

PROVISION FOR THE APPLICATION OF IAEA
SAFETY STANDARDS AND SECURITY GUIDANCE



**INFRASTRUCTURE APPRAISAL FOR
ESTONIA OF RADIATION SAFETY AND
THE SECURITY OF RADIOACTIVE SOURCES**

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INTERNATIONAL ATOMIC ENERGY AGENCY

IAEA

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ADDITIONAL SECURITY RELATED REFERENCES

The IAEA has developed a comprehensive *Nuclear Security Action Plan*, which was approved by the Board of Governors in March 2002 (GOV/2002/10). This plan includes activities for the prevention, detection and response to acts of terrorism involving nuclear or other radioactive material in use, storage or transport, whether for nuclear or non-nuclear purposes. It recognizes the need for a comprehensive approach, leaving no gaps or vulnerabilities that can be exploited by terrorists or criminals.

Nuclear security is first and foremost the responsibility of the State. The Agency has taken a multi-track approach by promoting awareness building for nuclear security, by providing security guidelines and by providing direct assistance to the States.

In addition, the IAEA revised the *Code of Conduct on the Safety and Security of Radioactive Sources* to strengthen its security provisions. The text of the revised code was approved by the IAEA Board of Governors in September 2003, and in resolution GC(47)/RES/7, the IAEA General Conference endorsed the objectives and principles set out in the code, while recognizing that the code is not a legally binding instrument.

To support the implementation of the code, the IAEA also provided interim guidance on the security of radioactive sources in TECDOC-1355, and integrated radioactive sources in the scope of the draft guidance of the definition of a design basis threat. Ultimately, these documents will be published as part of a dedicated suite of nuclear security documents.

INFRASTRUCTURE APPRAISAL FOR
ESTONIA
OF RADIATION SAFETY AND THE SECURITY OF
RADIOACTIVE SOURCES

EDITORIAL NOTE

Although great care has been taken to maintain the accuracy of information contained in this publication, neither the IAEA nor its Member States assume any responsibility for consequences, which may arise from its use. The use of particular designations of countries or territories does not imply any judgement by the publisher, the IAEA, as to the legal status of such countries or territories, of their authorities and institutions or of the delimitation of their boundaries. The mention of names of specific companies or products (whether or not indicated as registered) does not imply any intention to infringe proprietary rights, nor should it be construed as an endorsement or recommendation on the part of the IAEA.

FOREWORD

Many States have engaged in an extensive programme to enact laws¹ and establish a regulatory infrastructure to implement the requirements of the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radioactive Sources (the BSS), published as Safety Series No. 115 in 1996 and the requirements of the IAEA Safety Standard GS-R-1 on Legal & Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety. In support of this programme, the IAEA introduced a technical cooperation programme (Model Project on Upgrading Radiation Protection Infrastructure) to improve the infrastructure for radiation protection and safety of radioactive sources, initially in more than 50 States. A first priority was assistance for strengthening their regulatory programmes for radiation safety. Subsequently, on 25 September 1998, the IAEA's General Conference adopted resolution (GC(42)/RES/12), which encouraged all governments to; *“take steps to ensure the existence within their territories of effective national systems of control for ensuring the safety of radioactive sources and the security of radioactive materials”*. More than 90 States have received technical cooperation assistance through the model projects, regional agreements and national projects.

Appraisal of the effectiveness of a regulatory programme for radiation safety is an important part of quality assurance, both with regard to implementation of the BSS and meeting the objectives of the General Conference resolution of 25 September 1998. Consequently, a document (IAEA-TECDOC-1217) was developed to provide a methodology by which the status of the infrastructure for a regulatory programme for radiation safety could be assessed. Appraisal also identifies areas where improvements are necessary or useful. Initially, appraisals were provided through IAEA ‘Radiation Safety Regulatory Infrastructure’ (RSRI) missions. By the end of 2002 some 56 appraisals (peer reviews) based on TECDOC-1217 methodology had been completed and experience gained has been invaluable in developing this present document.

More recently, the IAEA adopted an integrated safety appraisal system (ISAS). The underlying concept of ISAS is that all technical, legal and governmental bodies involved in radiation, waste and transport safety need to be evaluated against the relevant IAEA standards. ISAS consists of specific appraisals covering the radiation safety regulatory infrastructure, occupational radiation exposure control, medical radiation exposure control; control of public radiation exposure; radioactive waste safety; radiation emergency preparedness; safe transport of radioactive material; education and training.

Following the events of 11 September 2001, the IAEA revised the *Code of Conduct on the Safety and Security of Radioactive Sources* to strengthen its security provisions. The text of the revised code was approved by the IAEA Board of Governors in September 2003, and in resolution GC(47)/RES/7 the IAEA General Conference welcomed the Board's approval and endorsed the objectives and principles set out in the code, while recognizing that the code is not a legally binding instrument. The General Conference urged each State to; *“write to the Director General that it fully supports and endorses the Agency's efforts to enhance the safety and security of radioactive sources, is working toward following the guidance contained in the Code and encourages other countries to do the same”*. Many countries have done this. The IAEA also developed additional, more detailed guidance on the import and

¹ There is some variation in the terminology used by States. However, in the context of this document “law” is taken to mean the primary *legislation* (Act, Statute, Decree, etc) which establishes both the regulatory body and the principles by which workers, the public and the environment are to be protected against the hazards of ionizing radiation, as well as the *regulations*. For the purposes of the RaSSIA, legislation and regulations are appraised separately.

export controls on radioactive sources in support of the *Code of Conduct* and provided more interim guidance on the security of radioactive sources in TECDOC-1355.

The IAEA has established a methodology for assessment of the regulatory infrastructure and is providing its support to States, at their request, through the *Radiation Safety and Security Infrastructure Appraisal* (RaSSIA).

As adopted by the Board of Governors and the general Conference in GOV/2004/52-GC(48)/15 on *Promoting Effective and Sustainable National Regulatory Infrastructure for the Control of Radiation Sources*, the IAEA will substantially strengthen and accelerate its activities for promoting regulatory infrastructure in Member States and non-Member States in particular through the provision of RaSSIA, the *Regulatory Authority Information System* (RAIS) and the training packages for regulators on authorization and inspection of radiation sources in medical and industrial practices, and the establishment of a network *Radiation Safety Regulators Network*.

As a result of these actions, the infrastructure appraisal process was further revised to include consideration of the provisions of the *Code of Conduct* and the guidance on the security of radioactive sources, so that a comprehensive review of the regulatory infrastructure now includes the legal regime and the procedures implemented to ensure the safety and security of radioactive sources.

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REPORT OF THE IAEA INFRASTRUCTURE APPRAISAL OF RADIATION SAFETY AND THE SECURITY OF RADIOACTIVE SOURCES IN ESTONIA

SUMMARY, CONCLUSIONS AND MAIN RECOMMENDATIONS

SUMMARY

Background

S01 In response to the request of the Government of Estonia, the IAEA organized and conducted an appraisal of Estonia's regulatory infrastructure for radiation safety and security of radioactive sources from 25-29 July 2005. The appraisal team's principle contact with the counterpart was through representatives of the Estonian Radiation Protection Centre (ERPC).

Mission objectives

S02 RaSSIA is designed to provide the IAEA and the State in question with a means for evaluating progress in establishing and implementing a national regulatory infrastructure for radiation safety and security of radioactive sources. RaSSIA fulfils the requirements of the IAEA's Integrated Safety Appraisal Service (ISAS) and also the recommendations for infrastructure related to the security of radioactive sources and, therefore, encompasses many separate areas of IAEA expertise. The primary objectives of RaSSIA are to:

- determine the detailed status of development of each element of the regulatory regime; and,
- provide advice and recommendations with regard to any identified needs for improvement.

S03 The objective of any RaSSIA mission is to assist the requesting State in assessing and, if needed, improving its regulatory infrastructure for radiation safety and the security of radioactive sources by:

- conducting an appraisal of the current status of the national regulatory infrastructure for radiation safety and security of radioactive sources with regard to international standards, the *Code of Conduct for the Safety and Security of Radioactive Sources* and other IAEA publications (in particular those listed in section 2 below).
- recommending actions and improvements in areas where shortcomings and deficiencies (against relevant international standards and the *Code of Conduct*) have been identified.
- providing an action plan for improving the national regulatory infrastructure in accordance with standards and the *Code of Conduct*.

Scope of appraisal:

S04 A RaSSIA appraisal covers wide-ranging aspects of the requesting State's infrastructure for radiation safety and security of radioactive sources. However, the appraisal

may be modified according to the circumstances of the requesting State. The scope of the appraisal for Estonia was:

- to report on progress made further to previous IAEA missions to Estonia;
- to appraise Estonia's national regulatory infrastructure for radiation safety and security of radioactive sources, with particular reference to the:
 - legislative and statutory framework, i.e.:
 - legislation;
 - regulations and guidance;
 - regulatory body establishment and independence;
 - regulatory body staffing and training;
 - regulatory body funding;
 - coordination and cooperation at the national level;
 - international cooperation.
 - activities of the regulatory body:
 - notification and national register of radiation sources;
 - authorization;
 - safety and security of radioactive sources;
 - inspection;
 - enforcement;
 - information management;
 - quality management.
- to prepare an appraisal report incorporating findings, conclusions and recommendations for strengthening the national regulatory infrastructure for radiation safety and security of radioactive sources in accordance with international standards and the *Code of Conduct*.
- to prepare an action plan based on the above.
- to develop, or update as appropriate, an IAEA *Radiation and Waste Safety Infrastructure Profile* (RaWaSIP).

Tasks and activities prior to appraisal

S05 To assist the counterpart in the preparation for the mission, the IAEA provided a pre-appraisal questionnaire covering the different elements of a national regulatory infrastructure. This was returned to the IAEA by the OAP prior to commencement of the mission.

S06 In response to a detailed request from the IAEA, the OAP forwarded pertinent documents to the IAEA in advance of the mission. (Appendix 2 of this report).

S07 A detailed day-by-day work schedule was developed by the IAEA and agreed to by the counterpart prior to commencement of the mission (Appendix 4 of this report).

Appraisal team

S08 The RaSSIA appraisal team consisted of A Wrixon (team leader), D Dabrova, S Ebdon-Jackson and E. Kettunen.

Conduct of appraisal

S09 The appraisal process included:

- a preparatory meeting of the appraisal team;
- an entrance meeting with officials of the Ministry of the Environment (MOE) and ERPC where the objectives of the mission were explained;
- subsequent discussions to obtain clarification/further information;
- interviews with users of radiation sources;
- visits to facilities using radiation sources;
- prior to departing from Estonia, preparation of draft findings, recommendations and action plan based on information gathered against RaSSIA appraisal criteria;
- an exit meeting with officials of the MOE and ERPC where the preliminary findings of the RaSSIA team were presented.

