 4 of HAEA NERP – Protective Actions For The Public
Appendix 1 of HAEA NERP – List of Internal Regulations Corresponding to the HAEA NERP
Annex 3.2 of HAEA NERP – Technical description on Paks NPP for media information
Annex 3.4 of HAEA NERP – Sample press release on an event occurred in domestic nuclear power
plant – Press release 1
Annex 3.5 of HAEA NERP – Sample press release on an event occurred in domestic nuclear power
plant – Press release 2
Annex 3.6 of HAEA NERP – Sample press release on an event occurred in foreign nuclear power
plant – Press release 3
Annex 3.7 of HAEA NERP – Sample press release on an event occurred during illicit trafficking –
Press release 4
Annex 3.8 of HAEA NERP – Sample press release on an event occurred during transportation – Press
release 5
Annex 3.9 of HAEA NERP – Sample press release on environmental radiological contamination due
to isotope melting – Press release 6
HA5601 – Operating licence in the case of "Application for the operation of Unit 1 of Paks Nuclear Power Plant beyond the design service lifetime"
Inspection record
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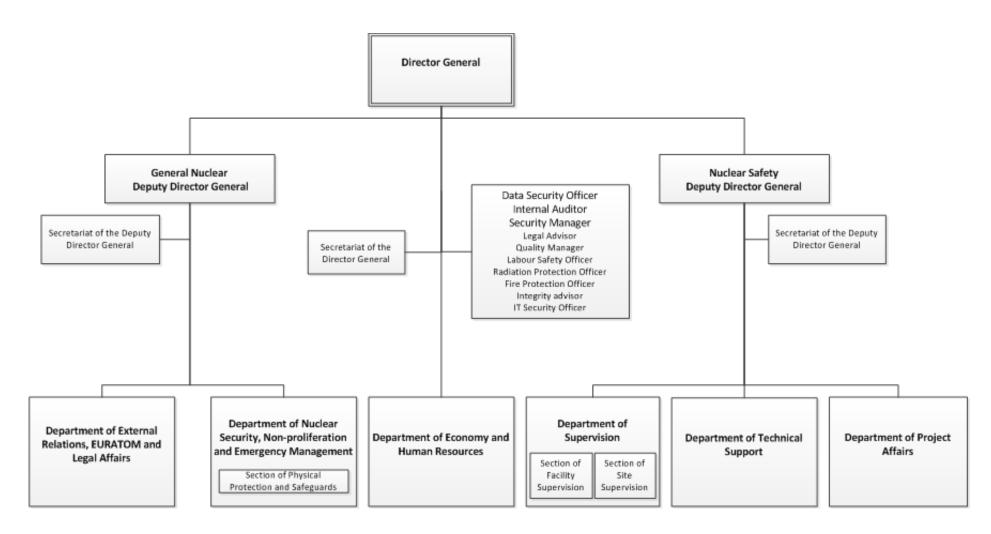
APPENDIX VII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW

1.	INTERNATIONAL ATOMIC ENERGY AGENCY - Fundamental Safety Principles, No SF-1, IAEA, Vienna (2006)
2.	INTERNATIONAL ATOMIC ENERGY AGENCY - Governmental, Legal and Regulatory Framework for Safety, General Safety Requirements Part 1, No. GSR Part 1, IAEA, Vienna (2010).
3.	INTERNATIONAL ATOMIC ENERGY AGENCY – The Management System for Facilities and Activities. Safety Requirement Series No. GS-R-3, IAEA, Vienna (2006).
4.	INTERNATIONAL ATOMIC ENERGY AGENCY - Preparedness and Response for Nuclear and Radiological Emergencies, Safety Requirement Series No. GS-R-2, IAEA, Vienna (2002).
5.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety assessment for facilities and activities, General Safety Requirements Part 4, No. GSR Part 4, IAEA, Vienna (2009)
6.	INTERNATIONAL ATOMIC ENERGY AGENCY - Predisposal Management of Radioactive Waste, General Safety Requirement Part 5, No. GSR Part 5, IAEA, Vienna (2009).
7.	INTERNATIONAL ATOMIC ENERGY AGENCY - Decommissioning of Facilities, Safety Requirement Series No. GSR Part 6, IAEA, Vienna (2014).
8.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Nuclear Power Plants: Design, Specific Safety Requirements No. SSR-2/1, IAEA, Vienna (2012).
9.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Nuclear Power Plants: Commissioning and Operation, Specific Safety Requirements Series No. SSR-2/2, IAEA, Vienna (2011).
10.	INTERNATIONAL ATOMIC ENERGY AGENCY - Site Evaluation for Nuclear Installations, Safety Requirement Series No. NS-R-3, IAEA, Vienna (2003).
11.	INTERNATIONAL ATOMIC ENERGY AGENCY - Disposal of Radioactive Waste, Specific Safety Requirements No. SSR-5, IAEA, Vienna (2011)
12.	INTERNATIONAL ATOMIC ENERGY AGENCY – Regulations for the Safe Transport of Radioactive Material, Specific Safety Requirements No. SSR-6, IAEA, Vienna (2012)
13.	INTERNATIONAL ATOMIC ENERGY AGENCY - Organization and Staffing of the Regulatory Body for Nuclear Facilities, Safety Guide Series No. GS-G-1.1, IAEA, Vienna (2002).
14.	INTERNATIONAL ATOMIC ENERGY AGENCY - Review and Assessment of Nuclear Facilities by the Regulatory Body, Safety Guide Series No. GS-G-1.2, IAEA, Vienna (2002).
15.	INTERNATIONAL ATOMIC ENERGY AGENCY - Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body, Safety Guide Series No. GS-G-1.3, IAEA, Vienna (2002).

