

TECHNICAL REPORTS SERIES NO.

1002

Notification, Authorization, Inspection and Enforcement for the Safety and Security of Radiation Sources



IAEA

International Atomic Energy Agency

NOTIFICATION, AUTHORIZATION,
INSPECTION AND ENFORCEMENT
FOR THE SAFETY AND SECURITY
OF RADIATION SOURCES

The following States are Members of the International Atomic Energy Agency:

AFGHANISTAN	GERMANY	PALAU
ALBANIA	GHANA	PANAMA
ALGERIA	GREECE	PAPUA NEW GUINEA
ANGOLA	GRENADA	PARAGUAY
ANTIGUA AND BARBUDA	GUATEMALA	PERU
ARGENTINA	GUYANA	PHILIPPINES
ARMENIA	HAITI	POLAND
AUSTRALIA	HOLY SEE	PORTUGAL
AUSTRIA	HONDURAS	QATAR
AZERBAIJAN	HUNGARY	REPUBLIC OF MOLDOVA
BAHAMAS	ICELAND	ROMANIA
BAHRAIN	INDIA	RUSSIAN FEDERATION
BANGLADESH	INDONESIA	RWANDA
BARBADOS	IRAN, ISLAMIC REPUBLIC OF	SAINT KITTS AND NEVIS
BELARUS	IRAQ	SAINT LUCIA
BELGIUM	IRELAND	SAINT VINCENT AND THE GRENADINES
BELIZE	ISRAEL	SAMOA
BENIN	ITALY	SAN MARINO
BOLIVIA, PLURINATIONAL STATE OF	JAMAICA	SAUDI ARABIA
BOSNIA AND HERZEGOVINA	JAPAN	SENEGAL
BOTSWANA	JORDAN	SERBIA
BRAZIL	KAZAKHSTAN	SEYCHELLES
BRUNEI DARUSSALAM	KENYA	SIERRA LEONE
BULGARIA	KOREA, REPUBLIC OF	SINGAPORE
BURKINA FASO	KUWAIT	SLOVAKIA
BURUNDI	KYRGYZSTAN	SLOVENIA
CAMBODIA	LAO PEOPLE'S DEMOCRATIC REPUBLIC	SOUTH AFRICA
CAMEROON	LATVIA	SPAIN
CANADA	LEBANON	SRI LANKA
CENTRAL AFRICAN REPUBLIC	LESOTHO	SUDAN
CHAD	LIBERIA	SWEDEN
CHILE	LIBYA	SWITZERLAND
CHINA	LIECHTENSTEIN	SYRIAN ARAB REPUBLIC
COLOMBIA	LITHUANIA	TAJIKISTAN
COMOROS	LUXEMBOURG	THAILAND
CONGO	MADAGASCAR	TOGO
COSTA RICA	MALAWI	TONGA
CÔTE D'IVOIRE	MALAYSIA	TRINIDAD AND TOBAGO
CROATIA	MALI	TUNISIA
CUBA	MALTA	TÜRKIYE
CYPRUS	MARSHALL ISLANDS	TURKMENISTAN
CZECH REPUBLIC	MAURITANIA	UGANDA
DEMOCRATIC REPUBLIC OF THE CONGO	MAURITIUS	UKRAINE
DENMARK	MEXICO	UNITED ARAB EMIRATES
DJIBOUTI	MONACO	UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND
DOMINICA	MONGOLIA	UNITED REPUBLIC OF TANZANIA
DOMINICAN REPUBLIC	MONTENEGRO	UNITED STATES OF AMERICA
ECUADOR	MOROCCO	URUGUAY
EGYPT	MOZAMBIQUE	UZBEKISTAN
EL SALVADOR	MYANMAR	VANUATU
ERITREA	NAMIBIA	VENEZUELA, BOLIVARIAN REPUBLIC OF
ESTONIA	NEPAL	VIET NAM
ESWATINI	NETHERLANDS	YEMEN
ETHIOPIA	NEW ZEALAND	ZAMBIA
FIJI	NICARAGUA	ZIMBABWE
FINLAND	NIGER	
FRANCE	NIGERIA	
GABON	NORTH MACEDONIA	
GEORGIA	NORWAY	
	OMAN	
	PAKISTAN	

The Agency's Statute was approved on 23 October 1956 by the Conference on the Statute of the IAEA held at United Nations Headquarters, New York; it entered into force on 29 July 1957. The Headquarters of the Agency are situated in Vienna. Its principal objective is "to accelerate and enlarge the contribution of atomic energy to peace, health and prosperity throughout the world".

TECHNICAL REPORTS SERIES No. 1002

NOTIFICATION, AUTHORIZATION,
INSPECTION AND ENFORCEMENT
FOR THE SAFETY AND SECURITY
OF RADIATION SOURCES

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2022

COPYRIGHT NOTICE

All IAEA scientific and technical publications are protected by the terms of the Universal Copyright Convention as adopted in 1952 (Berne) and as revised in 1972 (Paris). The copyright has since been extended by the World Intellectual Property Organization (Geneva) to include electronic and virtual intellectual property. Permission to use whole or parts of texts contained in IAEA publications in printed or electronic form must be obtained and is usually subject to royalty agreements. Proposals for non-commercial reproductions and translations are welcomed and considered on a case-by-case basis. Enquiries should be addressed to the IAEA Publishing Section at:

Marketing and Sales Unit, Publishing Section
International Atomic Energy Agency
Vienna International Centre
PO Box 100
1400 Vienna, Austria
fax: +43 1 26007 22529
tel.: +43 1 2600 22417
email: sales.publications@iaea.org
www.iaea.org/publications

© IAEA, 2022

Printed by the IAEA in Austria

November 2022

STI/DOC/010/1002

IAEA Library Cataloguing in Publication Data

Names: International Atomic Energy Agency.

Title: Notification, authorization, inspection and enforcement for the safety and security of radiation sources / International Atomic Energy Agency.

Description: Vienna : International Atomic Energy Agency, 2022. | Series: Technical reports series (International Atomic Energy Agency), ISSN 0074-1914 ; no. 1002 | Includes bibliographical references.

Identifiers: IAEAL 21-01458 | ISBN 978-92-0-126622-4 (paperback : alk. paper) | ISBN 978-92-0-134321-5 (pdf) | ISBN 978-92-0-134421-2 (epub)

Subjects: LCSH: Radiation — Safety measures. | Radiation — Security measures. | Radiation sources.

Classification: UDC 614.876 | STI/DOC/010/1002

FOREWORD

Authorization, inspection and enforcement are the core functions of regulatory bodies, necessary to ensure the effective regulatory control of facilities and activities. IAEA Safety Standards Series Nos GSR Part 1 (Rev. 1), Governmental, Legal and Regulatory Framework for Safety; GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards; GSG-12, Organization, Management and Staffing of the Regulatory Body for Safety; and GSG-13, Functions and Processes of the Regulatory Body for Safety, establish requirements and provide recommendations for the establishment of a regulatory framework for safety and the main functions of regulatory bodies.

From the security perspective, IAEA Nuclear Security Series No. 11-G (Rev. 1), Security of Radioactive Material in Use and Storage and of Associated Facilities, is the primary Implementing Guide for IAEA Nuclear Security Series No. 14, Nuclear Security Recommendations on Radioactive Material and Associated Facilities. It provides guidance on how to establish a regulatory programme for the security of radioactive sources and how to establish security requirements for radioactive material, including a system of evaluation and authorization, inspection and enforcement.

This publication aims to enhance safety and security by means of a harmonized approach to the conduct of regulatory functions. It is also hoped that it will increase the quality and effectiveness of safety and security related reviews and inspections.

Given that many States have a single regulatory body responsible for safety and security of radioactive material and associated facilities and activities, this publication addresses both safety and security in the regulatory functions for notification, authorization, inspection and enforcement. Like IAEA-TECDOC-1525 and IAEA-TECDOC-1526, this publication also contains annexes and practice specific examples of procedures, with forms and checklists that can be adapted for use by regulatory bodies.

This publication contains input by experts from different regulatory bodies and provides a broad view of the techniques and methods used in the regulatory function.

The IAEA wishes to express its gratitude to all those who were involved in the drafting and review of the publication. The IAEA officers responsible for this publication were R. Pacheco of the Division of Radiation, Transport and Waste Safety and R. Schlee and L. Betancourt Hernandez of the Division of Nuclear Security.

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.

This publication does not address questions of responsibility, legal or otherwise, for acts or omissions on the part of any person.

Guidance provided here, describing good practices, represents expert opinion but does not constitute recommendations made on the basis of a consensus of Member States.

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.

The IAEA has no responsibility for the persistence or accuracy of URLs for external or third party Internet web sites referred to in this book and does not guarantee that any content on such web sites is, or will remain, accurate or appropriate.

CONTENTS

1.	INTRODUCTION.....	1
1.1.	Background	1
1.2.	Objective	2
1.3.	Scope	2
1.4.	Structure	3
2.	THE SYSTEM OF REGULATORY CONTROL.....	4
2.1.	Objective	4
2.2.	Graded approach.....	5
2.3.	Special circumstances.....	5
2.4.	Notification and authorization	6
2.5.	Inspection	7
2.6.	Enforcement.....	7
2.7.	Managing transitions in regulatory control	7
3.	MANAGEMENT AND ORGANIZATION	8
3.1.	Integrated management system	8
3.2.	Structure of the regulatory body.....	9
3.3.	Coordination among multiple regulatory bodies and other authorities	9
3.4.	Resource management	11
3.5.	Safety and security culture	12
3.6.	Management of notification and authorization	13
3.7.	Management of inspection	15
3.8.	Management of enforcement	17
3.9.	Independence of the regulatory body.....	19
3.10.	Human resources	21
3.11.	Guidance and procedures	23
3.12.	Information management system	24
3.13.	Access to external expertise, including legal support	25
4.	NOTIFICATION AND AUTHORIZATION PROCESS.....	28
4.1.	Introduction	28
4.2.	Notification.....	28

4.3.	Authorization	29
5.	INSPECTION PROCESS	40
5.1.	Introduction	40
5.2.	Types of inspection.	42
5.3.	Inspection programmes and plans	43
5.4.	Preparation for an inspection	45
5.5.	Entrance briefing	46
5.6.	Conduct of inspection.	47
5.7.	Exit briefing	50
5.8.	Inspection reports	51
5.9.	Post-inspection activities	52
6.	ENFORCEMENT PROCESS	53
6.1.	Introduction	53
6.2.	Overview of the enforcement process	54
6.3.	Identification of violations or non-compliances.	54
6.4.	Assessment of violations or non-compliances	55
6.5.	Selection of enforcement actions	58
6.6.	Participation in the enforcement process	61
6.7.	Managing evidence.	61
	REFERENCES	63
ANNEX I:	EXAMPLE OF NOTIFICATION FORM.	65
ANNEX II:	CONTENT OF APPLICATION FORMS FOR AUTHORIZATION.	67
ANNEX III:	EXAMPLE OF GUIDANCE ON THE REVIEW AND ASSESMENT OF APPLICATIONS FOR AUTHORIZATION.	119
ANNEX IV:	EXAMPLE OF CERTIFICATE FORM FOR AUTHORIZATION.	167
ANNEX V:	EXAMPLE OF GUIDANCE ON REGULATORY INSPECTIONS.	170

ANNEX VI: EXAMPLE OF A CODE OF CONDUCT FOR INSPECTORS..... 224

ANNEX VII: EXAMPLE OF A MEMORANDUM OF UNDERSTANDING BETWEEN THE REGULATORY BODY AND THE DEPARTMENT OF CUSTOMS..... 226

CONTRIBUTORS TO DRAFTING AND REVIEW 235

1. INTRODUCTION

1.1. BACKGROUND

This publication has been developed to assist States in establishing and maintaining regulatory control through notification, authorization, inspection and enforcement in relation to facilities and activities with radiation sources, in order to achieve the fundamental safety and security objectives.

This publication addresses the implementation of the requirements for safety and security in a harmonized way, taking into account differences in the requirements as well as differences in States' regulatory infrastructures. For example, in some States the same regulatory body is responsible for the control of safety and security, while in other States safety and security are controlled by separate regulatory bodies. A harmonized approach for notification, authorization, inspection and enforcement in relation to facilities and activities with radiation sources may improve the efficiency and effectiveness of regulatory body control, for example through concurrent inspection for safety and security.

The publication is intended to provide practical guidance on how to implement IAEA safety requirements and recommendations, as well as applicable guidance on nuclear security, related to radiation sources and associated planned exposure situations as defined in IAEA Safety Standards Series No. GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards [1]. In particular, IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), Governmental, Legal and Regulatory Framework for Safety [2], and GSR Part 3 [1] establish the requirements related to facilities and activities with radiation sources, and IAEA Safety Standards Series Nos GSG-12, Organization, Management and Staffing of the Regulatory Body for Safety [3], and GSG-13, Functions and Processes of the Regulatory Body for Safety [4], provide recommendations on how to meet these requirements.

This publication is consistent with the guidance provided in the IAEA Nuclear Security Series publications, specifically IAEA Nuclear Security Series No. 20, Objective and Essential Elements of a State's Nuclear Security Regime [5], IAEA Nuclear Security Series No. 14, Nuclear Security Recommendations on Radioactive Material and Associated Facilities [6], and IAEA Nuclear Security Series No. 11-G (Rev. 1), Security of Radioactive Material in Use and Storage and of Associated Facilities [7]. The latter publication applies to the use and storage of radioactive sources in industry, medicine, agriculture, research and education. This publication is also consistent with the IAEA Code of Conduct on the Safety and Security of Radioactive Sources [8] and its supplementary Guidance on

the Import and Export of Radioactive Sources [9] as well as its supplementary Guidance on the Management of Disused Radioactive Sources [10].

The terms used in this publication are consistent with the definitions in the IAEA Safety Glossary [11] and those used in IAEA Security Series publications.

This publication provides updated information for safety and security regulators, taking into account the latest IAEA recommendations. The information in IAEA-TECDOC-1525, Notification and Authorization for the Use of Radiation Sources [12], and IAEA-TECDOC-1526, Inspection of Radiation Sources and Regulatory Enforcement [13], is still useful. However, these publications have to be used with caution, since they were published more than a decade ago and may be out of date in certain respects.

1.2. OBJECTIVE

The objective of this publication is to provide the regulatory body (in particular authorization, inspection and enforcement staff) with practical guidance on the organization, management and implementation of a system for (1) notification and authorization for the regulatory control of radiation sources with respect to safety and security, and (2) inspection and enforcement to achieve regulatory compliance with the requirements for safety and security.

Guidance provided here, describing good practices, represents expert opinion but does not constitute recommendations made on the basis of a consensus of Member States.

1.3. SCOPE

This publication provides information and practical guidance to complement GSG-12 [3] and GSG-13 [4] with respect to the following:

- Organization and management by the regulatory body of a system for notification and authorization with respect to the safety of all radiation sources and the security of radioactive material.
- Notification and authorization procedures using standardized forms, with details of the content of the documentation to be submitted by applicants; the basis for decisions made by the regulatory body; the conduct of pre-authorization visits as part of the review and assessment of authorizations; the handling of renewals, amendments, suspension, revocation and termination of authorizations.

- Organization and management by the regulatory body of a system for safety and security inspections and enforcement.
- Procedures for inspections and enforcement using standard inspection plans for assessment of compliance.

In relation to safety, this guidance applies to all radiation sources. In relation to security, this guidance applies only to radioactive material.

This publication does not include guidance on granting exemptions from regulatory requirements as defined in GSR Part 3 [1]. In addition, it does not address justification of practices. Recommendations on justification are provided in IAEA Safety Standards Series No. GSG-5, Justification of Practices, Including Non-Medical Human Imaging [14].

Notification and authorization procedures related to decommissioning and predisposal management of radioactive waste are outside the scope of this publication. The related safety requirements are established in IAEA Safety Standards Series Nos GSR Part 6, Decommissioning of Facilities [15], and GSR Part 5, Predisposal Management of Radioactive Waste [16], respectively.

In the annexes, this publication provides selected examples of the content of applications for authorization, of guidance on review and assessment of applications for authorization, and of guidance on regulatory inspections. Some of this material is general in nature, while other material is practice specific, addressing the following practices:

- Medical use of radiation sources:
 - Radiotherapy;
 - Nuclear medicine;
 - X ray imaging in radiology.
- Industrial use of radiation sources:
 - Industrial gamma irradiators;
 - Industrial radiography;
 - Well logging using radioactive sources;
 - Nuclear gauges.

1.4. STRUCTURE

Section 2 provides a short overview of the system of regulatory control, with emphasis on the processes of notification, authorization, inspection and enforcement. Section 3 provides guidance on the management and organization of these and other regulatory processes. The intended audience of Section 3 consists of regulatory body managers responsible for authorization, inspection and enforcement.

Sections 4 to 6 provide practical guidance for regulatory body staff performing authorization, inspection and enforcement activities, respectively. Annexes I–VI contain example forms and guidance relating to authorization (Annexes I–IV) and inspection (Annexes V and VI). Annex VII contains an example of a memorandum of understanding between the regulatory body and the department of customs.

2. THE SYSTEM OF REGULATORY CONTROL

2.1. OBJECTIVE

IAEA Safety Standards Series No. SF-1, Fundamental Safety Principles [17], states that the fundamental safety objective is to protect people and the environment from harmful effects of ionizing radiation. IAEA Nuclear Security Series No. 20 [5] states that the objective of a State’s nuclear security regime is to protect persons, property, society and the environment from harmful consequences of a nuclear security event. The person(s) or organization(s) responsible for facilities and activities that give rise to radiation risks have the prime responsibility for safety and security. A system of regulatory control comprises effective processes that ensure safety and security in the management of radiation sources at all stages of their life cycle. The responsibility for establishing and maintaining these processes has to be clearly assigned to a regulatory body that is independent of the person(s) or organization(s) responsible for facilities and activities that give rise to radiation risks.

An effective regulatory body can only be achieved through consistent management and organization of its various functions (e.g. development, review and revision of regulations and guides). Authorization, inspection and enforcement are among the core functions of a regulatory body for safety and security. Requirements with respect to the responsibilities and functions of a regulatory body for safety are established in GSR Part 1 (Rev. 1) [2] and GSR Part 3 [1]. Recommendations on meeting the requirements relating to the core functions of a regulatory body for safety and the associated processes to implement those functions are provided in GSG-13 [4]. Recommendations and guidance on the responsibilities and functions of a regulatory body for security can be found in IAEA Nuclear Security Series Nos 14 [6] and 11-G (Rev. 1) [7].

In fulfilling its statutory obligations, the regulatory body defines policies, principles and criteria as a basis for its regulatory activities, including authorization and inspection processes, and enforcement actions. Authorization, inspection and enforcement activities are based on applicable laws, regulations and guides.

The regulatory body responsible for control of safety and security needs to appropriately coordinate and cooperate with other competent authorities with specific responsibilities related to safety and security, as stated in GSR Part 3 [1], in Requirement 7 and para. 2.18 of GSR Part 1 (Rev. 1) [2] and in IAEA Nuclear Security Series No. 20 [5].

2.2. GRADED APPROACH

The extent of regulatory control, including notification and authorization, inspection and enforcement, needs to be based on a graded approach (i.e. the degree of control needs to be commensurate with the radiation and security risks associated with the facilities and activities with radiation sources, taking into account the likelihood and consequences of accidental exposure and of malicious acts). Details on the graded approach to regulatory control are provided in GSR Part 1 (Rev. 1) [2], GSR Part 3 [1], GSG-12 [3] and GSG-13 [4], as well as in IAEA Nuclear Security Series Nos 14 [6] and 11-G (Rev. 1) [7].

2.3. SPECIAL CIRCUMSTANCES

In the event of special circumstances, such as the COVID-19 pandemic crisis, the regulatory activities for the safety and security of radiation sources, like many other human activities, would be adversely affected. As a consequence, the implementation of the core regulatory functions could be significantly hindered. In particular, measures such as quarantines, social restrictions and physical distancing could hinder the conduct of regulatory inspections of licensees of radiation sources.

In order to ensure the effective implementation of its regulatory functions, especially the conduct of its inspection activities, the regulatory body needs to develop measures that could be introduced under such special circumstances. Accordingly, the regulatory body might consider the following:

- Carrying out only essential inspections of licensees by limiting physical visits to medium and high risk facilities and activities, including reactive inspections in response to safety incidents and accidents and security events;
- Introducing additional reporting requirements, including self-assessment of compliance with regulations and authorization conditions, and desktop reviews of information submitted by licensees;
- Collecting and analysing the additional information, if any, provided by service providers (quality control, dose rate measurements, etc.);

- Carrying out virtual inspections for the oversight of facilities and activities, including the use of video conferencing for interviews, photographs and videos taken by the licensee for observations, and collecting information electronically for review.

The appropriate protection of specific or detailed information, which could compromise the security of radioactive material, associated facilities and associated activities if disclosed, needs to be ensured.