Appraisal report

S10 This report documents the RaSSIA appraisal conducted in Estonia from 25-29 July 2005. It includes, in section 3, the appraisal findings against each element of the agreed scope, together with an overview and the basis for any findings. Appendix 1 of this report presents an action plan for Estonia arising from the RaSSIA appraisal.

FINDINGS OF THE RaSSIA APPRAISAL FOR ESTONIA

S11 A detailed account of the RaSSIA team's findings appears in section 3 of this document. However, the detailed conclusions and recommendations are also found in section 3. A summary of the main conclusions and recommendations are given below:

SUMMARY OF CONCLUSIONS & RECOMMENDATIONS

S12 Estonia introduced a Radiation Act in 2004. Its legislation and regulations are largely consistent with the BSS (SS115). However, they are not fully consistent with GS-R-1 and the Code of Conduct. Estonia has established the Ministry of the Environment as its regulatory body. The RaSSIA appraisal team has concluded that this is effectively independent of promotional activities. The operational functions are undertaken by the Estonian Radiation Protection Centre (ERPC) and the Environmental Inspectorate. The team was assured that there was a comprehensive register of sources, which is well maintained. Much of the recent work of ERPC has focused on reissuing licences and good quality processes have been developed. This is a direct consequence of the dedication and quality of the ERPC's staff. A further example is demonstrated by the weight that they have assigned to their relationships and collaboration with institutions in neighbouring countries, particularly the Nordic countries.

S13 The Environmental Inspectorate's inspection and enforcement activities did not seem to be of the same standard. Developments of all regulatory processes are not currently consistent with a risk-based approach.

S14 In the future, the regulatory body needs to increase its activities with regard to the assessment of practices to supplement its administrative approach to ensure good radiation safety and security. It is essential that ERPC maintain a clear separation between its regulatory and advisory functions. The imminent amendment of the Radiation Act and the introduction of new regulations for medical exposures provide an opportunity for regularizing

the Estonian legal framework, ensuring that there are no inconsistencies, omissions, or overlap. ERPC should develop sector specific guidelines to improve compliance with the legislation and regulations and hence for radiation protection in some sectors.

S15 There is a need for ERPC and the Environmental Inspectorate to formally agree an enhanced level of supporting expertise that will be required for a fully developed licensing and inspection programme.

1. INTRODUCTION

Background

1.1 The International Atomic Energy Agency (IAEA) is responsible for the development of international standards for the safety and protection of health, environment and property against ionizing radiation and for assisting their application in States through appropriate mechanisms such as appraisal and training. This has led to the publication of the *International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radioactive Sources (BSS)* and the IAEA Safety Requirements Standard *Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety*. The IAEA applies these standards to its own operations and wherever it is assisting Member States. In addition, at the request of third parties, the IAEA applies these standards to operations under bilateral or multilateral arrangements or, at the request of a State, to any of that State's activities concerning nuclear energy.

To support Member States in ensuring adequate security for radioactive sources, the IAEA has updated the *Code of Conduct for the Safety and Security of Radioactive Sources* and is developing a set of recommendations and guidance for the integration of security requirements within the national regulatory framework.

1.2 The IAEA carries out appraisals and advisory services worldwide to verify whether standards and recommendations are adequately applied at national level and evaluations of the effectiveness and the sustainability of State regulatory infrastructures. In this context, an integrated appraisal system covering all aspects of radiation, transport and waste safety and security of radioactive sources has been developed.

This system, called *Radiation Safety, and Security of Radioactive Sources, Infrastructure Appraisal (RaSSIA)* builds on experience gained through more than 70 appraisals carried out to date. It applies, among others, the provisions of the *Code of Conduct on the Safety and Security of Radioactive Sources* and guidance found in TECDOC 1344 *Categorization of Radioactive Sources* and TECDOC 1355 *Security of Radioactive Sources*.

1.3 IAEA standards and guidances are based on the presumption that a national infrastructure is in place to enable a government to discharge its responsibilities for radiation protection, safety and the security of radioactive sources. The essential components of a national infrastructure for radiation safety and security of radioactive sources are:

- legislation and regulations;
- a regulatory body empowered to authorize and inspect regulated activities and to enforce the laws and regulations;
- sufficient resources and
- adequate numbers of trained personnel.

1.4 A national infrastructure for radiation safety and security of radioactive sources includes all persons, organizations, qualified experts, systems, documents, facilities and equipment, and technical services that are, in whole or in part, dedicated to radiation safety and security of radioactive sources.

2 DOCUMENTS RELEVANT TO THE RASSIA APPRAISAL

2.1 Collectively, the documents listed below set out the requirements, guidance and technical information to facilitate implementation of a regulatory infrastructure that meets international standards for radiation safety and security of radioactive sources.

SAFETY STANDARDS AND SECURITY GUIDANCE

(SS1) *International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources Safety Series No. 115 1996 (BSS)*

The purpose of the BSS is to establish basic requirements for protection against the risks associated with exposure to ionizing radiation and for the safety of radiation sources.

The BSS has been developed from widely accepted radiation protection and safety principles, such as those published by ICRP and the IAEA Safety Series. They are intended to ensure the safety of all types of radiation sources

States would be expected to use the BSS to:

- establish a national radiation safety infrastructure in accordance with international standards (legislation and regulations);
- establish an independent regulatory body empowered to authorize and inspect regulated activities and to enforce legislation and regulations;
- establish national standards for protection against ionizing radiation.

(SS2) *Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety (GS-R-1)*

GS-R-1 establishes the requirements for legal and governmental responsibilities in respect of the safety of nuclear facilities, the safe use of ionizing radiation, radiation protection, the safe management of radioactive waste and the safe transport of radioactive material. It supersedes both the *Code on the Safety of Nuclear Power Plants: Governmental Organization* (Safety Series No. 50-C-G (Rev. 1) (1988) and the safety standard on *Establishing a National System for Radioactive Waste Management* (Safety Series No. 111-S-1 (1995)).

States would be expected to use GS-R-1 to:

- prepare legislation for effective control of nuclear, radiation, radioactive waste and transport safety;
- define the Government's responsibilities and, in particular, the functions and activities of the regulatory body;
- structure the regulatory body so as to ensure that it is capable of discharging its responsibilities independently and fulfilling its functions efficiently and effectively;
- enable and adequately resource services for training and education, dosimetry, calibration and radioanalysis, special emergency equipment, appropriate medical resources, national and international cooperation;
- establish effective supporting infrastructures for emergency preparedness, radioactive waste management and intervention during incidents and accidents.

(SS3) *Regulatory Control of Radiation Sources Safety Guide (GS-G-1.5)*

GS-G-1.5 covers the elements of a national regulatory infrastructure necessary to achieve an appropriate level of protection and safety for radiation sources used in medicine, industry, agriculture, research and education. It also provides guidance on the organization and implementation of a system for the regulatory control of radiation sources.

States would be expected to use GS-G-1.5 to:

- implement the requirements established by the IAEA Safety Standard document *Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety (GS-R-1)*;
- establish national infrastructures, which will deliver an appropriate level of radiation protection and safety in terms of both practices and sources and regulating intervention.

(SS4) *Code of Conduct on the Safety and Security of Radioactive Sources (CoC 2004)*

The *Code of Conduct* serves as guidance to States for the development and harmonization of policies, laws and regulations on the safety and security of radioactive sources.

States would be working towards following the guidance contained in the *Code of Conduct* to:

- prepare legislation and regulations that prescribe responsibilities to ensure safety and security of radioactive sources and their effective control;
- specify the requirements for radiation protection and the safety and security of radioactive sources;
- establish a regulatory body to fulfil its responsibilities in terms of radiation safety and security;
- devise effective measures for the management of the import and export of radioactive sources.

0 BOARD OF GOVERNORS, GENERAL CONFERENCE AND OTHER RELEVANT INTERNATIONAL ADVISORY GROUP'S RECOMMENDATIONS

(RR1) *Board of Governors and the General Conference in GOV/2004/52-GC(48)/15 on Promoting Effective and Sustainable National Regulatory Infrastructure for the Control of Radiation Sources*

This document describes the IAEA's policy for promoting effective and sustainable regulatory infrastructures for the control of radiation sources. It also outlines actions for implementation of the policy. In particular, it recommends that the IAEA substantially strengthen and accelerate its activities for promoting regulatory infrastructure in Member States and non-Member States.

States would be expected to use GC(48)/15 to become familiar with the IAEA policy and to guide the implementation of national infrastructures for the control of radiation sources.

(RR2) *International Nuclear Safety Advisory Group (INSAG-17): Independence in Regulatory Decision Making*

This report provides advice on the measures that ensure the quality of regulatory decision-making, including the quality of the scientific and technical information used in making decisions, together with the independence and competence of the decision-makers.

States would be expected to use INSAG-17 to devise measures that ensure the quality of independent and competent regulatory decision-making.

The above standards, guidance and recommendations are supplemented by other IAEA publications (e.g. safety reports, IAEA-TECDOCs). A summary of the most relevant publications is attached in Annex 8.

3 APPRAISAL OF THE ESTONIAN INFRASTRUCTURE FOR RADIATION SAFETY AND SECURITY OF RADIOACTIVE SOURCES

3.1 This section presents, in full, the RaSSIA team's findings, conclusions and recommendations made in accordance with the scope of the appraisal as stated below:

- Legislative and statutory framework:
 - Legislation;
 - Regulations and guidance;
 - Regulatory body establishment and independence;
 - Regulatory body staffing and training;
 - Regulatory body funding;
 - Coordination and cooperation at the national level;
 - International cooperation.
- Activities of the regulatory body:
 - Notification and national register of radiation sources;
 - Authorization;
 - Security of radioactive sources;
 - Inspection;
 - Enforcement;
 - Information management;
 - Quality management.

LEGISLATIVE AND STATUTORY FRAMEWORK

Legislation

Appraisal criteria and objectives

Adequate legislation is the key to being able to establish a national infrastructure for radiation safety and security of radioactive sources. It provides the legal provisions for the formation and effective operation of a regulatory body and the various means to achieve radiation safety and security of radioactive sources.

<i>Appraisal criterion</i>	Legislation (act, law, decree, others) is in place and is compatible with the BSS, GS-R-1 and the Code of Conduct. *
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<i>Objective of appraisal</i>	To evaluate relevant information in order to determine the extent to which the State has achieved the above criterion. In particular, to evaluate the existing national legislation governing radiation safety and security of radioactive sources and especially the essential elements and concepts such as the allocation of responsibilities, and the establishment of an effectively independent and resourced regulatory body.
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Appraisal findings

3.2 The legislative and statutory framework for radiation safety is provided primarily through the:

* The relevant sections/paragraphs of the IAEA documents providing the bases for the appraisal criteria are quoted in Appendix 1: RaSSIA action plan for Estonia.

