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**DEPARTMENT OF NUCLEAR SAFETY AND SECURITY**
**DIVISION OF RADIATION, TRANSPORT AND WASTE SAFETY**

**DEPARTMENT OF TECHNICAL COOPERATION**
**DIVISION FOR EUROPE**

# PILOT ADVISORY MISSION ON RADIATION PROTECTION AND SAFETY IN MEDICAL EXPOSURE

## ESTONIA

**22-30 March 2022**

# REPORT OF THE IAEA PILOT ADVISORY MISSION ON RADIATION PROTECTION AND SAFETY IN MEDICAL EXPOSURE IN ESTONIA

22-30 March 2022, Tallinn, Estonia

*The Mission Team and the Estonian Counterparts*

**Conducted by:**

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**The number of recommendations, suggestions and good practices is in no way a measure of the status of the regulatory and practical arrangements for radiation protection and safety specific to medical exposure. Comparisons of such numbers between Mission reports from different countries should not be attempted.**

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# EXECUTIVE SUMMARY

This pilot Advisory Mission on Radiation Protection and Safety in Medical Exposure was requested by the Government of Estonia through the Environmental Board, Climate and Radiation Safety Department of Estonia. The mission concept and guidance were developed on the initiative of the Member States from the IAEA Technical Cooperation region for Europe. The mission was implemented under the TC project RER9/157.

The mission provided a comprehensive assessment of implementation of the IAEA Safety Standards related to medical exposure on the national level, taking into account both regulatory and practical arrangements. The scope of the mission included radiation therapy, nuclear medicine, diagnostic radiology, and image guided interventional procedures.

The Advisory Mission Team consisted of seven international experts whose expertise covered the regulatory and practical aspects in all areas, including education and training of health professionals, and one IAEA staff member.

From Estonia, the mission included, in addition to the Environmental Board, counterparts from the Ministry of Environment and Ministry of Social Affairs, as both have regulatory functions for radiation protection and safety in medical exposure, Estonian Society of Radiology, Estonian Nuclear Medicine Society, Estonian Society of Radiographers, Estonian Society of Biomedical Engineering and Medical Physics, Estonian Society of Clinical Oncologists and Estonian Society of Oncology, University of Tartu, Tartu Health Care College, University of Tartu and Tartu Health Care College, providing education and training of professionals involved in medical uses of radiation, national PACS foundation, the Health Insurance Fund, and representatives of medical facilities.

The Mission activities included review of regulations and other written material, interviews, discussions, and site visits with direct observations. The Advisory Mission Team visited both radiotherapy and all three nuclear medicine departments, and a representative sample of diagnostic and interventional departments. These involved the Tartu University Hospital, North-Estonia Medical Centre, East Tallinn Central Hospital, Childrens Hospital Tallinn, Pärnu Hospital, East-Viru Central Hospital and the private medical center Medicum.

The Advisory Mission Team acknowledged the interest of the regulatory bodies of Estonia to host the pilot Advisory Mission in this area. The involvement of all relevant stakeholders, their openness and cooperation during the mission activities demonstrated the willingness of Estonia to improve the regulatory and practical arrangements for radiation protection and safety specific to exposure of patients, carers and comforters and volunteers in programmes for biomedical research.

Estonia has established, as a part of the national health information system, a national picture archiving communication system (PACS), in which patient exposure data is also included. The team identified the following good practice:

- Health professionals can consult the information about patient medical history in the national PACS when referring patients to a radiological procedure, or when deciding what procedure to be performed. This contributes toward improved individual justification.

During site visits to medical facilities a strong collaboration was identified between professionals (medical radiological practitioners, medical radiation technologists and medical physicists) that contributes towards effective optimization of radiation protection of patients.

The Advisory Mission Team also identified issues warranting attention or in need of improvement and believes that consideration of these would enhance the national radiation protection and safety framework related to medical exposure. These issues include:

- The Government should establish a formal mechanism for recognition of medical physicists, medical radiation technologists and radiopharmacists as health professionals, and strengthen training in radiation protection and safety related to medical exposures.
- The Ministry of Social Affairs should ensure that generic justification of a radiological procedure is carried out, and evidence-based referral guidelines for individual justification are provided, in cooperation with the relevant professional bodies.
- The Ministry of Social Affairs should ensure that the licensees develop a comprehensive quality assurance programme that includes performance tests and patient dosimetry made by or under the supervision of a medical physicist.
- The Ministry of Environment and the Ministry of Social Affairs should strengthen communication with professional bodies and medical radiation facilities in the process of developing regulations and guides, for example for establishing diagnostic reference levels.
- The Health Board and the Environmental Board should ensure having a sufficient number of qualified and competent staff to perform its functions and to discharge its responsibilities related to medical exposures.

# I. INTRODUCTION

IAEA Safety Standards Series No. SF-1, Fundamental Safety Principles, presents the fundamental safety objective and principles of protection and safety. Requirements designed to meet this objective and these principles are established in IAEA Safety Requirements. With regard to medical exposure, requirements are set in the IAEA Safety Standards Series No. GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards. Specific recommendations and guidance on fulfilling the requirements of GSR Part 3 with respect to medical uses of ionizing radiation are provided in the Specific Safety Guide on Radiation Protection and Safety in Medical Uses of Ionizing Radiation SSG-46, jointly sponsored by the IAEA and the International Labour Office, the Pan American Health Organization and the World Health Organization.

Medical exposure that includes patients, carers and comforters and volunteers in biomedical research differs from occupational and public exposure in that persons are deliberately, directly and knowingly exposed to radiation for their benefit. Consequently, ensuring radiation protection of patients requires specific approaches that are well established in the GSR Part 3 and the Safety Guide SSG-46.

A number of Member States in the Technical cooperation for Europe (TCEU) region have expressed a need for further assistance and support with the practical application of the safety standards in this specific area, which was the motivation to develop this new advisory programme. In response to this request from the Member States, under the Technical Cooperation Project RER 9/147 “Enhancing Member States' Capabilities for Ensuring Radiation Protection of Individuals Undergoing Medical Exposure”, the IAEA developed Guidelines for Advisory Missions on Radiation Protection and Safety in Medical Exposure.

The Advisory Mission on Radiation Protection and Safety in Medical Exposure is complementary to other relevant IAEA review missions and advisory services that have components related to medical uses of ionizing radiation. The particular focus of this advisory mission is to provide a comprehensive assessment of implementation of the IAEA Safety Standards related to medical exposure on national level taking into account both regulatory and practical arrangements for radiation protection and safety specific to medical exposure.

This pilot mission in Estonia was developed and implemented according to these Guidelines.

# II. OBJECTIVE AND SCOPE

## OBJECTIVE

The mission offered Estonia a means to assess, through peer review, the status of the radiation protection and safety related to medical exposure on national level against IAEA Safety Standards. Moreover, the mission provided a means to assess whether arrangements are functioning to the extent that the practical provisions for medical exposure are effective and efficient.

The objective of the mission was to enhance radiation protection and safety related to medical exposure by:

- providing Estonia with an objective assessment of its arrangements for radiation protection and safety related to medical exposure;
- identifying areas where performance should be improved to meet IAEA Safety Standards, international guidance and best practices;
- identifying the strengths in Estonia which may be unique and worthy of bringing to the attention of others;
- making recommendations and suggestions to assist Estonia to be in line with Safety Standards and giving advice on developing an action plan;
- providing to Estonia a tool to improve collaboration between relevant authorities, professional bodies and end users as required in the GSR Part 3;
- promoting sharing of experience and exchange of lessons learned among regulators and health professionals;
- promoting the use of self-assessment by Estonia.

## SCOPE OF THE MISSION

This Advisory Mission provided Estonia with a comprehensive assessment on the national level of implementation of the IAEA safety standards related to medical exposure that is the exposure incurred by patients, carers and comforters and volunteers in biomedical research.

The mission covered all aspects related to medical exposure based on the requirements of the GSR Part 3 (paras 3.145–3.185). To obtain a full view of the subject, the mission considered other relevant requirements and recommendation of the IAEA safety standards.

The scope of the mission included diagnostic radiology, image guided interventional procedures, nuclear medicine and radiation therapy. A graded approach was applied, with more attention paid to activities associated with medical exposure on high-risk end.

# III. BASIS FOR THE MISSION

## PREPARATORY WORK

This Advisory Mission was requested by the Government of Estonia through the Environmental Board, Climate and Radiation Safety Department of Estonia on 8 September 2021. After assessing eligibility, the IAEA initiated dialog with Estonia for organizing the mission.

The Preparation meeting was held virtually on 11 and 12 November 2021. The meeting was attended by the appointed Team Leader Ms. Ritva Bly, the IAEA coordinator Ms. Jenia Vassileva, the Host State Contact Point Mr. Ilmar Puskar, and some of the key counterparts identified by the Host. During the meeting, the objectives and scope of the Advisory Mission were presented by the IAEA Coordinator. The Estonian counterparts presented the status of radiation protection and safety in medical exposure from the regulatory perspective, as well as the status of implementation in practice. The site visits were agreed to include a representative sample of Estonian medical facilities, including all radiotherapy and nuclear medicine departments, and diagnostic and interventional departments in five hospitals situated in Tallinn, Tartu, Pärnu and East Viru county, as well the main educational institutions in Tallinn and Tartu that provide training of health professionals. All administrative and logistical aspects were also agreed.

The duration of the main mission was set at nine working days, excluding the day of travel and the first meeting of the Team. Prior to the full mission, arrangements were made to provide each participating organization in Estonia with information about the scope and conduct of the mission.

After the Preparation meeting, the IAEA Coordinator created a shared space in Microsoft Teams for collecting and sharing information and for communication between the Team and the Host State Coordinator.

Within the agreed timeframe, Estonian counterparts and the IAEA Coordinator prepared a package of background information as presented further in this report.

The Mission Team consisted of seven experts whose expertise covered the areas related to medical exposure, including the regulatory aspects, and the applications of radiation protection requirements in diagnostic and interventional radiology, nuclear medicine and radiotherapy, as well as education and training of health professionals. The Team comprised three regulators with extensive experience in medical exposure regulatory practices, two medical physicists, one radiologist with qualification in pediatric radiology and one radiographer. Most of the Team members have also academic involvement relevant to the Mission.

The IAEA Coordinator, in consultation with the Team Leader, assigned specific tasks to each Team Member and confirmed that each agrees with and accepts his or her assigned responsibilities.

Considering the piloting character of this mission, the team meeting was organized 21-25 February 2022 in Vienna, with the purpose to familiarize the Team members with the methodology and agree on the details of conducting the mission. The meeting included sharing initial impressions, preparing questions for interviews and site visits, and agreeing on the formulation of findings, recommendations, suggestions and good practices for the mission report.

The pre-mission activities were implemented under the Technical cooperation Projects RER 9/147 "Enhancing Member States' Capabilities for Ensuring Radiation Protection of Individuals Undergoing Medical Exposure", and the main mission – under the project RER9/157 "Strengthening implementation of the justified and optimized use of ionizing radiation in medicine".

## CONDUCT OF THE MISSION

The Mission was conducted according to the programme outlined in Appendix 1.

The initial Team meeting took place on Monday, 21 March 2022 in Tallinn, directed by the Team Leader. The Host Contact Point was present at the initial Team meeting, in accordance with the Guidelines, and presented logistical arrangements planned for the mission. Discussions encompassed the general overview, the scope and specific issues of the mission, clarified the basis for the review and the background, context and objectives of the mission. The understanding of the methodology for review was reinforced. As required by the Advisory Mission Guidelines, the Team members presented their initial impressions of the assigned areas of review, and highlighted issues to be addressed during the mission. The agenda for the mission was presented to the Team.

The Entrance meeting was held on Tuesday, 22 March 2022, with participation of the Team and the Estonian Counterparts identified by the Host (Appendix 2). Because of the restrictions due to the ongoing pandemic, the meeting was held in a hybrid format, with the Team and six key counterparts present on site and others virtually. Opening remarks were made by Dr. Heidi Alasepp, the Deputy Secretary General for Health of the Ministry of Social Affairs, Ms. Ritva Bly, Team Leader and Ms. Jenia Vassileva, IAEA Team Coordinator. The IAEA coordinators presented a summary of the IAEA requirements and relevant Safety standards used as the basis for the mission (Appendix 3), the place of the Advisory Mission within the framework of other IAEA Review Missions, mission objectives and process. Mr. Ilmar Puskar presented the expectations from the mission and gave an overview of the status of the regulatory framework for radiation protection and safety in medical exposure in Estonia. Representatives of five different stakeholders presented their views on the current goals in the development of radiation protection and safety in medical exposure in Estonia.

During the mission, a review was conducted within the agreed scope with the objective of providing Estonia with recommendations and suggestions for improvement and where appropriate, identifying good practice. It was conducted through review of written material, meetings, interviews and discussions, direct observations and site visits at medical radiation facilities.

The Advisory Mission Team acknowledged the interest of the regulatory bodies of Estonia to host the pilot Advisory Mission in this area. The involvement of all relevant stakeholders, their openness and cooperation during the mission activities demonstrated the willingness of Estonia to improve the regulatory and practical arrangements for radiation protection and safety specific to exposure of patients, carers and comforters and volunteers in programmes for biomedical research.