2.4. NOTIFICATION AND AUTHORIZATION

Requirement 7 of GSR Part 3 [1] states that: “**Any person or organization intending to operate a facility or to conduct an activity shall submit to the regulatory body a notification and, as appropriate, an application for authorization.**”

GSR Part 3 [1] defines notification and authorization as follows:

- Notification: “A document submitted to the regulatory body by a person or organization to notify an intention to carry out a practice or other use of a source”;
- Authorization: “The granting by a regulatory body or other governmental body of written permission for a person or organization (the operator) to conduct specified activities.”

The objective of granting authorizations is to establish effective regulatory control for safety and security by the regulatory body throughout the lifetime of a facility or the duration of an activity.

In order to obtain the authorization, the applicant has to demonstrate to the regulatory body that facilities and activities will meet the applicable requirements for safety and security. Once the applicant has made this demonstration, the regulatory body issues the authorization. Compliance with the applicable requirements for safety and security is generally made a condition of the authorization. The person or organization receiving such permission is called the authorized party. The authorization may take the form of either a registration or a licence, based on the graded approach as specified in GSR Part 3 [1]. The authorization process, including review and assessment of an application for authorization, is discussed further in Section 4.

2.5. INSPECTION

Regulatory control includes inspections of authorized facilities and activities by the regulatory body, that is, assessment of facilities and activities for compliance with regulatory requirements provided in relevant law and regulations, and limitations and conditions specified in the authorization. An inspection may address compliance with requirements and conditions pertaining to safety, security or both.

Following an inspection, the regulatory body prepares a written inspection report with findings and provides it to the authorized party. The report includes inspection findings and identifies any actions to be taken by the authorized party in order to address deficiencies identified in the inspection. The report may also provide evidence that may be used later by the regulatory body to make decisions on enforcement actions. The inspection process, including planning for inspections, is discussed in further detail in Section 5.

2.6. ENFORCEMENT

The regulatory body, based on the national circumstances, develops and implements an enforcement policy, which establishes formal arrangements with the relevant authorities, taking into consideration a graded approach. A process needs to be considered for taking enforcement actions against an authorized party to correct and, as appropriate, penalize non-compliance with relevant law, regulations and conditions of an authorization. The application of enforcement actions strongly depends on a State's overall legal regime. The enforcement process is discussed in further detail in Section 6.

2.7. MANAGING TRANSITIONS IN REGULATORY CONTROL

When the processes of authorization, inspection and enforcement are introduced for the first time or undergo major changes, the regulatory body needs to allow for an appropriate transition period to enable regulatory staff and authorized parties to adapt to the new or revised processes. The regulatory body needs to take a proactive approach in informing applicants, authorized parties and all others involved in ensuring safety and security about new or updated requirements, for example by sending information letters and conducting information meetings.

3. MANAGEMENT AND ORGANIZATION

3.1. INTEGRATED MANAGEMENT SYSTEM

The regulatory body has to administer its processes for regulatory control through an integrated management system. This management system needs to include notification, authorization, inspection and enforcement as core processes. The requirements for establishing, implementing, assessing and continuously improving a management system that integrates safety, health, environmental, security, quality, and human and organizational factors, as well as societal and economic elements, are established in IAEA Safety Standards Series No. GSR Part 2, Leadership and Management for Safety [18], and in Requirement 19 of GSR Part 1 (Rev. 1) [2].

The management system of the regulatory body has the following three purposes:

- (1) To ensure that the responsibilities assigned to the regulatory body are properly discharged;
- (2) To maintain and improve the performance of the regulatory body by means of the planning, control and supervision of its safety and security related activities;
- (3) To foster and support a safety and security culture in the regulatory body through the development and reinforcement of leadership as well as good attitudes and behaviour in relation to safety and security on the part of individuals and teams.

Requirement 3 of GSR Part 2 [18] states that: “**Senior management shall be responsible for establishing, applying, sustaining and continuously improving a management system to ensure safety.**”

Examples of process descriptions for an integrated management system, including the processes of notification, authorization, review and assessment, inspection and enforcement are provided in the annex to GSG-12 [3]. These processes are carried out using specific procedures.

In accordance with GSG-12 [3], the regulatory body needs to develop procedures and criteria for evaluation of its efficiency and performance. Such procedures may include different tools for evaluation (internal and external), including self-assessment, review of authorization decisions and inspection results, feedback from the public, review of results of appeals of regulatory decisions, and government audits. Additional details on regulatory body performance management are provided in table A–3 of GSG-12 [3]. Evaluation

tools may also include international peer review missions, such as the International Physical Protection Advisory Service and the Integrated Regulatory Review Service, both conducted by the IAEA. The regulatory body also needs to develop action lists for improving the performance of regulatory functions in response to identified deficiencies. Such lists prioritize steps for improving regulatory functions and provide for monitoring of results and deadlines.

3.2. STRUCTURE OF THE REGULATORY BODY

Recommendations on the roles and responsibilities within the regulatory body are provided in para. 4.61 of GSG-12 [3]. In efficiently exercising its regulatory functions, the regulatory body needs to clearly define the responsibilities assigned to the units of its organization. The organizational structure of the regulatory body may be arranged in accordance with any of several bases, such as the following:

- Regulatory functions (a process based organizational structure), for example with separate units responsible for authorization, for inspections and for other functions, such as finance and technical support;
- Technical areas to be covered (a line organizational structure), for example with separate units responsible for safety, for security and for any other technical areas, such as safeguards;
- Types of facility and activity regulated (a practice based organizational structure), for example with separate units responsible for medical practices and for industrial practices, respectively;
- A mixture of these (a matrix or project organizational structure).

In order for the regulatory body to discharge its responsibilities and perform its functions effectively, it may be appropriate to establish an organizational structure that is flexible and adaptable to different circumstances and demands, and that also evolves over time.

3.3. COORDINATION AMONG MULTIPLE REGULATORY BODIES AND OTHER AUTHORITIES

In many cases, the regulation of facilities and activities is spread across several organizations. Where several authorities have regulatory responsibilities for safety and security, legislation needs to establish clear lines of authority and responsibility so as to avoid gaps, overlaps and conflicts. The various regulatory

bodies and other authorities need to formally establish a system of liaison and working arrangements and procedures so as to ensure an appropriate degree of coordination and cooperation.

A particular need for coordination may arise in connection with inspections. For example, joint inspections for radiation protection and fire protection may be conducted. Similarly, inspections with respect to medical practices may include inspectors from the regulatory body for radiation protection and from the ministry of health.

There are a number of different organizations with which the regulatory body might need to coordinate, including the following:

- The customs authorities ensuring the implementation and enforcement of legislation on imports and exports;
- The authority responsible for controlling imports and exports of radioactive sources (if other than the regulatory body);
- Civil defence authorities managing nuclear and radiological emergencies;
- The food and agriculture authority controlling radioactivity in foodstuffs, fertilizer production and food irradiation;
- Fire protection authorities;
- The competent authority for transport;
- Intelligence and security agencies;
- Police involved in emergency response, in providing assistance during an inspection and in case of prosecution;
- Environmental authorities setting standards related to the protection of the environment.

The liaison might be necessary in the authorization process, as in the following examples:

- Appropriate fire protection needs to be ensured before using a radioactive source;
- The import of a radioactive source posing a significant risk requires appropriate authorization of a practice before the source enters the State, taking into account coordination with other States consistent with the IAEA Code of Conduct on the Safety and Security of Radioactive Sources [8] and its supplementary Guidance on the Import and Export of Radioactive Sources [9].

In particular, a process of authorization needs to ensure that, where an authorization bears on the responsibilities of other governmental agencies or

regulators, they are informed when the regulatory body grants, refuses, amends, revokes or suspends an authorization.

The liaison might be related to the inspection process, for example:

- The competent authority for transport might share information on the transport route related to a source, in order to facilitate inspection conducted by the regulatory body for safety and security of radioactive material;
- The customs, police and regulatory body for safety and security might conduct a joint inspection related to orphan sources at the State borders.

The regulatory body needs to establish an organizational structure that is conducive to the efficient exercise of regulatory functions. Where safety and security functions are shared between several authorities, their respective roles and responsibilities need to be clearly stated in legislation or memoranda of understanding in order to avoid potential gaps, overlaps and conflicts. For example, responding to the loss of a radioactive source may involve cooperation between the regulatory body responsible for authorization and inspection of the facility where the source was lost, the customs authority and the police. Similar arrangements may need to be established for orphan source discovery and other types of safety and nuclear security event. In such cases, arrangements for jointly conducted security inspections may be appropriate.

Memoranda of understanding among regulatory bodies and other authorities, as applicable, are a useful tool to facilitate coordination and cooperation. An example of a memorandum of understanding is provided in Annex VII. Additional guidance on developing regulations and associated administrative measures for nuclear security is provided in IAEA Nuclear Security Series No. 29-G [19].

3.4. RESOURCE MANAGEMENT

The regulatory body's senior management has to ensure that essential resources are identified and made available. Such resources include financial resources, human resources, information and knowledge, and other resources, as appropriate. The role and responsibilities of managers of a regulatory body do not differ greatly from roles and responsibilities of managers in other organizations. Essentially, these responsibilities involve managing their own organizational units in compliance with the integrated management system and in accordance with the mission, policies, strategies and plans laid out by senior management. Recommendations on roles and responsibilities of managers are provided in GSG-12 [3].

In particular, management of the regulatory body has the responsibility and authority to recruit and retain sufficient staff with the necessary skills and technical expertise to carry out assigned regulatory functions. Such necessary skills and expertise include the following:

- Competence in the relevant scientific and technical areas;
- Competence with regard to the facilities and activities of authorized parties;
- Competence in applying the regulatory processes in accordance with the legislative and regulatory framework, ethical principles and codes of conduct for regulatory staff.

An example of a code of conduct for inspectors, taking into account their responsibilities as defined in GSR Part 1 (Rev. 1) [2] and GSG-13 [4], is provided in Annex VI.

Managers also have to pay due attention to procurement of appropriate equipment and devices to carry out authorization, inspection and enforcement activities (e.g. IT equipment, cars for inspections, personal protective equipment, radiation detection instrumentation — including survey meters and individual dosimeters), as well as to the availability of technical support organizations such as dosimetry and calibration services.

If the regulatory body is collecting fees for its functions (e.g. authorization fees or fees for authorization maintenance), appropriate financial policies need to be established and followed in order to ensure that financial operations with such fees are transparent.

3.5. SAFETY AND SECURITY CULTURE

Requirement 12 of GSR Part 2 [18] states that: “**Individuals in the organization, from senior managers downwards, shall foster a strong safety culture. The management system and leadership for safety shall be such as to foster and sustain a strong safety culture.**”

Expected attitudes and behaviours (including those of external experts and technical support organizations, if any) that promote a strong safety culture have to be defined and communicated throughout the regulatory body. Recommendations related to safety culture in the regulatory body are provided in GSG-12 [3].

IAEA Nuclear Security Series No. 20 [5] indicates that the regulatory body has to develop, foster and maintain a robust nuclear security culture. IAEA Nuclear Security Series No. 14 [6] indicates that all organizations and individuals involved in implementing nuclear security need to give due priority to the development and maintenance of a nuclear security culture with regard to

radioactive material so as to ensure its effective implementation across the entire organization. Guidance related to nuclear security culture is provided in IAEA Nuclear Security Series No. 7 [20].

3.6. MANAGEMENT OF NOTIFICATION AND AUTHORIZATION

The management of notification and authorization processes is one of the core functions of the regulatory body and is described in detail in GSG-13 [4]. The responsibilities of the manager who leads a notification and authorization unit or is responsible for notification and authorizations include the following:

- Ensuring his/her own knowledge of authorization duties is adequate;
- Selecting a sufficient number of appropriate persons to be trained as authorization staff;
- Establishing the appropriate priorities for scheduling notification and authorization activities;
- Developing procedures and guidelines for notification and authorization staff, including the review and assessment of applications;
- Developing guidelines for applicants;
- Determining the other resource requirements for the notification and authorization function for inclusion in the regulatory body's annual budget;
- Managing information with respect to notification and authorization;
- Coordinating notifications and authorizations with inspections;
- Providing authorization staff with feedback from inspections;
- Providing necessary information to inspectors, external experts and technical support organizations;
- Providing for initial and refresher training of authorization staff;
- Liaising internally and externally in relation to inspection and enforcement.

The number and expertise of authorizing staff is discussed in Subsection 3.10. The authorization of higher risk practices (e.g. radiotherapy) generally involves a high level of expertise. Accordingly, authorization staff are usually specialized, to the extent feasible. For example, there could be specific staff assigned to conduct authorizations involving radiotherapy, industrial radiography, well logging and nuclear medicine, recognizing that in smaller regulatory bodies such specialization may not be feasible.

The manager of the notification and authorization function needs to be responsible for ensuring that every notification and application for authorization is processed in a timely manner, consistent with applicable legislation and regulations and internal guidance and procedures. For each authorization, a staff

member needs to be designated to conduct the review and assessment, to prepare the proposed authorization decision (e.g. to grant or refuse the application), and to document the process in the regulatory body's information management system. Depending on the regulatory body's practice and the type of facility or activity involved, the designated staff member may make the final authorization decision or propose the decision to be approved at a higher level within the regulatory body.

As notification and authorization are processes which require clear and consistent communication between the regulatory body and the applicant, a systematic approach to this communication is essential. The use of standardized forms for notification and application for authorization such as those provided in Annexes I and II enables this. The use of forms facilitates gathering the necessary information to be used by the regulatory body in its decision making processes. The forms in Annexes I and II reflect the IAEA safety standards and other international guidance. The regulatory body could prepare guidance based on these forms for the use of applicants and regulatory body staff.

Authorization of complex facilities may be carried out in several steps, as described in para. 3.115 and appendix II of GSG-13 [4]. Examples include industrial irradiators and facilities where industrial radiography, nuclear medicine or radiotherapy practices are conducted. In such cases, the regulatory body may require the operator to apply for and obtain authorization to construct the facility before construction can begin. The regulatory body may also prohibit the procurement of radiation sources (including their import from the State of origin) until a particular stage of construction has been completed and the safe and secure storage of sources can be ensured. The authorization process may also be subdivided into various steps (e.g. acceptance tests and commissioning), for which the regulatory body may ask for additional information before the subsequent steps of the authorization process can be completed.

If the authorization process is being introduced for the first time, the regulatory body's resources generally have to be directed to authorizing those facilities and activities that present the most significant risks, such as those involving higher category radioactive sources.

The preparation of an annual programme for authorization by a manager of the authorization function needs to be considered, in order to ensure appropriate staffing and resources are made available, based on anticipated authorization activities during the coming year.

3.7. MANAGEMENT OF INSPECTION

An inspection is an assessment by the regulatory body of an authorized party's compliance with requirements provided in legislation, regulations or authorization conditions. Inspections have to be carefully coordinated across the various functions of the regulatory body. Sound management of the inspection process is critically important, both to ensure that inspections accurately identify instances of non-compliance and the resulting risks and to ensure that inspections are conducted professionally and impartially so as to withstand challenges from authorized parties or others.

Inspection activities may be under the responsibility of a single organizational unit within the regulatory body or spread across multiple units. The responsibilities of the manager who leads an inspection unit or is responsible for the inspection function usually include the following:

- Ensuring his/her own knowledge of inspection duties is adequate.
- Selecting a sufficient number of appropriate persons to be trained as inspectors.
- Establishing the appropriate priorities for scheduling inspection activities (i.e. preparing the inspection programme).
- Developing procedures for inspectors, including practice specific checklists.
- Determining whether an inspection will be announced or unannounced.
- Determining the other resource requirements for the inspection programme (e.g. purchase and calibration of survey meters; expenses associated with the use of dosimetry services; inspectors' travel, accommodation and incidentals) for inclusion in the regulatory body's annual budget.
- Coordinating inspections with those responsible for assessing authorization applications and renewals.
- Managing information with respect to inspections.
- Ensuring that corrective actions arising from inspections are followed up in a timely manner.
- Keeping all inspectors informed of inspection results for learning purposes.
- Providing for initial and refresher training of inspectors.
- Coordinating joint inspections (e.g. with other regulatory bodies).
- Coordinating with external experts and technical support organizations when necessary (e.g. when the technical support organization is performing sampling during an inspection).
- Liaising with legal support on guidance for enforcement actions.

As with authorization, if the regulatory process is being introduced for the first time, the regulatory body's inspection effort generally has to be directed to

those facilities and activities that present the most significant risks, such as those involving higher category radioactive sources.

Inspectors need to have appropriate experience and expertise in all relevant areas, including the subject matter (safety and/or security as applicable), inspection techniques (e.g. document review, observation, interviewing, testing and measurement), legal and regulatory requirements and authorization conditions, ethical obligations, collection and management of evidence, report preparation, and the regulatory body's policies and practices. As with authorization staff, inspectors of high risk practices (e.g. radiotherapy) are usually specialized, to the extent feasible. At a minimum, all inspectors have to be familiar with the types of facility and activity that they inspect. Qualification of inspectors is further discussed in Subsection 3.10.

Different types of inspection are described elsewhere, for example in GSG-13 [4]. Different preparations are necessary for different types of inspection. Each inspection needs to have a well defined goal which determines not only the course of the on-site inspection but also the whole inspection process including its preparation as well as enforcement activities.

Inspections provide an opportunity not only to assess compliance with regulatory requirements but also to assess the safety and security culture of the authorized party, using indicators such as the following:

- Quality of housekeeping;
- Financial stability;
- Sufficiency of staffing;
- Turnover of staff;
- Adequacy of record retrieval systems;
- Specification of investigation levels;
- Procedures to be followed when investigation levels are exceeded;
- Adequacy of staff training;
- Provision for retraining of staff;
- Levels of occupational exposure.

The regulatory body has to prepare inspection procedures covering the entire inspection process. These procedures need to address the following:

- Preparing the inspection programme and scheduling the inspections;
- Designating inspectors or an inspection team for specific inspections;
- Planning for an inspection (e.g. how to announce an inspection, involve technical support organizations and cooperate with the authorization unit);
- Conducting inspections (e.g. how to conduct entrance meeting, perform measurements and take evidence);

- Documenting inspection results (e.g. preparation of an inspection report, dissemination of results and management of evidence collected at an inspection);
- Conducting follow-up activities related to results of inspections (e.g. monitoring of corrective actions and referral to enforcement process, as appropriate);
- Preparing analyses of inspection results (e.g. identifying trends and patterns).

Inspection findings have to be documented in an inspection report. The findings have to be reported to the authorized party. The report and all documentary evidence (e.g. photographs) have to be filed in the regulatory body's information management system.

The effectiveness and efficiency of the inspection programme is subject to periodic assessment by the regulatory body. It is expected that the regulatory body compiles and analyses data on the performance of authorized parties using findings of inspections, identifying generic issues and making arrangements to enable all inspectors and authorization staff and others, as appropriate, to meet, to exchange views and to discuss findings and issues. The regulatory body's continuous improvement programme has to identify potential areas for improvement in the performance of authorized parties and in regulatory processes. The reports of such assessments and analyses have to be shared and communicated within the regulatory body as well as externally, as appropriate. Some regulatory bodies publish reports on generic issues identified during inspections such as non-compliances identified during inspections of disused sources, either in printed form or on the regulatory body's website.

In some States, inspectors have responsibilities in the authorization process, particularly in the case of authorization of sources posing a significant risk or complex practices. This is an opportunity for the regulatory body to verify the contents of the documents submitted by means of inspection of the site where the radiation sources are to be installed or used. These inspections will also allow the regulatory body to verify the adequacy of safety and security arrangements and to extend its practical understanding of the managerial, engineering and operational aspects of the practice. Such a visit has some of the characteristics of an inspection and is usually referred to as a pre-authorization visit or a pre-authorization inspection.

3.8. MANAGEMENT OF ENFORCEMENT

Enforcement actions are intended to encourage compliance with the requirements for safety and security and correct non-compliance. With respect to

the establishment and implementation of an enforcement policy by the regulatory body, paras 4.54–4.60 of GSR Part 1 (Rev. 1) [2] state:

“4.54. The response of the regulatory body to non-compliances with regulatory requirements or with any conditions specified in the authorization shall be commensurate with the significance for safety of the non-compliance, in accordance with a graded approach.

“4.55. Enforcement actions by the regulatory body may include recorded verbal notification, written notification, imposition of additional regulatory requirements and conditions, written warnings, penalties and, ultimately, revocation of the authorization. Regulatory enforcement may also entail prosecution, especially in cases where the authorized party does not cooperate satisfactorily in the remediation or resolution of the non-compliance.

“4.56. At each significant step in the enforcement process, the regulatory body shall identify and document the nature of non-compliances and the period of time allowed for correcting them, and shall communicate this information in writing to the authorized party.

“4.57. The authorized party shall be held accountable for remedying non-compliances, for performing a thorough investigation in accordance with an agreed timetable and for taking all the measures that are necessary to prevent recurrence of the non-compliances.

“4.58. The regulatory body shall establish criteria for corrective actions, including enforcing the cessation of activities or the shutting down of a facility where necessary. On-site inspectors, if any, shall be authorized to take corrective action if there is an imminent likelihood of safety significant events.