16.	INTERNATIONAL ATOMIC ENERGY AGENCY - Documentation Used in Regulating Nuclear Facilities, Safety Guide Series No. GS-G-1.4, IAEA, Vienna (2002).
17.	INTERNATIONAL ATOMIC ENERGY AGENCY - Arrangements for Preparedness for a Nuclear or Radiological Emergency, Safety Guide Series No. GS-G-2.1, IAEA, Vienna (2007)
18.	INTERNATIONAL ATOMIC ENERGY AGENCY - Criteria for use in Preparedness and Response for a Nuclear or Radiological Emergency, General Safety Guide Series No. GSG-2, IAEA, Vienna 2011)
19.	INTERNATIONAL ATOMIC ENERGY AGENCY - Commissioning for Nuclear Power Plants, Safety Guide Series No. SSG-28, IAEA, Vienna (2014)
20.	INTERNATIONAL ATOMIC ENERGY AGENCY - Periodic Safety Review of Nuclear Power Plants, Safety Guide Series No. SSG-25, IAEA, Vienna (2013)
21.	INTERNATIONAL ATOMIC ENERGY AGENCY - A System for the Feedback of Experience from Events in Nuclear Installations, Safety Guide Series No. NS-G-2.11, IAEA, Vienna (2006)
22.	INTERNATIONAL ATOMIC ENERGY AGENCY - Deterministic Safety Analysis for Nuclear Power Plants, Specific Safety Guides Series No. SSG-2, IAEA, Vienna (2010)
23.	INTERNATIONAL ATOMIC ENERGY AGENCY - Development and Application of Level 1 Probabilistic Safety Assessment for Nuclear Power Plants, Specific Safety Guide Series No. SSG-3, IAEA, Vienna (2010)
24.	INTERNATIONAL ATOMIC ENERGY AGENCY - Development and Application of Level 2 Probabilistic Safety Assessment for Nuclear Power Plants, Specific Safety Guide Series No. SSG-4, IAEA, Vienna (2010)
25.	INTERNATIONAL ATOMIC ENERGY AGENCY - Licensing Process for Nuclear Installations, Specific Safety Guide Series No. SSG-12, IAEA, Vienna (2010)
26.	INTERNATIONAL ATOMIC ENERGY AGENCY - Geological Disposal Facilities for Radioactive Waste Specific Safety Guide Series No. SSG-14, IAEA, Vienna (2011)
27.	INTERNATIONAL ATOMIC ENERGY AGENCY - Storage of Spent Nuclear Fuel Specific Safety Guide Series No. SSG-15, IAEA, Vienna (2012)
28.	INTERNATIONAL ATOMIC ENERGY AGENCY - Classification of Radioactive Waste, General Safety Guide No. GSG-1, IAEA, Vienna (2009)
29.	INTERNATIONAL ATOMIC ENERGY AGENCY - Decommissioning of Nuclear Power Plants and Research Reactors, Safety Guide Series No.WS-G-2.1, IAEA, Vienna (1999)
30.	INTERNATIONAL ATOMIC ENERGY AGENCY - Decommissioning of Medical, Industrial and Research Facilities (1999) Safety Guide Series No.WS-G-2.2, IAEA, Vienna (1999)

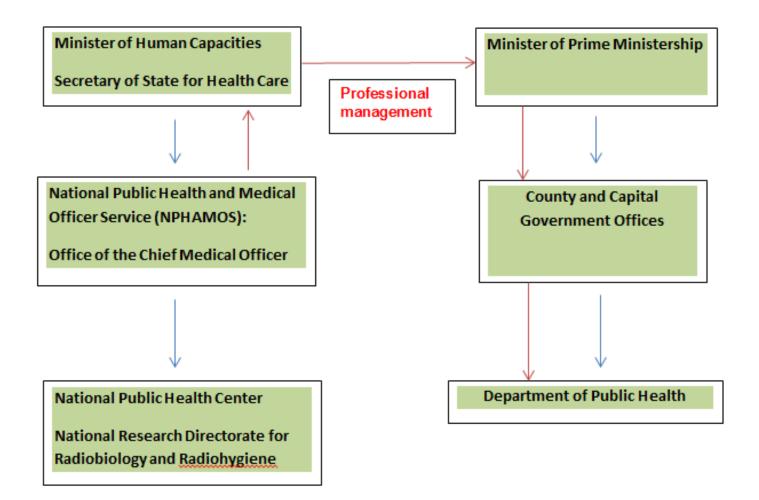
APPENDIX VIII – ORGANIZATIONAL CHART

HAEA



OCMO

STRUCTURE OF THE RADIATION HYGIENE AUTHORITIES since April 1., 2015.



BCDEPN