- Government of the Republic Act (RT I 1995, 94, 1628; as amended);
- Statute of the Ministry of the Environment (RT I 2000, 2, 7; as amended);
- Environmental Supervision Act (RT I 2001, 56, 337; as amended);
- Statute of the Environmental Inspectorate (RTL 2004, 3, 30);
- Radiation Act (RT I 2004, RT I 2004, 26,173)
- Statute of the (Estonian) Radiation Protection Centre (RTL 2004, 97, 1528)

Other legislative documents of relevance include:

- Occupational Health and Safety Act (June 1999)
- Environmental Impact Assessment and Environmental Auditing Act (June 2000)
- Environmental Monitoring Act (January 1999)
- Emergency Preparedness Act (November 2000)
- The first two (7 & 8) specifically mention radiation or radioactive substances; the last two (9 & 10) are very general in nature.
- Relevant regulations of the Government include:
- Limits for the Total Amounts of Radioactive Substances and Limits for the Specific Activity therefore Exempted from the Requirements of Licensing for Activity Involving Radiation
- Effective Dose and Equivalent Dose Limits for the Lens of the Eye. Skin, and Extremities
- Procedure Specifications for Processing Documents of Import, Export and Transit of Radioactive Waste Based on Country of Origin and Destination
- Statutes for Maintenance of the State Dose Register of Exposed Workers

3.3 Relevant regulations of the Minister of the Environment include:

- Procedures for Issuing Licences for Activities Involving Radiation
- Requirements for Exposed Workers Radiation Safety Training
- Intervention and Action Levels and Emergency Exposure Guidance in a Radiological Emergency
- Requirements on the Radiological Monitoring Data on the Outside Worker and on Recording of these Outside Workers Dose Card Form
- Requirements for the Rooms where the Radiation Sources are Situated and for Labelling thereof and for the Working Rules for the Radiological Work Performance
- The Form of Qualified Expert Licence and its Request Form and Order of Issuing, Renewing, Suspension and Invalidation of the Licence

- The Classification of Radioactive Waste, the Requirements for Registration, Management and Delivery of Radioactive Waste and the Acceptance Criteria for Radioactive Waste
- The Clearance Levels for Radioactive Substances and Materials Contaminated with Radioactive Substances Resulting from Radiation Practices and the Requirements for their Clearance, Recycling and Reuse

Other Acts of relevance include:

- Administrative Procedure Act
- Public Information Act
- Penalty Code

3.4 The team only had access to English translations of 1, 3, 5, 7, 8, 9, and 10. A presentation covering the essential aspects of 15 was however given since these regulations were considered to be the most relevant to review team. A full review of the legislative arrangements in Estonia was therefore not possible. Nevertheless, the following points can be made.

3.5 The Act was a revision of the 1997 Radiation Act, the amendments being necessary in order to bring the requirements into line with the relevant Euratom Directives. An amendment to this Act is being developed to incorporate the additional requirements of the High Activity Sealed Sources (HASS) Directive.

3.6 It should be noted that the above Statutes and Acts do not address radioactive source security independently of radiation safety.

3.7 Paragraph 61 of the Government of the Republic Act specifies the ‘area of government’ of the Ministry of the Environment, which includes radiation protection and environmental supervision. It goes on to say that the following executive agencies and inspectorates shall be within the area of government of the Ministry of the Environment:

- Land Board;
- Environmental Inspectorate.

3.8 There appears to be no specific mention of ERPC but this would not be expected because of its status.

3.9 The Radiation Act is the main law governing radiation safety in Estonia. Article 4 specifies that the performance of activities related to radiation protection shall be organized by the Ministry of Environment within the limits of its competence through the Environmental Inspectorate and ERPC. It goes on to say that ERPC is a state agency within the Ministry of the Environment whose main functions are provided for in the Act.

3.10 Despite the fact that the Radiation Act was published in 2004 and largely follows the BSS, it is not fully consistent with the approach of GS-R-1. The Radiation Act is quite detailed and is more than simply an enabling piece of legislation that establishes and empowers the regulatory body. It places requirements on the Ministry of Environment, ERPC, and users of radiation sources. It contains much of what is often included within regulatory requirements and covers, for example, the designation of areas and the monitoring and health surveillance of workers.

3.11 The Act does not fully address the security of radioactive sources as set out in the *Code of Conduct* (2004).

3.12 The MOE is the regulatory body, as defined in the Radiation Act 2004. However it carries out no operational regulatory functions, except to countersign the activities of the agencies established within it, i.e. ERPC and the Environmental Inspectorate. In addition, all the radiation safety competence is located within the ERPC: this is in stark contrast with the fact that there is no such competence in the Environmental Inspectorate (although some support including training in radiation safety was provided by ERPC).

3.13 According to the Radiation Act, the Environmental Inspectorate undertakes inspections while ERPC provides the operational elements of the licensing function. The team notes that as a consequence of the Act, there is a requirement to renew or replace all existing licences. The ERPC has been undertaking visits that may not be inspections, as part of this transitional phase. The Environmental Inspectorate has yet to begin a consolidate inspection programme.

3.14 The ERPC also provides services and advice to users of radiation sources.

3.15 The RaSSIA appraisal team were informed that the legal basis for inspections and enforcement regarding radiation protection was provided for by the Radiation Act, Article 68. This referenced the Environmental Supervision Act. Article 16(7) of this act defines “place of business” in relation to inspection functions, but these have no relevance to many if not most radiation practices. This act is directed at environmental issues.

3.16 The fact that, first, the ERPC does not actually sign the licences, second that inspection is carried out by another body within MOE and third that the ERPC provides advice and services, could lead to significant confusion amongst users, the Ministry itself and potentially even within ERPC.

3.17 The review team noted:

- There is no notification requirement or provision for registration;
- There were no specific transport safety regulations;
- There did not appear to be a fully effective cradle to grave approach to radiation sources;
- The appeal process against licensing conditions is not transparent within the Radiation Act (the process is given in the Administrative Procedure Act – Articles 71ff);
- The Act recognizes categorization of practices in accordance with risk but on a limited basis associated with effective dose. Differential requirements for licensing based on this categorization are minimal;
- There is no categorization of sources within the Act.

3.18 Regarding medical exposure and practices, Article 51 states that radiation protection requirements shall be established by a regulation of the Ministry of Social Affairs. ERPC is not formally required to be involved in the process; neither does it seem to be practically engaged throughout the process. It is understood that these regulations will cover occupational and public protection as well as that of the patient. Even though ERPC undertakes activities relating to the provision of services, the Review Team did not find clear evidence that its functions had been substantially compromised by the juxtaposition of

service and regulatory responsibilities. However, there is no explicit empowerment of ERPC by this Act to take enforcement action.

3.19 The Review Team also noted an evident desire to establish practice specific guidance.

Regulations and guidance

Appraisal criteria and objectives

<i>Prescriptive and performance based regulations are required to provide an appropriate level of radiation safety and security of radioactive sources.</i>	
<i>Appraisal criterion</i>	A system of national regulations and guidance related to radiation safety and security of radioactive sources has been established. It includes administrative and technical requirements that suit the nature and extent of the facilities and activities to be regulated and is compatible with the BSS, GS-R-1 and the <i>Code of Conduct</i> as well as associated, relevant IAEA publications.
<i>Objective of appraisal</i>	To evaluate the existing regulations on radiation safety and security of radioactive sources with regard to their consistency with the applicable laws and international guidance in order to determine the extent to which the State has achieved the above appraisal criterion.

Appraisal findings

3.20 The RaSSIA appraisal team was informed that the legislation and Regulations were effectively written as a single package and this has enhanced the congruence of the two elements of the total framework. Regulations were completed in June 2005.

3.21 The recent development of the law and regulations has resulted in regulations, which are largely consistent with BSS 115, although the structure of the legislation does not follow the approach outlined under GSR1 in that the legislation is more detailed than expected. This however has been influenced by the speed in which legislation can be revised – months rather than years.

3.22 Regulations were not available in English and so detailed analysis was not possible. However, regulations addressing occupational radiation exposure, public radiation exposure, dose limits and the management of radioactive waste are all in place.

3.23 The RaSSIA appraisal team were informed that the regulations provide more detail than the Radiation Act, but do so in accordance with Article 19 of the Act.

3.24 Regulations on emergency exposures are also available but some important elements are addressed in the Radiation Law.

3.25 The regulation of transport of radioactive waste is covered by a generic law covering the transport of dangerous material.

3.26 The Ministry of Social Affairs is currently drafting, with the assistance of ERPC, regulations for medical exposures. It is intended that the regulatory body for these regulations, as with other radiation regulations, will be the Ministry of the Environment.

3.27 Sector specific regulations were issued in 2004 on radioactive waste management. No other areas have been addressed. It is intended that this work will commence in Autumn 2005 and will include non-statutory guidance and more detailed prescriptive guidance. These will be developed in conjunction with user groups.

3.28 Practice specific guidelines relating to radioactive source security are not in place and therefore the recommendations outlined in the Code of Conduct have not been introduced.

Regulatory body establishment and independence

Appraisal criteria and objectives

<i>An effectively independent regulatory body is key to being able to implement and maintain the practical provisions (e.g. regulations) necessary to achieve appropriate levels of radiation safety and security of radioactive sources</i>	
<i>Appraisal criterion</i>	An effectively independent regulatory body has been established and is adequately empowered by legislation, with the right to communicate directly with higher-level governmental authorities. Where more than one effectively independent regulatory body has been established, appropriate formal arrangements have been made to ensure that responsibilities and functions are clearly defined, properly coordinated and not duplicated.
<i>Objective of appraisal</i>	To determine the extent to which the State has achieved the above appraisal criterion. This includes evaluating relevant information related to the functions and responsibilities of the regulatory body and its relationship and interaction with other national bodies involved in radiation safety and security.

Appraisal findings

3.29 The Radiation Act establishes the MOE as the regulatory body. The MOE appears to be independent of any promotional activities associated with the use of ionizing radiation. The MOE reports directly to Parliament.

3.30 The legislation establishing the regulatory body and its functions is largely comprehensive and more prescriptive than recommended under GSR-1. It does not include general powers e.g. power to request any information it may feel is necessary in support of its activities.

3.31 It is intended that the MOE will remain the single regulatory body following the implementation of acts and regulations covering medical exposures. This legislation is being drafted by the Ministry of Social Affairs, but by retaining MOE as the regulatory body, there should be no conflict of interest regarding promotional activities relating to healthcare provision.

3.32 It is noted however that the Regulatory body delegates its functions to the Environmental Inspectorate and to ERPC. Both of these agencies are part of the MOE's organizational structure.

3.33 Although the MOE is an independent regulatory body, it has no developed competence in radiation protection. ERPC alone holds a recognized body of radiation protection expertise.

3.34 The arrangements in place have preserved the position of ERPC as a provider of radiation services and have ensured that radiation protection expertise is maintained and available in an advisory capacity and at an appropriate level to all government departments and agencies within Estonia.