“4.59. In the event that unforeseen radiation risks are identified, whether or not they are due to non-compliances with regulatory requirements or authorization conditions, the regulatory body shall require the authorized party to take appropriate corrective actions to reduce the risks.

“4.60. Finally, the regulatory body shall confirm that the authorized party has effectively implemented any necessary corrective actions.”

A State’s system of enforcement strongly depends on its national legal system. The management of the regulatory body needs to ensure that authorization

staff and inspectors are familiar with the availability of enforcement actions and the overall process and responsibilities for taking enforcement action. In some States, at least some enforcement actions may be taken directly by inspectors. In most States, significant enforcement actions involve the support of regulatory body's management and legal support. The use of external legal support in connection with enforcement activities is discussed in Subsection 3.13.

The management of the regulatory body needs to develop an enforcement policy with the assistance of legal advisers and in accordance with national regulation. It is a good practice to provide guidance for authorization staff and inspectors regarding the process and decision criteria for the selection of enforcement actions. Application of the graded approach to enforcement action is discussed in Section 6.

The enforcement policy of the regulatory body needs to include guidelines on the following:

- Enforcement actions to be applied;
- Procedures for each type of enforcement action;
- Uses of external legal support;
- Procedures for submission of violations and non-compliances to court, appeals and hearing in court.

3.9. INDEPENDENCE OF THE REGULATORY BODY

Requirement 17 of GSR Part 1 (Rev. 1) [2] states that: **“The regulatory body shall perform its functions in a manner that does not compromise its effective independence.”**

With respect to security, para. 3.6 of IAEA Nuclear Security Series No. 14 [6] recommends (italics omitted):

“The State should designate one or more competent authorities, including a regulatory body, for the establishment, implementation and maintenance of a nuclear security regime, which have a clearly defined legal status and independence from the operator...and which have the legal authority to enable them to perform their responsibilities and functions effectively.”

In particular, the regulatory body has to be effectively independent in its decision making and needs to have functional separation from entities having responsibilities or interests that could unduly influence its decision making. In addition, each staff member of the regulatory body involved in decision making in authorization, inspection or enforcement processes has to be vigilant to conduct

the tasks without being subject to such influence; for example, authorization staff cannot be involved in the decision to authorize a particular facility or activity if the staff cannot demonstrate independence from the applicant. The regulatory body needs to develop and apply procedures to identify and promptly resolve any conflict of interest. The staff of the regulatory body have to perform their functions in relation to safety and security without reference to any personal views. The competence and professionalism of staff is a necessary element in achieving effective independence in decision making by the regulatory body.

With respect to the effective independence of the regulatory body, paras 4.8 and 4.9 of GSR Part 1 (Rev. 1) [2] state:

“To maintain the effective independence of the regulatory body, special consideration shall be given when new staff members are recruited from authorized parties, and the independence of the regulatory body, regulatory aspects and safety considerations shall be emphasized in their training. The regulatory body shall ensure that its staff operate professionally and within its remit in relation to safety.

“To maintain its effective independence, the regulatory body shall ensure that, in its liaison with interested parties, it has a clear separation from organizations or bodies that have been assigned responsibilities for facilities or activities or for their promotion.”

The regulatory body needs to develop and apply procedures to ensure that, when technical support organizations or external experts are involved in authorization or inspection processes, their independence from the applicant or authorized party is demonstrated.

In some States, the regulatory body provides technical services to authorized parties. For example, the regulatory body might operate calibration laboratories for radiation measuring instruments or dosimetry services for the measurement of occupational radiation doses. When such functions are undertaken, the regulatory body needs to ensure that any conflict with its main regulatory functions is avoided and that the prime responsibility of the authorized party for safety and security is maintained. Management of the regulatory functions and of such technical support services has to be located in separate organizational units within the regulatory body.

3.10. HUMAN RESOURCES

As recommended in GSG-12 [3], human resource management is one of the supporting processes in the regulatory body's integrated management system. The regulatory body has to employ a sufficient number of personnel with the necessary qualifications, experience and expertise to undertake its functions and responsibilities. The numbers of persons necessary to perform the authorization, inspection and enforcement functions need to be determined according to the expected workload. Although the resources needed by a regulatory body for authorization, inspection and enforcement depend essentially on the number, complexity and risks of current and planned facilities and activities, the resources needed may also depend on legislation and other factors, such as the involvement of external experts and distances to be travelled to conduct inspections.

The regulatory body may analyse the national register of radiation sources in order to estimate the staff resources needed to properly perform its authorization and inspection functions. The national register will indicate the number of radiation sources under regulatory control as well as the numbers of premises involved and the geographical locations of those premises. Figure 1 in IAEA-TECDOC-1525 [12] presents an example of a process to determine the number of staff required by a regulatory body to review and assess applications for authorization for different types of radiation practice and categories of radioactive source. The example process presented in figure 1 in IAEA-TECDOC-1526 [13] might be used for determining the number of staff required for inspection activities. Table 3 in Subsection 5.3 of the present publication suggests a frequency of inspection for different facilities and activities that might be used for this purpose.

Workload planning is a continuous process as staffing needs can change over time owing to a variety of influences (e.g. building new radiotherapy units in the State, increasing use of radioactive sources in industry, changing requirements related to the validity of authorizations). Workload estimates also have to take into consideration unplanned authorizations, unplanned inspections, annual leave, training and staff development.

Authorization and inspections can be carried out by one person or by a team. In most cases, authorization is performed by a single individual, except in the case of very complex facilities. In some States, a single inspector carries out inspections of a simpler nature and a team of two or more inspectors undertakes inspections of more complex facilities. It is good practice, at least in the developmental stage of the inspection programme and in order to train new inspection personnel, for inspectors to work in pairs. For a State with a limited number of radiation sources, two persons might be appropriate for all inspections.

Other considerations for staffing may include the following:

- Non-routine tasks to be performed by staff, such as drafting regulations, preparation of guidelines and involvement in emergency preparedness and response;
- Available budget;
- Recruitment of new staff and succession planning;
- Verification of trustworthiness through background checks and other means.

As important as the number of personnel needed are staff qualification, experience and training. Staff of the regulatory body who have responsibility for reviewing and assessing applications for authorization, conducting inspections and taking enforcement actions need to have relevant qualifications and appropriate training in the fundamentals of safety and security. Additional qualifications in a science related discipline or in engineering are often appropriate. However, further training in the implementation of a regulatory programme for radiation sources is essential. In other words: training in being a regulator is necessary in addition to a sound scientific or engineering education. Such training is usually focused on the following:

- Practices to be regulated, in particular training related to the particularities of the practices using radiation sources;
- Regulatory processes, including national regulations, policies, procedures and guidance (e.g. for assessment of applications for authorization).

The level and depth of training of regulatory staff will depend on potential risks associated with the regulated radiation practices and facilities in the State. The regulation of high risk practices involves a high level of expertise, and it is appropriate that regulatory staff with responsibilities for such practices is highly specialized (e.g. authorization staff and inspectors for radiotherapy).

The development of regulatory staff expertise also depends on the regulatory process or processes they are to conduct. In most cases, separate staff are responsible for authorization, inspection and enforcement. In some cases, particularly in regulatory bodies with small regulatory frameworks, the same staff may be responsible for performing multiple regulatory functions. In the former instance, at least some training can be specialized based on staff role. In the latter instance, the staff performing multiple roles will need training that is pertinent to all of them.

Recommendations related to qualification and training of personnel are provided in GSG-12 [3]. The IAEA has developed information on the training needed for staff responsible for authorization and inspection. For example,

a comprehensive list of subjects related to safety to be covered in the training programme for inspectors is provided in IAEA-TECDOC-1526 [13]. This compilation indicates that inspectors are expected to be able to: (1) make a quick assessment of external and internal doses; (2) use radiation monitoring instrumentation; and (3) assess compliance with the law and enforcement procedures. Also, security issues need to be covered in training programmes for the regulatory staff, as appropriate.

Retraining of the staff is needed to keep their expertise, particularly their expertise in specialized areas, such as radiotherapy and use of industrial irradiators, current and at the appropriate level. The regulatory body needs to establish policies regarding not only initial qualification but also retraining, for example: training of inspectors at least once every five years.

In addition to qualification and training using relevant practical exercises, formal training needs to be supplemented by on the job training and closely supervised work activities, so that authorization staff and inspectors are made aware of all technical aspects of each practice and radiation source that they authorize or inspect. Use of new media (e.g. videos) can supplement such training.

Staff conducting security authorization and inspections need to have specialized training in security, consistent with qualification requirements established by the regulatory body's management.

Staff may also benefit from rotating between authorization or inspection duties for different kinds of facilities and activities to broaden their experience and improve staff utilization, particularly where they can learn from staff with specialized knowledge of specific practices and radioactive sources.

The regulatory body needs to keep up to date records of the qualifications earned and training completed by its staff. Such records may be used to track needs for training and schedule appropriate courses.

3.11. GUIDANCE AND PROCEDURES

In order to ensure a systematic and consistent approach to regulatory control, the regulatory body develops guidance and procedures, for both its own staff and the interested parties. Such guidance and procedures have to be based on a graded approach, such that the level of detail and stringency of control is proportionate to the risk, consistent with national legislation.

The regulatory body is expected to make all guidance and procedures publicly available, unless security or other considerations require confidentiality. Publication of guidance and procedures is an important aspect of communication with the regulated community and other interested parties. Such openness

demonstrates that the regulatory body is discharging its responsibilities in an appropriate manner.

At a minimum, the regulatory body has to develop guidance and procedures for performing each of the core regulatory functions: authorization, inspection and enforcement. Such guidance and procedures could be either generic (covering all practices) or practice specific. In addition, the regulatory body may consider developing supporting procedures to address topics such as the following:

- Performing measurements at the location of inspections, including use of suitable meters for the purpose, measurement or sampling techniques, data to be collected, templates for the measurements and guidance on when measurements are needed;
- Conducting performance tests of security equipment and security systems, as part of the inspection process;
- Involving external experts and technical support organizations in the processes of authorization, inspection and enforcement;
- Liaison with other regulatory bodies and governmental authorities, in connection with jointly conducted activities, such as inspections.

3.12. INFORMATION MANAGEMENT SYSTEM

As part of its integrated management system, the regulatory body needs to develop and maintain an information management system for managing all data and documents generated in exercising the notification, authorization, inspection and enforcement functions.

The information management system could be integrated with, or linked to, other information systems that are maintained by the regulatory body or other governmental authorities. For example, if the regulatory body uses the Regulatory Authority Information System (RAIS), then this system may be part of the information management system. Alternatively, some regulatory bodies may choose to use the Regulatory Authority Information System as the basis for their entire information management system. As another example, if a different authority or external expert organization manages the national register of radioactive sources, then the regulatory body could establish an interface between such register and the regulatory body's information management system, in order to efficiently exchange information.

The information management system has to ensure the integrity and security of records, including secure backup of electronic data and proper management of paper documents. The system needs to have quality control features, such as automated indication of deadlines for authorization steps or corrective actions, in

order to ensure consistency in regulatory processes. The regulatory body needs to have a clear policy related to access to information within the system (whether in paper or digital form) in accordance with national legislation (such as access to information of public interest and requirements for protection of classified, confidential and personal information) and related to the management of records and to the information management system as a whole.

The information management system is also expected to contain data related to other functions of the regulatory body (e.g. records of the qualifications of and training completed by its staff and dose records of inspectors).

Information can be stored in digital and/or paper form. Some of the records may need to be kept for as long as several decades or more. Staff background checks and other forms of trustworthiness verification need to be applied to ensure that the security of the information management system is not compromised.

3.13. ACCESS TO EXTERNAL EXPERTISE, INCLUDING LEGAL SUPPORT

The regulatory body may need the support of external experts on various issues related to notification, authorization, inspection and enforcement. Potential forms of such support are provided in para. I.3 of GSG-12 [3] and could include, for example, certified testing and analytical laboratories as well as financial organizations and legal support. The processes for obtaining such external expertise are supporting processes in the integrated management system and are described in detail in GSG-12 [3].

3.13.1. Advisory committees

The government or the regulatory body may choose to give formal structure to the processes by which expert opinion and advice are provided to the regulatory body by establishing one or more advisory committees. The need for such committees is determined by many factors, such as the nature and level of expertise available within the regulatory body. In establishing advisory committees, the regulatory body has to take into account the need to maintain its independence on matters concerning safety and security. Therefore, it is necessary that the regulatory body prepare clearly defined terms of reference and specific criteria for the selection of advisory committee members, based on qualifications and expertise. Nominees have to be appointed on the basis of satisfying these criteria; they cannot represent any interested party or professional association. To avoid any conflict of interest, it is necessary that advisory committee members be required to formally disclose any personal or business interests in any

matters under consideration by the committee and refrain from participation in discussions relating to those matters.

In accordance with para. 4.22 of GSR Part 1 (Rev. 1) [2], obtaining advice from the advisory committee(s) does not relieve the regulatory body of its responsibilities for decision making.

3.13.2. Legal support

It is necessary that the regulatory body have access to legal advice for a range of matters in relation to notification, authorization, inspection and enforcement.

In connection with the authorization process, the regulatory body may need legal advice for a range of matters, such as the following:

- Ensuring the validity of conditions, restrictions or limitations that might be included in authorizations;
- Reviewing refusals of applications for authorization.

The regulatory body needs to consider seeking appropriate legal advice when making decisions, particularly when refusing applications for authorization, as a decision to refuse an application may result in an appeal by the applicant, with potentially lengthy and costly legal action. The rights of the applicant to seek reconsideration or appeal of a regulatory decision have to be clearly articulated in the decision letter, as appropriate. An example of a certificate form for authorization is provided in Annex IV.

In relation to inspection and enforcement, the regulatory body may need legal advice for a range of matters, such as the following:

- Legal bases and permissible scope of an inspection;
- Inspectors' rights of access to information and facilities, and any limitations thereon;
- Instructions on evidence collection and interview procedures during an inspection;
- Inspector's rights to require authorized parties to take immediate corrective action(s) to address a safety hazard or security vulnerability identified during the course of an inspection;
- Advice on activities to be undertaken after an inspection (e.g. whether there is sufficient reason to take an enforcement action);
- Advice on whether there are indications of criminal violations that may justify criminal investigation.

Legal advice and support may also be necessary if inspectors are prevented by authorized parties from carrying out their duties. For example, if the inspection was announced, but upon arrival the inspector finds that the facility is closed and the inspection is not possible, the regulatory body might need to determine its legal rights for immediate access.

In the case of serious breaches, it is necessary that the regulatory body consider referring the case to the designated entity for further investigation and, as appropriate, prosecution. Depending on the State, that entity might be internal to the regulatory body or might be the police, public prosecutor, ministry of justice or other governmental authority.

3.13.3. External experts and technical support organizations

Consistent with national legislation, the regulatory body might involve qualified individual experts or technical support organizations in some aspects of the authorization or inspection processes to give advice on particular safety or security matters. The need for such advice may most often arise where the issues are novel or complex and personnel with the necessary expertise are not available within the regulatory body. Under such circumstances, delegating decision making responsibility to the external experts is not appropriate. The regulatory body has to retain full responsibility for reaching regulatory decisions, such as granting or refusing applications for authorization.

If external expertise is used by the regulatory body, it is necessary to establish procedures for determining when and how such expertise is acquired and applied. For example, such procedures might specify when the regulatory body engages external experts to evaluate the applicant's supporting documents for the authorization of complex facilities, such as radioactive source manufacturing facilities, where the review and assessment needed is beyond the capacity of the regulatory body. The regulatory body would then review the results of the experts' evaluations in order to decide whether to grant the authorization. For more routine applications, review by external experts might not be necessary.

The regulatory body might also involve external experts and technical support organizations in the inspection processes, for example to take samples and make measurements of contamination.

4. NOTIFICATION AND AUTHORIZATION PROCESS

4.1. INTRODUCTION

This section describes the process by which an applicant for authorization notifies the regulatory body of its intention to operate a facility or conduct an activity and obtains permission to do so from the regulatory body. The authorization process is the principal means by which the regulatory body assumes regulatory control of a radiation source. Authorization can take the form of either registration or licensing. Registration is a form of authorization for facilities or activities of low or moderate risk. Licensing is the form of authorization for other facilities or activities. In either case, the facility or activity may be authorized with conditions or limitations, as appropriate. The requirements for safety assessment and the conditions or limitations applied to the facilities or activities would be less stringent for registration than for issuing a licence. Recommendations on registration are provided in GSR Part 3 [1]. The regulatory body will determine which facilities and activities may obtain authorization by registration only and those for which a licensing process is required.

4.2. NOTIFICATION

Paragraph 3.7 of GSR Part 3 [1] states (footnote omitted):

“Any person or organization intending to carry out any of the actions specified in para. 3.5 [of GSR Part 3] shall submit a notification to the regulatory body of such an intention. Notification alone is sufficient provided that the exposures expected to be associated with the practice or action are unlikely to exceed a small fraction, as specified by the regulatory body, of the relevant limits, and that the likelihood and magnitude of potential exposures and any other potential detrimental consequences are negligible.”

The regulatory body needs to specify the information to be submitted in the notification. An example notification form is provided in Annex I.

Upon receipt of a notification, the regulatory body needs to inform the operator whether or not an authorization is required. If an authorization is required, the regulatory body informs the operator about the content required to be included in an application. The regulatory body needs to have established a tracking system to manage all incoming notifications.

4.3. AUTHORIZATION

Where notification alone is insufficient, based on criteria specified by the regulatory body as described above, the regulatory body will require the operator to apply for and obtain an authorization. For example, the regulatory body may require practices involving category 1, 2 or 3 radioactive sources to be authorized, based on safety and security considerations. Additional guidance in this area can be found in the IAEA Code of Conduct on the Safety and Security of Radioactive Sources [8]. For practices requiring an authorization, the regulatory body may provide that an application for authorization also serves as notification.

The regulatory body needs to establish procedures for granting authorizations. These procedures follow a graded approach and at a minimum address the following topics, organized according to the type of authorization (registration or licence) and the type of authorized facility or activity:

- The information and any supporting materials to be provided by the applicant, as detailed in the application form for authorization;
- The principles and associated criteria on which requirements, judgements and decisions of the regulatory body are based;
- The time period within which the regulatory body will reach a decision;
- The term of the authorization;
- The process for appeal by the applicant of an adverse decision.

4.3.1. Application for authorization

For complex facilities or activities, the regulatory body may consider implementing a preparatory phase before the applicant submits an application, in order to make clear to the applicant the requirements for safety and security that have to be met and the authorization process which has to be followed. Recommendations in this area can be found in GSG-13 [4].

In the authorization process, the applicant needs to demonstrate compliance with all the requirements for safety and security. To assist the applicant in making the necessary demonstration, the regulatory body may provide guidance on each type of practice and, if relevant, on necessary security measures, including the contents of the security plan to be submitted as part of the application.

This guidance provides a clear statement of the regulations and standards to be applied throughout the lifetime of the facility or the duration of the activity, as well as clear descriptions of the format and content of the documents to be submitted by the applicant, including printed or electronic forms. Recommendations on this topic are provided in para. 3.30 of GSG-13 [4]. Also,

an example of practice specific guidance for the content of applications for authorization with references to IAEA publications is provided in Annex II.

4.3.2. Safety–security interface

In many States, a single regulatory body is responsible for regulatory control with respect to both safety and security. In such cases, the regulatory body may conduct authorization as a single, integrated process covering both subjects. In some of these States, the regulatory body’s authorization process for safety purposes may already be in place when the authorization process is revised to cover security as well. In such cases, the regulatory body ensures that security is addressed by existing authorized parties through the amendment of existing authorizations, either as of a specified date, or when their authorizations come up for renewal. If different regulatory bodies are responsible for authorization with respect to safety and security, the regulatory bodies need to closely coordinate their authorization processes to ensure consistency in the application of the requirements for safety and security, in accordance with IAEA Nuclear Security Series No. 11-G (Rev. 1) [7]. Regardless of whether safety and security are addressed in a single authorization process or in separate authorization processes, the safety–security interface needs to be specifically addressed.

When specified by the regulatory body, based on a graded approach, a security plan is one of the documents to be submitted by the applicant to the regulatory body as part of the authorization process, in line with IAEA Nuclear Security Series No. 11-G (Rev. 1) [7].

The security plan has to document the design, operation and maintenance of the entire security system as well as the implementation of security management elements. The security plan enables the authorized party to demonstrate to the regulatory body its compliance with security requirements and provides relevant information to facility security personnel for the operation, maintenance and continuous improvement of the security system. For additional guidance on this topic, see IAEA Nuclear Security Series No. 43-T, Security Management and Security Plans for Radioactive Material and Associated Facilities [21].

Security plans may be different for mobile and portable devices using radioactive material, or for devices stored between periods of use. Security plans will contain sensitive information and need to be managed by the authorized party accordingly (see IAEA Nuclear Security Series No. 11-G (Rev. 1) [7]). Additional guidance on this topic can be found in IAEA Nuclear Security Series No. 43-T [21].