The Exit meeting was held on Wednesday, 30 March 2022. The opening remarks at the Exit meeting were presented by Meelis Münt, Secretary General, Ministry of Environment, and were

followed by the presentation of the results of the mission by the Team Leader Ms. Ritva Bly, and remarks in response to the mission findings by the Host Contact Point Mr. Ilmar Puskar. Closing remarks were made by Mr. Miroslav Pinak, IAEA, Acting Director, Division of Radiation, Transport and Waste Safety and Ms. Eve-Külli Kala, IAEA, Director, Division for Europe, Department of Technical Cooperation.

An IAEA news story was published after the mission: https://www.iaea.org/newscenter/news/iaea-steps-up-efforts-to-ensure-patient-safety-during-medical-procedures-using-radiation.

The Recommendations, Suggestions and Good Practices identified during the Mission are summarized in Appendix 4.

## REFERENCES FOR THE REVIEW

Key topical areas of the mission were based on the requirements of the GSR Part 3 related to medical exposure (paras 3.145–3.185):

Requirement 34: Responsibilities of the government specific to medical exposure (paras 3.147–3.149).

Requirement 35: Responsibilities of the regulatory body specific to medical exposure (para. 3.150).

Requirement 36: Responsibilities of registrants and licensees specific to medical exposure (paras 3.151–3.154).

Requirement 37: Justification of medical exposures (paras 3.155–3.161).

Requirement 38: Optimization of protection and safety (paras 3.162–3.174).

Requirement 39: Pregnant or breast-feeding female patients (paras 3.175–3.177).

Requirement 40: Release of patients after radionuclide therapy (para. 3.178).

Requirement 41: Unintended and accidental medical exposures (paras 3.179–3.181).

Requirement 42: Reviews and records (paras 3.182–3.185).

To obtain a full view of the subject, the mission was not limited to the above-mentioned requirements, but other relevant requirements and recommendation of the safety standards were also considered.

The mission included review of national regulations, guidelines and other relevant material provided by the Host.

The references for the review are listed in Appendix 3.

# IV. FINDINGS, RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

## 1. LEGAL AND REGULATORY FRAMEWORK

The legal framework established provides the statutory basis for requirements for protection and safety specific to medical exposures. These provisions are established in §42(1) and §25 of the Radiation Act by the Estonian Parliament (issued 08.06.2016, last amended 10.07.2020). The provisions are complemented with Regulation 71 "Medical exposure: radiation safety requirements, medical exposure procedures, clinical audit requirements and diagnostic reference values and requirements for their determination" by the Minister of Health and Labor (issued 19.12.2018).

Estonia's framework for safety requires the establishment of a regulatory body with responsibilities and functions for control of medical exposures in §25, §30, §69 and §112(1) of the Radiation Act.

Two Ministries are involved as Regulatory Bodies for medical exposure: the Ministry of Environment (MoE) and the Ministry of Social Affairs (MoSA). Competent authorities under these Ministries are the Environmental Board (EB) under MoE, and the Health Board (HB) under MoSA. Their organizational charts are presented in Appendix 5. The EB is responsible for authorization, review and assessment, inspection, and enforcement of radiation practices. The HB is responsible for authorization, review and assessment, inspection, and enforcement of specialized medical care practices.

## 2. EDUCATION, TRAINING AND COMPETENCE

The Team identified that basic education and training programmes are in place for relevant professionals involved in medical exposure. Education of medical doctors and dentists, as well as residency programmes in radiology (including nuclear medicine) and radiation oncology are provided by the University of Tartu, education of medical radiation technologists (radiographers) by the Health Care College in Tartu. The academic programmes include mandatory training in radiation protection (dentists: 2 ECTS*, doctors: 6.5 ECTS, medical radiation technologists: 14.5 ECTS, residents: 3 days, specialists 1-2 days).

The education of medical physicists is provided by the Tallinn University of Technology (TalTech). The Team was informed about TalTechs' Master Programme "Medical Technology and Physics" which, at the end of a nominal study period of 4 semesters providing 120 ECTs credits, confers the degree of Master of Science in Engineering. For the medical physicist, a residency programme with supervised training in the clinical environment similar to the one for medical doctors, is not yet established. The possibility of further expanding the provisions of education and training for the medical physicists provided by TalTech were explored, in conjunction with the possibility of having in the near future a residency programme for the medical physicists similar to the one for medical doctors.

The Team was informed that Estonian occupational qualifications system forms a part of the Estonian qualifications system that links life-long learning system and the labor market. Within this framework, professionals are certified by the Estonian Qualifications Authority. Among others, this applies to medical physicists and medical radiation technologists.

Health professionals are precisely defined within the Health Services Organization Act as being doctors, dentists, nurses and midwives only and thus not all relevant professionals in medical exposure are included, specifically medical physicists, medical radiation technologists, radiopharmacists or radiochemists.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| Observation | The legal definition of health care professionals in the Health Services Organization Act includes doctors, dentists, nurses and midwives, but not medical physicists, medical radiation technologists or radiopharmacists. |
| Basis 1 | GSR Part 3 defines **health professional** as *"An individual who has been formally recognized through appropriate national procedures to practise a profession related to health (e.g., medicine, dentistry, chiropractic, podiatry, nursing, medical physics, medical radiation technology, radiopharmacy, occupational health)."* |

*ECTS = European Credit Transfer System, where 1 ECTS = 20-25 hours of learning activity

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| Basis 2 | GSR Part 3 defines **medical radiation technologist as** *"A health professional, with specialist education and training in medical radiation technology, competent to perform radiological procedures, on delegation from the radiological medical practitioner, in one or more of the specialties of medical radiation technology. Competence of persons is normally assessed by the State by having a formal mechanism for registration, accreditation or certification of medical radiation technologists in the various specialties (e.g., diagnostic radiology, radiation therapy, nuclear medicine). States that have yet to develop such a mechanism would need to assess the education, training and competence of any individual proposed by the licensee to act as a medical radiation technologist and to decide on the basis of either international standards or standards of a State where such a system exists, whether such an individual could undertake the functions of a medical radiation technologist, within the required specialty*." |
| Basis 3 | GSR Part 3 defines **medical physicist** as "*A health professional with specialist education and training in the concepts and techniques of applying physics in medicine and competent to practise independently in one or more of the subfields (specialties) of medical physics. Competence of persons is normally assessed by the State by having a formal mechanism for registration, accreditation or certification of medical physicists in the various specialties (e.g., diagnostic radiology, radiation therapy, nuclear medicine). States that have yet to develop such a mechanism would need to assess the education, training and competence of any individual proposed by the licensee to act as a medical physicist and to decide, on the basis of either international accreditation standards or standards of a State where such an accreditation system exists, whether such an individual could undertake the functions of a medical physicist, within the required specialty*." |
| Basis 4 | GSR Part 3 defines **radiopharmacist** as "*A health professional, with specialist education and training in radiopharmacy, who is competent to prepare and dispense radiopharmaceuticals used for the purposes of medical diagnosis and radionuclide therapy. Competence of persons is normally assessed by the State by having a formal mechanism for registration, accreditation or certification of radiopharmacists. States that have yet to develop such a mechanism need to assess the education, training and competence of any individual proposed by the licensee to act as a radiopharmacist and to decide, on the basis of either international standards or standards of a State where such a system exists, whether such an individual could undertake the functions of a radiopharmacist"* |
| **R1. Recommendation** | **The Government should establish a formal mechanism for recognition of medical physicists, medical radiation technologists and radiopharmacists as health professionals.** |

Regulation 128 “Requirements for quality assurance of health care services” by the Minister of Social Affairs (issued 15.12.2004) stipulates that health care professionals (doctors, dentists, nurses and midwives) must complete 60 hours per year of ongoing training to maintain their competence. The same is not required for medical physicists, medical radiation technologists and radiopharmacists and is instead guided by professional bodies and by employers. The Team was informed by the professional bodies that medical physicist re-certification, which is provided by the Estonian Society of Biomedical Engineering and Medical Physics, requires completion of at least 80 hours of on-going training activity in a five-year period, while medical radiation technologists are recommended to complete 8 ECTS (208 hours) in the same period, although this is not mandatory.

The Team was informed during site visits that at a local level these professionals along with all users of medical radiation have on-going radiation protection updates and training in radiation protection organized by employers, which is typically delivered on a very practical basis using local equipment and resources. The quantity of this training appears to be dependent on local resources and the Team was informed that this training may range from delivering the minimum mandatory 4 hours of education every 5 years, to having more frequent training as issues arise in settings with more resources. The Team observed that recording of such on-going training does not appear to be systematically documented.

The Team was also informed of a lack of academic staff in the educational institutions, which was limiting the potential of current education delivery and potentially impacting the sustainability of radiation protection education and training into the future.

The Team was informed that there is potential to organize the on-going training of professionals in medical exposure more systematically in collaboration with professional bodies, who represent the collective expertise of the given health professions and, as such, can strongly influence the practice of radiation protection and safety.

Re-training in radiation protection is stipulated in § 4 of Regulation 57 “Requirements for radiation safety training for exposed workers and radiation safety officers” by the Minister of the Environment (issued 24.11.2016) but is only specified relative to occupational radiation protection updates, with no reference to specific radiation protection for medical exposures, in particular relative to patients.

| **RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES** | |
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| Observation | The requirement for maintaining competence of persons with responsibilities for protection and safety is limited in Regulation 57 (2016) to occupational safety of exposed workers and in Regulation 128 (2004) §8(2) to annual training of health care professionals, with no specific requirement for education and training in medical exposures. |
| Basis 1 | GSR Part 3, para 2.22 states: “*The government shall ensure that arrangements are in place for the provision of the education and training services required for building and maintaining the* |

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| | *competence of persons and organizations that have responsibilities relating to protection and safety"* |
| Basis 2 | GSR Part 3, para 2.32 states: "*The regulatory body shall ensure the application of the requirements for education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety*" |
| Basis 3 | GSR Part 3, Requirement 35: Responsibilities of the regulatory body specific to medical exposure states: "*The regulatory body shall require that health professionals with responsibilities for medical exposure are specialized in the appropriate area and that they fulfil the requirements for education, training and competence in the relevant specialty*.<br><br>Para 3.150 states: "The regulatory body shall ensure that the authorization for medical exposures to be performed at a particular medical radiation facility allows personnel (radiological medical practitioners, medical physicists, medical radiation technologists and any other health professionals with specific duties in relation to the radiation protection of patients) to assume the responsibilities specified in these Standards only if they: (a) Are specialized in the appropriate area; (b) Meet the respective requirements for education, training and competence in radiation protection, in accordance with para. 2.32…". |
| Basis 4 | Para 2.136 of SSG-46 states **"**…*Health professionals should maintain their core competencies in medical and occupational exposures, including radiation protection and safety, and should keep abreast of new developments in medical uses of radiation. One way to achieve this is through formal continuing medical education or continuing professional development programmes*." |
| **R2. Recommendation** | **The Government should ensure specific training in radiation protection and safety related to medical exposures.** |

Regulation 71 §7 additionally lists 'other radiation worker who has received professional training' as being entitled to perform a medical exposure procedure under the supervision of a radiologist or other physician trained in the performance of such procedure. Details of the educational, training and competency requirements for such individuals is not clear. The Team was informed that this was to facilitate transition arrangements for previously trained nurses. It is suggested that to avoid confusion within the regulations that this be removed from the regulation and for transition regulations to specify that such trained nurses can continue to work.

# 3. JUSTIFICATION

## *3.1. Generic justification*

Regulation 62 issued on the basis of subsection 31 (2) of the Health Insurance Act, stipulates generic justification of medical procedures for reimbursement purposes. However, for other purposes generic justification (level 2 justification) of radiological procedures is not regulated, which is not in line with the IAEA Safety Standards.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| Observation | Generic justification (Level 2 justification) is only included in legislation/regulation for reimbursement purposes. |
| Basis 1 | GSR 3, para 3.156 states: "*Generic justification of a radiological procedure shall be carried out by the health authority in conjunction with appropriate professional bodies, and shall be reviewed from time to time, with account taken of advances in knowledge and technological developments*" |
| Basis 2 | SSG-46, para 2.55 states : "*The health authority has particular roles in the application of the radiation protection requirements for justification, namely with respect to: (a) Generic justification of radiological procedures; (b) Justification of radiological procedures in health screening programmes; (c) Criteria for the justification of radiological procedures for health assessment of asymptomatic individuals intended for the early detection of disease, but not as part of a health screening programme*"<br><br>Para 2.56 states: "*Generic justification of radiological procedures is an ongoing process as new procedures become available and as established procedures are reviewed in the light of new knowledge and developments. It should be decided whether a new radiological procedure should become a new addition to the existing procedures. Conversely, an existing radiological procedure may need to be withdrawn from use if there is evidence that an alternative modality or technology has greater efficacy. The health authority, together with relevant professional bodies, should make these decisions*." |
| **R3. Recommendation** | **The MoSA should ensure that generic justification of a radiological procedure is carried out by the health authority in conjunction with appropriate professional bodies, and is reviewed from time to time, with account taken of advances in knowledge and technological developments.** |

## *3.2. Individual justification*

The principle of individual justification (level 3 justification) is stated in the Radiation Act §42 (1) and further provisions for individual justification are in Regulation 71.