Regulatory body staffing and training

Appraisal criteria and objectives

<i>An effective and efficient regulatory body requires appropriately qualified and trained personnel who have a sound knowledge of practices and current technology for radiation safety and security of radioactive sources.</i>	
<i>Appraisal criterion</i>	The regulatory body employs a sufficient number of personnel with the necessary qualifications, experience and expertise to undertake its functions and responsibilities (taking account of the availability of assistance by consultants and advisory bodies). There are well-defined training programmes for staff members.
<i>Objective of appraisal</i>	To evaluate relevant information related to the functions and organizational structure of the regulatory body, including the qualifications and experience of the staff, in order to determine how much progress has been made by the State in achieving the above appraisal criterion.

Appraisal findings

3.35 Information regarding staffing for radiation protection at the Ministry of the Environment (the regulatory body) suggests that there is no radiation expertise and minimal staffing at the Ministry. This is consistent with the decision to delegate the operational functions of the regulatory body to ERPC and the Environmental Inspectorate. No information was available regarding staffing levels at the Environmental Inspectorate, although the RaSSIA appraisal team were informed that ERPC had provided some training, including training regarding medical exposures.

3.36 Staffing numbers and staff qualification was available for ERPC. The Centre considers itself to be adequately staffed, with job descriptions in place, which can be, used to profile new or replacement posts if required. ERPC has 18 professional staff including: legal (1), accountancy (1), co-ordination and communication, laboratory (personal dosimetry) (4), monitoring (3), radiation protection for licensing, source register, inspections etc (7). There is a need to fill a medical physicist post soon but this is in hand.

3.37 Staff training is provided through internal training courses, but with the assistance of external experts. Training requirements for staff are assessed annually. The major areas identified do not tend to be scientific, but it is recognized that there is a need to enhance administrative and language skills. The training programme for new recruits is not formalized.

3.38 Although ERPC is authorized to use external consultants, it has not been necessary to do so for its day-to-day activities.

Regulatory body funding

Appraisal criteria and objectives

<i>So that the regulatory body can properly carry out its obligations under the legislation, appropriate budget processes must be in place, with funding not linked to the income that might be provided through the authorization process.</i>	
<i>Appraisal criterion</i>	The regulatory body is provided with adequate financial and other resources (for staffing, staff training, buildings, facilities, equipment and use of consultants) to discharge its responsibilities and maintain its inde-

	pendence. The funding is provided directly to the regulatory body and is independent of any charges for authorization, inspection and fines related to enforcement.
<i>Objective of appraisal</i>	To evaluate relevant information related to the adequacy of the regulatory body's budget and the way that it is used to discharge its legal responsibilities, in order to determine how much progress has been made by the State in achieving the above appraisal criterion.

Appraisal findings

3.39 Building provisions are sufficient for ERPC to provide the necessary technical and administrative support to the Ministry of the Environment in its regulatory activities.

3.40 There is access to appropriate and accredited laboratory facilities abroad (Latvia and Sweden).

3.41 The ERPC has sufficient technical and office support equipment (including access to computers) and access to Internet and a library with current literature, including that produced by the Agency, relating to radiation safety and security.

3.42 The ERPC has sufficient access to transport.

3.43 ERPC submits a budget through MOE to Parliament each year, and considers itself to be adequately funded, taking into consideration a number of funding mechanisms. ERPC is authorised to sell certain services and retain this function. All licensing fees are taken by Government, but in return the Government supplies adequate funding, taking into ERPC's other funding sources.

Coordination and cooperation at the national level

Appraisal criteria and objectives

<i>Appraisal criterion</i>	Cooperation and coordination at the national level have been formally established and are maintained with other authorities, intervening organizations, customs, law enforcement, professional societies, universities and technical services, as appropriate. This includes the formal and clear definition of respective responsibilities and functions.
<i>Objective of appraisal</i>	To evaluate relevant information related to arrangements made with other national bodies and organizations involved in radiation safety and security of radioactive sources in order to determine the extent to which the State has achieved the above appraisal criterion.

Appraisal findings

3.44 ERPC cooperates with other national agencies over a comprehensive range of issues.

3.45 The RaSSIA appraisal team was informed that formal arrangements are in place, in accordance with the radiation Act, with Customs authorities etc regarding the import and export of radiation sources. These operational arrangements seem to exceed the requirements set out in the Radiation Law.

For nuclear material security issues, the ERPC has cooperative arrangements with the Security Police.

International cooperation*Appraisal criteria and objectives*

<i>Appraisal criterion</i>	Necessary cooperation is formally established and maintained with other regulatory authorities in the region and with appropriate international organizations.
<i>Objective of appraisal</i>	To evaluate relevant information related to arrangements made with neighbouring countries and international organizations, in order to determine the extent to which the State has achieved the above appraisal criterion.

Appraisal findings

3.46 The Government of Estonia, through the ERPC, has arrangements for the exchange of safety information with Finland and Latvia and with the USA for safety and security matters.

3.47 There is a broad cooperation with Nordic Countries in know-how and equipment transfer.

3.48 A database is in use but this is not consistent with the Agency's Regulatory Authority Information System (RAIS). The decision not to use RAIS relates to Government policy regarding the use of Microsoft based products

CONCLUSIONS (Legislative and statutory framework)

The RaSSIA team concludes that:

3.49 The legislative and statutory framework for radiation safety is provided primarily through the Radiation Act 2004. This Act established the Ministry of the Environment (MOE) as the regulatory body. The MOE has no promotional role and thus there would appear to be no conflict of interest. However, it is noted that the MOE is a member of the 4-man Board of A.L.A.R.A.

3.50 The framework however is not totally consistent with the approach in GS-R-1 in that the basic legislative documents – particularly the Radiation Act – contain a considerable level of detail normally reserved for regulations. While this may be satisfactory at the present time, there may be long-term difficulties with this. (It is however understood that all obligations have to be in the act.)

3.51 Nevertheless, radiation safety requirements of the Act are largely consistent with those set out in BSS-115.

3.52 The Act and regulations are not however complete. In particular, they do not address medical exposures in detail. Article 51 of the Radiation Act requires the Ministry of Social Affairs to establish regulations for the protection of persons undergoing medical exposure, and the review team was given to understand that these regulations were in the process of being developed.

The cradle to grave approach does not appear to be totally explicit for all radioactive sources.

3.53 Neither the Radiation Act nor any other legislative requirements explicitly addresses the security of radioactive sources; the security of sources however that is essential for safety is implicit in the requirements for radiation protection. The additional guidance in the Code

of Conduct and the supporting guidance on import/export control relating to the safety and security of radioactive sources above and beyond the requirements already contained in the BSS have not been specifically addressed in the legislative and regulatory documents. Thus, while the MOE considers itself the regulatory body for the safety and security of radioactive sources, it lacks clear authority to deal with these additional security issues. On a point of detail, there is currently no categorisation of radioactive sources consistent with the Code, although there is a categorization of practices within the Radiation Act, based on the levels of dose that workers are likely to receive.

3.54 The team notes that an amendment to the Radiation Act is currently being prepared to accommodate the requirements of the HASS Directive, and this may well provide an opportunity to strengthen the requirements for the safety and security of radioactive sources – both the cradle to grave approach and the additional matters covered by the Code and supporting guidance.

3.55 MOE retains formal responsibilities for licensing, and inspection and enforcement. These operational functions associated with a regulatory body are provided by the ERPC and the Environmental Inspectorate, respectively. This allows the ERPC to continue to provide services, including advice. Nevertheless, within the context of its licensing functions, the team recognized that the ERPC would need to place increasing emphasis on this regulatory role, as distinct from its advisory role during its inspections to support the licensing process.

3.56 The legal basis for inspection and enforcement is the Environmental Supervision Act, which is general in nature and not explicitly concerned with radiation protection. As a consequence, it is not totally transparent and this may lead in future to legal challenge.

3.57 The legislation does not require the MOE, as the regulatory body, to have or obtain expert advice in the field of radiation protection. As the MOE currently has no such expertise of its own, but relies on that the advice of the ERPC, the MOE is potentially vulnerable with regard to its ability to ensure that its statutory functions are discharged. The ERPC has to provide the advice to MOE but it is not stated the other way round.

3.58 It is intended that MOE will be the regulatory body for medical exposures, thus avoiding any potential conflict of interest with regard to the use of ionising radiation in healthcare. This may have further implications regarding its need for expertise to be available to it.

3.59 There is no notification process, but a comprehensive approach to licensing largely ensures that the ERPC is kept informed of the practices and sources being held or in use and this provides data for the national register of radiation sources.

3.60 There are currently no sector specific guidelines and this may have implications for compliance with the legislation and regulations and hence for radiation protection in some sectors.

3.61 There is evidence of international cooperation but the failure to establish bilateral agreements with Russia may limit knowledge of previous activities involving radiation sources

RECOMMENDATIONS (Legislative and statutory framework)

The Government of Estonia should, as part of its amendment of the Radiation Act, and formulation of its new regulations:

- Review the structure and content of the amended act in accordance with the approach recommended in GSR-1
- Consider inclusion of comprehensive inspection and enforcement powers within the amended act
- Consider inclusion of the appeal process
- Consider inclusion of specific security elements within the act
- Introduce a more transparent approach to categorisation of sources and practices
- Require the regulatory body has, or has available to it, adequate finances and specialist practice-specific radiation protection expertise to ensure that all regulatory functions can be carried out. This is particularly necessary for medical exposures
- Require the involvement of ERPC in the drafting process for medical exposure regulations
- Ensure that there is appropriate legislative basis for the proposed medical exposure regulations
- Ensure that the requirements regarding the protection of workers and the public in the medical exposure regulations do not conflict with the existing requirements in the Radiation Act.

3.62 The Government of Estonia should consider immediate actions pending the establishment of new legislation and regulations relating to the safety and security of radioactive sources. In particular:

- Direct the MOE to adopt and implement interim requirements for source security (including security during transport);
- Carry out a national threat assessment regarding radioactive source security;
- Produce sector specific guidance where appropriate;
- Enhance cooperation with all neighbouring States and intergovernmental agencies, to establish mechanisms for the exchange of information, expertise and advice on radiation safety and security of sources. ERPC has its own agreements on the exchange of data with Latvia and Lithuania.

ACTIVITIES OF THE REGULATORY BODY

Notification and national register of radiation sources

Appraisal criteria and objectives

A fully functioning notification system and a complete register of sources are key to achieving control over the use of radiation sources

Appraisal criterion

The notification system of the regulatory body is fully operational and covers all practices and sources. A complete register of sources exists at the level of the regulatory body. At a minimum, the regulatory body has a complete register of Category 1 and 2 sources and all registrants and licensees have complete site-specific inventories for all the other sources.

	The register and inventories are kept up to date and are regularly verified by the regulatory body.
<i>Objective of appraisal</i>	To evaluate relevant information related to the responsibilities, procedures and guidance for notification, as necessary for establishing and maintaining a national register, in order to determine the extent to which the State has achieved the above appraisal criterion

Appraisal findings

3.63 The ERPC appears to lack a comprehensive notification system consistent with the BSS and GS-R-1. In practice, the licensing function undertaken by ERPC amalgamates notification, and authorization into a single process. The legislation requires all users to have a licence before commencing practices using ionizing radiation, unless exempted by the provisions given in the Radiation Act.