4.3.3. Receipt, review and assessment of the application

On receipt of an application, the regulatory body needs to conduct an administrative verification to ensure that the information provided is complete and adequate for technical review. If the application is not complete, the regulatory body requests that the applicant submit any information that is missing. This request may be in the form of a formal notice. The applicant is obliged to respond within a timeframe specified by the regulatory body, such as within 30 days. If no answer is received from the applicant, the regulatory body may consider issuing a further request or refusing the authorization request and undertaking enforcement actions, if applicable.

4.3.3.1. Collect inputs

The regulatory body staff responsible for authorization collect all necessary inputs in addition to the application and other documents submitted by the applicant, including the following:

- Legal and regulatory requirements, guidance and regulatory procedures specific to review and assessment, including acceptance criteria;
- Technical and other documents needed to assess compliance with the regulatory requirements and the authorization;
- National and international feedback from similar practices and outputs of other regulatory processes (e.g. inspection results, previous reviews and assessment results) as a means of mitigating any potential gaps in relevant experiences;
- Developments in international standards and research.

4.3.3.2. Establish review and assessment plan

Authorization staff establish a review and assessment plan specifying the purpose and technical scope of the review and assessment (including, for example, key elements and acceptance criteria), as well as a schedule and assigned responsibilities for conducting the review assessment. The plan could be based on the suggested content of applications for authorization provided in Annex II for selected practices. The suggested content includes the following nine elements:

- (1) General information;
- (2) Administrative information;
- (3) Integrated management system;
- (4) Technical information;

- (5) Safety assessment;
- (6) Protection of workers;
- (7) Protection of the public;
- (8) Protection of patients;
- (9) Security of sources.

Element (8) is used only for medical practices. If the authorization covers security, that topic needs to be integrated into the review and assessment plan. If the authorization covers safety or security alone, the plan needs to address safety–security interface issues.

4.3.3.3. Conduct review and assessment

Authorization staff perform the review and assessment to determine whether the applicable safety and security objectives and regulatory requirements have been met for each aspect or topic. The regulatory body might involve independent external experts, such as technical and scientific support organizations, qualified individual experts, and advisory committees associated with the regulatory body. Liaison with other authorities takes place at this stage, as appropriate. Confidential information, such as that in the security plan, needs to be managed in accordance with national information security policy.

4.3.3.4. Assemble results and prepare report

Authorization staff collect and integrate assessment results and request additional information from the applicant or others if necessary. Once they have obtained, reviewed and assessed all relevant information, authorization staff prepare a report documenting the results as an input to the authorization decision.

The report needs to clearly highlight issues that may result in authorization conditions. Some information submitted by the applicant is considered confidential (for proprietary, security or privacy reasons) in accordance with national legislation and regulations (see IAEA Nuclear Security Series No. 11-G (Rev. 1) [7]). Guidance on handling of this information by both the authorized party and the regulatory body needs to be developed and implemented.

Where review and assessment determine that the applicant has not satisfactorily demonstrated that facilities and activities have implemented appropriate measures for safety and for security, the regulatory body considers refusing the requested authorization and undertaking enforcement actions, if applicable. Once non-compliances leading to a refusal have been addressed, the applicant may submit a new request for authorization to the regulatory body.

In respect of the security of sources, the regulatory body may require that security measures, including security equipment, be in place before granting the authorization or allowing possession of radioactive material. Reaching a decision on whether to impose such a requirement may involve consideration of whether the applicant is already authorized or is a known entity, results of pre-authorization site visits, inspection history and clear commitments by the applicant as a condition of the authorization.

Regulatory processes need to be clearly established, from the early stages of development of the regulatory body’s integrated management system. Authorization is a core process related directly to the discharge of the regulatory responsibilities of review and assessment of facilities and activities.

Table 1 indicates the purpose, inputs, process, outputs, interfaces and performance criteria for the review and assessment within the integrated management system of the regulatory body. Table 1 lists the different steps to be followed during the review and assessment of applications for authorization. Table 1 is based on table A–9 in GSG-12 [3].

TABLE 1. REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES

Purpose	To review and assess technical and other information relating to safety and security, in order to verify the adequacy of the proposed safety and security measures as part of the authorization process, and determine whether the facility or activity complies with regulatory requirements and the authorization
Inputs	<p>Legal and regulatory requirements, guidance and regulatory procedures specific to review and assessment</p> <p>Application forms and other documents submitted in support of applications for authorization</p> <p>Technical and other documents required to assess compliance with the regulatory requirements and the authorization</p> <p>Feedback on operating experience</p> <p>Developments in international standards, guidance and research</p> <p>Outputs of other regulatory processes (e.g. inspection results, previous review and assessment results)</p>
Process	<p>Review and assessment to support the authorization process:</p> <p>(a) Extract relevant information from inputs.</p> <p>(b) Establish a review and assessment plan. Identify key issues and tasks, milestones and assigned resources (both internal and external).</p> <p>(c) Request additional technical and other documents, if necessary.</p>

TABLE 1. REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES
(cont.)

	(d) Conduct review and assessment activities.
	(e) Collect and integrate assessment results ^a and request additional information, if necessary.
	(f) Document the conduct of the review and assessment and the results.
	(g) Propose authorization conditions.
	(h) Provide feedback to the authorization process.
Outputs	Reports and documents covering review and assessment results (i.e. granting or refusing authorization), proposed conditions for authorization
Interfaces	Authorization and notification Inspection of facilities and activities Enforcement Event reporting Document control Communication and consultation with interested parties
Performance criteria	Review completed with planned resources and within set time limits Successful communication with the applicant or authorized party and other interested parties

^a After issuing the authorization, follow-up of review and assessment results should be conducted through regulatory compliance activities.

4.3.4. Verification activities as part of the authorization process

The purpose of verification is to determine whether the information provided by the applicant is accurate and meets the applicable regulatory requirements. Verification can be performed through on-site visits, interviews, correspondence and other means. On-site visits are performed for practices involving significant radiological safety or security risk, and for unusual or complex practices. Such on-site visits (also referred to as pre-authorization visits or inspections) need to be well prepared and the resulting findings properly recorded.

Consistent with a graded approach to security, the regulatory body generally performs on-site visits as part of the authorization process for all sites with radioactive sources of categories 1 and 2 as well as sites with multiple radioactive sources that aggregate to category 1 or 2. Authorization staff document the results of verification activities in the review and assessment report.

4.3.5. Decision making including limits, conditions and controls

The regulatory review and assessment process leads to a regulatory decision to do one of the following:

- Grant the authorization;
- Grant the authorization with conditions, limitations or controls;
- Refuse to grant authorization.

Recommendations on decision making by the regulatory body can be found in GSG-12 [3] and GSG-13 [4].

The period of validity of the authorization needs to be based on specific criteria (e.g. working life of the radioactive source, risk associated with the practice) established by regulation or included in the regulatory body's guidance and procedures for authorization. Some States provide for periodic renewal of authorizations. Consistent with the graded approach and as provided in the regulatory body's guidance and procedures for authorization, depending on the practice and the associated safety or security risk, the authorization decision could be made by the authorization staff who conducted the review and assessment, by the manager of the regulatory body's authorization unit or by senior management of the regulatory body.

4.3.6. Records of decision and decision making process

The regulatory body needs to document the basis for its decision in files that include all application materials, the review and assessment plan, all communications between the regulatory body and the applicant, intermediate work products of authorization staff and any external experts, the review and assessment report and the authorization decision. Materials that are confidential (for proprietary, security, privacy, or attorney–client or attorney work product reasons) need to be segregated and appropriately protected from unauthorized disclosure. Moreover, the regulatory body needs to keep all relevant regulatory databases up to date (for example, the national register of radiation sources).

4.3.7. Issuing or refusing the authorization and provisions for appeals

The regulatory decision on issuing or refusing the authorization needs to be provided to the applicant in writing and signed by an appropriately designated member of the regulatory body's staff. Upon receipt of the authorization, the applicant becomes the authorized party and is subject to all the conditions of

the authorization and/or national legislation. Annex IV presents an example of an authorization.

In most States, the regulatory body's decision can be appealed by the applicant and adjudication of the appeal could necessitate seeking legal advice, as discussed in Subsection 3.13.2.

4.3.8. Subsequent regulatory actions on authorizations

As stated in GSR Part 1 (Rev. 1) [2], the regulatory body may take any of several actions affecting the status of the authorization following its issuance. These actions include renewal, amendment, termination, suspension and revocation. Depending on the type of action, the regulatory body may act on its own initiative or at the request of the authorized party. The regulatory body needs to establish and follow clearly defined procedures for undertaking such actions. These procedures are based on a graded approach.

4.3.8.1. Renewal

Typically, the regulatory body grants an authorization for a specified period, often referred to as the term of the authorization. For example, in some States all authorizations have to be renewed after the same interval, such as every five years, while in other States a graded approach applies, and registrations are valid for a longer period, such as ten years, while licences are valid for a shorter period, such as five years. Generally, the applicable regulations and often the authorization itself allow the authorized party to request renewal of the authorization for one or more additional terms. The regulatory body establishes procedures for renewals. These procedures may address the following topics (among others), organized according to the type of authorized facility or activity:

- The time at which the authorized party has to submit an application for renewal (such as six months before the end of the current authorization);
- The information and any supporting materials (such as an updated security plan) to be provided by the applicant;
- The criteria to be applied by the regulatory body in determining whether to issue the renewal;
- The period within which the regulatory body will reach a decision;
- Whether or not the current authorization will remain in force if the regulatory body does not act before it expires;
- The term of the renewed authorization;
- The process for appeal by the applicant of an adverse decision.

4.3.8.2. *Amendment*

An authorization is generally limited to specified facilities and activities. Generally, the applicable regulations and the authorization specify the types of change in radiation sources, in activities or in facility operations or other circumstances that would require the authorized party to apply for and obtain an amendment to the authorization before proceeding. The relevant procedures for an amendment to an authorization may address the following topics, among others:

- The circumstances requiring an amended authorization;
- The time at which the authorized party has to submit an application for amendment (such as six months before the modification is proposed to be introduced);
- The information and any supporting materials (such as a security plan) to be provided by the applicant;
- The criteria to be applied by the regulatory body in determining whether to issue the amendment;
- The period within which the regulatory body will reach a decision;
- The term of the amended authorization;
- The process for appeal by the applicant of an adverse decision.

4.3.8.3. *Termination*

An authorized party may seek to terminate its authorization before the end of the authorization term — for example, if the authorized party decides to go out of business or is forced into bankruptcy. This situation is different from revocation or suspension of the authorization by the regulatory body, as discussed below. The regulatory body needs to require the authorized party to obtain specific authorization to terminate the authorized activity or facility to ensure that safety or security is not compromised as a result. Procedures for such an authorization may address the following topics, among others:

- The time at which the authorized party has to submit an application for termination (such as six months before the contemplated termination);
- The information and any supporting materials to be provided by the applicant;
- The criteria to be applied by the regulatory body in determining whether to issue the authorization;
- The period within which the regulatory body will reach a decision;
- Any continuing obligations of the authorized party in respect of the authorized radioactive material or facility following termination;
- The process for appeal by the applicant of an adverse decision.

Recommendations on the renewal of authorizations are provided in GSG-13 [4] and references therein.

4.3.8.4. *Suspension or revocation*

An authorization is generally based on the authorized party's compliance with applicable regulatory requirements and with any further conditions specified in the authorization as well as on prompt and full compliance with any corrective action(s) required as a result of the inspection and enforcement process. As discussed in Section 6, in addition to other types of enforcement action in the event of non-compliance, such as the imposition of monetary penalties, the regulatory body may choose to temporarily suspend the authorization or even revoke it altogether. Such an action may be particularly appropriate when the regulatory body concludes that there is not adequate assurance that the authorized party will conduct the authorized activity or operate the authorized facility in a safe and secure manner. The applicable procedures may address the following topics, among others:

- The reasons for suspending or revoking an authorization;
- The form of notice by the regulatory body to the authorized party of the regulatory body's intent to suspend or revoke the authorization;
- The means by which the authorized party may challenge the suspension or revocation;
- The period within which the regulatory body will reach a decision;
- The continuing obligations of the authorized party in respect of the authorized material or facility following suspension or revocation;
- The process for appeal by the applicant of an adverse decision.

A flow chart summarizing the authorization process as discussed in this section is provided in Fig. 1. The chart starts with the receipt of an application for a new authorization, or for the renewal, amendment or termination of an existing authorization.

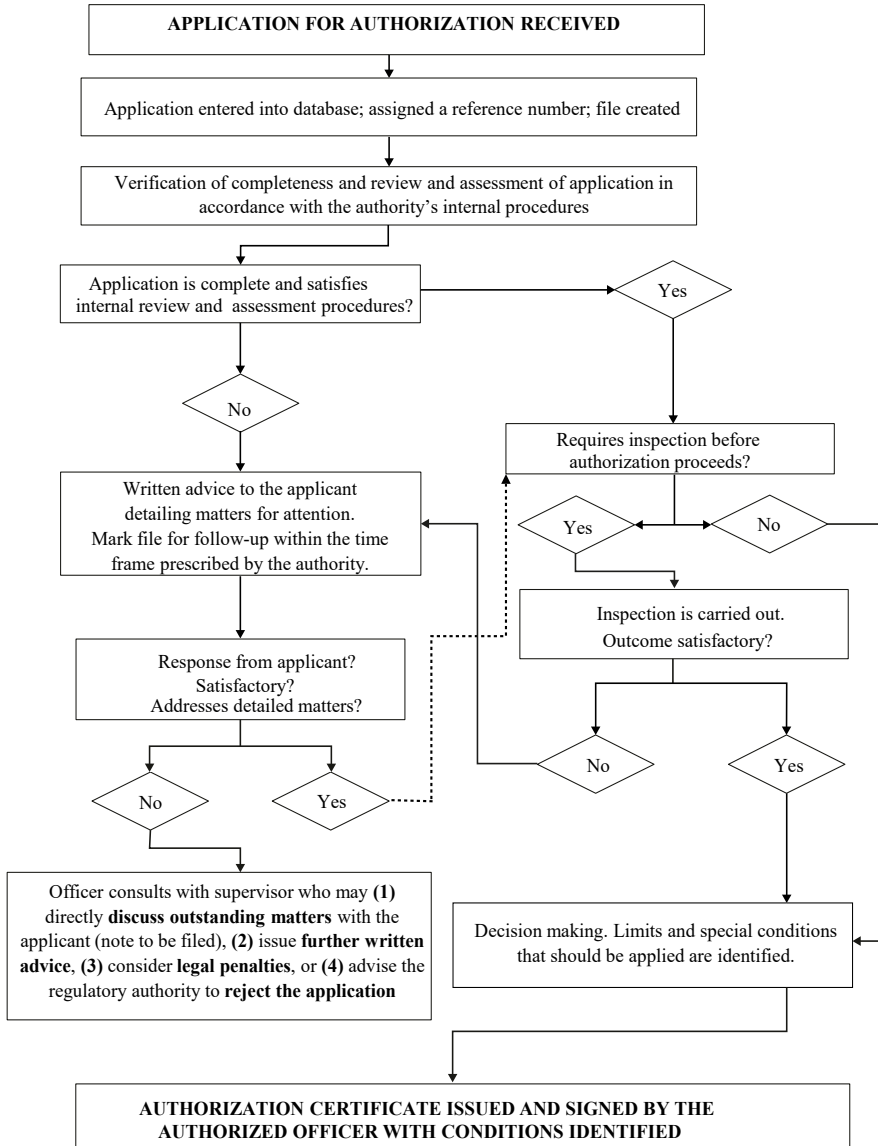


FIG. 1. Flowchart for the regulatory authorization process.

5. INSPECTION PROCESS

5.1. INTRODUCTION

Inspection is the process by which the regulatory body determines whether the authorized party is in compliance with regulatory requirements and the authorization conditions; see Requirements 27, 28 and 29 of GSR Part 1 (Rev. 1) [2]. Recommendations on the matters to be assessed by inspection are provided in GSG-13 [4]. Many of these matters are also relevant to the conduct of security specific inspections.

Inspection is one of the pillars on which the regulatory framework for safety and security is set out. Table 2 indicates the purpose, inputs, process, outputs, interfaces and performance criteria for the inspection of facilities and activities within the integrated management system of the regulatory body. Table 2 lists the interfaces of the inspection with other regulatory compliance activities, including enforcement, which is one of the criteria for evaluating the performance of the inspection process. Table 2 is based on table A-10 in GSG-12 [3].

TABLE 2. INSPECTION OF FACILITIES AND ACTIVITIES

Purpose	To inspect facilities and activities of the authorized parties to verify they are in compliance with regulatory requirements and the conditions specified in authorizations
Inputs	Legal and regulatory requirements, guidance and regulatory procedures specific to inspection List of licensed facilities and activities and the relative risk posed by each Relevant authorizations and issues or concerns for follow-up Safety performance of the authorized parties, including results of regulatory inspections Strategic directions and plans Reports of incidents and events Outputs of other core regulatory processes
Process	Develop an overall programme for inspection of facilities and activities: (a) Identify key aspects (see GSR Part 1 (Rev. 1) [2]) to be included in the baseline inspection programme, as appropriate to the type of facility and activity. (b) Identify priorities and safety significant targets for the programme.

TABLE 2. INSPECTION OF FACILITIES AND ACTIVITIES (cont.)

	<ul style="list-style-type: none"> (c) Allocate inspection resources across facilities and activities in proportion to the relative risk posed by each, taking into account safety performance, results of regulatory inspections, and the number and nature of outstanding issues. (d) Make provisions for reactive inspections.
	<p>Develop specific inspection plans for individual facilities and activities:</p> <ul style="list-style-type: none"> (a) Prepare the inspection plan for different types of facility and activity, including objectives and outcomes, number and type of inspections, method(s), resources, and schedules and timetables. (b) Prepare plans for each individual inspection, including objectives, resources, sets of questions, method of conducting inspection and collecting data. Identify non-compliances, prepare the inspection report and communicate the report to the authorized party. Individual inspections can be performed either announced or unannounced. (c) Record findings and follow-up.
	<p>Develop procedures for inspections, covering all facilities and activities under regulatory control</p>
	<p>Develop procedures for reactive inspections:</p> <ul style="list-style-type: none"> (a) Assess unplanned situations or incidents against relevant inspection selection criteria and decide if a reactive inspection is necessary. (b) For each reactive inspection, select objectives consistent with the nature and significance of the incident or event. (c) Within the context of the overall inspection plan for the facility or activity and the authorized party's performance, assign resources, prepare sets of questions, verify access arrangements and analyse relevant documents. \ (d) Conduct inspection and data collection, prepare the inspection report and communicate the report to the authorized party. (e) Record findings and follow-up.
Outputs	<p>Programme of inspection of facilities and activities Inspection plan for individual facilities and activities Report(s) of inspection, findings, conclusions on non-compliance, correspondence and communication with the authorized party Inspection records</p>
Interfaces	<p>Authorization and notification Enforcement of regulatory requirements Review and assessment of facilities and activities Document control Communication and consultation with interested parties</p>

TABLE 2. INSPECTION OF FACILITIES AND ACTIVITIES (cont.)

Performance criteria	Degree of completion of planned inspection programme
	Number of, and reason for, additional announced and unannounced inspections
	Number of enforcement cases

5.2. TYPES OF INSPECTION

The regulatory body needs to conduct both programmed inspections (planned inspections) and reactive inspections (inspections performed in response to a particular issue) throughout the lifetime of a facility or the duration of an activity. Inspections may be conducted by one or two individuals or by larger teams and may be announced in advance or unannounced (with little or no advance notice). Inspections may be conducted during various phases of the facility or activity life cycle, including the following:

- Initial or pre-operational inspections, which may be carried out prior to the authorized party’s use of a radiation source;
- Inspections during the operating phase of authorized facilities;
- Inspections carried out in connection with termination or revocation of the authorization, to provide an independent check on matters such as confirmation of the removal of radioactive sources and radiation warning signs, and decontamination of the facilities.

Announced inspections provide the inspectors with an opportunity to make prior arrangements with the authorized party for an effective inspection. Such arrangements could include, for example, ensuring the availability of key personnel for interviews and of relevant specific documentation for review. The regulatory body may consider the timing of an announced inspection relative to any specific inspection objectives. Inspections may be announced and scheduled, for example, to enable the regulatory body to observe a specific test or activity, to review a specific self-assessment by the authorized party while it is in progress, or to interview a specific member of its staff. Announced inspections may enhance efficiency. However, their disadvantage is that the authorized party has time to prepare and potentially raise compliance beyond the normally existing level. For this reason, the effectiveness of regulatory oversight can be enhanced by the use of some unannounced inspections.

An unannounced inspection provides the regulatory body with the opportunity to see a facility or activity operating under usual working conditions. The advantage of unannounced inspections is that the actual state of the facility and the way in which it is being operated can be observed. Disadvantages are that key personnel may not be available or part of the facility may not be functioning at the time of the inspection. Selecting the time for an unannounced inspection generally implies that the inspectors have a reasonable working knowledge of the facility or activity, in order to determine the significance of those disadvantages. In order to be able to carry out unannounced inspections, the regulatory body needs to have the legal powers to ensure unrestricted access to the whole facility and all records and documentation at all times. However, the regulatory body needs to take into account the nature of the activities at the site, such as being sensitive to privacy concerns that would occur at a medical facility during patient treatment.