Justification of a procedure for an individual patient is stated in Regulation 71 §8, with a detailed description of responsibilities of the person performing a medical radiology procedure. The person who performs the procedure also has the right to amend or decline an unjustified procedure (Regulation 71 §8 (3)), which is important and good practice. However, Regulation 71 §7 states that a medical radiology procedure can be performed not only by a radiologist or other physician, but also by a medical radiation technologist or other radiation worker who has received professional training, under the supervision of a radiologist or other physician trained in the performance of such procedure. The role of the radiation medical technologist or another radiation worker, as defined in Regulation 71 §7, is not clear. The Team was informed that the medical radiation technologists always have a possibility to consult a radiologist regarding changing or declining a procedure. However, during a site visit the Team was informed that the medical radiation technologists always have the right to decline an unjustified examination. They do not have to consult a radiologist, though they usually do so. There is also wide variation in the way of documentation of declining or changing a procedure.

| **RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES** | |
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| Observation | The role of the radiation medical technologist or another radiation worker, as defined in Regulation 71 §7, is not clear regarding amending / declining procedures. |
| Basis 1 | GSR 3, para 3.157 states: "*The justification of medical exposure for an individual patient shall be carried out by means of consultation between the radiological medical practitioner and the referring medical practitioner*." |
| Basis 2 | SSG-46, para 3.145 states: "*For some radiological procedures, primarily 'well established' procedures and low dose procedures, the practical implementation of justification in many States is carried out by the medical radiation technologist, who is effectively representing the radiological medical practitioner with the formal understanding that, if there is uncertainty, the radiological medical practitioner is contacted and the final decision is taken by the radiological medical practitioner in consultation with the referring medical practitioner. Such justification is guided by national or international referral guidelines. It should be noted that, in all cases, the responsibility for justification lies with the radiological medical practitioner and the referring medical practitioner*." |
| **R4. Recommendation** | **The MoSA should ensure that the role of radiation medical technologist or another radiation worker is clarified regarding responsibilities for amending/ declining a procedure.** |

The Team was informed that national picture archiving communication system (PACS) has been part of the Estonian national health information system since 2014. Patient health information including images and radiological reports can be reached by the health care professionals everywhere in the country. Also, the patients have access to their own records. Most of the patient exposure data is already included in the national PACS, and the Team was informed that new

software planned to be installed in 2022-2023 will enable automatic extraction, analyses and management of the patient exposure data. This may also help to use patient doses for optimization of radiation protection of patients, including establishing national diagnostic reference levels (DRLs).

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| Observation | Nationwide PACS exists that provides access to all the information about patient medical history and previous procedures, and archives also dose information in a standard format (DICOM RDSR). |
| Basis 1 | GSR Part 3, para 3.157 states: "*The justification of medical exposure for an individual patient shall be carried out by means of consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate, with account taken, in particular for patients who are pregnant or breast-feeding or are paediatric, of: (a) The appropriateness of the request; (b) The urgency of the radiological procedure; (c) The characteristics of the medical exposure; (d) The characteristics of the individual patient; (e) Relevant information from the patient's previous radiological procedures.*" |
| Basis 2 | GSR Part 3, para 3.185 states: "*Registrants and licensees shall maintain for a period as specified by the regulatory body and shall make available, as required, the following records for medical exposure: (a) For diagnostic radiology, information necessary for retrospective assessment of doses, including the number of exposures and the duration of fluoroscopic radiological procedures; (b) For image guided interventional procedures, information necessary for retrospective assessment of doses, including the duration of the fluoroscopic component and the number of images acquired; (c) For nuclear medicine, the types of radiopharmaceutical administered and their activity; (d) For external beam radiation therapy or brachytherapy, a description of the planning target volume, the absorbed dose to the centre of the planning target volume, and the maximum and minimum absorbed doses delivered".* |
| **GP 1. Good practice** | **Health professionals can consult the information about patient medical history in the national PACS when referring patients to a radiological procedure, or when deciding what procedure to be performed. Also, patients have access to the relevant information in their electronic medical records. This contributes toward improved individual justification.** |

Regulation 71 §5 states the responsibility of the referrer to inform the patient of the need for the procedure and the risk of radiation. The Team was informed during site visits that the referrers do not usually inform the patients, and in practice the medical radiation technologists inform the patient about procedures and radiation risks. Regulation 71 §6 states that an adequate referral is required and §11 states some criteria for the contents of the referral.

The use of referral guidelines is stated in Regulation 71, and according to §4(4) the planning of a diagnostic medical procedure has to be based on the guidelines of the European Commission (EC). The reference on the HB website is EC publication 'Referral Guidelines for Imaging', Radiation Protection 118, from the year 2001. This document has been withdrawn from the EC publications website, because it is outdated. Some hospitals have developed their own guidelines and expressed a need for national referral guidelines that should ideally be integrated into the hospital information system.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| Observation | Regulations were noted to refer to a specific document regarding referral guidelines, which requires continuous up-dating of the regulation. The referred guideline has already been withdrawn from EC website as it is outdated. |
| Basis 1 | GSR 3, para 3.158 states: "*Relevant national or international referral guidelines shall be taken into account for the justification of the medical exposure of an individual patient in a radiological procedure."* |
| **R5. Recommendation** | **The MoSA should ensure that relevant referral guidelines are taken into account in the justification practices.** |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| Observation | The Regulation refers to an already withdrawn EC document for referral to medical imaging. The professionals have knowledge of evidence-based imaging and some hospitals have developed their own guidelines. |
| Basis 1 | SSG-46, para 2.59 states: "*National or international referral guidelines should be used as an important tool in the application of the process of justification of medical exposure for an individual patient. The health authority should support the relevant professional bodies in developing and implementing evidence-based referral guidelines (see also para. 2.65)."* |
| Basis 2 | SSG-46, para 2.65 states:" Professional *bodies should take the lead in the development of referral guidelines (also called appropriateness criteria in some States) for use in justification of medical exposure for an individual patient (para. 2.59). It might not be possible for every State to develop its own referral guidelines. The significant work of a number of professional bodies around the world could be utilized by many other States through adoption or adaptation by the local professional bodies (see also paras 3.143 and 4.160)."* |

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| **S1. Suggestion** | **The MoSA should consider supporting the relevant professional bodies in developing/adopting and implementing evidence-based referral guidelines.** |

## *3.3. Justification for asymptomatic individuals and volunteers in biomedical research*

Justification of screening programmes is stated in Regulation 71 §8(5) and is in line with IAEA Safety Standards. Breast cancer screening with mammography was organized in collaboration with different organizations (MoSA, professional bodies, National Institute for Health Development, HB and National Insurance Fund).

Regulation 71 §8 (4) (2) states that radiological procedures for asymptomatic individuals for early detection of disease outside of a screening programme require specific justification for that individual. By this regulation, justification has to be documented individually by the radiological medical practitioner in consultation with the referring medical practitioner. The Team was informed on site visits that asymptomatic patients with high genetic risk for breast cancer have yearly mammography according to guidelines of a national multidisciplinary board that will be part of the National Cancer Plan.

Regulation 71 §8(6) stipulates justification of medical exposure of volunteers in biomedical research and the role of ethics committees. The §2(3) of the Medical Devices Act by the Estonian Parliament (issued 13.10.2004, last amended 01.02.2022) stipulates involvement of both a medical physics expert and a relevant doctor in the field of medical exposure in the assessment of applications. Establishment of dose constraints for volunteers in biomedical research is stated in Regulation 71 §9 (5) (6).

# 4. OPTIMIZATION

## *4.1. Design considerations*

Regulation 71 §13 stipulates that medical radiation devices used in medical radiology procedures have to comply with the criteria presented for medical radiation devices in the radiation protection guidelines of the EC. The EB holds responsibility for publishing guidelines on its website. Currently, the referenced document is the publication 'Criteria for Acceptability of Medical Radiological Equipment used in Diagnostic Radiology, Nuclear Medicine and Radiotherapy', Radiation Protection 162 from the year 2012. However, the EC states in the foreword that "the Commission does not recommend the direct adoption of the RP162 suspension levels in national regulations". For further recommendations regarding the use of RP162 see section 4.6 of this report.

Regulation 71 §13 states the license holder is responsible for proper installation of medical radiation equipment and for ensuring that the conditions of use prescribed by the manufacturer are met. It also states a requirement for new equipment to enable registration and archiving of the relevant dose metrics together with the image data. There is also a requirement that equipment used for procedures on paediatric patients has to enable adequate optimization of procedures.

In all visited medical radiological facilities, the Team was informed that specifications for new equipment are prepared by each facilities multidisciplinary team that consist of all key professional groups, including medical physicists, medical doctors of the relevant speciality, medical radiation technologists.

The Team observed on site visits that equipment in diagnostic and interventional radiology is modern with appropriate radiation protection capabilities enabling delivery of lower patient doses. The Team was also informed that optional extra radiation protection equipment features were acquired, due to the importance of radiation protection. The Team considers this as evidence of a strong safety culture amongst professionals.

The Team observed during site visits that equipment for diagnostic nuclear medicine (PET/CT and SPECT/CT) is modern with high sensitivity enabling reduction in administered activity. Ancillary equipment (such as automatic injectors in PET) enabling more accurate delivery of planned administered radiopharmaceutical activity are available and used. Ancillary equipment such as performance phantoms are available and used in quality control. All three centers are equipped with a minimum of two activity meters to measure the activities injected to the patients. None of the centers meet fully the requirements of good manufacturing practice (GMP) for radiopharmaceutical products, (see for example IAEA SSG-46; Para 4.299), although the Team was informed that in two centers there are programmes in place to meet such requirements connected with the relocation of the nuclear medicine (NM) department or with the realization of a new PET facility. Regulation 20 "Clauses for preparation of radiopharmaceutical preparations" by the Minister of Health and Labor (issued 17.02.2022) stipulates the terms of implementation of current good radiopharmaceutical practice (cGRPP). While most of the requirements of cGRPP come into immediate effect, some more resource intensive requirements come into effect on 01.07.2023 and 01.01.2024, respectively.

The Team observed during the site visits that equipment and software for external beam radiotherapy and brachytherapy is modern and well maintained. Both radiotherapy centres are well equipped with patient positioning devices. It enables high conforming external radiotherapy techniques to be used in a safe way. Also, both RT departments are well equipped with dosimetry equipment needed for comprehensive verification of treatment.

## *4.2. Operational considerations*

Optimization is regulated in Regulation 71 §9. Although responsibility for optimization is not assigned to specified personnel and there is no requirement for collaboration between relevant professionals as it is in IAEA Safety Standards, the Team was informed during site visits of strong collaboration between professionals (medical radiological practitioners, medical radiation technologists and medical physicists) to achieve effective optimization of medical exposures, through high quality protocols and practices.

Regulation 71 §7 states that a medical radiology procedure can be performed not only by a radiologist or other physician, but also by a medical radiation technologist or other radiation worker who has received professional training, under the supervision of a radiologist or other physician trained in the performance of such procedure. See also the last paragraph of Section 2, Education, training, and competence of this report.

## *4.3. Calibration*

The Radiation Act §32 (7) stipulates that a holder of a radiation practice license has the obligation to ensure regular control and calibration of measuring instruments.

The Team was informed on site visits that the reference dosimeters used in radiotherapy are periodically calibrated and in the interim period functional tests are performed using sealed sources with calibration certificates under the responsibility of a medical physicist. The Team was informed that radiotherapy units are calibrated in terms of appropriate quantities using international protocols. It is done at the time of commissioning, after any maintenance procedure that could affect the dosimetry and at intervals given by the guidelines published by the EB on its website (at the moment this is EC RP 162). The team was informed on site visits, that calibrations of linear accelerator beams are independently verified prior to clinical use through the IAEA TLD postal dose audit service for linear accelerator beams. One of the departments also uses the services of an independent outsourced medical physicist to do the measurements for licensing purpose, that include calibration of sources giving rise to medical exposure.

The Team was informed on site visits in nuclear medicine departments that in one medical radiological facility the activity meters were sent periodically for calibration to a standard calibration laboratory with traceable calibration, while in two facilities the activity meters only underwent periodical functional checks using sealed sources with calibration certificates. The Team was also informed that the survey monitors are periodically calibrated, traceable to a standard dosimetry laboratory. In the interim period functional checks are performed using sealed sources with calibration certificates under the responsibility of a medical physicist or RPO.

## 4.4. Dosimetry of patients

The Radiation Act §95 stipulates patient dosimetry as one of the responsibilities of the medical physics experts.

The Regulation 71 §9(4) states that in radiation therapy individual treatment plans are to be developed for each patient to ensure that exposure is optimized. The Team was informed on site visits that in external beam therapy and brachytherapy dosimetry of patients is performed and documented by or under the supervision of a medical physicist, using calibrated dosimeters and following internationally accepted protocols, including dosimetry to determine the absorbed doses to the planning target volume for each patient and absorbed doses to relevant tissues or organs as determined by the radiological medical practitioner.

Regulation 71 §15 stipulates the methodology for data collection for patient dose optimization. It states that the holder of a radiation practice license has to collect the necessary data concerning at least ten patients over 15 years of age during the year. According to the IAEA SSG-46 recommendations, the sample size should depend on the frequency of the imaging procedure and variability in patient doses, but a larger sample size will reduce the statistical uncertainties. Therefore SSG-46 provides recommendations for representative sample sizes for different types of procedures. Regulation 71 §15 also stipulates that data collected for the optimization of patient doses shall be forwarded to the HB. Additional guidelines for assessment of patient doses for medical exposure procedures were published by the HB.