3.64 Estonia has not adopted authorization by registration only (as per BSS). All practices are treated the same way and are required to be licensed.

3.65 A national register of sources has been established. It is maintained by the ERPC. There is no categorization of sources consistent with TECDOC-1344.

3.66 The ERPC does not intend to use RAIS, as this would be inconsistent with the government policy to use open software systems.

3.67 The ERPC has not initiated a programme to ensure that it is notified of all non-exempt radioactive sources. The team was informed that all sources are included within an appendix to the licence. Thus, the national register of sources is not maintained through a notification process.

Authorization

Appraisal criteria and objectives

<i>Appraisal criterion</i>	The authorization system of the regulatory body is fully operational and covers all practices and sources.
<i>Objective of appraisal</i>	To evaluate relevant information related to the system of authorization, in particular the procedures for application by the users, the internal procedures for review and appraisal and the issue of authorizations, including import, export and transshipment, in order to determine the extent to which the State has achieved the above appraisal criterion.

Appraisal findings

3.68 Article 16 of the Radiation Act makes clear that it is prohibited to commence radiation practices or to perform radiation work without a licence. Article 16 further specifies which practices require the licence.

3.69 Article 15 of the Radiation Act empowers the MOE to grant the licence or to refuse it under specified conditions, and Article 19 lists the conditions to be set out in the licence by the MOE.

3.70 The appropriate licence application forms are defined and published on the ERPC web site.

3.71 The MOE is responsible for issuing licences for all radiation practices. To achieve this the MOE delegated the operational functions to ERPC. The ERPC carries out the pre-licensing assessment including on site visit and prepares the licence for formal approval by the MOE.

3.72 Article 23 of the Radiation Act specifies that the licence be issued for up to five years. The actual terms of individual licences issued vary from one to five years according to the particular circumstances as judged by ERPC staff. There is no written rule concerning the definition of licence term. The process seems not to be transparent enough.

3.73 Radiation practices are divided into risk categories based exclusively on the potential for annual effective dose to workers. This approach does not therefore appear to take account of potential hazard. The Estonian categorization system, which is not consistent with TECDOC-1344, is not used to set the terms of the licence in a systematic manner: the duration of the licence (in years) does not always correspond with the categorization number. The experience of ERPC staff comes into play.

3.74 Security measures are only to limited extent required as part of the authorization process.

3.75 There is some guidance to assist the user with the licensing process.

3.76 The licensing of complex facilities is not formally required to proceed through several discrete stages (e.g. siting, design, construction and operation). Nevertheless, in practice, the ERPC did appear to work in a progressive manner in an advisory capacity.

3.77 The ERPC undertakes a thorough review and assessment of a licensee's technical submission in support of any part of the authorization process.

3.78 In accordance with the Procedure for Issuing Licences for Activities Involving Radiation, the licence application must be reviewed and assessed within 90 days. A first assessment of the application is required to be carried out within 10 days. The team was informed that about 90% of applications were dealt with in the 90 day time period. Difficulties had been encountered during the transition phase to full implementation of the Radiation Act, which had put considerable pressure on the ERPC.

3.79 The Radiation Act requires the notification by the licensee of proposed modifications to safety related aspects of a facility or activity and those are subject to review and appraisal.

3.80 In Article 30 of the Radiation Act, there is an obligation placed on licence holders relating to the change of ownership of a radiation source to provide the new owner with comprehensive information to ensure radiation safety. Article 24 requires notification of delivery of the radiation source to another person to prohibit unauthorized transfer of radioactive sources from one person to another. The team was informed that the licensee would be required in future (under the amended Radiation Act) to check whether the recipient of the source has a licence before the source can be supplied.

3.81 The ERPC procedures appear to be adequate to ensure that:

- the available information demonstrates the safety of the facility or activity;
- the information contained in user submissions is accurate and sufficient to enable confirmation of compliance with regulatory requirements;
- the user's technical solutions, and in particular any novel ones, have been proven or qualified by experience or testing or both, and are capable of achieving the required level of safety.

3.82 The ERPC does not formally:

consider the adequacy of security, as distinct from safety that is inherently part of safety;
 amend, renew, suspend or revoke an authorization in accordance with a clearly defined and established procedure;
 review and assess an authorization using procedures in accordance with the potential magnitude and nature of the hazard and security risk associated with the particular facility or activity;
 define and make available its principles and associated criteria on which its judgments and decisions are based;

3.83 The appraisal team reviewed a sample of regulatory actions including the licence application process. The following files were reviewed:

Licensee	Practice
A.L.A.R.A. Ltd, Paldiski	Waste Management (mostly dealing with contaminated material from former nuclear submarine training centre)
Tallinna Masinatehas Ltd, Tallinn	Industrial radiography (mainly fixed installation)
North Estonian Regional Hospital	Radiotherapy hospital
Viruplatsi Arstikeskus	Clinic with diagnostic radiology

3.84 The review of the above revealed the licensing process was consistent although approved written procedures were not used. The staff members involved in the licensing process provided consistent descriptions of the process, including the following steps:

- A staff member is assigned to review and process the application upon receipt. A cover sheet is attached to the application that provides key information (application number, dates of actions and approvals, etc.) that remains with it throughout the process.
- The application is reviewed for completeness against a documented checklist (Section 19 of the Radiation Act). Incomplete or unclear information is identified and the applicant is required to supplement the application with additional information.
- The technical content of the application is reviewed, using a documented checklist. This review includes the use of the radioactive material, facility layout (controlled areas, public areas, storage areas), worker radiation protection and emergency procedures.
- If additional information or commitments are required of the applicant, these are identified and an amendment of the application (by the applicant) is required. The facility will be inspected prior to granting the licence to verify facility layout or to confirm other information. The licence is specific to the facility, key personnel such as the radiation safety officer, and equipment/procedures.
- Once the application is deemed sufficient, a licence is granted authorizing the practice and a licence number is assigned. The licence is issued by the Minister of Environment. The entire authorized inventory of radionuclides is listed on each licence or licence revision, facilitating easy understanding of exactly what the licensee is authorized to possess and use.

Safety and security of radioactive sources

Appraisal criteria and objectives

<i>Appraisal criterion</i>	The notification, authorization, inspection, enforcement and national
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	cooperation systems of the regulatory body are fully operational and maintain an appropriate level of safety and security for all radioactive sources.
<i>Objective of appraisal</i>	To evaluate information relevant to the safety and security of radioactive sources in order to determine the extent to which the State has achieved the above appraisal criterion.

Appraisal findings

3.85 The ERPC has not established a categorization of sources consistent with the Agency's standards.

3.86 The ERPC has a responsibility for radiation protection and security of sources is included within this insofar as it is relevant. It does not have a formal remit for the other elements of security of radioactive sources. However, it was apparent from the visit to the waste repository that the ERPC staff were fully involved in the bilateral work done by the US Department of Energy in upgrading the security arrangements at the site.

3.87 Procedures and emergency plans have been established for sources that have been found or lost from authorized control as required under Article 60 of the Radiation Act. Both the staff at the Rescue Board of the Ministry of Internal Affairs and the Radioactive Waste Management Agency have been trained to deal with lost and orphan sources. The Rescue Board's prime responsibility is to secure the situation; the Radioactive Waste Management Agency, which is under the Ministry of Economy and Communications, and is responsible for the collection and storage of radioactive waste.

3.88 The issue of bankruptcy and where a licensee ceases operations are taken into consideration during the licensing process. However, in extreme circumstances, the Rescue Board and the Radioactive Waste Management Agency would take responsibility for the sources.

3.89 The Radioactive Waste Management Agency has the equipment and facilities for the handling, transport and temporary storage of radioactive sources following recovery of an orphan or vulnerable source.

3.90 At ports of entry, the team was informed that there are safe and secure storage areas for radioactive sources held pending import/export. The team was also informed that a recently acquired cobalt-60 source (for blood irradiation) from Canada was imported over land from Germany and in Estonia was accompanied by a police escort. Road transport requires permission from the Road Administration of the Ministry of Economy and Communications.

3.91 The team was informed that scrap metal dealers, in order to protect their economic interests, have demonstrated sufficient concern to install radiation monitors to detect radioactive sources. ERPC consider that it was in the interest of the scrap metal dealers to ensure that their instruments function properly. ERPC had actually licensed one scrap metal dealer.

3.92 The safety and security of radioactive sources routinely stored on vehicles or at field sites is addressed as part of the licence application.

Inspection

Appraisal criteria and objectives

<i>Appraisal criterion</i>	<p>The inspection and review system is fully operational, including:</p> <ul style="list-style-type: none"> • meeting inspection procedures and frequencies established in relevant inspection programmes; • reviewing information, from operating experience, submitted by operators in accordance with reporting rules established by the regulatory body; • reviewing reports on accidents, incidents and other unusual events submitted by operators in accordance with reporting rules established by the regulatory body; • requiring and controlling the implementation of follow-up actions for accidents, incidents and other unusual events; including the collation and dissemination of information to other relevant users.
<i>Objective of appraisal</i>	To evaluate relevant information relating to the inspection and review processes in order to determine the extent to which the State has achieved the above appraisal criterion.

Appraisal findings

3.93 The team were informed that the Environmental Inspectorate prepares annually an inspection plan. For 2005, 110 inspections are planned; more would be undertaken if resources were available. These inspections are done by regional offices – involving about 160 inspectors, of whom, about 30% would deal with the radiation licenses (they have been trained). In approximately 10% of these inspections, the Environmental Inspectorate would be accompanied by ERPC staff. It is intended that this cooperation will be extended. At present, the inspections of the Environmental Inspectorate would appear to be more focused on administrative matters rather than assessment of good radiation protection practice.

3.94 The frequency of inspections was reported to be based on the risk categorization given in the Radiation Act – high risk being every year; medium risk, every two years. This frequency can change depending on the conditions of the licence and previous experience of the practice.

3.95 Inspections of dentists are undertaken solely for radiation protection purposes. Other inspections may well be combined with inspection of other environmental issues.

3.96 During inspections, Environmental Inspectorate verify the accuracy of the user's radiation source inventory. The most difficult problem identified was the absence of a current licence.

3.97 The team was informed that the inspectors of the Environmental Inspectorate had received training from the ERPC and made use of a checklist in undertaking their inspections. This however, was not evident in the inspection of the waste management facility witnessed by the team.

3.98 Reports are presented to the licensee at the end of the visit and must be signed by both parties. Only if things are not in order is further documentation sent. The team was informed that there was a process for following up the issues identified during inspection.

3.99 Most (90%) inspections are announced; unannounced inspections are undertaken when there is a suspicion of unacceptable practice.