Recommendations on types of inspection are provided in paras 3.236–3.251 of GSG-13 [4].

5.3. INSPECTION PROGRAMMES AND PLANS

The regulatory body prepares an inspection programme on a regular basis, generally annually. Such a programme needs to specify the facilities and activities that the regulatory body plans to inspect (usually known as programmed inspections), consistent with (i) any provisions on inspection frequencies in regulations or authorization conditions; (ii) the anticipated need for reactive inspections (for example, based on historical data); (iii) the number of inspectors needed and their qualifications; and (iv) the necessary legal and technical support.

The frequency of inspections reflected in the inspection programme is based on a graded approach, taking into account risks associated with the authorized facilities and activities. An example of such frequencies, based on the assessment of the safety and security risks, is provided in Table 3.

Inspection frequencies may be adjusted, taking into account other considerations such as the following:

- Review of safety assessments and security plans made by the authorized party;
- New safety and security issues identified, for example, risk associated with computer security and changes in national threat assessment;
- The performance record of the authorized party and the facility, for example, the number of instances of non-compliance with regulatory requirements,

- violations of authorization conditions, deficiencies, incidents and deviations from normal operation, and the number of reactive inspections needed;
- Timeliness of submission of reports by the authorized party to the regulatory body;
 - The investigation and follow-up of events and deviations from normal operation;
 - Operational experience and lessons learned from operating a facility or conducting an activity, including similar facilities and activities at national and international level as well as results of research and development;
 - Knowledge gained from inspection programmes of the regulatory bodies in other States, as identified for example through the IAEA.

TABLE 3. SUGGESTED INSPECTION FREQUENCIES

Practices for the use of radiation sources	Inspection frequency (years)	
	Based on safety risk	Based on security risk
Dental radiography	5	
Nuclear medicine	1–2	2
Radiotherapy	1	1
Diagnostic radiology — centres with other than conventional radiography equipment (e.g. computed tomography, interventional radiology, fluoroscopy, mammography)	2–3	
Diagnostic radiology — centres with conventional radiography equipment only	3–5	
Industrial radiography	1	1
Irradiators (for industrial purposes)	1	1
Irradiators (for research purposes)	3–5	1
Nuclear gauges	3–5	3–5
Well logging	1–3	1–3

The inspection programme may provide for cooperation with other regulatory bodies as well as the involvement of legal support and other internal or external experts or technical support organizations, as appropriate. The programme could include inspection campaigns related to specific issues of concern, such as problems arising in particular practices (e.g. an inspection campaign targeted to well logging sources following a series of incidents in this practice).

In conducting an inspection, inspectors use a systematic approach by following an inspection plan. In Annex V, an example of guidance for inspections is provided for several specific practices. By design, this material reflects the example content for applications for authorization provided in Annex II and the example guidance for review and assessment of applications for authorization provided in Annex III. All three of these annexes are based on the same background information (i.e. IAEA Safety Standards Series publications, as well as IAEA Nuclear Security Series publications and other publications).

Information in Annex V can be adapted to prepare a specific inspection plan for an actual inspection. Thus, for example, when technical data related to industrial radiography are inspected, the inspectors can use that part of Annex V to perform the inspection. The inspection plan for a specific facility or activity is flexible enough to permit inspectors to respond to particular needs and situations as they arise during the course of an inspection: for example, when inspectors find evidence of a leaking source, they focus on the need for taking the appropriate safety measures to prevent spread of contamination.

5.4. PREPARATION FOR AN INSPECTION

Before carrying out an inspection, the inspection personnel (including any external experts) need to be thoroughly prepared for the task. They need to develop an inspection plan that includes specific assignments for each individual taking part in the inspection, the lead inspector in particular. Other details of the inspection plan will depend on the type and methods of inspection. It is generally useful to include a questionnaire and a list of the documents to be reviewed with the authorized party, as well as to identify the necessary documentation and equipment that inspectors need to bring with them to the inspection. Depending on the particular circumstances and the nature of the facility or activity to be inspected, these may include the following:

- Relevant inspection procedures, questionnaires and checklists, and other relevant documents;

- Regulatory requirements relating to the authorized facility or activity, and conditions of the authorization;
- The facility's security plan;
- Findings of previous inspections and enforcement actions relating to the facility or activity, and particularly any unresolved issues from previous inspections;
- Accreditation of the inspector;
- Personal dosimeters;
- Appropriate survey meters or other necessary measuring equipment;
- Safety equipment, such as high visibility clothing, safety shoes and hard hats;
- A camera.

The inspection plan may also include an assessment of the potential exposures of inspectors and any other personnel participating in the inspection activities. Such exposures need to be limited, based on justification, optimization and dose limitation principles.

5.5. ENTRANCE BRIEFING

Unless otherwise arranged, the inspectors need to present themselves at the authorized party's reception area and request to meet the most senior manager. Following introductions and production of credentials, the lead inspector gives an outline of the objectives of the inspection and the anticipated duration. In addition, the lead inspector may arrange with the authorized party's representative to identify personnel to be interviewed and schedule interviews. This enhances efficiency and gives the authorized party the opportunity to identify the most appropriate individuals to respond to questions. The entrance briefing also needs to address the management of inspectors' access to areas with restricted access.

For unannounced inspections, the inspectors may decide to observe work practices without the knowledge of the workers who are using the radiation sources. This approach might be particularly appropriate for field sites where industrial radiography or well logging sources are used. Before undertaking such observation, the inspectors may arrange a discussion with managers to obtain information on the operations being conducted at the time of the inspection and on any precautions necessary to prevent the inspectors from placing themselves in any physical danger. Following the initial observation of work practices, the inspectors need to introduce themselves to the workers performing their duties, further review all relevant practices being undertaken at the site and proceed as for an announced inspection.

5.6. CONDUCT OF INSPECTION

There are a number of common aspects (focus areas) to be inspected for safety and security purposes, including source inventory, training programmes, safety and security equipment, and procedures. The regulatory body may also carry out confirmatory and performance tests and measurements as necessary, at fixed points or in places of special interest, as applicable, using its own equipment. The extent to which the regulatory body conducts its own confirmatory tests and measurements independently of the authorized party differs greatly between States, depending on factors such as the qualifications of personnel available to the regulatory body, its regulatory approach, and the experience and demonstrated performance of authorized parties. These common aspects to be inspected are described in detail in Annex V for selected practices and include the following topics:

- (1) General information;
- (2) Administrative information;
- (3) Integrated management system;
- (4) Technical information;
- (5) Safety assessment;
- (6) Protection of workers;
- (7) Protection of the public;
- (8) Protection of patients;
- (9) Security of sources.

5.6.1. Methods of inspection

The inspection procedures of the regulatory body may incorporate a variety of methods, such as the following:

- Monitoring and direct observation of work practices and equipment;
- Discussions and interviews with personnel of the authorized party and the authorized party's contractors, as applicable;
- Examinations of procedures, records and other documentation;
- Independent and confirmatory tests and measurements (including performance tests of security systems and measures).

In individual inspections, one or more of these methods may be used in a suitably balanced way, depending on the specific issues being considered. Recommendations on the above methods of inspection are provided in paras 3.269–3.280 of GSG-13 [4].

Inspections are conducted in accordance with an approved inspection programme, plan, guidelines and procedures. The techniques utilized for the inspections are commensurate with the inspection requirements and the activity or area being inspected.

Inspectors may use guides, forms or checklists for inspections, especially if the regulations are prescriptive. This approach may simplify the management of the inspection, but equally importantly, it will ensure that no issues are unintentionally overlooked. The purpose of these tools is therefore to ensure the efficiency of the inspection process. In using such tools, inspectors may include narrative comments and explanations that explain their results rather than simply ‘ticking boxes’.

The inspection plan needs to identify the key safety and security elements that are to be reviewed by an inspector to determine regulatory compliance; it is to be based on the regulatory body’s code of practice or regulatory guide or practice specific regulations. Examples of the topics to be addressed in inspection plans for different radiation practices are provided in Annex V. This example guidance is not intended to be used by the inspector as merely a checklist to answer ‘yes’ or ‘no’ questions, but is designed to encourage the inspector to make substantive judgements of compliance with requirements and document the basis for conclusions. The proper collection of inspection findings — and documentary evidence to support them — is an important part of the inspection process. This publication can assist in guiding the inspector through the process of collecting evidence, such as radiation measurements, samples and photographs.

Inspectors may identify a safety or security problem that requires immediate action, such as a significant safety hazard, wilful non-compliance, a major breach in the security system or another potentially significant enforcement issue. The regulatory body needs to have procedures for dealing with such eventualities that clearly identify the regulatory actions that are to be taken, consistent with the legal powers of inspectors. In unforeseen circumstances requiring urgent actions, inspectors need to consider notifying their supervisors without delay to ensure appropriate management of the situation.

5.6.2. Security aspects of an inspection

In preparation for an inspection covering security aspects, the inspector needs to review all relevant documents submitted by the authorized party, including the security plan and the security response plan (if separate from the security plan). The inspector also needs to review any memoranda of understanding or other arrangements with competent authorities for security or private contractors addressing such topics as trustworthiness evaluation, alarm monitoring, and security response and verify those arrangements with the relevant

third parties. At the start of the inspection, the inspector may ask to be taken on an overview tour of the facility and its security system. The inspector needs to be alert to any work practices or facility conditions that may indicate poor security culture and note them for follow-up later during the inspection.

The inspector also needs to verify that the facility is as described in the application for authorization, that the security system is as described in the security plan, and that any subsequent significant modifications of the facility or the security system have been reported to, and approved by, the regulatory body as appropriate.

The inspector needs to examine the overall layout of the security system and check the operational status of the equipment. The inspector determines whether there are any facility design or operational factors (such as mechanical or electrical issues) that could prevent the security system from functioning properly. These could include, for example, a problem with the electrical backup system or physical barriers in a camera's field of vision.

The inspector also needs to verify that the inventory reflects the correct categorization of radioactive material and assignment of the appropriate security level. Inspectors need to verify that the authorized party is correctly applying the guidance for aggregation in the categorization of radioactive material and the assignment to security levels, based on a graded approach (see IAEA Nuclear Security Series No. 11-G (Rev. 1) [7]).

For radioactive sources used at field sites remote from the principal premises, such as for industrial radiography or well logging, inspectors need to verify that such sources are accounted for in a source movement register, which clearly identifies the present location of each source.

The inspector also needs to verify that security system components are installed where appropriate, for example that locks are fitted where needed and that they function correctly. The inspector needs to verify that the security system as installed is in accordance with the security plan.

Determinations regarding compliance with regulatory requirements and authorization conditions are to be based on direct observation of work activities; performance testing of communications, monitoring and detection systems; interviews with authorized party workers; demonstrations by appropriate workers performing tasks regulated by the regulatory body and, where appropriate, a review of selected records within the scope of the requirements. A direct examination of these authorized activities and discussions with workers will provide an inspector with reasonable assurance of an authorized party's ability to control and secure radioactive material.

5.6.3. Evidence collection

The inspector's assessment needs to be based on evidence — documentary, physical and other materials that demonstrate the facts necessary to support inspection findings. Such evidence may include the following:

- Regulatory body records pertaining to the authorized party's authorization;
- Records of the individual inspectors or other staff or external experts who participated in an inspection;
- Records of observations, monitoring and test results, including photographs and electronic media;
- Records copied or removed from the premises inspected;
- Interviews and statements;
- Physical evidence, including forensic evidence.

Such evidence is needed to prepare the inspection report, which is described in detail in Subsection 5.8, as well as to take enforcement actions as described in Subsection 6.7, which discusses management of evidence by the regulatory body, including the role of inspectors in that regard.

5.7. EXIT BRIEFING

Upon completion of the inspection, the inspectors need to conduct an exit briefing with the authorized party's senior management and share the details about the inspection activities, observations, good practices, deficiencies and deviations with the inspected organization. Inspectors also need to seek feedback from the authorized party about the conduct of inspections (see para. 3.282 of GSG-13 [4]).

Such a briefing generally includes the following:

- Findings from the inspection;
- Any matters of non-compliance with regulatory requirements or authorization conditions;
- Any deviations from the security plan;
- Safety related and security related deviations not reaching the level of non-compliance;
- Unresolved items identified during the inspection;
- Immediate corrective actions needed;
- The status of any previously identified non-compliant items.

If safety or security concerns or items of non-compliance are identified that affect the safe or secure operation of the facility or performance of the activity, consistent with their legal powers, the inspectors need to direct the authorized party to initiate prompt corrective action(s). If there is disagreement over the significance of the matters or the potential impact on the facility's operations or activity, the inspectors will explain to the authorized party any procedures for recourse.

5.8. INSPECTION REPORTS

The inspector needs to prepare a report of each inspection. The regulatory body's management needs to review and approve the report in accordance with regulatory body's guidance and procedures. The scope, format, content, timing and distribution of inspection reports may vary depending on considerations such as the following:

- General administrative and legal structure in the State and the requirements established by the regulatory body;
- Type of facility or activity and its stage of authorization;
- Location of the inspection;
- Type of inspection (planned or reactive, announced or unannounced);
- Purpose of the inspection (e.g. team inspection, special inspection, site visit by a non-resident inspector, weekly inspection activities carried out by the resident inspector).

Recommendations on the purposes, content and distribution of inspection reports are provided in paras 3.285–3.287 of GSG-13 [4].

The regulatory body forwards inspection findings to the authorized party for its information and records as well as for any necessary corrective actions. Whenever corrective action is needed, formal communication including findings detailed in inspection reports will be sent to the authorized party. In some States, the full inspection report is forwarded to the authorized party. The regulatory body may need to protect inspection reports containing information that is confidential (for proprietary, security or privacy reasons) and to redact such information when sharing inspection results or reports with authorized parties.

The authorized party may be provided the opportunity to respond to inspection findings as a matter of good practice, even if significant enforcement action is not foreseen.

5.9. POST-INSPECTION ACTIVITIES

The regulatory body needs to systematically monitor any follow-up actions to verify that the authorized party is taking necessary actions in response to inspection findings. Upon satisfactory completion of the actions, the regulatory body in some States formally closes the inspection. In any case, the regulatory body retains all inspection documents and records (see para. 3.294 of GSG-13 [4]). In some States, an electronic database is used for tracking inspection findings and corrective actions, as part of the regulatory body's information management system.

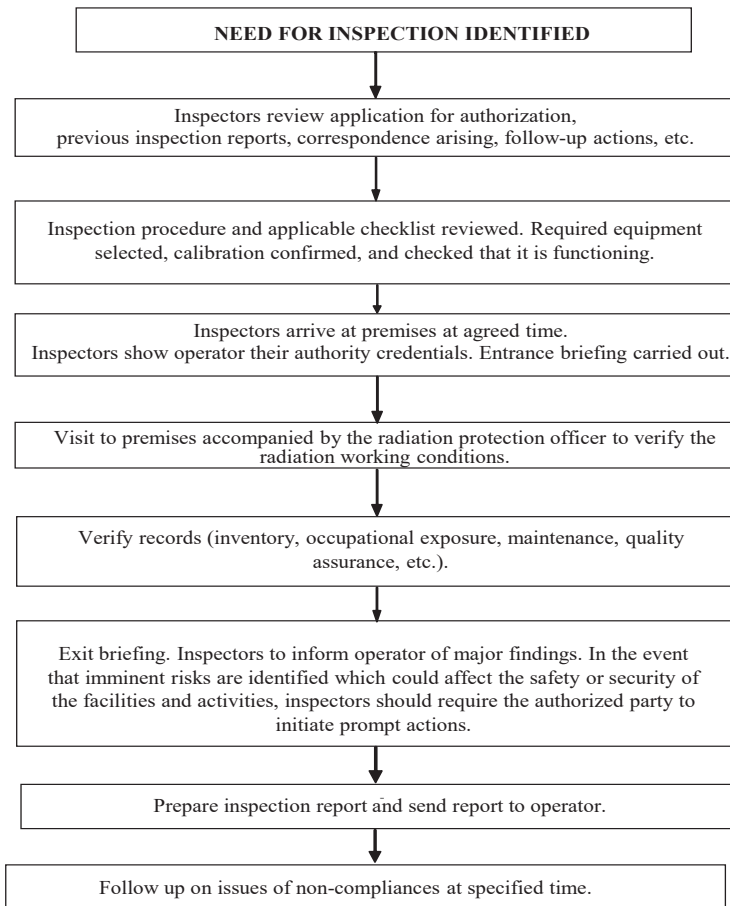


FIG. 2. Flowchart for the inspection process.

The regulatory body needs to regularly review inspection reports to analyse trends, patterns, areas of concern and good practices — both for individual authorized parties and for authorized parties as a group. As appropriate, the regulatory body will use such results in planning future inspections, in amending its regulations, guidance or procedures, and in sharing good practices and concerns with the regulatory bodies of other States, for example in international forums.

In order to inform the public of the safety and security status of facilities and activities and of the effectiveness of the regulatory body, the regulatory body may publish findings of inspections and the associated regulatory decisions. The extent of such public information sharing will depend on the legal provisions in the State concerned (see para. 3.292 of GSG-13 [4]).

A flow chart summarizing the inspection process as discussed in this section is provided in Fig. 2. The chart starts with the identification of the need for conducting a programmed or reactive regulatory inspection.

6. ENFORCEMENT PROCESS

6.1. INTRODUCTION

Through the enforcement process, the regulatory body addresses an authorized party's non-compliance with regulatory requirements and authorization conditions. The importance of establishing and implementing an enforcement process is stressed in Requirements 2, 30 and 31 of GSR Part 1 (Rev. 1) [2] as well as in para. 3.3 of IAEA Nuclear Security Series No. 20 [5]. Enforcement serves several important purposes. First, it provides an incentive for authorized parties to meet their regulatory obligations through the prospect of sanctions for non-compliance as well as the potential for adverse publicity and associated impact on the authorized party's reputation with patients, customers and other interested parties. Second, enforcement signals to each authorized party that the regulatory body is acting fairly and impartially and is not allowing other authorized parties to avoid meeting their obligations. Third, enforcement builds public confidence in the integrity of the regulatory process by demonstrating that the regulatory body holds authorized parties accountable for compliance and requires corrective action(s) to address deficiencies.

6.2. OVERVIEW OF THE ENFORCEMENT PROCESS

While the details of the enforcement process are likely to vary based on the relevant primary legislation and national practice, the process generally includes at least the following steps:

- Identification of violations or non-compliances;
- Assessment of violations or non-compliances;
- Selection of enforcement actions.

The different steps of the enforcement process are summarized in Fig. 3. Recommendations related to the enforcement process are provided in GSG-12 [3]. The cornerstones of enforcement legislation are summarized in Ref. [22].

6.3. IDENTIFICATION OF VIOLATIONS OR NON-COMPLIANCES

The first step in the enforcement process is the identification of violations. Instances of non-compliance are most commonly identified through regulatory body inspections, as described in Section 5. In most situations, if permissible under applicable law, inspectors will make the authorized party aware of violations by the close of the inspection and direct the authorized party to correct them promptly and to provide a report to the regulatory body within a specified timeframe. Depending on the gravity of the matter, the inspector might also direct

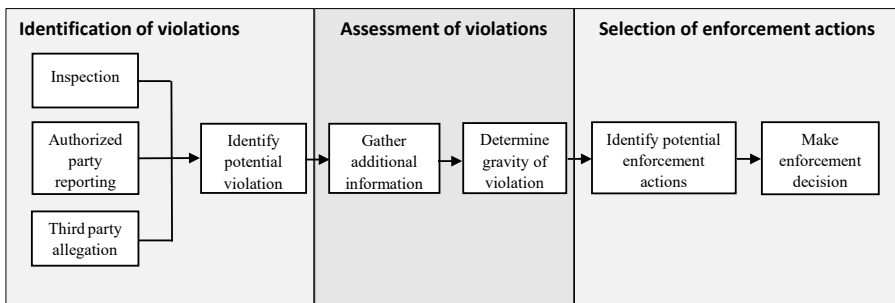


FIG. 3. Summary of the enforcement process.

the authorized party to conduct an investigation into why the non-compliance occurred and to identify measures to prevent a recurrence.

Whether or not addressed orally at the close of the inspection, the regulatory body needs to promptly communicate instances of serious non-compliance in writing. The interval between the inspection and such follow-up correspondence is to be kept to a minimum. Issues that were discussed during the exit briefing or pointed out during the inspection, whether minor or major, need to be confirmed in writing.

The regulatory body needs to establish internal procedures to verify that any directions provided to the authorized party are followed within the specified time frame. Depending on the potential safety and security consequences associated with the matters of non-compliance, the regulatory body may consider whether to schedule a specific follow-up inspection or to mark the file so that those matters are checked at the next regularly scheduled inspection. In the meantime, the inspector provides the inspection report to the regulatory body's management to assess any violations, as discussed in Subsection 6.4.