The Team was informed by several professionals that the methodology for determination of typical patient doses was considered inadequate.

The Team was informed on site visits that most of the visited facilities collect patient dose data following the methodology prescribed in Regulation 71. However, the Team was informed on site visits, that typical doses are not available in all facilities. In image guided interventional procedures, patient doses are considered and recorded, but typical doses are not determined. Some of the visited facilities use their typical doses as an optimization tool, but with national DRLs established for only 5 procedures the choice of the reference values is in most cases arbitrary. In the area of nuclear medicine, typical doses for the most common diagnostic procedures set in activity administered to the patient, are only established in one out of three facilities.

| **RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES** | |
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| Observation | The methodology for collecting patient data for dose optimization as prescribed in Regulation 71 is not in line with SSG-46. |
| Basis 1 | SSG-46, para 2.39 states "…*For each room or facility in which the given procedure is performed, the sample size depends on the frequency of the imaging procedure and variability in patient doses, but clearly a larger sample size will reduce the statistical uncertainties (for further guidelines, see para. 3.213 for diagnostic and interventional radiology and para. 4.205 for nuclear medicine)*…." |
| Basis 2 | SSG-46, para 3.213 states "… *A representative sample of 10–20 patients per procedure type is needed for non-complex examinations such as* |

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| | *radiography and CT, preferably 20–30 patients for complex procedures such as fluoroscopy and fluoroscopically guided procedures, and 50 patients for mammography [14] (see also paras 2.39–2.41*).” |
| Basis 3 | SSG-46, para 4.205 states “… *In nuclear medicine, DRLs are set in activity administered to the patient (MBq) or in activity per unit of body mass (MBq/kg). … Such sample sizes are typically in the range of 10–20 patients: the larger sample size the lower the statistical uncertainties (see also paras 2.39–2.41 and Refs [14, 242*]).” |
| Basis 4 | SSG-46, paras 3.210-3.219 provide further specific recommendations for dosimetry of patients in diagnostic radiology, paras 2.220-3.223 for image guided interventional procedures, and paras 4.203-4.413 for nuclear medicine |
| **S2. Suggestion** | **The MoSA should consider establishing an updated methodology for determination of typical doses to be in line with SSG-46.** |

## *4.5. Diagnostic reference levels*

Regulatory provisions related to establishment of DRLs are in place. The Radiation Act §44 and Regulation 71 §19 stipulate that DRLs have to be established for radiology and nuclear medicine procedures. Regulation 71 §19 stipulates that DRLs have to be based on national data and reviewed at least every 5 years. The Radiation Act §44 stipulates HB the responsibility for establishment of DRLs. Methodology for collection of dose data to be used for establishment of the DRLs is stipulated in the Regulation 71 (see section 4.4 of this report). A list of imaging procedures for which DRLs are to be established is provided in Appendix 1 of Regulation 71 and includes 13 procedures. In practice DRLs are established for just 5 radiography procedures defined in terms of anatomical regions being imaged.

| **RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES** | |
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| Observation | Diagnostic reference levels are established only for a small subset of medical exposures incurred in medical imaging (3 conventional radiography procedures and for 2 mammography projections). |
| Basis 1 | SSG-46, para 2.37 states “*The imaging procedures for which DRLs are to be established should be decided upon at a national or regional level. The criteria that may help in this decision are the relative frequencies of the imaging procedures and the magnitude of the doses incurred. A graded approach may be used to select procedures for which DRLs are to be established for adults and children — the more frequent and higher dose procedures should have a higher priority. Specific consideration should be given to pediatric imaging“.* |
| **S3. Suggestion** | **The MoSA should consider establishing diagnostic reference levels for the most frequent procedures, for high-dose procedures and for paediatric patients.** |

The Team was informed by a representative of the MoSA that in 2020, dose data were collected for the 13 diagnostic radiology procedures listed in Annex 1 of Regulation 71 and that the collected data were analyzed in 2021 with the aim to establish new DRLs in 2022. The Team was informed that the existing methodology was recognized as inadequate by the MoSA, that the importance of cooperation with counterparts was recognized and that the MoSA is aware that DRLs should be established for a broader range of procedures. As reported in section 3 of this report, most of the patient dose data is available in the national PACS system. The Team was informed that software for automatic extraction, analysis and management of the exposure data has been procured and will be used in the establishment and utilization of DRLs for optimization.

Regulation 71 §15 stipulates annual patient dosimetry surveys in each facility. Radiation Act §44 stipulates that measures for decreasing relevant patient doses have to be considered if typical doses exceed the relevant DRLs for a given procedure, but there is no requirement for a review if typical doses fall substantially below the DRLs. Guidelines for assessment of patient doses for medical exposure procedures were published by the HB.

The Team was informed by several professionals that they did not feel collective ownership of national DRLs due to the identified weaknesses in the DRL methodology and this negatively impacts acceptance of DRLs among the medical professionals and consequently their implementation into practice.

| **RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES** | |
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| Observation | Weaknesses in the DRL methodology lead to inadequate implementation of the process of establishing DRLs and their utilization in practice. |
| Basis 1 | SSG-46, para 2.42. The processes and steps towards establishing DRLs, as described in paras 2.36–2.41, are likely to involve many parties, including the imaging facilities, the health authority, professional bodies and the regulatory body. In particular, there should be collective ownership of the DRLs in deciding which procedures and age groups will be used, how the data will be collected, who will manage the data, and when the DRLs should be reviewed and updated. In some States, a national governmental body administers the national patient dose database that underpins the establishing of DRLs. In other States, this role may be taken by the regulatory body or a professional body. There is no preferred custodian: what is important is that a patient dose database for DRLs is established and maintained, DRL values are set and then promulgated through the regulatory processes, and a process for periodic review is established. It may be more appropriate to take a regional rather than a national approach to DRLs (see para. 2.34). |
| **S4. Suggestion** | **The MoSA should consider ensuring that the methodology for establishing diagnostic reference levels is adequately developed and implemented in line with SSG-46.** |

## 4.6. *Quality assurance*

Establishment of a quality assurance programme for medical exposures is stipulated in §35 (1) (2) of Radiation Act and in the Regulation 71 §13 and 17. The licensees are obliged to conduct an acceptance test and regular functional tests in accordance with the relevant European Commission Radiation Protection Guidelines and the device manufacturer's recommendations, unless otherwise specified in the terms of the radiation practice license. Currently, the referenced document is the EC publication Radiation Protection 162 (see section 4.1 of this report).

The Team was informed on site visits that the quality control programmes are based on the EC publication RP 162 and tests performed biannually and that the results are sent to the EB. Some departments established more comprehensive quality control programmes that follow international guidance, and the tests are documented and performed by the medical physicists.

The Team was informed by the EB that they consider it important to have minimum national requirements for quality control and might consider initiating update of the current requirements based on EC publication Radiation Protection 162.

| **RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES** | |
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| Observation | Currently the requirement for performance of QC in Regulation 71 is limited to recommendations in the EC publication RP 162 and manufacturers recommendations. |
| Basis 1 | GSR Part 3, para 3.170 states: "*Registrants and licensees, in applying the requirements of these Standards in respect of management systems, shall establish a comprehensive programme of quality assurance for medical exposures with the active participation of medical physicists, radiological medical practitioners, medical radiation technologists and, for complex nuclear medicine facilities, radiopharmacists and radiochemists, and in conjunction with other health professionals as appropriate. Principles established by the World Health Organization, the Pan American Health Organization and relevant professional bodies shall be taken into account*." |
| Basis 2 | GSR Part 3, para 3.171 states: *"Registrants and licensees shall ensure that programmes of quality assurance for medical exposure include, as appropriate to the medical radiation facility:*<br>*(a) Measurements of the physical parameters of medical radiological equipment made by, or under the supervision of, a medical physicist:*<br>*(i) At the time of acceptance and commissioning of the equipment prior to its clinical use on patients; (ii) Periodically thereafter; (iii) After any major maintenance procedure that could affect protection and safety of patients; (iv) After any installation of new software or modification of existing software that could affect protection and safety of patients.*<br>*(b) Implementation of corrective actions if measured values of the physical parameters mentioned in (a) above are outside established tolerance limits.* |

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| | *(c) Verification of the appropriate physical and clinical factors used in radiological procedures.*<br>*(d) Maintaining records of relevant procedures and results.*<br>*(e) Periodic checks of the calibration and conditions of operation of dosimetry equipment and monitoring equipment."* |
| Basis 3 | SSG-46, para 3.238 states: "There are many published reports from international and national organizations and national and regional professional bodies giving detailed guidance on the performance tests and quality control tests that should be performed on the various modalities, including recommended frequencies (see Refs [104, 105, 109–114, 156, 161, 166, 167, 170–173, 181–201]). In addition, many of these organizations and professional bodies publish on their web sites new or updated publications on the topic. The regulatory body may have its own specific requirements for the tests that should be performed, their frequencies and the competence of the specialists involved. Such specific requirements should be established with consultation between the regulatory body and the relevant professional bodies." |
| **R6. Recommendation** | **The MoSA should ensure that requirements for establishing a comprehensive QA programme include all the attributes stated in the GSR Part 3, para 3.171, not limiting to any particular guideline.** |
| **S5. Suggestion** | **EB should consider establishing, adopting or adapting guidelines for the performance tests and quality control tests that should be performed on the various modalities, including recommended frequencies, with consultation with the relevant professional bodies.** |

| **RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES** | |
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| Observation | According to Regulation 71, chapter 4, para 13.4, approval and functional tests may be performed by: 1) an expert in medical physics who represents the holder of a radiation practice license by complying with the conditions of the quality management system; 2) a person authorized by the manufacturer of the medical irradiation device; 3) an institution accredited in the relevant field of measurement. This is not in line with GSR Part 3. |
| Basis | GSR Part 3, para 3.171 states: *"Registrants and licensees shall ensure that programmes of quality assurance for medical exposure include, as appropriate to the medical radiation facility:*<br>*(a) Measurements of the physical parameters of medical radiological equipment made by, or under the supervision of, a medical physicist: (i) At the time of acceptance and commissioning of the equipment prior to its clinical use on patients; (ii) Periodically thereafter; (iii) After any major maintenance procedure that could affect protection and safety of patients; (iv) After any installation of new software or* |

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| | *modification of existing software that could affect protection and safety of patients.*<br>*(b) Implementation of corrective actions if measured values of the physical parameters mentioned in (a) above are outside established tolerance limits.*<br>*(c) Verification of the appropriate physical and clinical factors used in radiological procedures.*<br>*(d) Maintaining records of relevant procedures and results.*<br>*(e) Periodic checks of the calibration and conditions of operation of dosimetry equipment and monitoring equipment."* |
| **R7. Recommendation** | **The MoSA should ensure that the commissioning and performance tests of medical radiological equipment are made by or under the supervision of a medical physicist.** |

### *4.7. Pregnant patients*

Regulation 71 states that female patients of reproductive age have to be asked about the possibility and the status of pregnancy, when planning a medical radiological procedure. Special attention has to be paid to ensuring the optimization of medical exposure when performing an unavoidable procedure on a pregnant woman and when performing a nuclear medicine procedure on a woman who is breastfeeding. Licensees are required to prepare standard operating manuals for all medical radiological procedures performed in the health care institution. In preparing quality manuals, a licensee takes into account the radiation equipment, procedures and methodologies in use and specific characteristics of patients. However, it is not regulated to have signs in public places, waiting rooms for patients, cubicles and other appropriate places.

The Team observed during site visits that signs were available in the majority of clinical departments or X-ray rooms to highlight the importance of pregnancy checking to patients. The Team was informed on site visits that pregnancy inquiry was either lacking or substandard in some centres, for example: there was no process for pregnancy inquiry during interventional cardiology procedures or simply binary inquiry in CT, no process for elaborating inquiries during high dose examinations (e.g., CT abdomen) or applying rules to minimize inadvertent fetal exposure.

| **RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES** | |
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| Observation | There are no regulatory requirements for registrants and licensees to ensure that signs in appropriate languages are placed in public places, waiting rooms for patients, cubicles and other appropriate places. |
| Basis 1 | GSR Part 3, Requirement 39 states" *Registrants and licensees shall ensure that there are arrangements in place for appropriate radiation protection in cases where a female patient is or might be pregnant or is breast-feeding.*"<br><br>GSR Part 3, para 3.175 states: "*Registrants and licensees shall ensure that signs in appropriate languages are placed in public places, waiting rooms for patients, cubicles and other appropriate places, and that other means of communication are also used as appropriate, to* |

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| | *request female patients who are to undergo a radiological procedure to notify the radiological medical practitioner, medical radiation technologist or other personnel in the event that: (a) She is or might be pregnant; (b) She is breast-feeding and the scheduled radiological procedure includes the administration of a radiopharmaceutical.*" |
| **R8. Recommendation** | **The MoSA should ensure that signs in appropriate languages are placed in public places, waiting rooms for patients, cubicles and other appropriate places.** |

## *4.8. Dose constraints*

Requirements for dose constrains are in place. Regulation 71 §9 (5, 6) states that registrants and licensees have to establish and use dose constraints for carers and comforters and volunteers in biomedical research. If the constraint exceeds 5 mSv for carers and comforters or 10 mSv for volunteers in biomedical research, the dose constraint has to be approved by the HB. The Team was informed that situations when dose constraints are needed are rare, therefore licensees rarely establish them.