3.100 In addition to these inspections, ERPC carries out 'inspections' as part of the process of licensing and renewal of licences. These 'inspections' appeared to include a large advisory component. This appears to have been a major component of ERPC's work because the

Radiation Act only came into force in May 2004 – such work was however done before under the previous Radiation Act.

3.101 Section 30 (8) of the Radiation Act requires licensees to inform ERPC, but not the regulatory body, if there is an accident or when dose limits are exceeded. It does not however indicate that licensees should undertake an investigation following an unexpected event or exposure. Indeed, the Act does not require the use of dose constraints or investigation levels.

3.102 The team was informed that an investigation is carried out if an individual's dose exceeds 6 mSv in a year. If ERPC is the provider of the dosimetry service, it officially notifies the licensee and asks for an explanation, although this is not explicitly required by the Radiation Law.

Enforcement

Appraisal criteria and objectives

<i>Appraisal criterion</i>	The regulatory body is empowered by law to undertake enforcement actions relating to the findings of inspections and regulatory reviews. The system of enforcement actions is fully developed and operational.
<i>Objective of appraisal</i>	To evaluate relevant information relating to the enforcement processes, in order to determine the extent to which the State has achieved the above appraisal criterion.

Appraisal findings

3.103 Articles 64-69 of the Radiation Act specify the enforcement authority. Article 69 refers to the relevant provisions of the Penal Code and authority is granted to the Environmental Inspectorate to undertake proceedings.

3.104 Article 26 provides for the revocation of a radiation practice licence by the issuer (presumably the MOE). Such revocation requires prior notice, the implication being therefore that the revocation cannot be implemented immediately.

3.105 Article 27 indicates that a holder of a radiation practice licence shall suspend the practice in the event of an overexposure until the reasons have been determined and eliminated. The role of enforcement body in this respect is therefore not clear.

3.106 The Environmental Inspectorate has not developed an enforcement policy with clearly defined criteria. The team was informed that the Penal Code provides for discretion on the part of the inspector.

3.107 The Environmental Supervision Act provides for the suspension of 'activities damaging the environment'. It was not clear to the team whether this provision would in fact be sufficient to allow the Environmental Inspectorate to suspend activities in the event of observed failure to observe radiation safety.

3.108 There is no explicit requirement to rectify the non-compliance. The approach taken is that an investigation should be made by the licence holder under Article 27 and the practice returned to the state where it satisfies the requirement of Article 30 (1), i.e. the licensee is responsible for radiation safety. This emphasizes the importance of the licence conditions.

3.109 The team was informed that the Environmental Inspectorate confirm any enforcement action in writing.

3.110 The legislation/regulations do not set out the enforcement actions that inspectors can take on the spot. They can stop the activity, but everything else cannot be done on the spot.

Information management

Appraisal criteria and objectives

<i>Appraisal criterion</i>	An information system has been established to inform the public, through its representatives and the media, about the radiation safety and security related aspects of regulated practices, intervention situations and the regulatory process. The State takes appropriate steps to ensure that sensitive information is held in a secure manner and protected to prevent misuse.
<i>Objective of appraisal</i>	To evaluate information management systems in order to determine the extent to which the State has achieved the above appraisal criterion

Appraisal findings

3.111 The ERPC has a designated member of staff for the collection and collation of national and international information on safety and security of sources. They disseminate relevant information through their web page, informal meetings with other agencies and specific training initiatives. Where necessary, information has been relayed to the public through the public relations service of Rescue Board or Ministry of Environment. A publication on orphan sources was issued in December 2004.

3.112 The team understands that there is no specific policy ensuring that sensitive radiation safety and security information is held in a secure manner and protected to prevent misuse. All members of staff of the ERPC sign confidentiality agreements as part of their contracts of employment. ERPC however only allows 2 members of staff to access and change the source inventory (the inventory is password protected). The database is on a server rather than a single discrete computer and there is a policy on the disposal of all State equipment, including computers.

3.113 The team was informed that users of high-risk radioactive sources are not yet required to protect the confidentiality of information, the disclosure of which might compromise the security of sources. Licenses are not however open documents.

3.114 The ERPC has not yet established secure communications on security issues related to radioactive sources.

Quality management

Appraisal criteria and objectives

<i>Appraisal criterion</i>	The regulatory body has established procedures, including those for quality management and analysis of programme data, to ensure that it maintains an effective and efficient regulatory programme for the radiation safety and security of radioactive sources.
<i>Objective of appraisal</i>	To evaluate relevant information relating to all aspects of the regulatory body's quality management provisions, in order to determine the extent to

	which the State has achieved the above appraisal criterion
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Appraisal findings

3.115 The ERPC has been accredited for some of its laboratory services. There was also evidence of a strong quality management approach within ERPC and the team was given to understand that quality manuals are currently in the process of development. A range of draft quality management procedures were in fact provided to the team.

3.116 The ERPC has developed a checklist based on TECDOC-1113 for use in inspections by the Environment Inspectorate. It was not however clear whether these checklists were in routine use.

CONCLUSIONS (Activities of the regulatory body)

The RaSSIA team concludes that:

3.117 The ERPC, in its support to the MOE as regulator, has been going through a major transition phase due to the fact that the Radiation Act only came into force in May 2004. This has had significant consequences for the ERPC with much of its efforts being devoted to regularizing the licensing situation in Estonia. There is clear evidence of the strong commitment of ERPC to get on top this administrative work and much has been achieved. Even though this has been the major thrust of activities, ERPC has clearly recognized the value of developing quality systems and communicating the relevant stakeholders (users of radiation, Ministries and the public). A further example of their dedication to quality is demonstrated by the weight that they have assigned to their relationships and collaboration with institutions in neighbouring countries, particularly the Nordic countries.

3.118 Because of this thrust on licensing activities, the ERPC and the Environmental Inspectorate have yet not developed a fully risk-based approach to all their activities.

3.119 There is no formal requirement of notification of practices. However, the national register of sources has been developed through the licensing process and therefore there would appear to be no need for the introduction of a notification process in the legislative or regulatory documents.

3.120 The IAEA Categorization of Sources is not used at present, and this may have implications for the approaches to the safety and security of radioactive sources.

3.121 The absence of a fully risk-based approach is evident in the fact that the licensing and inspection approaches have not focused on the higher risk practices.

3.122 Although there are no formal requirements specifically relating to security apart from those that are essential for safety, it was clear that there is a strong awareness of issues relating to the security of radioactive sources.

3.123 The enforcement provisions of the Radiation Act are only applicable to licensing violations. This restriction together with the lack of Environmental Inspectorate policy and procedures for their implementation, constrains the capability of the MOE as the regulatory body to enforce the legal obligations of users.

3.124 Current Environmental Inspectorate staff lack training and expertise in radiation protection and security and, therefore, seem to be reluctant to implement the inspection programme in higher risk practices.

3.125 The Environmental Inspectorate has not yet established a quality approach to continuously improve its policies, procedures and activities regarding inspection and enforcement. Such an approach would avoid inconsistencies.

RECOMMENDATIONS (Activities of the regulatory body)

3.126 Notwithstanding the effort involved in the current transition stage, which has focused on the licensing requirements consequence to the introduction of the Radiation Act, the ERPC and Environmental Inspectorate should begin to shift the emphasis of their activities towards radiation practice assessment rather than simply continuing to rely on licensing activities as the major demonstrator of radiation safety. In addition, there is a need for both bodies to formally agree an enhanced level of supporting expertise that will be required for a fully developed licensing and inspection programme. For example, consideration should be given to increasing the percentage of inspections in which the ERPC staff participate. Specifically, inspections of all practices identified as ‘high-risk’ should involve ERPC staff..

3.127 The MOE should take further measures to address the security of radioactive sources pending the development of amendments to the Radiation Act.

The ERPC should:

- ensure the maintenance and updating of the national register of radiation sources, which is currently based on the information provided through applications by users. categorization of sources consistent with the Agency’s standards should be introduced;
- strengthen the risk-based approach (defined in the Radiation Act) taking into account aspects additional to the effective dose to workers (with reference to international standards and guidance) in their licensing function. This should lead to a consistent specification of such things as license duration;
- enhance its training of the staff of the Environmental Inspectorate based on the type of practice that is expected to be encountered,
- enhance its training programmes and relationships with professional organizations to promote a radiation safety culture within types of practice (e.g. medical and dental),
- complete the development of its quality systems.

The Environmental Inspectorate should:

- review the inspection programme placing emphasis on the high-risk practices, while simultaneously reducing effort on the low-risk practices (e.g. dental x-ray practices);
- develop written policy and procedures for its inspection and enforcement programmes;
- develop their safety and security cultures.

APPENDIX 1: RaSSIA ACTION PLAN FOR ESTONIA

Each element of the action plan arising from a RaSSIA appraisal is set out in detail in the two tables that follow. The first deals with recommended actions relating to legislation and the statutory framework and the second sets out actions specifically relating to the activities of the regulatory body.

1 LEGISLATION AND THE STATUTORY FRAMEWORK

Legislation

Regulations and guidance

Regulatory body establishment and independence

Regulatory body staffing and training

Regulatory body funding

Coordination and cooperation at the national level

International cooperation

2 ACTIVITIES OF THE REGULATORY BODY

Notification and national register of radiation sources

Authorization

Safety and Security of radioactive sources

Inspection

Enforcement

Information management

Quality management

APPENDIX 1: ACTION PLAN (continued)

The purpose of this action plan is to identify the fundamental tasks essential to the establishment / upgrading of a national regulatory infrastructure. It includes references to a range of IAEA and other publications. Member States should consult these publications for more detailed information.