Violations may also be identified through self-reporting by the authorized party, or as a result of an investigation conducted by the regulatory body in response to allegations made by a third party, such as an employee of the authorized party or a member of the general public. In the interest of safety and security, the regulatory body may encourage authorized parties to self-report, for example by giving credit for such reporting in subsequent selection of enforcement actions, as discussed in Subsection 6.5. Similarly, the regulatory body needs to be open to the receipt of allegations by third parties and promptly evaluate their validity through inspection or investigation. Consistent with national law and practice, the regulatory body needs to consider protecting the anonymity of those making allegations, in order to encourage such reporting.

6.4. ASSESSMENT OF VIOLATIONS OR NON-COMPLIANCES

The second step in the enforcement process is the assessment of violations to determine the gravity of the non-compliance by gathering any additional information that may be necessary and then evaluating the seriousness of the violations.

6.4.1. Information gathering

In order to fully assess a particular violation, the regulatory body may need to gather further information through means such as discussion with the inspector or subject matter experts, review of documents, or consultation with the

regulatory body's internal or external legal advisers. Questions that may need to be addressed include the following:

- What regulatory requirement or authorization condition was violated?
- Is the regulatory requirement or authorization condition legally enforceable?
- When did the violation occur?
- How long did the violation continue?
- How, when and by whom (authorized party or inspector) was the violation discovered?
- Was the violation wilful?
- What was the apparent cause?
- What corrective actions have been taken or are planned?
- Was the authorized party required to report the violation and, if so, what was the applicable reporting requirement?
- If a report was required, when was the report made to the regulatory body?
- If a report was not required, did the authorized party voluntarily self-report?

6.4.2. Determining the gravity of violations

Using the information obtained, the regulatory body then determines the gravity of the violation, according to established criteria. There is no single best method for making this determination, which necessitates judgement by the regulatory body. However, the regulatory body may consider establishing a structured approach rather than just using a list of factors to be taken into account.

As an example, one such approach would be to establish a set of graded levels based on the type of consequence that the regulatory body considers most important in assessing the gravity of the violation. Table 4 is an example of such an approach; however, the regulatory body may consider developing its own graded approach based on the actual or potential safety and security consequences of the violations being assessed, and in accordance with the national legislation.

The regulatory body would initially assign a non-compliance or violation to one of these grades based on safety or security significance and then adjust the assigned grade up or down, based on consideration of additional factors.

Adjustment factors that may increase the gravity of the non-compliance or violation include the following:

- The non-compliance or violation affected the ability of the regulatory body to perform its regulatory oversight function — such as failure to provide complete and accurate information; failure to seek and receive prior approval by the regulatory body for changes in authorized activities, when required; failure to notify the regulatory body of changes in authorized activities,

when required; and failure to comply with requirements for reporting or record keeping.

- The non-compliance or violation was wilful — that is, it involved careless disregard for compliance with a regulatory requirement or authorization condition, a deliberate violation of a regulatory requirement or authorization condition, or knowing falsification of information.
- The non-compliance or violation represents a programmatic failure on the part of the authorized party — that is, management inattention resulting in a systemic breakdown in the authorized party’s safety and/or security programme preventing it from functioning properly.
- The non-compliance or violation is a repeated one.

TABLE 4. GRAVITY OF VIOLATIONS

Gravity level	Consequences of violation (defines gravity level)	Example of violation	
		Safety violation	Security violation
Grade 1	Resulted in, or could have resulted in, <i>very serious</i> safety or security consequences	Failure to promptly notify the regulatory body of lost or missing radioactive source	Security system inoperable
Grade 2	Resulted in, or could have resulted in, <i>significant</i> safety or security consequences	Radioactive source presence not verified at specified intervals	Non-authorized person present in radioactive source location without escort
Grade 3	Resulted in, or could have resulted in, <i>moderate</i> safety or security consequences	Radioactive source and its container not properly marked	Security plan not reviewed and updated at specified interval
Grade 4	Resulted in <i>no or relatively inappreciable</i> safety or security consequences, but is of more than minor concern	Inventory records not present in designated location	Relocation of sensors not documented in security plan
Grade 5	<i>Less significant than a Grade 4 violation</i> ; does not warrant enforcement action but needs to be corrected	Training records not kept up to date	Delay in cancellation of access authorization after employee no longer needs access

Adjustment factors that may decrease the gravity of the non-compliance or violation include the following:

- The authorized party voluntarily and promptly reported the non-compliance or violation.
- The authorized party has positive compliance history.
- The authorized party took prompt and effective corrective action(s).

The regulatory body would then use the adjusted grade assigned to select an appropriate enforcement action.

6.5. SELECTION OF ENFORCEMENT ACTIONS

The third step in the enforcement process is the selection of enforcement actions, that is determining whether to take any enforcement action, and if so, which specific actions to take. This step involves consideration of the types of enforcement actions available under applicable law, and then determining the gravity of the violation, as previously assigned, to select the enforcement action(s) to be taken, if any.

6.5.1. Types of available enforcement action

The types of enforcement action available to the regulatory body will depend on the State's legal system, the provisions of applicable primary legislation and the practice of the regulatory body. In some cases, the available enforcement actions may depend on the details of the violation. For example, wilfulness may be required for criminal prosecution. The following types of enforcement actions are common:

- Oral or written notifications;
- Written warnings or directives;
- Penalties;
- Modification, suspension or revocation of the authorization.

In a given case, the various enforcement actions are not mutually exclusive. For example, serious non-compliance could result in both a written directive requiring corrective action and the imposition of monetary penalties.

The various types of enforcement actions are discussed further in this section.

6.5.1.1. Oral or written notifications

In many cases, it may be possible to resolve minor safety or security items during the exit briefing at the close of an inspection by means of oral notification of the problem and discussion with the authorized party to identify an appropriate solution. Such an oral notification generally is formalized in a subsequent written notification to the authorized party that documents both the issues identified and the agreed resolution, in accordance with the legal system of the State.

6.5.1.2. Written warnings or directives

In the case of non-compliance with regulatory requirements or other items that have more than minor safety or security significance, the regulatory body may issue a written warning or directive to the authorized party. The exact form of such an action may vary depending on the legal practice of the State and could include, for example, a corrective action letter or corrective action order. Regardless of form, this communication needs to specify the nature and regulatory basis for each instance of non-compliance or other unsatisfactory situation and a deadline for taking corrective action(s). The regulatory body could either specify the required corrective action(s) or leave the choice of corrective action(s) to the authorized party, provided it satisfactorily addresses the issues identified. This is the most common form of enforcement action and in most cases will be sufficient to remedy identified safety or security issues.

6.5.1.3. Penalties

The regulatory body needs to have the power to impose or to recommend penalties (e.g. monetary fines) on the authorized party, whether a corporate body or an individual, or to institute criminal prosecution through the legal process, depending on the legal system and the practice of the State. The imposition of penalties is usually reserved for serious non-compliance with regulatory requirements and for repeated violations. Experience in some States suggests that imposing penalties on the authorized party rather than on individual employees is preferable as it is more likely to lead to improved safety and security performance.

6.5.1.4. Modification, suspension or revocation of the authorization

Most legal systems give the regulatory body the power to modify, suspend or revoke an authorization in such circumstances as persistent or extremely serious or wilful non-compliance with regulatory requirements or authorization conditions, a significant release of radioactive material to the environment or a

serious nuclear security event. In such cases, the regulatory body may choose to modify the authorization to include new conditions or limitations on authorized activities, suspend the authorization pending implementation of corrective action(s) to rectify unsafe or unsecure practices, or — in very extreme cases — revoke the authorization altogether. In considering the suspension or revocation of an authorization, the regulatory body ensures that operations or activities important to maintain safety and security continue to be performed by the authorized party. The regulatory body also takes into account the possible harm to third parties who would no longer have access to benefits — for example, patients requiring radiological procedures for medical diagnosis or medical treatment.

6.5.2. Enforcement decisions

Based on the assessment of a non-compliance or violation described in Subsection 6.4, the regulatory body needs to decide whether to take one or more of the enforcement actions described in Subsection 6.5.1. As with the assessment, the regulatory body will not make enforcement decisions in a mechanistic manner, rather it will apply its judgement. Nonetheless, a systematic framework may be used to assist the regulatory body in exercising its discretion in a consistent manner. Such a framework is summarized in Fig. 4, in this case for making an enforcement decision for a Grade 2 violation, where a monetary civil penalty may be imposed.

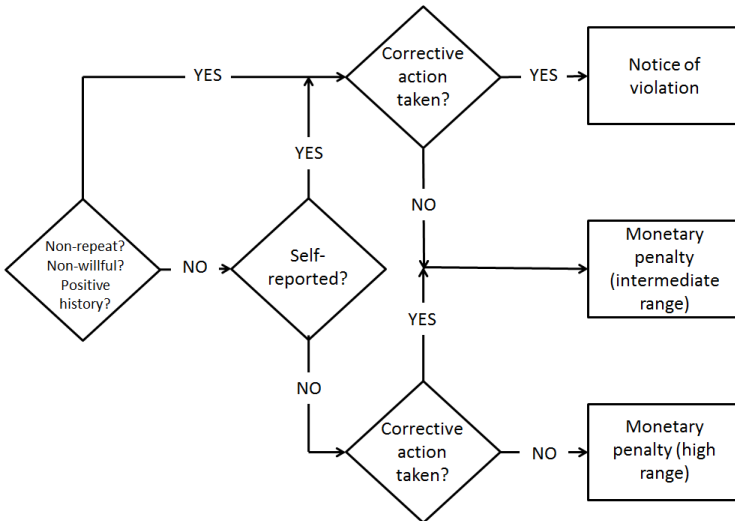


FIG. 4. Framework for selecting an enforcement action for a Grade 2 violation.

6.6. PARTICIPATION IN THE ENFORCEMENT PROCESS

Consistent with national law and practice, the regulatory body will afford the authorized party an opportunity to participate in the enforcement process. For example, the regulatory body could, upon request from the authorized party or on the regulatory body's own initiative, hold a conference with the authorized party at the information gathering phase described in Subsection 6.4.1, in order to clarify facts relevant to determining the existence and gravity of a potential violation. The regulatory body could also provide for a pre-decisional meeting prior to making an enforcement decision as described in Subsection 6.5.2, in order to allow the authorized party, for example, to present any mitigating circumstances that might be relevant to the enforcement decision. Primary legislation, as well as the regulatory body's regulations, may also provide for more formal means of participation, such as a hearing before an administrative tribunal. Where enforcement is conducted through the judicial system, participation will generally be governed by applicable rules of procedure.

Public participation in the enforcement process, including participation in pre-decisional meetings, will also be considered. The extent and nature of such participation will be governed by State law, regulatory body practice and policy considerations. The importance of an open and transparent regulatory process is widely recognized. For example, para. 4.66 of GSR Part 1 (Rev. 1) [2] requires that the regulatory body establish provision for effective mechanisms of communication, including communication with interested parties and the public on regulatory judgements and decisions. At the same time, enforcement actions, particularly in relation to security matters, may involve sensitive information that could be advantageous to potential adversaries. In such instances, the regulatory body will need to balance the interest in transparency with the interest in protecting sensitive information. In a particular case, the regulatory body might conclude, for example, that while the fact of the enforcement action could be made public, the nature of the deficiencies has to be withheld.

6.7. MANAGING EVIDENCE

In the case of less formal enforcement actions, such as oral or written notifications or written warnings or directives, evidence is not generally presented formally when the enforcement action is taken, but if the authorized party were to initiate a proceeding to challenge the enforcement action administratively or judicially, the regulatory body would need to introduce the relevant evidence in order to defend its determinations. In the case of more formal enforcement

actions brought before an administrative or judicial tribunal, the regulatory body would need to introduce the relevant evidence to prove its case.

To ensure that the necessary evidence is available when needed, admissible and persuasive, the regulatory body needs to establish a system for managing the evidence it collects. Such a system could include the following elements:

- Evidence collection plan;
- Chain of custody procedures;
- Evidence custodian;
- Evidence log and log entry procedures;
- Unique identifier.

As noted in Subsection 6.3, the regulatory body may identify violations or instances of non-compliance through an inspection, through self-reporting by the authorized party or through an investigation conducted by the regulatory body in response to allegations made by a third party. Self-reporting and third party allegations do not originate with the regulatory body; consequently, they would not be the subject of evidence collection planning. In the case of inspections and investigations, however, the regulatory body needs to prepare an evidence collection plan. Such a plan may address what evidence is to be collected, how it is to be collected, by whom it will be collected, and how it will be transmitted or transported to the offices of the regulatory body.

In order to introduce an item of physical evidence in a formal administrative or judicial proceeding, the regulatory body ordinarily has to be able to authenticate the item — that is, demonstrate to the tribunal that the item is in fact what the regulatory body claims it to be. In the case of physical evidence, the regulatory body needs to be able to show that, since the time when the item was collected, there has been an unbroken chain of custody (i.e. that procedures have been followed to ensure that another item has not been substituted for the original evidence). In some jurisdictions, an imperfect chain of custody may affect the weight accorded to the evidence but not preclude its admissibility.

Thus, once evidence is obtained, the inspector or investigator maintains custody until bringing it or arranging for its transport to the regulatory body's offices. From then on, the evidence is to be managed by an evidence custodian designated by the regulatory body. The custodian is responsible for ensuring that the receipt of each item is recorded in a log, indicating the case or matter to which it relates. For each item, the log needs to include an item number (i.e. a unique identifier for the particular item), a brief verbal description of the item, the name of the individual who recovered the item (e.g. the inspector), and the date and time when the item was received by the regulatory body. Until needed

by regulatory body staff in connection with an enforcement action, items of evidence are stored in a secure location to which access is controlled.

REFERENCES

- [1] EUROPEAN COMMISSION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014).
- [2] INTERNATIONAL ATOMIC ENERGY AGENCY, Governmental, Legal and Regulatory Framework for Safety, IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), IAEA, Vienna (2016).
- [3] INTERNATIONAL ATOMIC ENERGY AGENCY, Organization, Management and Staffing of the Regulatory Body for Safety, IAEA Safety Standards Series No. GSG-12, IAEA, Vienna (2018).
- [4] INTERNATIONAL ATOMIC ENERGY AGENCY, Functions and Processes of the Regulatory Body for Safety, IAEA Safety Standards Series No. GSG-13, IAEA, Vienna (2018).
- [5] INTERNATIONAL ATOMIC ENERGY AGENCY, Objective and Essential Elements of a State's Nuclear Security Regime, IAEA Nuclear Security Series No. 20, IAEA, Vienna (2013).
- [6] INTERNATIONAL ATOMIC ENERGY AGENCY, Nuclear Security Recommendations on Radioactive Material and Associated Facilities, IAEA Nuclear Security Series No. 14, IAEA, Vienna (2011).
- [7] INTERNATIONAL ATOMIC ENERGY AGENCY, Security of Radioactive Material in Use and Storage and of Associated Facilities, IAEA Nuclear Security Series No. 11-G (Rev. 1), IAEA, Vienna (2019).
- [8] INTERNATIONAL ATOMIC ENERGY AGENCY, Code of Conduct on the Safety and Security of Radioactive Sources, IAEA/CODEOC/2004, IAEA, Vienna (2004).
- [9] INTERNATIONAL ATOMIC ENERGY AGENCY, Guidance on the Import and Export of Radioactive Sources, 2012 Edition, IAEA/CODEOC/IMO-EXP/2012, IAEA, Vienna (2012).
- [10] INTERNATIONAL ATOMIC ENERGY AGENCY, Guidance on the Management of Disused Radioactive Sources, 2018 Edition, IAEA/CODEOC/MGT-DRS/2018, IAEA, Vienna (2018).
- [11] INTERNATIONAL ATOMIC ENERGY AGENCY, IAEA Safety Glossary: Terminology used in Nuclear Safety and Radiation Protection, 2018 Edition, IAEA, Vienna (2019).

- [12] INTERNATIONAL ATOMIC ENERGY AGENCY, Notification and Authorization for the Use of Radiation Sources (Supplement to IAEA Safety Standards Series No. GS-G-1.5), IAEA-TECDOC-1525, IAEA, Vienna (2007).
- [13] INTERNATIONAL ATOMIC ENERGY AGENCY, Inspection of Radiation Sources and Regulatory Enforcement (Supplement to IAEA Safety Standards Series No. GS-G-1.5), IAEA-TECDOC-1526, IAEA, Vienna (2007).
- [14] INTERNATIONAL ATOMIC ENERGY AGENCY, Justification of Practices, Including Non-Medical Human Imaging, IAEA Safety Standards Series No. GSG-5, IAEA, Vienna (2014).
- [15] INTERNATIONAL ATOMIC ENERGY AGENCY, Decommissioning of Facilities, IAEA Safety Standards Series No. GSR Part 6, IAEA, Vienna (2014).
- [16] INTERNATIONAL ATOMIC ENERGY AGENCY, Predisposal Management of Radioactive Waste, IAEA Safety Standards Series No. GSR Part 5, IAEA, Vienna (2009).
- [17] EUROPEAN ATOMIC ENERGY COMMUNITY, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, INTERNATIONAL MARITIME ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Fundamental Safety Principles, IAEA Safety Standards Series No. SF-1, IAEA, Vienna (2006).
- [18] INTERNATIONAL ATOMIC ENERGY AGENCY, Leadership and Management for Safety, IAEA Safety Standards Series No. GSR Part 2, IAEA, Vienna (2016).
- [19] INTERNATIONAL ATOMIC ENERGY AGENCY, Developing Regulations and Associated Administrative Measures for Nuclear Security, IAEA Nuclear Security Series No. 29-G, IAEA, Vienna (2018).
- [20] INTERNATIONAL ATOMIC ENERGY AGENCY, Nuclear Security Culture, IAEA Nuclear Security Series No. 7, IAEA, Vienna (2008).
- [21] INTERNATIONAL ATOMIC ENERGY AGENCY, Security Management of Radioactive Material in Use and Storage and of Associated Facilities, IAEA Nuclear Security Series No. 43-T, IAEA, Vienna (2022).
- [22] STOIBER, C., BAER, A., PELZER, N., TONHAUSER, W., Handbook on Nuclear Law, IAEA, Vienna (2003).

Annex I

EXAMPLE OF NOTIFICATION FORM

NOTIFICATION OF INTENTION TO USE RADIATION SOURCES

1. Complete this notification form and return it to the regulatory body at the address below. Where space is insufficient for any item, attach additional signed sheets.
2. Administrative information
 - Legal person: specify the formal name of the legal person.
 - Address of head office: specify the address of the headquarters of the legal person.
 - Name and title of the representative of the legal person: specify the name and title of the representative of the legal person.
 - Contact person: specify the name of the person to be contacted with respect to the notification.
 - Contact details: specify contact details of the person to be contacted with respect to the notification.

Telephone number: _____ Email address: _____

3. Field of application and purpose(s) of the activity in which the radiation sources¹ will be used²
4. Information on radiation sources to be used

Note: If space is insufficient, please complete and attach additional sheets with the information shown below. If a radiation source is not labelled, provide

¹ 'Radiation source' means any radioactive substance and any electrical device that produces ionizing radiation when energized. It includes sources that the owner or the person in possession has reason to believe are, or should be, exempt from regulatory control. The regulatory body will rule on the exemption status of any particular source and inform the holder accordingly.

² 'Use' means to possess, store, manufacture, sell, operate, import and export, or any other meaning given in the legislation.

any identifying information that may be available, including copies of any relevant documents.

RADIOACTIVE SOURCES

Radionuclide (e.g. ^{192}Ir)	Identification number	Location	Activity (Bq)	Activity date	Form (unsealed, sealed, solid, liquid, gas, etc.)

RADIATION GENERATORS (e.g. X ray equipment, accelerators, cyclotrons)

Manufacturer	Model	Serial number	Location	Maximum power (e.g. max radiographic kVp, mA)	

5. Endorsement of notification

Notification must be signed by the representative of the legal person.

Name _____ Signature _____ Date _____

Official stamp/seal

Return the completed and signed form to: [regulatory body address (telephone number)]. No fee is required for notification.

Annex II

CONTENT OF APPLICATION FORMS FOR AUTHORIZATION


Information provided in this annex is intended to be used by regulatory bodies as a reference when establishing and implementing a national authorization system based on current IAEA Safety Standards Series and IAEA Nuclear Security Series publications, following a graded approach. Regulatory bodies need to adapt this annex for consistency with their national legislation and regulations.

Examples in this annex illustrate the application content for various practices. They include the use of radiotherapy, nuclear medicine, X ray imaging in radiology, industrial irradiators, industrial radiography, well logging and nuclear gauges. Most of the application content related to security is presented separately, according to the security level. Application content has been grouped into the following nine elements:

- (1) General information;
- (2) Administrative information;
- (3) Integrated management system;
- (4) Technical information;
- (5) Safety assessment;
- (6) Protection of workers;
- (7) Protection of the public;
- (8) Protection of patients (applicable only to medical practices);
- (9) Security of sources.