## *4.9. Release of patients after radionuclide therapy*

Regulation 71 §14 (3) states that the holder of a radiation practice license has to ensure the existence of operating instructions for the discharge of a patient who has undergone a nuclear medicine procedure from a hospital and for the provision of further radiation safety recommendations to a patient.

The Team was informed on site visits that in all three facilities performing radionuclide therapy with unsealed sources, there are criteria in place for releasing patients after radionuclide therapy, based on measured dose rates at 1 m of distance from the patient, which are performed by a medical physicist or by the facility's radiation protection officer. In all three facilities the patient or the legal guardian is provided with written instructions for keeping doses to person in contact with or in the vicinity of the patient as low as reasonably achievable and for avoiding the spreading of contamination. In all three facilities patients are provided with information on radiation risks.

Both radiotherapy departments also perform low dose rate brachytherapy with seed implants. The Team was informed that in both facilities patients are usually released the day following treatment and they all receive written instructions before release.

## 5. UNINTENDED OR ACCIDENTAL MEDICAL EXPOSURES

The Radiation Act stipulates the involvement of a medical physics expert in the analysis of unintended or accidental medical exposures, and the Regulation 71 §16 (1) stipulates obligation of the holder of radiation practice license to ensure that a risk analysis is performed for the purpose of preventing unplanned medical exposure in radiotherapy. The Regulation 71 §16 (2) stipulates that the holder of a radiation practice license has to ensure the documentation of cases of unplanned medical exposures, identification of the causes and implementation of corrective measures and notification of the persons concerned of the occurrence and reasons thereof in order to ensure analysis and improvement of the quality of unplanned or accidental medical exposures. Regulation 71, Annex 2 (5), states that all above mentioned aspects have to be part of Quality Assurance/ Quality Control system of the licensee.

GSR Part 3 gives detailed explanation on what has to be implemented in order to minimize number and impact of unintended or accidental medical exposures (criteria of accidents that should be promptly investigated (GSR Part 3, para 3.180) and investigation process (GSR Part 3, para 3.181). This is not regulated.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| Observation | Regulatory requirements for investigation, analysis and reporting of unintended and accidental medical exposure events are inadequate. |
| Basis 1 | GSR Part 3, para 3.180 states: "*Registrants and licensees shall promptly investigate any of the following unintended or accidental medical exposures*:<br>*(a) Any medical treatment delivered to the wrong individual or to the wrong tissue or organ of the patient, or using the wrong radiopharmaceutical, or with an activity, a dose or dose fractionation differing substantially from (over or under) the values prescribed by the radiological medical practitioner, or that could lead to unduly severe secondary effects;*<br>*(b) Any diagnostic radiological procedure or image guided interventional procedure in which the wrong individual or the wrong tissue or organ of the patient is subject to exposure;*<br>*(c) Any exposure for diagnostic purposes that is substantially greater than was intended;*<br>*(d) Any exposure arising from an image guided interventional procedure that is substantially greater than was intended;*<br>*(e) Any inadvertent exposure of the embryo or fetus in the course of performing a radiological procedure;*<br>*(f) Any failure of medical radiological equipment, failure of software or system failure, or accident, error, mishap or other unusual occurrence with the potential for subjecting the patient to a medical exposure that is substantially different from what was intended."* |
| Basis 2 | GSR Part 3, para 3.181 states: *"Registrants and licensees shall, with regard to any unintended or accidental medical exposures investigated as required in para. 3.180:* |

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| | *(a) Calculate or estimate the doses received and the dose distribution within the patient;*<br>*(b) Indicate the corrective actions required to prevent the recurrence of such an unintended or accidental medical exposure;*<br>*(c) Implement all the corrective actions that are under their own responsibility;*<br>*(d) Produce and keep, as soon as possible after the investigation or as otherwise required by the regulatory body, a written record that states the cause of the unintended or accidental medical exposure and includes the information specified in (a)–(c) above, as relevant, and any other information as required by the regulatory body; and for significant unintended or accidental medical exposures or as otherwise required by the regulatory body, submit this written record, as soon as possible, to the regulatory body, and to the relevant health authority if appropriate;*<br>*(e) Ensure that the appropriate radiological medical practitioner informs the referring medical practitioner and the patient or the patient's legal authorized representative of the unintended or accidental medical exposure."* |
| **R9. Recommendation** | **The MoSA should ensure that investigation, analysis and reporting of unintended and accidental medical exposures are fully in line with GSR Part 3.** |

The Team observed on site visits that systems for reporting of unintended and accidental medical exposures exist in both radiotherapy departments. Lower awareness was observed in diagnostic and interventional radiology facilities, where formal processes of recording, monitoring or disseminating findings were rarely in place. In two visited facilities the system was established as a part of hospital quality management system covering also nuclear medicine and diagnostic interventional radiology departments. The Team was informed that reporting criteria were not defined in any of the visited facilities, and no event has been reported to the regulatory bodies.

The Team observed that in some departments analyses of the reported events are performed and used for establishing safety barriers, in-house lessons learning and improvement of practices. No evidence of sharing of knowledge between hospitals was observed.

| **RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES** | |
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| Observation | There is no dissemination of lessons learned between hospitals from events reported in their local systems. |
| Basis | SSG-46 para 2.68 states: "*Professional bodies should encourage their members to perform proactive risk assessment, especially in radiotherapy. They can also play an active role by encouraging their members to contribute to relevant international or national anonymous and voluntary safety reporting and learning systems, and by contributing to developing of such systems. Such databases provide a wealth of information that can help to minimize unintended and* |

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| | *accidental medical exposures. Examples of international safety reporting systems are the IAEA safety reporting systems Safety in Radiation Oncology (SAFRON) and Safety in Radiological Procedures (SAFRAD), and the Radiation Oncology Safety Education and Information System (ROSEIS).*" |
| **S6. Suggestion** | **The relevant professional bodies should consider continuing to play an active role in building safety culture among health workers by encouraging their members to disseminate lessons learned between hospitals from reported event and to contribute to relevant international or national anonymous and voluntary safety reporting and learning systems such as SAFRON or SAFRAD.** |

## 6. RADIOLOGICAL REVIEWS

The requirement for conducting clinical audits is stipulated in the Radiation Act §43 and Regulation 71 §18 which states that both internal and external clinical audits are to be organized by the license holder.

The Team was informed that external IAEA Comprehensive Audits of Radiotherapy Practices (QUATRO) and Quality Management Audits in Nuclear Medicine Practices (QUANUM) audits have so far been performed in one facility. Internal audits/self-assessments of radiation protection and safety practices are being done in many facilities. The Team was informed of concerns related to the feasibility of organizing national audits in radiotherapy given that only two departments exist.

The Team was informed that there is no national framework for clinical audit in place. The Team was informed that resources allocated for this are not sufficient. On request from the EB, a national workshop with involvement of different stakeholders and international lecturers was organized in 2021 to increase awareness and understanding of clinical audits and discuss the steps to begin external clinical audits in Estonia.

The Team found that the IAEA Safety Standards do not provide sufficient basis for establishment of the national framework for clinical audit, including ensuring sufficient resources.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| Observation | There is no national framework for clinical audit specific to medical uses of ionizing radiation |
| Basis | SSG-46, para 2.148. The management system should include a review cycle. The general principles for audits and reviews are well established (see GS-G-3.1 [25] and GSR Part 2 [47]). For a medical radiation facility, a possible tool for this is the clinical audit. Clinical audits can be considered as a systematic and critical analysis of the quality of clinical care, including the procedures used for diagnosis and treatment, the associated use of resources and the effect of care on the outcome and quality of life for the patient. A clinical audit looks beyond a strict radiation protection and safety focus and seeks to assess the quality and efficacy of the medical practice offered in the facility, ultimately the patient health outcome. This should include the radiation protection and safety aspects of medical uses of ionizing radiation and, importantly, should keep these aspects in the context of medical practice, ensuring a common goal. Thus, while GSR Part 3 [3] does not require a clinical audit, its use can be seen as fulfilling both the radiation protection and safety and the medical aspects of the medical radiation facility's management system. More detailed guidance on clinical audits is given in Refs [48–50]. |
| **S7. Suggestion** | **The MoSA should consider establishing a national framework for clinical audit specific to medical uses of ionizing radiation, in cooperation with the relevant professional bodies and EB.** |

## 7. RECORDS

In Annex 2 of Regulation 71 stipulates the contents of the quality manual, including data that are to be maintained by the registrant or licensee. However, it is not required to maintain records related to radiation protection training of personnel and dosimetry of patients (typical patient doses). Regulation 71 §9 (1), §9 (4), §11 and §12 require that medical exposure doses of diagnostic and interventional radiology procedures, radiotherapy procedures and administrated activities in nuclear medicine shall be recorded. The Team was informed that radiological images and medical exposure data are recorded in the national PACS.

| **RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES** | |
|---|---|
| Observation | Maintaining records related to radiation protection training of personnel and dosimetry of patients is not required by the regulations. |
| Basis 1 | GSR 3, Requirement 42: Reviews and records states: "*Registrants and licensees shall ensure that radiological reviews are performed periodically at medical radiation facilities and that records are maintained*."<br>Para 3, para 183 states: "*Registrants and licensees shall maintain for a period as specified by the regulatory body and shall make available, as required, the following personnel records: …(b) Records of training of personnel in radiation protection (as required in para. 3.150(b)"* |
| Basis 2 | GSR 3, para 3.184 states: "*Registrants and licensees shall maintain for a period as specified by the regulatory body and shall make available, as required, the following records of calibration, dosimetry and quality assurance: …(b) Records of dosimetry of patients, as required in para. 3.168"* |
| **R10. Recommendation** | **The MoSA should ensure that registrants and licensees maintain records related to radiation protection training of personnel and dosimetry of patients.** |

# 8. REGULATORY FUNCTIONS FOR THE MEDICAL EXPOSURE

## *8.1. Authorization and review and assessment*

The Radiation Act provides that the license for low-risk radiation practices is issued for an unspecified term instead of a 5-year term as it is for moderate and high-risk radiation practices. The Radiation Act §34 stipulates risk levels based on occupational doses while for high-risk practices some additional criteria are stipulated. Risks from medical exposures are not considered in the graded approach. See R11 and R12 of this report.

The review and assessment of applications on nuclear medicine and radiotherapy in Estonia requires an in-depth understanding of the radiation safety aspects related to medical exposure, because many state-of-art techniques are already in use and new facilities and activities with new equipment and radiopharmaceuticals are planned to be taken into use in the near future. For example, the Team was informed on site visits that there will be new radiopharmacy and PET facilities. However, currently the EB staff members do not have adequate expertise in radiotherapy or nuclear medicine practices. See section 8.4 of this report.

The authorization and review & assessment processes were not reviewed, as they have been reviewed as a part of the IRRS mission in 2016 and followed up in the 2019 mission.

## *8.2. Inspection and enforcement*

A graded approach is applied for inspections with intervals based on potential occupational doses. Radiation Act §34 (2) stipulates that low risk means effective doses of less than 1 mSv a year for a worker. The risks from medical exposures are not taken into account. The Team was informed that the EB is currently working on implementation of graded approach for regulatory activities taking into account risks from all type of exposures, including medical.

The Team was informed during site visits on nuclear medicine and radiotherapy departments that inspectors of the EB do not have adequate practical experience with radiation therapy or nuclear medicine to perform their regulatory oversight. See R13 of this report.

The inspection and enforcement processes were not reviewed, as they have been reviewed as a part of the IRRS mission in 2016 and followed up in the 2019 mission.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| Observation | Periods for validity of authorization of facilities and activities related to medical exposures and inspection intervals of same are based on occupational exposures. Risks from medical exposures are not considered. |
| Basis 1 | GSR Part 1 Requirement 16, para 4.5 states that: "*The regulatory body has the responsibility for structuring its organization and managing its available resources so as to fulfil its statutory obligations effectively. The regulatory body shall allocate resources commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach....*" |

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|---|---|
| Basis 2 | GSR Part 1 Requirement 29 states that: "*Inspections of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach*." |
| **R11. Recommendation** | **The Government should ensure that radiation risks include risks from all exposures, including medical exposure.** |
| **R12. Recommendation** | **The EB should ensure that authorization and inspection of facilities and activities are commensurate with the radiation risks taking into account all exposures, including medical exposure.** |

### *8.3. Regulations and guides*

The main regulations are listed in the Appendix 3.

The Team was informed by the professional societies, licensees and the regulatory bodies that several requirements in the regulations were not considered appropriate. The need for revision and amendment of regulation and guides was identified in most of the recommendations and suggestions of this report.

### *8.4. Staffing and competence of the regulatory body*

The EB has a limited number of staff with qualification and competence related to radiation protection and safety in medical exposure (see also Section 8.1 and 8.2 of this report). This may jeopardize performing regulatory functions and discharging responsibilities. The Team was informed that they have challenges in recruiting additional staff.