1. LEGISLATION and STATUTORY FRAMEWORK

TASKS for each ELEMENT	ACTION TAKEN BY:	IAEA INPUT ²	REFERENCES
1.1 Legislation <ul style="list-style-type: none"> Complete the process of developing new (or amended) legislation on radiation safety, and security of radioactive sources ensuring consistency with IAEA Basic Safety Standards and other referenced IAEA documents. 	Estonian Government		Ref (1) BSS Ref (2) GS-R-1 Ref (3) Code of Conduct Ref (13) INSAG 17 Ref (6) GS-G-15 Ref (7)
1.2 Scope of legislation <ul style="list-style-type: none"> Ensure that the legislation provides for effective control of radiation and radioactive sources, radioactive waste and transport safety, including 	Estonian Government		Ref (2) GS-R-1, Items 2.1, 2.4 Ref (3) Code of Conduct, Items 18–19

² Input from the IAEA requires a formal request for assistance from the National Government

TASKS for each ELEMENT	ACTION TAKEN BY:	IAEA INPUT	REFERENCES
<p>the import and export of radiation sources.</p> <ul style="list-style-type: none"> • Ensure that the legislation addresses the security of radioactive sources. 			
<p>1.3 Government responsibilities/national infrastructures</p> <ul style="list-style-type: none"> • Improve provisions for inspection and enforcement of the Estonian legislation through the regulatory body. • Define the nature and level of the expected domestic security threat. 	Estonian Government		<p>Ref (1) BSS 115, Principles and Fundamental Objectives Page 6</p> <p>Ref (2) GS-R-1, Items 1.5, 2</p> <p>Ref (3) Code of Conduct, Items 8 – 17, 18</p>
<ul style="list-style-type: none"> • Enact legislation 	Estonian Government / Parliament		
<p>1.4 Regulations and guidance</p> <ul style="list-style-type: none"> • Review, update or replace regulations appropriate to the nature and range of facilities 	Regulatory body / Government		<p>Ref (1) BSS, Detailed Requirements</p> <p>Ref (2) GS-R-1 Items</p>

TASKS for each ELEMENT	ACTION TAKEN BY:	IAEA INPUT	REFERENCES
and radiation practices that are to be regulated within Estonia.			5.25–5.28 Ref (3) Code of Conduct Item 18 Ref (4) Ref (7)
<ul style="list-style-type: none"> Ensure that regulations specifically address occupational and public radiation exposure, dose limits, medical exposures, radioactive waste management, transport of radioactive sources and emergency exposures situations. <p><i>Note: The main purpose of the regulations is to establish requirements with which all operators are expected to comply.</i></p>	Regulatory body		Ref (1) BSS, Detailed Requirements Ref (2) GS-R-1 Items 5.25–5.28 Ref (3) Code of Conduct Item 18 Ref (7) Ref (11)
<ul style="list-style-type: none"> Ensure that regulations specifically address security of radioactive sources issues such as: security measures to deter, detect and delay the unauthorized access to, or the theft, loss or unauthorized use or removal of radioactive sources; verification of security measures; import and export; response to security incidents 	Regulatory body		Ref (3) Code of Conduct, Items 8, 12, 19 Ref (5)
<ul style="list-style-type: none"> Develop guidance documents (codes of practice, 	ERPC for the		Ref (2) GS-R-1, Items

TASKS for each ELEMENT	ACTION TAKEN BY:	IAEA INPUT	REFERENCES
<p>generally non-mandatory) that, for example, explain how to comply with legislation and regulations; how to submit an application for authorization; procedures for assessing the adequacy of building design; instruction and training on the safety and security of radioactive sources and the devices or facilities in which they are housed etc.</p>	<p>Regulatory body</p>		<p>5.25 – 5.28 Ref (3) Code of Conduct, Item 22(m) Ref (16)</p>
<ul style="list-style-type: none"> • Ensure that the organization of the regulatory body is capable of properly discharging its responsibilities and fulfilling its functions effectively and efficiently. This includes ensuring that it has appropriate resources (financial, personnel, facilities and equipment). 	<p>Estonian Government</p>		<p>Ref (2) GS-R-1 Items 2.2(4), 4 Ref (3) Code of Conduct, Item 21</p>
<p>1.5 Regulatory body staffing and training</p> <ul style="list-style-type: none"> • On the basis of the national register of radiation sources and the range and extent of activities regulated, recruit and train personnel in administrative, radiation safety, legal, inspection and enforcement processes. • Ensure that regulatory body staff have the necessary qualifications and expertise to properly 	<p>Regulatory body</p>	<p>Provision of training packages dealing with authorization and inspection of radiation sources in diagnostic radiology, nuclear medicine, radiotherapy, irradiators, industrial</p>	<p>Ref (2) GS-R-1 Items 4.6 – 4.8; Ref (3) Code of Conduct Item 21 Ref (14) Ref (8) Ref (9)</p>

TASKS for each ELEMENT	ACTION TAKEN BY:	IAEA INPUT	REFERENCES
undertake the statutory functions.		radiography, gauges and well logging, cyclotron facilities	
<ul style="list-style-type: none"> • Develop and implement a planned programme of structured training and continuous professional development for personnel of the regulatory body so that proper skills are acquired and maintained, particularly in relation to new technologies, safety and security principles and concepts. 	Regulatory body	Provision of funding for the participation of designated ERPC staff in international or regional training on physical protection of radioactive sources and nuclear material.	Ref (2) GS-R-1 Item 4.7 Ref (3) Code of Conduct Item 10
<p>1.6 National coordination and cooperation</p> <ul style="list-style-type: none"> • Ensure that the regulatory body has the authority to cooperate with other relevant authorities to advise and provide information on radiation safety and security matters such as in: <ul style="list-style-type: none"> • environmental protection • public and occupational health • import and export of radiation sources • emergency planning and preparedness • management of radioactive waste 	Regulatory body/Estonian Government	Provision of example Memorandum of understanding	Ref (2) GS-R-1 Item 3.4 Ref (3) Code of Conduct Item 13(a), 13(b)

TASKS for each ELEMENT	ACTION TAKEN BY:	IAEA INPUT	REFERENCES
<ul style="list-style-type: none"> • physical protection and safeguards • water use and food consumption • land use and planning • transport of dangerous goods. <p><i>Note: Coordination and cooperation can be formalized through written memoranda of understanding between the relevant authorities.</i></p>			
<p>1.7 International cooperation</p> <ul style="list-style-type: none"> • Enhance arrangements for the exchange of safety and security related information, bilaterally or regionally, with all neighbouring States and other interested States, and with relevant intergovernmental organizations. 	Regulatory body/Estonian Government	Provision of funding for participation in security-related regional seminars, workshops and training.	Ref (2) GS-R-1, Item 4.11 Ref (3) Code of Conduct, Items 12, 20(n)

2. ACTIVITIES of the REGULATORY BODY

TASKS for each ELEMENT	ACTION TAKEN BY:	IAEA INPUT	REFERENCES
<p>2.1 National register of radiation sources</p> <ul style="list-style-type: none"> • Develop and maintain a comprehensive national register of ionizing radiation sources (non-exempt radioactive sources and radiation generators). • As a minimum, the register should include Category 1 and 2 radioactive sources as given in Appendix 1 to the Code of Conduct. • Implement appropriate measures to protect the confidentiality of information contained in the source register (inventory), particularly in relation to radioactive sources. 	Regulatory body		<p>Ref (3) Code of Conduct, Items 11, 17. Appendix 1.</p> <p>Ref (8)</p> <p>Ref (8)</p>
<ul style="list-style-type: none"> • Ensure that authorizations are subject to renewal at prescribed intervals that take into account the nature of the radiation hazard and for radioactive sources, the nature of the security risk. 	Regulatory body		Ref (8)

TASKS for each ELEMENT	ACTION TAKEN BY:	IAEA INPUT	REFERENCES
<ul style="list-style-type: none"> • With the cooperation of the Customs Authority, regulate the import and export of all non-exempt radiation sources to ensure that: <ul style="list-style-type: none"> • For imports, recipients are authorized by the Regulatory Body to take possession of the source; • for export, the receiving State has authorized the recipient to receive and possess the source and, for radioactive sources in particular, has the appropriate technical and administrative capability, resources and regulatory structure to ensure the management of the sources in a manner consistent with the Code of Conduct. 	Regulatory body / customs authority		Ref (3) Code of Conduct, Items 20, 23–29 Ref (8)
<ul style="list-style-type: none"> • For both initial and renewal applications, develop authorization review and assessment procedures that take into account the potential magnitude and nature of the radiation hazard associated with the particular facility or activity as well as the security risk for radioactive sources. 	Regulatory body		Ref (2) GS-R-1, Items 5.7–5.11; Ref (3) Code of Conduct, Item 22(a); Ref (8)

TASKS for each ELEMENT	ACTION TAKEN BY:	IAEA INPUT	REFERENCES
<p>2.2 Safety and Security of Radioactive Sources</p> <ul style="list-style-type: none"> • Establish procedures designating different levels of safety and security based on source categorization including a graded approach to security of Category 1-3 sources. 	Regulatory body		<ul style="list-style-type: none"> • Ref (3) Code of Conduct, Item 18, 20 • Ref (5)
<ul style="list-style-type: none"> • Establish procedures for addressing specific situations regarding radioactive sources including: <ul style="list-style-type: none"> - found, lost or stolen sources; - cessation of licensed operations for economic reasons; - handling, transport and storage of recovered orphan or vulnerable sources; - safe and secure storage of sources at ports of entry; <ul style="list-style-type: none"> - scrap metal monitoring; - tracking the movement of high-risk sources; and, - safety and security of radioactive 	Regulatory body		<ul style="list-style-type: none"> • Ref (3) Code of Conduct, Items 9, 13 (b), 15, 19 (g), (h), 22 (g) • Ref (5) • Ref (10)

TASKS for each ELEMENT	ACTION TAKEN BY:	IAEA INPUT	REFERENCES
sources routinely stored on vehicles or at field sites.			
2.3 Inspection <ul style="list-style-type: none"> • Establish a planned and systematic inspection programme taking into account the potential magnitude and nature of the radiation hazard associated with particular facilities or activities. 	Regulatory body		Ref (2) GS-R-1, Items 5.14-5.17 Ref (9)
<ul style="list-style-type: none"> • Develop written inspection procedures appropriate to the types of radiation practices regulated. 	Regulatory body		Ref (9)
<ul style="list-style-type: none"> • Establish written protocols clearly defining the duties and responsibilities of inspectors in the conduct of inspections. e.g. demeanour, occupational safety, obtaining evidence, issuing informal and formal directions, the privacy of client information, confidentiality of 	Regulatory body		Ref (2) GS-R-1, Items 5.17, 5.23, 5.24 Ref (3) Code of Conduct, Item 22(i) Ref (9)

TASKS for each ELEMENT	ACTION TAKEN BY:	IAEA INPUT	REFERENCES
<p>security information, report preparation, correspondence preparation and follow-up of any specified corrective actions, etc.</p>			
<p>2.4 Enforcement</p> <ul style="list-style-type: none"> Establish approved written procedures for enforcement actions appropriate to the nature of the alleged breach including, if appropriate, any necessary cooperative arrangements with other government agencies (justice, police, security, etc). <p><i>Note: Legislation should specify the nature and scope of sanctions that may be imposed, e.g. the suspension or cancellation of an authorization and the maximum financial penalties. The use of ‘on-the-spot’ fines for minor violations might also be considered as this process can avoid the often-lengthy delays of the legal system.</i></p>	<p>Regulatory body (and other agencies as may be appropriate)</p>		<p>Ref (2) GS-R-1, Items 5.18 – 5.24 Ref (3) Code of Conduct, Item 22(j) Ref (9)</p>
<ul style="list-style-type: none"> Develop formal procedures to ensure that 			

TASKS for each ELEMENT	ACTION TAKEN BY:	IAEA INPUT	REFERENCES
sensitive information is held in a secure manner and protected to prevent misuse, including information received in confidence from another party.	Regulatory body		Ref (3) Code of Conduct, Items 17, 20 (e) (ix),
2.5 Quality Management <ul style="list-style-type: none"> • Complete the establishment of a quality management programme to ensure that the regulatory body's programmes and procedures are reviewed at specified intervals to assure efficiency and effectiveness. 	Regulatory body		Ref (2) GS-R-1, Item 4.5 Ref (17) Ref (15) Ref (18) Ref (19)