Elements (1) to (3), (5) to (7) and (9) each consist of a single table that details the administrative and technical information to be submitted by applicants for authorization. Tables II-1 to II-3, II-5 to II-7 and II-9 are applicable to all practices, subject to the clarifications in their footnotes. Elements (4) and (8) are addressed in practice specific Tables II-4.1 to II-4.7 and II-8.1 to II-8.3.

Figure II-1 illustrates the use of the tables in this annex as applied to various practices.

	General information (Table II-1)	Administrative information (Table II-2)	Integrated management system (Table II-3)	Technical information (Tables II-4.1 to II-4.7)	Safety assessment (Table II-5)	Occupational protection (Table II-6)	Public protection (Table II-7)	Patient protection (Tables II-8.1 to II-8.3)	Security (Table II-9)
	✓	✓	✓	Table II-4.1	✓	✓	✓	Table II-8.1	✓
	✓	✓	✓	Table II-4.2	✓	✓	✓	Table II-8.2	N/A *
	✓	✓	✓	Table II-4.3	✓	✓	✓	Table II-8.3	N/A
	✓	✓	✓	Table II-4.4	✓	✓	✓	N/A	✓
	✓	✓	✓	Table II-4.5	✓	✓	✓	N/A	✓
	✓	✓	✓	Table II-4.6	✓	✓	✓	N/A	✓
	✓	✓	✓	Table II-4.7	✓	✓	✓	N/A	✓ *

* Nuclear gauges incorporating low activity radioactive sources and nuclear medicine should be subject to prudent security management practices.

FIG. II-1. Developing practice specific application forms for authorization. N/A: not applicable.

II-1. GENERAL INFORMATION

TABLE II-1. APPLICATION FOR AUTHORIZATION — GENERAL INFORMATION FOR ALL PRACTICES

- (1) New
 - (2) Renewal (authorization number ____)
 - (3) Amendment (authorization number ____)
 - (4) In line with the regulatory framework in the State, confirm that the practice is justified as appropriate.
-

II-2. ADMINISTRATIVE INFORMATION

The administrative information to be submitted by applicants for authorization has been prepared in accordance with IAEA Safety Standards Series No. GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards (Requirements 4, 7 and 9) [II-1] and IAEA Safety Standards Series No. GSG-13, Functions and Processes of the Regulatory Body for Safety (paras 3.98 and 3.102) [II-2].

TABLE II-2. APPLICATION FOR AUTHORIZATION — ADMINISTRATIVE INFORMATION FOR ALL PRACTICES

- (1) Legal person. Specify the formal name of the applicant.
- (2) Address of head office. Specify the address of the headquarters of the legal person.
- (3) Name and title of the representative of the legal person. Specify the name and title of the representative of the legal person.
- (4) Location(s) of the practice. Specify the address(es) of the practice.
- (5) Contact person. Specify the name of the person to be contacted with respect to the application.
- (6) Contact details. Specify the contact details of the person to be contacted with respect to the application:
 - (a) Telephone number;
 - (b) Email address.

- (7) Contact details of the radiation protection officer(s). Specify the details of the radiation protection officer(s) to be contacted with respect to the authorization:
 - (a) Telephone number;
 - (b) Email address.
 - (8) Contact details of the qualified expert(s), if applicable.
 - (9) Endorsement of application (the application must be signed by the representative of the legal person):
 - (a) Name;
 - (b) Signature;
 - (c) Date;
 - (d) Official stamp/seal.
-

II-3. INTEGRATED MANAGEMENT SYSTEM

The information on the integrated management system to be submitted by applicants for authorization has been prepared in accordance with IAEA Safety Standards Series Nos GSR Part 2, Leadership and Management for Safety [II-3], GSR Part 3 (Requirement 5) [II-1] and GSG-13 (paras 3.98 and 3.102) [II-2].

TABLE II-3. APPLICATION FOR AUTHORIZATION — INTEGRATED MANAGEMENT SYSTEM FOR ALL PRACTICES

- (1) Management structure and responsibilities. Describe overall organizational system and integrated management system ensuring that protection and safety^a and security^b are effectively incorporated into the overall management system of the applicant. Describe and clearly define responsibilities for radiation safety and security^b for the following parties as appropriate: radiation protection officer(s), person(s) responsible for security^b, workers, itinerant workers, radiation safety committee and clients, including responsibilities for cooperation and consultation.
- (2) Verification of compliance. Describe the regular assessment of protection safety and security^b, such as a quality control programme and plans for regular reviews.

- (3) Submission of the following documentation, procedures and programmes to the regulatory body:
- (a) Radiation source inventory, supply of sources, prior assessment of radioactive sources and radiation generators, and inventory of disused sources^c;
 - (b) Education, training and competence of the staff and their training, retraining and informing;
 - (c) Testing, routine and periodic examination and maintenance^a, and quality assurance programme^d;
 - (d) Investigation of incidents and accidents;
 - (e) Emergency preparedness and response measures;
 - (f) Control of modification(s) of facilities, equipment and activity;
 - (g) Management of disused sources and depleted uranium, if applicable^b;
 - (h) Safe transport of radioactive material^b;
 - (i) Controlled import and export of radioactive sources^b;
 - (j) Control of visitors;
 - (k) Release of patients after radionuclide therapy^e;
 - (l) Programme for the improvement of the integrated management system.

^a As defined in the IAEA Safety Glossary [II-4].

^b Not applicable to X ray imaging in radiology.

^c For nuclear medicine, include inventory of radioactive waste and discharges. For X ray imaging in radiology, consider only radiation generators.

^d Applicable to radiotherapy, nuclear medicine and X ray imaging in radiology.

^e Applicable to nuclear medicine.

II-4. TECHNICAL INFORMATION

The technical information to be submitted by applicants for authorization has been prepared in accordance with GSR Part 3 (Requirements 7, 9, 14, 15, 17 and 38) [II-1] and GSG-13 (paras 3.98 and 3.102) [II-2].

The information to be provided by applicants for authorization includes the following:

- (1) Information on radiation sources;
- (2) Information on measuring instruments for quality control (only for radiotherapy, nuclear medicine, X ray imaging in radiology);
- (3) Information on the facilities;
- (4) Information of radiation monitoring equipment;

- (5) Safe and secure (except for X ray imaging in radiology) management and control of radiation sources once it has been decided to take them out of use, including financial provisions (except for X ray imaging in radiology);
- (6) Technical systems used in radiotherapy for patient protection.

The information to be considered for the items above is provided for each practice in the following Tables II-4.1 to II-4.7.

TABLE II-4.1. APPLICATION FOR AUTHORIZATION — TECHNICAL INFORMATION FOR RADIOTHERAPY

- (1) Information on radiation sources.
 - (a) Information on radiotherapy equipment using radioactive sources:
 - (i) Manufacturer of the radiotherapy device.
 - (ii) Supplier of the radiotherapy device.
 - (iii) Serial number of the radiotherapy device.
 - (iv) Model of the radiotherapy device.
 - (v) Compliance with standards and safety of exposure device. Demonstrate that the radiotherapy device is designed, manufactured and tested using an international standard (i.e. attach the certificate) or an equivalent national standard.
 - (vi) Safety features of radiotherapy equipment using gamma sources. Specify safety features related to the equipment, such as return of the source in the shielding position in case of electronic failure.
 - (b) Information on the radiotherapy sources, check sources and other than category 1-2 sealed sources:
 - (i) Radionuclide.
 - (ii) Manufacturer of the source.
 - (iii) Model.
 - (iv) Source serial number.
 - (v) Source activity and reference date.
 - (vi) Supplier of the source.
 - (vii) Special form certificate. Attach special form certificate for the radioactive source.
 - (viii) Design, manufacturing and testing of the source. Demonstrate that the design, manufacturing and testing of the source were conducted in accordance with ISO 2919:2012 or another appropriate standard.

- (ix) Leak test. Demonstrate that the leak test was conducted in accordance with ISO 9978:2020 or another appropriate standard.
- (x) Working life of the source. Specify recommended working life given by the manufacturer.
- (xi) Certificate for sealed radioactive source, according to ISO 2919:2012 or equivalent standard, specifying: source classification, model designation, serial number, content activity, leak test results according to ISO 9978:2020, radiation output, special form approval certificate number and recommended working life.
- (xii) Source assembly.
- (xiii) Compatibility of the equipment. Demonstrate compatibility of the source assembly with the radiotherapy device.
- (c) Details about depleted uranium, if any:
 - (i) Specify whether depleted uranium is used;
 - (ii) Specify the mass of the depleted uranium.
- (d) Information on linear accelerator:
 - (i) Type of the linear accelerator;
 - (ii) Manufacturer of the linear accelerator;
 - (iii) Model of the linear accelerator;
 - (iv) Serial number(s) of the linear accelerator;
 - (v) Supplier of the linear accelerator;
 - (vi) Nominal beam energies — separately for different beam types, such as photon and electron beams;
 - (vii) Maximum leakage radiation. Specify leakage radiation given by the manufacturer.
- (e) Information on simulator or imaging device:
 - (i) Type of the simulator (e.g. computed tomography);
 - (ii) Manufacturer of the simulator;
 - (iii) Model of the simulator;
 - (iv) Serial number(s) of the simulator (generator);
 - (v) Supplier of the simulator;
 - (vi) Maximum voltage (kV) and current (mA or mA · s).
- (2) Information on measuring instruments for quality control.
 - (a) Ionization chamber for photons (cylindrical chamber, well chamber for brachytherapy). Attach a calibration certificate to demonstrate an appropriate calibration that is traceable to a primary standard.
 - (b) Ionization chambers for electron beams (parallel plate chamber); attach a calibration certificate to demonstrate an appropriate calibration that is traceable to a primary standard.
 - (c) Electrometer. Describe suitability for the purpose.

- (3) Description of the facility.
- (a) Radiotherapy room(s) and adjacent areas:
- (i) Layout of the radiotherapy room. Demonstrate that the design of the radiotherapy room enables optimization of radiation protection for workers and members of the public. The layout needs to be given using a scale enabling analysis of the characteristics of the radiotherapy room and adjacent areas, e.g. entrances, maze, doors, roof, floors, and penetrations used for ventilation and electrical ducts. In particular, include details related to the control room, which needs to be located outside the radiotherapy room, and to all other adjacent offices or buildings. Specify all construction materials, e.g. material type, thickness and density. Specify which existing sources and equipment will be used in the radiotherapy room and provide a process flow diagram. Give the position(s) of source(s) and equipment, including the isocentre point, if any. Specify all adjacent equipment, such as radiotherapy or imaging devices, and their control rooms.
 - (ii) Shielding calculation and assumptions used. Demonstrate that the design and shielding, as well as the assumptions used (e.g. use factor and occupancy factor), took into account radiation fields produced by sources during irradiation. Provide dose and dose rate calculations related to exposure of workers and members of the public. In particular, demonstrate shielding from air scattered radiation ('sky shine'). Demonstrate that leakage radiation is taken into account. Specify the maximum operating conditions of the equipment, e.g. maximum workload and main directions of the beam. Provide a plan of the radiotherapy room surroundings. Demonstrate that doses are below the dose limit and dose constraints for workers and members of the public. Demonstrate that a qualified expert was involved in the calculations.
 - (iii) Safety features. Specify the position of all technical safety features and warning systems, such as emergency cord or button, radiation monitor(s) for radioactive sources (e.g. dose rate monitor in the room), door interlocks, use of key control, access control measures, barriers, monitors, and warning signals (acoustic and visual) and notices. Describe the design and function of safety and warning systems, including the independence and redundancy of interlock systems. Demonstrate that the text of the notices is in a language understandable to the persons likely to be in areas around the radiotherapy room(s). Specify how fire protection manages

- hazards related to the existing radioactive sources. Demonstrate that good engineering practices are taken into account.
- (iv) Boundaries of controlled and supervised areas. Demonstrate that controlled and supervised areas are designated.
- (b) Radioactive source storage:
- (i) Layout of the radioactive source storage. Demonstrate that the design of the storage enables optimization of radiation protection for workers and members of the public. The layout needs to be given using a scale enabling analysis of the storage characteristics, e.g. entrances, doors, roof, floors, penetrations and adjacent offices or buildings. Specify all construction materials, e.g. material type, thickness and density. Specify which existing sources and equipment will be stored in the storage area. Specify the maximum capacity of the storage.
 - (ii) Shielding calculation and assumptions used. Demonstrate that the design and shielding, as well as the assumptions used (e.g. workload and occupancy factor), took into account radiation fields produced by all sources to be stored. Demonstrate that doses are below dose limits, dose constraints for workers and members of the public are established, and doses are optimized to be as low as possible. Demonstrate that a qualified expert was involved in the calculations.
 - (iii) Safety features. Specify the position of all technical safety systems, e.g. monitors, sensors, access control measures, barriers, detectors causing warning signals, and notices. Describe the design and function of safety and warning systems. Demonstrate that the text of the notices is in a language understandable to the persons likely to be in areas around the radioactive source storage.
 - (iv) Boundaries of controlled and supervised areas. Demonstrate that controlled and supervised areas are designated.
- (4) Technical information of radiation monitoring equipment.
- (a) Radiation monitors installed in radiotherapy rooms with radioactive sources. Provide technical information related to permanently installed radiation monitors. Demonstrate the suitability and calibration of the monitors.
 - (b) Portable survey meters. Provide technical information related to portable survey meters to be used. Demonstrate the suitability and calibration of portable survey meters. Specify their use and number.
 - (c) Personnel monitoring devices. Demonstrate that personnel monitoring devices have been provided to all workers. Demonstrate that personal dosimetry devices with direct reading and alarm functions are

available, if required. Specify all technical information and dosimetry services to be used.

- (5) Safe and secure management and control of radiation sources once it has been decided to take them out of use, including financial provisions. Demonstrate that all disused sources, including depleted uranium, are managed in line with safety requirements, e.g. demonstrate that storage for disused sources is designed and controlled by applying optimization and dose limitations and that management of the storage includes all safety and security precautions. Specify financial provisions for safe and secure management of all disused sources, including depleted uranium.
 - (6) Technical patient protection systems. Demonstrate how patient protection is optimized using technical systems, such as treatment planning systems, image guiding systems and treatment verification systems, immobilization devices, and visual and acoustic communication systems between the control room and the treatment room.
-

TABLE II-4.2. APPLICATION FOR AUTHORIZATION — TECHNICAL INFORMATION FOR NUCLEAR MEDICINE

- (1) Information on radiation sources.
 - (a) Information on unsealed sources (information on each radionuclide to be provided separately):
 - (i) Radionuclide (chemical form);
 - (ii) Maximum activity at a specific time;
 - (iii) Physical form (e.g. liquid or encapsulated);
 - (iv) Main purposes of use (e.g. diagnostic imaging, therapy or marker) and location;
 - (v) Manufacturer of the source;
 - (vi) Supplier of the source.
 - (b) Information on sealed sources:
 - (i) Radionuclide.
 - (ii) Model.
 - (iii) Source serial number.
 - (iv) Source activity and reference date.
 - (v) Manufacturer of the source.
 - (vi) Supplier of the source.
 - (vii) Special form certificate. Attach special form certificate for the radioactive source.

- (viii) Design, manufacturing and testing of the source. Demonstrate that the design, manufacturing and testing of the source were conducted in accordance with ISO 2919:2012 or another appropriate standard.
- (ix) Leak test. Demonstrate that the leak test was conducted in accordance with ISO 9978:2020 or another appropriate standard.
- (x) Working life of the source. Specify the recommended working life given by the manufacturer.
- (xi) Certificate for the sealed radioactive source, according to ISO 2919:2012 or equivalent standard, specifying source classification, model designation, serial number, content activity, leak test results according to ISO 9978:2020, radiation output, special form approval certificate number and recommended working life.
- (xii) Purpose of use and location.
- (c) Information on imaging devices using radiation sources:
 - (i) Type of the device (e.g. computed tomography);
 - (ii) Manufacturer of the device;
 - (iii) Model of the device;
 - (iv) Serial number(s) of the device (generator);
 - (v) Supplier of the device;
 - (vi) Maximum voltage (kV) and current (mA or mA · s).
- (2) Information on measuring instruments for quality control. Activity calibrator.
 - (a) Manufacturer of the device;
 - (b) Model of the device;
 - (c) Serial number of the device;
 - (d) Supplier of the device.
- (3) Description of the facility.
 - (a) Nuclear medicine laboratory and adjacent areas:
 - (i) Layout of the nuclear medicine laboratory. Demonstrate that the design of the laboratory enables optimization of radiation protection for workers and members of the public. The layout needs to be given using a scale enabling analysis of the characteristics of the laboratory and adjacent areas, e.g. laboratory for preparation of the nuclear medicine dose and dosage; injection room; patient waiting areas; imaging rooms; patient toilets; offices and other working areas and areas for the staff; corridors; storages; and radionuclide therapy patient rooms. Include details of the patient flow and estimated stay in different rooms. Specify all construction materials, e.g. material type, thickness, density, and features to prevent contamination and to facilitate decontamination. Provide

air pressure differentials and directions of air flow. Mark release points for liquid and gaseous waste discharges. Specify which existing sources and equipment will be used in which room and provide a process flow diagram. Give the position(s) of source(s) and equipment. Specify all adjacent equipment, such as imaging devices and their control rooms.

- (ii) Shielding calculation and assumptions used. Demonstrate that the design and shielding, as well as the assumptions used (e.g. use factor and occupancy factor), took into account radiation fields produced by sources, including patients (assuming maximum activity of each radionuclide in the patient). Provide dose and dose rate calculations related to exposure for workers and members of the public. Specify the maximum operating condition of the equipment, e.g. workload. Provide a plan of the surrounding areas. Demonstrate that doses are below the dose limits and dose constraints for workers and members of the public. Demonstrate that a qualified expert was involved in the calculations.
 - (iii) Safety features. Specify the position of all technical safety features and warning systems, such as the emergency button of a device, radiation monitor(s) in case of a discharge, use of key control, and warning signs and notices. Describe the design of the facility for safety. Demonstrate that the text of the notices is in a language understandable to the persons likely to be in areas around the nuclear medicine facility. Specify how fire protection manages hazards related to the existing radioactive sources. Demonstrate that good engineering practices are taken into account.
 - (iv) Boundaries of controlled and supervised areas. Demonstrate that controlled and supervised areas are designated.
- (b) Radioactive source and temporary radioactive waste storage:
- (i) Layout of the radioactive source storage and the temporary radioactive waste storage. Demonstrate that the design of the storages enables optimization of radiation protection for workers and members of the public. The layout needs to be given using a scale enabling analysis of the storage characteristics, e.g. entrances, doors, roof, floors, penetrations and adjacent offices or buildings. Specify all construction materials, e.g. material type, thickness and density. Specify which existing sources and equipment will be stored in the storage area. Specify the maximum capacity of the storage.
 - (ii) Shielding calculation and assumptions used. Demonstrate that the design and shielding, as well as the assumptions used

- (e.g. workload and occupancy factor), took into account radiation fields produced by all sources to be stored. Demonstrate that doses are below dose limits, that dose constraints for workers and members of the public are established, and that doses are optimized to be as low as possible. Demonstrate that a qualified expert was involved in the calculations.
- (iii) Safety features. Specify the positions of all technical safety systems, e.g. monitors, sensors, access control measures and barriers. Describe the design and function of safety and warning systems. Demonstrate that the text of the notices is in a language understandable to the persons likely to be in areas around the radioactive source storage and temporal radioactive waste storage.
 - (iv) Boundaries of controlled and supervised areas. Demonstrate that controlled and supervised areas are designated.
- (4) Technical information of radiation monitoring equipment.
- (a) Radiation monitors installed in laboratories in 'hot cells' and for discharges as appropriate. Provide technical information related to permanently installed radiation monitors. Demonstrate suitability and calibration of the monitors.
 - (b) Portable survey meters. Provide technical information related to portable survey meters for monitoring external exposure, air contamination and surface contamination. Demonstrate suitability and calibration of portable survey meters and contamination monitors. Specify their use and number.
 - (c) Personnel monitoring devices. Demonstrate that personnel monitoring devices have been provided to all workers. Demonstrate that personal dosimetry devices with direct reading and alarm functions are available, if required. Specify all technical information and dosimetry services to be used.
- (5) Safe and secure management and control of radioactive waste and radiation sources once it has been decided to take them out of use, including financial provisions. Demonstrate that radioactive waste and disused sources are managed in line with safety requirements, e.g. demonstrate that storage for radioactive waste and disused sources is designed and controlled using optimization and dose limitations and that management of the storages includes all safety and security precautions. Specify financial provisions for safe and secure management of all disused sources and radioactive waste as applicable.
-

TABLE II-4.3. APPLICATION FOR AUTHORIZATION — TECHNICAL INFORMATION FOR X RAY IMAGING IN RADIOLOGY

- (1) Information on radiation sources.
 - (a) Information on imaging devices using radiation sources:
 - (i) Type of the device (e.g. radiography, mammography, computed tomography or interventional radiology);
 - (ii) Manufacturer of the device;
 - (iii) Model of the device;
 - (iv) Serial number(s) of the device (generator);
 - (v) Supplier of the device;
 - (vi) Maximum voltage (kV) and current (mA or mA · s).
- (2) Description of the facility.
 - (a) X ray imaging room and adjacent areas:
 - (i) Layout of the X ray imaging room and adjacent areas. Demonstrate that design of the X ray imaging room enables optimization of radiation protection for workers and members of the public. The layout needs to be given using a scale enabling analysis of the characteristics of the X ray imaging room and adjacent areas, e.g. control room, patient waiting areas and other areas accessed by members of the public. Include details related to other adjacent offices and areas. Specify all construction materials, e.g. material type, thickness and density. Specify which existing sources and equipment will be used in which room. Give the position(s) of source(s) and equipment. Specify all adjacent equipment.
 - (ii) Shielding calculation and assumptions used. Demonstrate that the design and shielding, as well as the assumptions used, e.g. use factor and occupancy factor, took into account the radiation fields produced by the sources during their use. Provide dose and dose rate calculations, as appropriate, related to the exposure of workers and members of the public. Specify the maximum operating condition of equipment, e.g. workload. Provide a plan of the surrounding areas. Demonstrate that doses are below the dose limit and dose constraints for workers and members of the public. Demonstrate that a qualified expert was involved in the calculations.
 - (iii) Safety features. Specify the positions of all technical safety features and warning systems, such as the emergency button of a device, use of key control, warning signs and notices. Describe the design of the facility for safety. Demonstrate that the text of the notices is in a language understandable to the persons likely

- to be in areas around the nuclear medicine facility. Demonstrate that good engineering practices are taken into account.
- (iv) Boundaries of controlled and supervised areas. Demonstrate that controlled and supervised areas are appropriately designated.
- (3) Technical information of radiation monitoring equipment.
- (a) Portable survey meters. Provide technical information related to portable survey meters to be used, as appropriate. Demonstrate the suitability and calibration of portable survey meters. Specify their use and number.
 - (b) Personnel monitoring devices. Demonstrate that personnel monitoring devices have been provided to all workers. Demonstrate that personal dosimetry devices with direct reading and alarm functions are available, if required. Specify all technical information and dosimetry services to be used.
-

TABLE II-4.4. APPLICATION FOR AUTHORIZATION — TECHNICAL INFORMATION FOR INDUSTRIAL GAMMA IRRADIATORS

- (1) Information on radiation sources.
- (a) Information on the gamma irradiator:
 - (i) Manufacturer of the gamma irradiator;
 - (ii) Address of the manufacturer of the irradiator;
 - (iii) Model;
 - (iv) Identification number;
 - (v) Name and address of the supplier, if different from the manufacturer of the gamma irradiator.
 - (b) Information on radioactive sources (all non-exempt sources, including sources for checking equipment and calibration sources):
 - (i) Radionuclide.
 - (ii) Model.
 - (iii) Source serial number. For sources in irradiator pencils, modules and racks give also the position of each source:
 - Number of sources per pencil;
 - Number of sources per module;
 - Number of sources per rack;
 - Total activity.
 - (iv) Source activity and reference date.
 - (v) Manufacturer of the source.
 - (vi) Supplier of the source.