It was not possible to assess staffing levels or competence of the HB, as no representative attended the mission activities directly with the Team. Regulation 71 stipulates several responsibilities for HB related to medical exposure. The Team was informed that HB does not have staff with competences related to these functions.

| **RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES** | |
|---|---|
| Observation | The HB has a limited number of staff with qualification and competence related to radiation protection and safety in medical exposure and EB has challenges in recruiting additional staff. |
| 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*." |
| **R13. Recommendation** | **The HB and EB should ensure a sufficient number of qualified and competent staff to perform its functions and to discharge its responsibilities related to medical exposures.** |

### *8.5. Communication and consultation with interested parties*

Estonia has published guidance for good practice of involvement of stakeholders in decision making processes. The Team was informed by the professional societies and management of some visited hospitals that they were not effectively consulted in the processes of developing regulations and only invited to provide comments during the final stage of draft regulations prior to publication. Adequate consultation might reduce unclear, unpractical, or misleading requirements.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| Observation | The professional societies and hospitals are not consulted effectively in the process of developing regulations and guides. |
| Basis 1 | GSR Part 1 Requirement 36 states that: "*The regulatory body shall promote the establishment of appropriate means of informing and consulting interested parties and the public about the possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body*." |
| Basis 2 | GSR Part 3 Requirement 3, para 2.36 states that: "*The regulatory body shall establish mechanisms for communication and discussion that involve professional and constructive interactions with relevant parties for all protection and safety related issues*." |
| **R14. Recommendation** | **MoE and MoSA should ensure establishing mechanisms for communication and discussion that involve professional and constructive interactions with professional bodies and medical radiation facilities in the process of developing regulations and guides.** |

## **APPENDIX 1.** MISSION PROGRAMME

**ENTRANCE MEETING, Tuesday, 22 March, 2022**

Ministry of Social Affairs, Suur-Amerika 1, Tallinn, Lõhmus room

| | | |
|---|---|---|
| 9:30 – 9:45 | Welcoming address | Heidi Alasepp (MoSA) |
| 9:30 – 10:15 | Opening of the Mission<br>Remarks by the Mission Team Leader and the IAEA | Ilmar Puskar (EB)<br>Ritva Bly (Finland)<br>Jenia Vassileva (IAEA) |
| | Introduction of the International Mission Team | Raija Seuri (Finland), Marco Brambilla (Italy), Dario Faj (Croatia), Shane Foley (Ireland), Julius Žiliukas (Lithuania), Dejan Žontar (Slovenia) |
| | Introduction of the local counterparts | Maria Leier (Senior Officer, Ambient Air and Radiation Department, Ministry of the Environment)<br>Maret Voore (Adviser, Medicine Department, MoSA)<br>Martin Reim (President, Estonian Society of Radiology)<br>Sergei Nazarenko (President, Estonian Nuclear Medicine Society<br>Maare-Liis Oinus (President, Estonian Society of Radiographers)<br>Jaanus Lass (Chairman of the Board, Estonian Society of Biomedical Engineering and Medical Physics)<br>Andrus Aavik (Member of Board, Foundation of Estonian PACS)<br>Malle Avarsoo (Estonian Health Insurance Fund); Jana Jaal (Estonian Society of Clinical Oncologists)<br>Eduard Gerškevitš, Kätlin Tiigi (Estonian Society of Oncology)<br>Jelena Šubina (EB)<br>Liina Henn (HB) |
| 10:15 – 11:15 | Advisory Mission within the framework of IAEA Safety Standards and other Review Missions. Mission objectives and process | Jenia Vassileva (IAEA) |
| | Mission's expectation from the Host | Ilmar Puskar (EB) |
| 11:15 – 11:45 | Group photo and break | |
| 11:45 – 12:30 | Current status of the regulatory framework for radiation | Ilmar Puskar (EB), Maret Voore (MoSA) |

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|---|---|---|
| | protection and safety in medical exposure in Estonia | |
| 12:30 – 13:30 | Current goals in the development of radiation protection and safety in medical exposure from the point of view of different stakeholders | Martin Reim (President, Estonian Society of Radiology),<br>Sergei Nazarenko (President, Estonian Nuclear Medicine Society),<br>Jaanus Lass (Chairman of the Board, Estonian Society of Biomedical Engineering and Medical Physics),<br>Malle Avarsoo (Estonian Health Insurance Fund);<br>Andrus Aavik (Member of Board, Foundation of Estonian PACS) |
| | Closing of the entrance meeting | |

| | | |
|---|---|---|
| 13:30 – 14:30 | Lunch Break | |
| 14:30 – 17:00 | Meetings of the Mission Team with the representatives of different stakeholders | Group 1: Maria Leier, Maret Voore, Ilmar Puskar and Jelena Šubina<br>Group 2: Martin Reim, Sergei Nazarenko, Maare-Liis Oinus, Jaanus Lass, Andrus Aavik, Gerškevitš, Kätlin Tiigi, Jana Jaal |
| 18:00 – 20:00 | Team meeting in the hotel board room | Team |

**Site Visits, Wednesday, 23 March 2022**

| | | |
|---|---|---|
| 6:30 – 7:15 | Hotel breakfast | |
| 7:15 – 9:45 | Transfer to Tartu University Hospital | All Team members accompanied by CP representatives |
| 9:45 – 10:00 | Welcome coffee | |

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|---|---|---|
| 10:00 – 10:30 | Meeting with hospital management. Introduction by IAEA, Objectives of the Mission | Team members: Raija Seuri, Marco Brambilla, Dario Faj, Shane Foley, Julius Žiliukas, Dejan Žontar, Jenia Vassileva.<br><br>CP: Andres Kotsar (Board Member, Tartu University Hospital),<br>Jõel Starkoph (Research and Development manager, Tartu University Hospital),<br>Ilona Pastarus (Head of Nursing and Patient Experience, Tartu University Hospital),<br>Pilvi Ilves (Head of the Department and radiologist, Radiology Clinic of Tartu University Hospital)<br>Martin Reim (President, Estonian Society of Radiology),<br>Kai Ulst (Head, Nuclear Medicine Department,<br>Radiology Clinic, Tartu University Hospital),<br>Dmitri Šutov (MPE, RPO, Nuclear Medicine Department, Radiology Clinic, Tartu University Hospital),<br>Markus Vardja (MPE, RPO, Clinic of Hematology and Oncology, Tartu University Hospital).<br>Ando Aasa (MPE, Clinic of Hematology and Oncology, Tartu University Hospital),<br>Kristiina Ojamaa (Head, Clinic of Hematology and Oncology, Tartu University Hospital)<br>Karin Grišan (acting Head, Radio- and Oncotherapy Department, Clinic of Hematology and Oncology, Tartu University Hospital) |
| 10:30 – 13:00 | Interviews and visits | RT: Dario Faj, Dejan Žontar<br>CP: Markus Vardja (MPE, RPO, Clinic of Haematology and Oncology, Tartu University Hospital);<br>Ando Aasa (MPE, Clinic of Haematology and Oncology, Tartu University Hospital);<br>Kristiina Ojamaa (Head, Clinic of Haematology and Oncology, Tartu University Hospital);<br>Jelena Šubina (EB)<br><br>NM: Marco Brambilla, Ritva Bly<br>CP: Kai Ulst (Head, Nuclear Medicine Department, Radiology Clinic, Tartu University Hospital), |

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| | | Dmitri Šutov (MPE, RPO, Nuclear Medicine Department, Radiology Clinic, Tartu University Hospital),<br><br>Radiology+Pediatric: Raija Sueri; Julius Žiliukas<br>CP: Maria Leier (EM)<br>Pilvi Ilves (Head of the Department and radiologist, Radiology Clinic of Tartu University Hospital),<br>Triin Noorhani (radiographer Radiology Clinic of Tartu University Hospital)<br>Tanel Torm (radiologist lecturer Radiology Clinic of Tartu University Hospital)<br>Vladimir Värv (radiologist lecturer Radiology Clinic of Tartu University Hospital)<br>Sulev Ulp (radiologist- lecturer in mammography, Radiology Clinic of Tartu University Hospital)<br>Gitana Kiudma (senior doctor lecturer, Radiology Clinic of Tartu University Hospital)<br>Jänelle Märs (radiographer, quality manager, Radiology Clinic of Tartu University Hospital)<br>Juhan Saaring (MPE, Radiology Clinic of Tartu University Hospital)<br>Ivo Pruul (MPE, Radiology Clinic of Tartu University Hospital).<br><br>IR: Shane Foley, Jenia Vassileva<br>CP: Martin Reim (radiologist, angiography department, Tartu University Hospital, President, Estonian Society of Radiology), Toomas Hermlin (cardiologist, angiography department, Tartu University Hospital). |
| 13:00 – 14:00 | Lunch break | |
| 14:00 – 16:00 | Roundtable with the education institutions: IAEA introduction, remarks from local stakeholders and discussion | Pilvi Ilves (Associate professor, Institute of Clinical Medicine, Faculty of Medicine, University of Tartu);<br>Mare Saag (Professor in Oral and Dental Diseases, University of Tartu, Institute of Dental Science);<br>Kristiina Ojamaa (Head, Clinic of Haematology and Oncology, Tartu University Hospital); |

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| | | Jana Jaal (senior researcher in oncology, Clinic of Hematology and Oncology, Tartu University Hospital)<br>Representatives from Tartu Health Care College: Kalle Kepler, Terje Markus, Janelle Märs, Markus Vardja |
| 16:00 – 17:00 | Team meeting | Team |
| 17:00 – 19:30 | Transfer to Tallinn | |

**Site visits, Thursday, 24 March 2022**

| | | |
|---|---|---|
| 6:30 – 7:30 | Hotel breakfast | |
| 7:30 – 9:30 | Hotel pick up and travel to Pärnu (Group 1) and to Jõhvi (Group 2) | Group 1 Pärnu: Shane Foley, Raija Seuri, Ilmar Puskar<br>Group 2 Jõhvi: Julius Žiliukas, Jelena Šubina |
| 9:30 – 9:45 | Welcome coffee | |
| 9:45 – 10:15 | Meeting with hospital management. Introduction by IAEA, Objectives of the Mission | Pärnu Hospital (Radiology Service and interventional radiology)<br>CP: Urmas Sule, Head of Board<br>Aadu Simisker, Head of Radiology Service,<br>Joosep Kepler, Head of Medical Technology Service<br><br>East Viru Central Hospital (Radiology Service and interventional radiology)<br>CP: Toomas Kariis, chief physician,<br>Ksenia Verhoskaja, head of nursing,<br>Tatjana Kozak, head of medical technology,<br>Natalia Vilde, Head of Nursing of the Radiology Service |
| 10:15 – 13:00 | Interviews and visits to radiology and IR | Pärnu Hospital (radiology and IR)<br>CP:<br>Aadu Simisker, Head of Radiology Service,<br>Joosep Kepler, Head of Medical Technology Service,<br>Eleri Uibo, quality manager, coordinator of radiographers<br>Mari-Liis Luide, Medical physicist<br>Evelin Simisker, CT-chief radiographer<br><br>East Viru Central Hospital (radiology and IR) |

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| | | CP: Tatjana Kozak, head of medical technology,<br>Natalia Vilde, Head of Nursing of the Radiology Service,<br>Sergei Iljin, Director of the Radiology Service.<br>Larisa Semjonova, radiographer,<br>Rudomjotova Inna, radiographer,<br>Tamm Maria, radiographer,<br>Margarita Mikk, cardiology nurse,<br>Tomas Hermlin, cardiologist |
| 13:00 – 14:00 | Lunch break | |
| 14:00 – 15:00 | Transfer to Tallinn | |

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|---|---|---|
| 7:30 – 8:00 | Hotel pick up and transfer to East Tallinn Central Hospital (Group 3) | Group 3: Dario Faj, Dejan Žontar, Marco Brambilla, Ritva Bly |
| 8:00 – 10:30 | Interviews and visits to radiology (Group 3A) and NM (Group 3B) | Group 3A: Radiology: Dario Faj, Dejan Žontar<br>Group 3B: NM: Marco Brambilla, Ritva Bly<br>CP: Maret Voore (MoSA)<br>Aleksandr Šamarin, head of diagnostic clinic<br>Dr Anne Poksi, head of centre of nuclear medicine<br>Kristi Rohtla, radiopharmacist<br>Jelena Veso-Petrov, head of nursing, centre of nuclear medicine<br>Dr Sulev Margus, head of catheterization laboratory<br>Priit Ruuge, radiation protection officer, medical physics expert<br>Dr Andres Reinart, cardiologist<br>Ande Pinnar, coordinator of radiographers<br>Dr Marti Lohu, radiologist<br>Taivi Aun, head of nursing, centre of radiology<br>Kristi Kaljulind, quality assurance specialist |
| 10:30 – 10:45 | Break | |
| 10:45 – 11:15 | Meeting with the hospital management. Introduction by IAEA, Objectives of the Mission | Group 3: Dario Faj, Dejan Žontar, Marco Brambilla, Ritva Bly<br>CP: Maret Voore (MoSA),<br>Tarmo Bakler – chairman of board<br>Dr Anne Poksi – head of centre of nuclear medicine |