APPENDIX 2: DOCUMENTATION PROVIDED BY COUNTERPART

1. Government of the Republic Act (RT I 1995, 94, 1628; as amended)
2. Environmental Supervision Act (RT I 2001, 56, 337; as amended)
3. Radiation Act (RT I 2004, RT I 2004, 26,173)
4. Occupational Health and Safety Act (June 1999)
5. Environmental Impact Assessment and Environmental Auditing Act (June 2000)
6. Environmental Monitoring Act (January 1999)
7. Emergency Preparedness Act (November 2000)
8. Guidance materials for applying radiation practice license and qualified expert license
9. Organizational charts of the institutions
10. Annual reports of the institutions
11. Staff descriptions for ERPC
12. Training receive and the plans for training in 2005
13. Working arrangement between ERPC and Ministry of the Environment to issue the radiation activity license
14. List of inspections carried out during the previous calendar year
15. Inspection plan for 2005
16. Overexposure procedure
17. Parts of the QA system for ERPC
18. Annual review of occupational exposures
19. Lists of service providers in radiation safety and security of radioactive source
20. Summary of radiological surveillance programme
21. Radiological risk assessment prepared based on the recommendations by Ministry of the Internal Affairs
22. Rules for action in radiological emergency situation
23. Rules for the case when the source is found
24. Copies of reports of events involving stolen, lost, found or orphan sources
25. Copies of reports of illicit trafficking of radioactive sources, such as those submitted to the IAEA's illicit trafficking database
26. Accreditation requirements by Estonian Accreditation Centre
27. Recommendations by the expert group about the radioactive waste management strategy

APPENDIX 3: PERSONS MET DURING APPRAISAL

NAME	FUNCTION	ORGANIZATION
Rein Raudsep	Head of Department	Ministry of the Environment
Kadri Tubli	Legal Department	Ministry of the Environment
Pavel Ojava	Senior Inspector	Environmental Inspectorate
Karin Muru	Radiation Protection Department	Estonian Radiation Protection Centre
Mare Varipuu	Radiation Protection Department	Estonian Radiation Protection Centre
Toomas Kõöp	Counsellor	Estonian Radiation Protection Centre
Merle Lust	Director	Estonian Radiation Protection Centre
Andrus Vukioja	Inspector	Environmental Inspectorate
Ethel Odras	Inspector	Environmental Inspectorate
Peeter Suit	Head of Laboratory, Radiation Safety Officer	Tallinna Masinatehas ltd
Mart Varvas	Technical Advisor	A.L.A.R.A, Paldiski
Valeri Badyrkhanov	Radiation Safety Officer	A.L.A.R.A, Paldiski
Eduard Gershkevitsh	Medical Physicist	North Estonian Regional Hospital
Jüri Ruudi	Main radiologist	Viruplatsi Arstikeskus

APPENDIX 4: WORK PROGRAMME

Date	PROGRAMME	Participants
25 July 2005	Entrance meeting with the senior management of the Regulatory Body of Estonia Discussion on the legislative and statutory framework Meeting held at the Ministry of the Environment	RaSSIA team and officials of the Ministry of the Environment, Estonian Radiation Protection Centre and the Environmental Inspectorate
26 July 2005	Meeting to discuss activities of the regulatory body held at the Estonian Radiation Protection Centre	RaSSIA team and officials of the Estonian Radiation Protection Centre and the Environmental Inspectorate
27 July 2005	Review of licences and approach to training at the Estonian Radiation Protection Centre Visits to licensed sites <ul style="list-style-type: none"> • ALARA, Paldiski • Oncology Hospital, Tallinn • Private clinic including radiology facilities 	RaSSIA team and officials of the Estonian Radiation Protection Centre and the Environmental Inspectorate (Regional Inspectors were involved in the visit to ALARA).
28 July 2005	Visit to industrial radiography facility Drafting of report at the Estonian Radiation Protection Centre	RaSSIA team and officials of the Estonian Radiation Protection Centre and the Environmental Inspectorate
29 July 2005	Meeting at the Ministry of Environment to discuss the findings and conclusion. Exit meeting with the Secretary General of the Ministry of the Environment	RaSSIA team and officials of the Estonian Radiation Protection Centre and the Ministry of the Environment

APPENDIX 5: COMPOSITION OF THE IAEA APPRAISAL TEAM

Anthony Wrixon	IAEA, Team Leader (Head of the Radiation and Transport Safety Section of the Division of Radiation, Transport and Waste Safety)
Dana Drabova	Czech Republic (President, State Office for Nuclear Safety)
Eero Kettunen	Finland (Director of Radiation Practices Regulation, Radiation and Nuclear Safety Authority (STUK))
Steven Ebdon-Jackson	UK (Head of Medical Exposures Section, Radiation Protection Agency)

APPENDIX 6: ABBREVIATIONS

The abbreviations below are for the purposes of this report only.

BSS	International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radioactive Sources
ERPC	Estonia Radiation Protection Centre
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiation Protection
MOE	Ministry of the Environment
RAIS	Regulatory Authority Information System
RaSSIA	Radiation Safety and Security Infrastructure Appraisal

APPENDIX 7: REFERENCES

1. International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radioactive Sources. Safety Series 115, IAEA, Vienna (1996).
2. Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety. Safety Series No. GS-R-1, IAEA, Vienna (2000).
3. Code of Conduct on the Safety and Security of Radioactive Sources. IAEA, Vienna (2004).
4. Categorisation of Radioactive Sources. TECDOC 1344. IAEA, Vienna (2003).
5. Security of Radioactive Sources- Interim Guidance for Comment. TECDOC 1355. IAEA, Vienna (2003).
6. Regulatory Control of Radiation Sources. Safety Guide No. GS-G-1.5. IAEA, Vienna (Draft Safety Guide).
7. Legislation and Establishment of a Regulatory Authority for the Control of Radiation Sources. IAEA, Vienna (Draft- This document will supersede TECDOC 1067)
8. Notification and Authorization for the Possession and Use of Radiation Sources. IAEA, Vienna (Draft Safety Report).
9. Inspection of Radiation Sources and Enforcement. IAEA, Vienna (Draft Safety Report).
10. Strengthening Control over Radioactive Sources in Authorised Use and Regaining Control of Orphan Sources. TECDOC 1388. IAEA, Vienna (2004).
11. Preparedness and Response for a Nuclear or Radiological Emergency, Safety Series No. GS-R-2, IAEA Vienna (2002).
12. Regulations for the Safe Transport of Radioactive Materials, Safety Series No. TS-R-1, IAEA, Vienna (2000)
13. Independence in Regulatory Decision Making. International Nuclear Safety Advisory Group (INSAG) Report 17, IAEA, Vienna (2003).
14. Building Competence in Radiation Protection and the Safe Use of Radiation sources. Safety Report No. 20 on Training in Radiation Protection and the Safe Use of Radioactive Sources. IAEA, Vienna,
15. Assessment Of Regulatory Effectiveness. PDRP-4, IAEA, Vienna (1999).
16. Application of the International Radiation Safety in Nuclear Medicine, Radiotherapy, Diagnostic Radiology and Interventional Procedures using X-Rays, Industrial Radiography and Industrial Irradiators (Draft)
17. Quality Assurance within Regulatory Bodies. IAEA-TECDOC-1090, Vienna (1999).
18. International Organization For Standardization, Quality Management Systems- Fundamentals and Vocabulary. ISO 9000: 2000, Geneva (2000).
19. The EFQM Excellence Model. European Foundation For Quality Management, Brussels (1999).

APPENDIX 8: RaSSIA RELATED DOCUMENTS

Organization and Implementation of a National Regulatory Infrastructure Governing Protection Against Ionizing Radiation and the Safety of Radiation Sources (TECDOC-1067)

This report helps States to establish or improve their national radiation safety infrastructure in order to meet international standards. In addition to providing advice on the essential elements of a radiation safety infrastructure at governmental level, TECDOC-1067 also advises on resource optimization within the infrastructure.

States would be expected to use TECDOC-1067 to:

- implement the elements of a regulatory programme;
- optimize resource efficiency within the regulatory infrastructure.

Categorization of Radioactive Sources (TECDOC-1344)

This TECDOC provides a logical system for ranking radioactive sources in terms of their potential to cause harm to human health and for grouping sources and the practices in which they are used into discrete categories. This categorization can assist regulatory authorities in establishing regulatory requirements that ensure an appropriate level of control for each authorized source.

States would be expected to use TECDOC-1344 to:

- devise a graded system of notification, registration, licensing and inspections;
- establish a graded basis for assisting in the determination of security measures;
- optimize decisions regarding which sources will be included in the national inventory of sources;
- optimize decisions regarding which sources may be subject to import and export controls.

Security of Radioactive Sources (TECDOC-1355)

This interim guidance is primarily addressed to regulatory authorities but also provides guidance to manufacturers, suppliers and users of sources. Its objective is to assist Member States in deciding which security measures are needed to ensure consistency with international basic safety standards and the revised *Code of Conduct for Safety and Security of Radioactive Sources*. This document recognizes the need for balance between managing sources safely and securely while still enabling them to be used without undue hindrance. The report focuses mainly on radioactive sources that are potentially dangerous (categories 1–3).

This document's recommended security measures are aimed at the prevention and countering of malicious acts by a combination of deterrence, detection, delay and response measures. .

States would be expected to use TECDOC-1355 to:

- develop a strategy for addressing malicious use of radioactive sources;

- assign radioactive sources to security groups;
- set performance objectives for security groups;
- carry out a vulnerability assessment to design security measures for specific sources;
- develop appropriate technical and administrative and specific security measures.

IAEA Working Material on “Legislation and Establishment of a Regulatory Body for the Control of Radiation Sources”

This document will supersede TECDOC 1067 and supplement GS-G-1.5, BSS and GS-R-1 in providing practical advice to States on the development of legislation and regulations. It includes sample laws and regulations.

IAEA working Material on “Notification and Authorization for the Possession and Use of Radiation Sources ”

This document will provide practical guidance on the process for dealing with applications for authorization and accepting notifications to regulatory bodies. It will supplement the Safety Guide on *Regulatory Control of Radiation Sources*.

IAEA working Material on “Inspection of Radiation Sources and Enforcement ”

This document will provide practical approaches on the process of radiation sources and facilities and enforcement. It will supplement the Safety Guide on Regulatory Control of Radiation Sources.

Strengthening Control over Radioactive Sources in Authorized Use and Regaining Control over Orphan Sources: National Strategies TECDOC-1388

This report provides States with background, practical guidance and methodology for the development of a national strategy for improving control over radioactive sources, particularly dangerous sources (Categories 1–3). Part of this process involves the determination of the magnitude of the potential problem with orphan and vulnerable sources and whether or not a national strategy is needed.

States would be expected to use TECDOC-1388 to develop and implement a national strategy and an action plan to manage all significant sources in a safe and secure manner.