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| | | Kristi Kaljulind – quality assurance specialist |
| 11:15 – 11:45 | Transfer to North Estonia Medical Centre | Group 3 |
| 11:45 – 12:45 | Lunch break | |
| 12:45 – 15:30 | Interviews and visits to RT (Group 3A) and NM (Group 3B) | Group 3A (RT): Dario Faj, Dejan Žontar<br>CP: Maret Voore (MoSA),<br>Eduard Gerškevitš – medical physicist, head of medical physics department in radiotherapy<br>Group 3B (NM): Marco Brambilla, Ritva Bly<br>CP: Kätlin Tiigi – medical physicist/ quality manager in radiotherapy, hospital radiation protection specialist,<br>Ilona Muoni – head of nuclear medicine department |
| 15:30 – 16:00 | Transfer to the hotel | |
| 18:00 – 20:00 | Team meeting (boardroom) | All Team |

**Friday, 25 March 2022**

| | | |
|---|---|---|
| 08:00 – 08:30 | Hotel pick up and transfer to Medicum | |
| 08:30 – 09:00 | Meeting with Medicum management. Introduction by IAEA, Objectives of the Mission | Team members: Julius Žiliukas, Dejan Žontar<br>CP: Tõnis Allik, Board member<br>Peeter Sillakivi, Head of Medical equipment,<br>Kätlin Aru, head of radiographer<br>Jelena Šubina (EB) |
| 09:00 – 11:00 | Interview and visit to radiology service | Team members: Julius Žiliukas, Dejan Žontar<br>CP: Peeter Sillakivi, Head of Medical equipment, Kätlin Aru, Head of radiographer,<br>Olga Lukaš, radiographer<br>Jelena Šubina (EB) |
| 11:00 – 11:30 | Transfer to EB | |
| 11:30 – 12:30 | Team works on the report | |

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| 07:45 – 08:15 | Hotel pick up and transfer to North Estonia Medical Centre | |
| 08:20 – 09:00 | Meeting with hospital management. Introduction by IAEA, Objectives of the Mission. | Team members: Raija Seuri, Shane Foley, Ritva Bly, Marco Brambilla, Dario Faj |

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| | | CP: Ilmar Puskar (EB), Maret Voore (MoSA), Terje Peetso – member of the management board,<br>Dr Peep Talving – member of the management board,<br>Kätlin Tiigi – medical physicist / quality manager in radiotherapy, hospital radiation protection specialist |
| 09:00 – 10:00 | Interview and visit to radiology | Team members: Raija Seuri, Shane Foley<br>CP: Maret Voore (MoSA),<br>Kätlin Tiigi – medical physicist / quality manager in radiotherapy, hospital radiation protection specialist,<br>Andrei Šamarin – head of radiology centre,<br>Eve Kliimann – chief nurse of diagnostic clinic,<br>Elvis Russki – chief technician of radiology centre |
| 10:00 – 10:30 | Walk to children hospital | Team members: Raija Seuri, Shane Foley<br>CP: Maret Voore (MoSA) |
| 10:30 – 12:00 | Meeting with the children hospital management. Introduction by IAEA, Objectives of the Mission. Interview and visit to radiology | Experts: Raija Seuri, Shane Foley<br>CP: Maret Voore (MoSA),<br>Aita Tilk – head of radiology department<br>Dr Katrin Luts – chairman of board |
| 12:00 – 12:30 | Transfer to EB | Team members: Raija Seuri, Shane Foley<br>CP: Maret Voore (MoSA) |

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|---|---|---|
| 09:00 – 09:30 | Transfer to Taltech | Team members: Ritva Bly, Marco Brambilla, Dario Faj<br>CP: Ilmar Puskar |
| 09:30 – 11:00 | Meeting with Taltech management. Introduction by Taltech | Team members: Ritva Bly, Marco Brambilla, Dario Faj<br>CP: Ilmar Puskar (EB)<br>Sergei Nazarenko, Adjunct Professor,<br>Department of Health Technologies, Tallinn University of Technology;<br>Eduard Gerškevitš, lecturer, Department of Health Technologies, TalTech;<br>Kalju Meigas, Professor Emeritus, Department of Health Technologies, TalTech; |

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| | | Jana Holmar, Director, Department of Health Technologies, TalTech;<br>Jelena Fomina, programme manager, Department of Health Technologies, TalTech;<br>Ivo Fridolin, Department of Health Technologies, TalTech;<br>Tiit Land, rector, TalTech;<br>Gert Jervan, full professor in tenure, Institute of Computer system, TalTech |
| 11:00 – 11:30 | Transfer to EB | |
| 11:30 – 12:30 | Team works on the report | |
| 12:30 – 13:30 | Lunch break | Team |
| 13:30 – 16:30 | Meeting in the EB | |
| 16:30 – 17:00 | Transfer to the hotel | |
| 18:00 – 21:00 | Team meeting in the board room | Team |

**26 March 2022, Saturday**

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|---|---|---|
| 10:00 – 20:00 | Team meeting in the board room: work on the report | Team |

**27 March 2022, Sunday**

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|---|---|---|
| 10:00 – 14:00 | Team meeting in the board room: work on the report and presentation to the CP | Team |
| 15:00 – 17:00 | Old town tour | |
| 18:00 | Social event | |

**28 March 2022, Monday**

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|---|---|---|
| 14:00 – 22:00 | Team meeting in the board room: work on the report | Team |

**29 March 2022, Tuesday**

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| 9:45 – 10:00 | Hotel pick up and transfer to the EB | Team |
| 10:00 – 12:45 | Meeting of the Team with key CPs to present project findings and develop Action Plan | |

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| 12:45 – 13:00 | Transfer to the hotel | |
| 15:00 – 19:00 | Team meeting in the board room: finalizing report | |

**EXIT MEETING, 30 March 2022, Wednesday**

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| 10:00 – 10:10 | Government official opening remarks | Meelis Münt, Secretary General, Ministry of Environment |
| 10:10 – 10:40 | Main findings of the Advisory Mission | Ritva Bly, Team Leader |
| 10:40 – 10:55 | Remarks by the Host in response to the Mission findings | Ilmar Puskar, Head of the Climate and Radiation Department, Environmental Board |
| 10:55 – 11:20 | Closing remarks | Miroslav Pinak, IAEA, Acting Director, Division of Radiation, Transport and Waste Safety<br>Eve-Külli Kala, IAEA, Director, Division for Europe, Department of Technical Cooperation |

## APPENDIX 2. LIST OF PARTICIPANTS

**ENTRANCE MEETING**

Team Leader: Ms. Ritva Bly (Finland)

Team Members: Ms. Raija Seuri (Finland), Mr. Marco Brambilla (Italy), Mr. Dario Faj (Croatia), Mr. Shane Foley (Ireland), Mr. Julius Žiliukas (Lithuania), Mr. Dejan Žontar (Slovenia)

IAEA Coordinator: Ms. Jenia Vassileva

Estonian Contact Point: Mr. Ilmar Puskar, Head of Climate and Radiation Safety Department, EB

Estonian Counterparts who participated on site:

Jelena Šubina, EB

Maria Leier, Senior Officer, Ambient Air and Radiation Department, MoE

Maret Voore, Adviser, Medicine Department, MoSA

Sergei Nazarenko, President, Estonian Nuclear Medicine Society

Andrus Aavik, Member of Board, Foundation of Estonian PACS

Estonian Counterparts participating virtually:

Martin Reim, President, Estonian Society of Radiology

Maare-Liis Oinus, President, Estonian Society of Radiographers

Jaanus Lass, Chairman of the Board, Estonian Society of Biomedical Engineering and Medical Physics

Malle Avarsoo, Estonian Health Insurance Fund

Jana Jaal, Estonian Society of Clinical Oncologists

Eduard Gerškevitš and Kätlin Tiigi, Estonian Society of Oncology

**METTINGS, DISCUSSIONS, SITE VISITS**

**Ministry of Social Affairs:** Ms. Maret Voore

**Ministry of the Environment:** Ms. Maria Leier

**Environmental Board:** Ms. Jelena Šubina, Ms. Merilin Šaitor, Ms. Marina Lacis

**University of Tartu:** Ms. Pilvi Ilves; Ms. Jana Jaal, Ms. Mare Saag, Ms. Anu Leht

**Estonian Society of Radiology:** Mr. Martin Reim

**Estonian Nuclear Medicine Society:** Mr. Sergei Nazarenko

**Tallinn University of Technology:** Mr. Sergei Nazarenko - Professor in Practice, Department of Health Technologies, Eduard Gerškevitš - lecturer, Kalju Meigas, Professor Emeritus, Jana Holmar – Director of Department of Health Technologies, Jelena Fomina - programme manager,

Ivo Fridolin Tiit Land – rector TalTech, Gert Jervan - full professor in tenure, Institute of Computer system.

**Health Insurance Fund:** Ms Malle Avarsoo

**Estonian Society of Radiographers:** Ms. Maare-Liis Oinus

**Estonian Society of Biomedical Engineering and Medical Physics:** Mr. Jaanus Lass

**Tartu Health Care College:** Mr. Kalle Kepler, Ms Terje Markus, Ms Jänelle Märs Mr Markus Vardja

**Foundation of Estonian PACS:** Mr. Andrus Aavik, Member of Board

**Tartu University Hospital:** Ms. Pilvi Ilves (Head of Radiology); Mr. Martin Rein (President of Estonian Society of Radiology, Interventional radiologist), Ms. Kai Ulst (Head, Nuclear Medicine Department, Radiology Clinic, Tartu University Hospital), Mr. Dmitri Šutov (MPE, RPO Nuclear Medicine Department, Radiology Clinic), Mr. Markus Vardja (MPE, RPO, radiotherapy), Mr. Ando Aasa (MPE, radiotherapy), Karin Grišan (radiotherapy), Ms. Liis Randle, Mr. Kulder Rahuelu

**North-Estonia Medical Centre:** Terje Peetso - member of the management board; Dr. Peep Talving - member of the management board; Eduard Gerškevitš – medical physicist / quality manager in radiotherapy, hospital radiation protection specialist; Kätlin Tiigi – medical physicist, head of medical physics department in radiotherapy; Ilona Muoni – Head of nuclear medicine department; Andrei Šamarin - head of radiology centre; Eve Kliimann – chief nurse of diagnostic clinic; Elvis Russki - chief technician of radiology centre.

**Childrens Hospital Tallinn**: Katrin Luts - chairman of board, Aita Tilk - head of radiology department

**Pärnu Hospital:** Mr. Urmas Sule (Board Member), Mr. Aadu Simisker (Chief of radiology), Mr. Joosep Kepler (Medical Physicist), Ms. Eleri Uibo (Radiation technologist, quality manager), Mr. Kaarel Puusepp (interventional cardiologist), Evelin Simiskeller (CT radiologist).

**East Tallinn Central Hospital:** Tarmo Bakler - Chairman of board; Aleksandr Šamarin - Head of diagnostic clinic; Dr. Anne Poksi - Head of centre of nuclear medicine; Kristi Rohtla - nuclear pharmacist; Jelena Veso-Petrov - head of nursing, centre of nuclear medicine; Dr. Sulev Margus – head of catheterization laboratoy; Priit Ruuge – radiation protection officer, medical physics expert; Dr. Andres Reinart – cardiologist; Ande Pinnar – coordinator of radiographers; Dr. Marti Lohu – radiologist; Taivi Aun - head of nursing, centre of radiology; Kristi Kaljulind - quality assurance specialist.

**East-Viru Central Hospital**: Ms. Tatjana Kozak, Mr. Sergei Iljin, Ms. Natalja Vilde

**Medicum**: Tõnis Allik, Board member, Peeter Sillakivi, Head of Medical equipment, Kätlin Aru, head radiographer.

## APPENDIX 3. REFERENCE MATERIAL USED FOR THE REVIEW

**IAEA REFERENCE MATERIAL**


1. EUROPEAN ATOMIC ENERGY COMMUNITY, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, INTERNATIONAL MARITIME ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Fundamental Safety Principles, IAEA Safety Standards Series No. SF-1, IAEA, Vienna (2006).
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11. INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Protection in Newer Medical Imaging Techniques: PET/CT, Safety Reports Series No. 58, IAEA, Vienna (2008).
12. INTERNATIONAL ATOMIC ENERGY AGENCY, Release of Patients after Radionuclide Therapy, Safety Reports Series No. 63, IAEA, Vienna (2009).
13. INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Protection in Paediatric Radiology, Safety Reports Series No. 71, IAEA, Vienna (2012).

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17. INTERNATIONAL ATOMIC ENERGY AGENCY, Quality Management Audits in Nuclear Medicine Practices, 2nd edn, IAEA Human Health Series No. 33, IAEA, Vienna (2015).
18. INTERNATIONAL ATOMIC ENERGY AGENCY, Comprehensive Audits of Radiotherapy Practices: A Tool for Quality Improvement, IAEA, Vienna (2007).
19. INTERNATIONAL ATOMIC ENERGY AGENCY, Strategic Approach to Education and Training in Radiation, Transport and Waste Safety 2011–2020 (Continuation of the Strategic Approach 2001–2010), Note by the Secretariat 2010/Note 44, IAEA, Vienna (2009).
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**HOST COUNTRY REFERENCE MATERIAL**

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2. Country Profile of Estonia from the IAEA system RASIMS 2.0
3. Radiation Act by the Estonian Parliament (issued 08.06.2016, last amended 10.07.2020)
4. Health Services Organisation Act by the Estonian Parliament (issued 09.05.2001, last amended 28.12.2017)
5. Health Insurance Act by the Estonian Parliament (issued 19.06.2002, last amended 10.01.2014)
6. Medical Devices Act by the Estonian Parliament (issued 13.10.2004, last amended 30.11.2010)
7. Regulation 71 “Medical exposure: radiation safety requirements, medical exposure procedures, clinical audit requirements and diagnostic reference values and requirements for their determination” by the Minister of Health and Labor (issued 19.12.2018).
8. Regulation 60 “Requirements for the application for a radiation practice license, lists of application and data of the radiation practice license and lists of data characterizing the

radiation sources used for keeping records of nuclear material" by the Minister of the Environment (issued 24.11.2016, last amended 31.01.2019).

9. Regulation 57 "Requirements for radiation safety training for exposed workers and radiation safety officers" by the Minister of the Environment (issued 24.11.2016)
10. Regulation 128 "Requirements for quality assurance of health care services" by the Minister of Social Affairs (issued 15.12.2004)
11. Guidelines on criteria for medical radiation equipment (by the Health Board)
12. Guidelines for the assessment of patient doses (by the Health Board)
13. A summary of the national infrastructure for regulatory control
14. Structure of the Ministry of the Environment and the Environmental Board
15. Structure of the Estonian Ministry of Social Affairs and the Estonian Health Board
16. Information about the health care providers, their location and available departments and equipment
17. List of the relevant governmental and professional organizations
18. Information about the educational institutions providing education and training of health professionals
19. Estonian Society of Radiology manual for 10 standard procedures

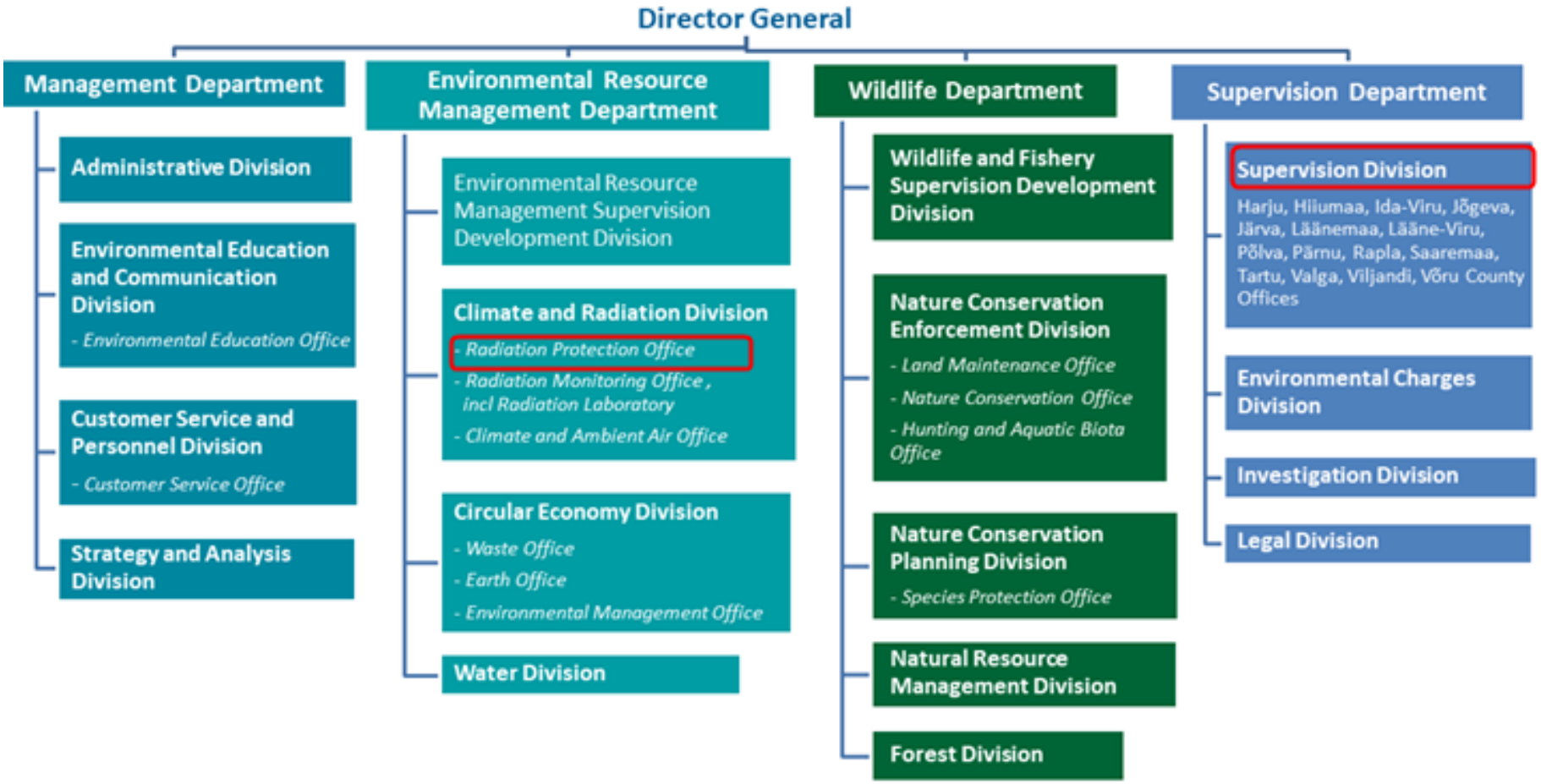
## APPENDIX 4. RECOMMENDATIONS, SUGGESTIONS, AND GOOD PRACTICES

| R: Recommendations S: Suggestions G: Good Practices | | |
|---|---|---|
| EDUCATION, TRAINING AND COMPETENCE | **R1** | The Government should establish a formal mechanism for recognition of medical physicists, medical radiation technologists and radiopharmacists as health professionals. |
| | **R2** | The Government should ensure specific training in radiation protection and safety related to medical exposures. |
| JUSTIFICATION | **GP1** | Health professionals can consult the information about patient medical history in the national PACS when referring patients to a radiological procedure, or when deciding what procedure to be performed. Also, patients have access to the relevant information in their electronic medical records. This contributes toward improved individual justification. |
| | **R3** | The MoSA should ensure that generic justification of a radiological procedure is carried out by the health authority in conjunction with appropriate professional bodies, and is reviewed from time to time, with account taken of advances in knowledge and technological developments. |
| | **R4** | The MoSA should ensure that the role of radiation medical technologist or another radiation worker is clarified regarding responsibilities for amending/ declining a procedure. |
| | **R5** | The MoSA should ensure that relevant referral guidelines are taken into account in the justification practices. |
| | **S1** | The MoSA should consider supporting the relevant professional bodies in developing/adopting and implementing evidence-based referral guidelines. |
| OPTIMIZATION | **R6** | The MoSA should ensure that requirements for establishing a comprehensive QA programme include all the attributes stated in the GSR Part 3, para 3.171, not limiting to any particular guideline. |
| | **R7** | The MoSA should ensure that the commissioning and performance tests of medical radiological equipment are made by or under the supervision of a medical physicist. |
| | **S2** | The MoSA should consider establishing an updated methodology for determination of typical doses to be in line with SSG-46. |
| | **S3** | The MoSA should consider establishing diagnostic reference levels for the most frequent procedures, for high-dose procedures and for paediatric patients. |

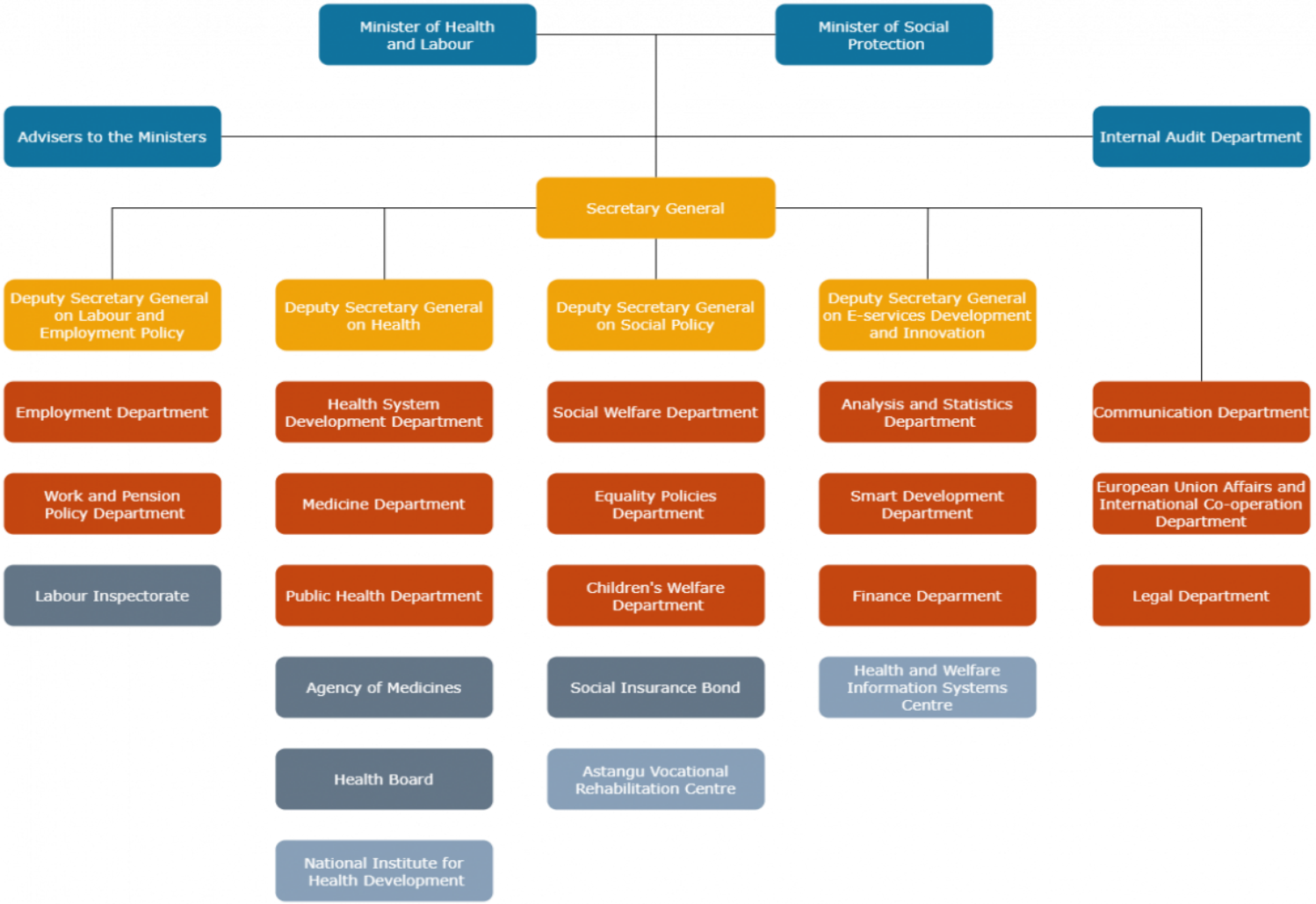
| | | |
|---|---|---|
| | **S4** | The MoSA should consider ensuring that the methodology for establishing diagnostic reference levels is adequately developed and implemented in line with SSG-46. |
| | **S5** | EB should consider establishing, adopting or adapting guidelines for the performance tests and quality control tests that should be performed on the various modalities, including recommended frequencies, with consultation with the relevant professional bodies. |
| PREGNANT PATIENTS | **R8** | The MoSA should ensure that signs in appropriate languages are placed in public places, waiting rooms for patients, cubicles and other appropriate places. |
| UNINTENDED OR ACCIDENTAL MEDICAL EXPOSURES | **R9** | The MoSA should ensure that investigation, analysis and reporting of unintended and accidental medical exposures are fully in line with GSR Part 3. |
| | **S6** | The relevant professional bodies should consider continuing to play an active role in building safety culture among health workers by encouraging their members to disseminate lessons learned between hospitals from reported event and to contribute to relevant international or national anonymous and voluntary safety reporting and learning systems such as SAFRON or SAFRAD. |
| RADIOLOGICAL REVIEWS | **S7** | The MoSA should consider establishing a national framework for clinical audit specific to medical uses of ionizing radiation, in cooperation with the relevant professional bodies and EB. |
| RECORDS | **R10** | The MoSA should ensure that registrants and licensees maintain records related to radiation protection training of personnel and dosimetry of patients. |
| REGULATORY FUNCTIONS FOR THE MEDICAL EXPOSURE | **R11** | The Government should ensure that radiation risks include risks from all exposures, including medical exposure. |
| | **R12** | The EB should ensure that authorization and inspection of facilities and activities are commensurate with the radiation risks taking into account all exposures, including medical exposure. |
| | **R13** | The HB and EB should ensure a sufficient number of qualified and competent staff to perform its functions and to discharge its responsibilities related to medical exposures. |
| | **R14** | MoE and MoSA should ensure establishing mechanisms for communication and discussion that involve professional and constructive interactions with professional bodies and medical radiation facilities in the process of developing regulations and guides. |

## **APPENDIX 5.** ORGANIZATIONAL CHARTS

**ENVIRONMENTAL BOARD (EB) STRUCTURE**



## MINISTRY OF SOCIAL AFFAIRS (MoSA) STRUCTURE



## HEALTH BOARD (HB) STRUCTURE