- (vii) Special form certificate. Attach special form certificate for the radioactive source.
 - (viii) Design, manufacturing and testing of the source. Demonstrate that the design, manufacturing and testing of the source were conducted in accordance with ISO 2919:2012 or another appropriate standard.
 - (ix) Leak test. Demonstrate that the leak test was conducted in accordance with ISO 9978:2020 or another appropriate standard.
 - (x) Working life of the source. Specify the recommended working life given by the manufacturer.
 - (xi) Certificate for sealed radioactive source, according to ISO 2919:2012 or equivalent standard, specifying source classification, model designation, serial number, content activity, leak test results according to ISO 9978:2020, radiation output, special form approval certificate number and recommended working life.
 - (xii) Source holder(s) and source assembly (rack). Demonstrate that the design, manufacturing and testing of the source holder and source assembly are in accordance with international or national standards. Submit a copy of the certificate provided by the supplier.
 - (xiii) Type of gamma irradiator in which sources are to be used: self-shielded gamma irradiator (category I), panoramic dry source storage irradiator (category II), underwater irradiator (category III) or panoramic wet source storage irradiator (category IV).
- (2) Description of the facility.
- (a) Irradiation room(s):
 - (i) Layout of the irradiation room^a. Demonstrate that the design of the irradiation room enables optimization of radiation protection for workers and members of the public. The layout needs to be given using a scale enabling analysis of the characteristics of the irradiation room and adjacent areas (e.g. entrances, maze, doors, roof, floors and penetrations used for ventilation and electrical ducts), source storage places, rooms for additional equipment if applicable (e.g. room for water treatment equipment, air control room and source hoist mechanism), and loading and unloading area. In particular, include details related to the control room, which needs to be located outside the irradiation room, and to all other adjacent offices or buildings. Specify all construction materials, e.g. material type, thickness and density. Specify which existing sources and equipment will be used in

the irradiation room and provide a process flow diagram. Give the position(s) of source(s) and equipment. Specify all adjacent equipment, such as the source hoist mechanism.

- (ii) Radioactive source storage. For dry storage in containers (category I and II gamma irradiators), provide a copy of the construction schemes, including inserts, brackets and other hardware used to anchor or hold in place items such as the source holder, guide rods or cables used for the movement the source (or the sample chamber), and various pipes for other services; specify all construction materials, e.g. material type, thickness and density; describe and include the radiation safety assessment provided by the manufacturer demonstrating that the design of the source container enables optimization of radiation protection for workers. For dry built-in storage (category II gamma irradiators) and wet (pool) storage (category III and IV gamma irradiators), provide all construction schemes, including inserts, brackets used to anchor or hold in place items such as the source holder, guide rods or cables used for the movement of the source (or the product container), and various pipes for other services (e.g. for the cooling system, if required). For dry storage, specify all construction materials, e.g. material type, thickness and density. For wet storage, specify the height of the water column. Demonstrate that doses are below the dose limit, dose constraints for workers are established, and doses are optimized to be as low as possible. Demonstrate that a qualified expert was involved in the calculations.
- (iii) Temporary radioactive source storage. If additional source storage is built within the irradiation room for other purposes, e.g. to facilitate maintenance/repair of the gamma irradiator, provide the information required in (ii) for the dry built-in storage or pool storage, as applicable, with the exception of those related to the movement of the source.
- (iv) Shielding calculation and assumptions used. Demonstrate that the design and shielding, as well as the assumptions used (e.g. use factor and occupancy factor), took into account radiation fields produced by sources during irradiation. Provide dose and dose rate calculations related to exposure for workers and members of the public. In particular, demonstrate shielding from air scattered radiation ('sky shine'). Demonstrate that leakage radiation is taken into account. Specify the maximum operating conditions of the equipment, e.g. maximum activity of the radioactive source and beam directions. Demonstrate temperature control as

appropriate. Provide a plan of the irradiation room surroundings. Demonstrate that doses are below the dose limit, dose constraints for workers and members of the public are established, and doses are optimized to be as low as possible. Demonstrate that a qualified expert was involved in the calculations.

- (v) Safety features. Specify the position of all technical safety features and warning systems. Describe the design and function of safety and warning systems, including the independence, redundancy and diversity of safety systems, as well as the emergency power supply system providing services essential for safety, such as emergency lighting, instrumentation and control. Describe in detail all safety systems^b and specify the procedures to assess them. Specify in detail how safety systems are controlled through the control console, e.g. emergency shutdown button (i.e. emergency stop device), device for disabling the irradiation at the control console for maintenance, single control and access key for the irradiator, light and acoustic signals showing operation of the irradiator, including radiation (source) status and viewing screen for the product conveyor system. Demonstrate that all equipment inside the irradiation room (including wiring, electrical equipment, notices and lighting) is selected to minimize the probability of failure due to prolonged exposure to radiation. Demonstrate that good engineering practices are taken into account. Demonstrate that the text of the notices is in a language understandable to the persons likely to be in areas around the irradiation room(s). Specify how fire protection manages hazards related to the existing radioactive sources. Describe in detail the preparation for irradiation, e.g. daily checks of safety systems, as required by the manufacturer, preparation of products to be irradiated, start-up sequence, irradiation process and releasing irradiated products.
 - (vi) Boundaries of controlled and supervised areas. Demonstrate that controlled and supervised areas are designated and attach a layout showing the controlled and supervised areas.
- (3) Technical information of radiation monitoring equipment.
- (a) Radiation monitors installed in the irradiation room and other areas. Provide technical information related to permanently installed radiation monitors. Demonstrate the suitability and calibration of the monitors.
 - (b) Portable survey meters. Provide technical information related to portable survey meters to be used. Demonstrate the suitability and calibration of portable survey meters and specify their use and number,

i.e. specify that survey meters used are suitable and the applicant has a sufficient number of portable survey meters.

- (c) Personnel monitoring devices. Demonstrate that personnel monitoring devices have been provided to all workers. Demonstrate that personal dosimetry devices with direct reading and alarm functions are available, if required. Specify all technical information and dosimetry services to be used.
- (4) Safe and secure management and control of radiation sources once it has been decided to take them out of use, including financial provisions. Demonstrate that all disused sources, including depleted uranium, are managed in line with safety requirements, e.g. demonstrate that storage for disused sources is designed and controlled using optimization and dose limitations and that management of the storage includes all safety and security precautions. Specify financial provisions for safe and secure management of all disused sources, including depleted uranium.

^a For category I, 'self-shielded' gamma irradiators, provide information on the non-shielded room holding the irradiator and its surroundings, on source storage and on safety features. For category III gamma irradiators that are not in a shielded irradiation room, specify the location above the source storage pool of the radiation monitor used to detect abnormal radiation levels, as well as the locations of the visual and acoustic alarms at the entrances to the access barrier around the source storage pool.

^b Elements of safety systems include: safety interlock systems for control of access to the radiation source; backup access control for personnel entry (e.g. photoelectric cell); removable irradiation room shield plugs (e.g. roof plugs); fixed radiation monitor with alarm; multipurpose access key attached to a portable survey meter; emergency stop device at the control console; device for disabling irradiation at the control console for maintenance work; safety delay timer inside the irradiation room with alarm; maze(s); emergency stop device (e.g. emergency cord) in the irradiation room and maze; emergency exit; shielding; temperature detection and control system; earthquake detectors; fire detection and fire extinguishing system; electrical power; non-electrical power (e.g. pneumatic power or hydraulic power); product conveyor mechanism; product movement timer; safety interlocks for product entry and exit ports; backup access control for product entry and exit ports (e.g. photoelectric cell); product exit radiation monitor; irradiation (source) status indicators; device for positioning and removing radioactive sources from a source rack; anti-collision system and source guard; emergency source cooling system; source travel timer; emergency access ports; source rack position indicators; ventilation and air control(including ozone control); control and safety interlock systems to storage pools; backup system for lowering the source rack; water treatment and conditioning system; radiation monitoring of the water treatment and conditioning system; control of storage pool integrity and materials; water control level; cooling of storage pool water (for source activities greater than 400 kCi or 15 PBq); automatic or manual water loss replacement system; storage pool guard and cover; in-pool piping preventing lowering the water level, which could compromise radiation shielding; acoustic signals; and labelling and posting at the facility.

TABLE II-4.5. APPLICATION FOR AUTHORIZATION — TECHNICAL INFORMATION FOR INDUSTRIAL RADIOGRAPHY

- (1) Information on radiation sources.
 - (a) Information on gamma exposure device(s):
 - (i) Manufacturer of the gamma exposure device.
 - (ii) Supplier of the gamma exposure device.
 - (iii) Model of the gamma exposure device.
 - (iv) Serial number of the gamma exposure device.
 - (v) Design, manufacturing and testing of the gamma exposure device. Demonstrate that the gamma exposure device is designed, manufactured and tested using ISO 3999:2004 (i.e. attach the certificate) or an equivalent national standard. Demonstrate that labelling is in line with ISO 3999:2004 or an equivalent national standard.
 - (vi) Safety features of the crawler equipment using the gamma source. Specify the safety features related to the equipment, such as return of the source in the shielding position in case of electronic failure.
 - (b) Information on radioactive sources (all non-exempt sources, including sources for checking equipment, calibration sources and crawler control sources):
 - (i) Radionuclide.
 - (ii) Manufacturer of the source.
 - (iii) Model.
 - (iv) Source serial number.
 - (v) Source activity and reference date.
 - (vi) Supplier of the source.
 - (vii) Special form certificate. Attach special form certificate for the radioactive source.
 - (viii) Design, manufacturing and testing of the source. Demonstrate that the design, manufacturing and testing of the source were conducted in accordance with ISO 2919:2012 or another appropriate standard.
 - (ix) Leak test. Demonstrate that the leak test was conducted in accordance with ISO 9978:2020 or another appropriate standard.
 - (x) Working life of the source. Specify the recommended working life given by the manufacturer.
 - (xi) Certificate for sealed radioactive source, according to ISO 2919:2012 or equivalent standard, specifying: source

classification, model designation, serial number, content activity, leak test results according to ISO 9978:2020, radiation output, special form approval certificate number and recommended working life.

- (xii) Source assembly (e.g. ‘pigtail’ assembly method).
 - (xiii) Design, manufacturing and testing of the source assembly. Demonstrate that the design, manufacturing and testing of the source assembly are in accordance with ISO 3999:2004 or an equivalent national standard.
 - (xiv) Compatibility of the equipment. Demonstrate the compatibility of the source assembly with the gamma exposure device and the compatibility of all ancillary equipment (such as the guide tube and collimators), including any source storage and storage container.
- (c) Details about depleted uranium used in exposure devices, source changers, storage containers and collimators, if any:
- (i) Specify whether depleted uranium is used;
 - (ii) Specify the mass of the depleted uranium.
- (d) Source changers and storage containers:
- (i) Dose level requirements and labelling requirements. Demonstrate that the source changers and storage containers meet the dose levels and labelling requirements of ISO 3999:2004 or an equivalent national standard.
 - (ii) Safety of changer and storage containers. Demonstrate the existence of a locking mechanism and that the source changer and storage container have been designed so that a source cannot fall out of the container.
- (e) Information on X ray generator(s):
- (i) Type of the X ray generator.
 - (ii) Manufacturer of the X ray generator.
 - (iii) Model of the X ray generator.
 - (iv) Serial number(s) of the X ray generator housing and panel.
 - (v) Supplier of the X ray generator.
 - (vi) Type, model and serial number of the tube.
 - (vii) Manufacturer of the tube.
 - (viii) Maximum voltage.
 - (ix) Maximum current intensity.
 - (x) Supplier of the tube.
 - (xi) Permanent and added filters. Provide information on the use of filters already installed in the equipment and filters installed by the user.

- (xii) Collimators. Provide information on the use of collimators.
 - (xiii) Maximum leakage radiation. Specify leakage radiation given by the manufacturer.
 - (xiv) Safety features of X ray generator equipment. Demonstrate that appropriate labels are posted, e.g. on the control panel. Demonstrate that the control panel has safety features, e.g. emergency stop button, appropriate indicators of status of the equipment and a lock to prevent unauthorized use. Demonstrate that the length of the X ray tube connection cable is at least 20 m for X ray generators up to 300 kV and longer for higher energy equipment.
 - (xv) Safety features of crawler equipment using X ray generator. Specify the safety features related to the crawler equipment, such as return of the source to the shielding position in case of electronic failure.
- (2) Description of the facility.
- (a) Radioactive source storage:
 - (i) Layout of the radioactive source storage facility. The layout needs to be given using a scale enabling analysis of the storage characteristics, e.g. entrances, doors, windows, roof, floors, penetrations and adjacent offices or buildings. Specify all construction materials e.g. material type, thickness and density. Specify which existing sources and equipment will be stored in the storage area and the maximum capacity of the storage.
 - (ii) Shielding calculation and assumptions used. Where radioactive sources are involved, demonstrate that the assumptions used (e.g. shielding design, including the shielding of exposure devices and storage containers, workload and occupancy factor) took into account the radiation fields produced by all sources to be stored. Demonstrate that doses are below the dose limits, dose constraints for workers and members of the public are established, and doses are optimized to be as low as possible. Demonstrate that a qualified expert was involved in the calculations.
 - (iii) Safety features. Specify the positions of all technical safety systems, e.g. monitors, sensors, access control measures, barriers, detectors producing warning signals, and notices. Describe the design and function of safety and warning systems. Demonstrate that the text of the notices is in a language understandable to the persons likely to be in areas around the radioactive source storage.

- (iv) Boundaries of controlled and supervised areas. Demonstrate that controlled and supervised areas are designated.
- (b) Irradiation room(s):
 - (i) Layout of any shielded enclosure to be used. The layout needs to be given using a scale enabling analysis of the characteristics of the irradiation room and adjacent areas, e.g. entrances, maze, doors, roof, if any, floors and shielding penetrations (e.g. used for ventilation and electrical ducts). Include details related to any control room outside the irradiation room and to all other adjacent offices, working places or buildings. Specify all construction materials, e.g. material type, thickness and density. Specify which existing sources and equipment will be used in the irradiation room and provide a process flow diagram. Give the position(s) of source(s) and equipment. Specify all adjacent equipment, such as cranes.
 - (ii) Shielding calculation and assumptions used. Demonstrate that the design and shielding, as well as the assumptions used (e.g. use factor and occupancy factor), took into account radiation fields produced by sources during irradiation. Provide dose and dose rate calculations related to the exposure of workers and members of the public. In designs with minimal or no roof, demonstrate that due consideration has been given to the air scattering of radiation (or 'sky shine') and to scattering from objects outside the enclosure, such as higher ceilings or walls in the vicinity of the enclosure, if it is to be constructed inside another building. Demonstrate that leakage radiation is taken into account. Specify the maximum operating conditions of the equipment, e.g. maximum activity of the radioactive source and directions of the beam. Provide a plan of the irradiation room surroundings. Demonstrate that doses are below the dose limit, dose constraints for workers and members of the public are established, and doses are optimized to be as low as possible. Demonstrate that a qualified expert was involved in the calculations.
 - (iii) Safety features. Specify the positions of all technical safety features and warning systems, such as emergency cords or buttons, radiation monitor(s) (e.g. dose rate monitors in the irradiation rooms), door interlocks, use of key control, sensors, access control measures, barriers, monitors, warning signals (i.e. acoustic and visual) and notices. Describe the design and function of safety and warning systems, including the independence, redundancy and diversity of safety systems. Demonstrate that

the text of the notices is in a language understandable to the persons likely to be in areas around the irradiation room(s). Specify how fire protection manages hazards related to the existing radioactive sources. Demonstrate that good engineering practices are taken into account.

- (iv) Boundaries of controlled and supervised areas. Demonstrate that controlled and supervised areas are designated and attach a layout showing the controlled and supervised areas.
- (c) Location of site radiography. Specify in detail how site radiography will be prepared, e.g. cooperation with the client, assessment of the location, preparation of time schedule, use of local rules and emergency preparedness, taking into account any additional risks at the site. Specify in detail how site radiography will be conducted, e.g. establishment of controlled areas, use of temporary shielding, use of warning signals and notices in a language understood by persons at the location, and establishment of all other precautions before, during and after irradiation. Specify the use of all sources and equipment to be available at the site, such as X ray exposure devices, collimators, guide tubes, control tubes, monitoring equipment, personal dosimeters and alarm dosimeters, warning signals and notices, and emergency kit. Demonstrate that radiation monitors are used, particularly after each exposure using radiation sources. Specify how the applicant ensures that at least two radiographers perform radiography with each source. Demonstrate that security is ensured. Demonstrate that arrangements are in place for the transport of radioactive sources and that transport packages (e.g. transport containers) are in line with IAEA Safety Standards Series No. SSR-6 (Rev. 1), Regulations for the Safe Transport of Radioactive Material [II-5], e.g. provide the certificate for the transport package. Specify the safety training provided to drivers, as well as data related to the vehicles to be used.
- (d) On-site radioactive source storage. In site radiography, provide procedures requiring appropriate arrangements to be established with the site operator ensuring that the same level of protection as in the user's source storage is granted at the temporary on-site source storage in the operating organization's main base. Describe the basic elements of the layout of a typical temporary storage of radioactive sources in remote locations and specify the maximum capacity of the storage. Demonstrate that doses are kept below dose limits, dose constraints for workers and members of the public are established, and doses are optimized to be as low as possible. Demonstrate that controlled and supervised areas are to be designated.

Demonstrate that a qualified expert was involved in the calculations. If the radiography vehicle is to be used as temporary storage of radioactive sources, specify all safety and security systems, as well as the assumptions used in the assessment of exposures of workers and members of the general public. Demonstrate that controlled and supervised areas are to be designated.

- (3) Technical information of radiation monitoring equipment.
 - (a) Radiation monitors installed in the irradiation room. Provide technical information related to permanently installed radiation monitors. Demonstrate the suitability and calibration of the monitors.
 - (b) Portable survey meters. Provide technical information related to portable survey meters to be used. Demonstrate the suitability and calibration of portable survey meters and specify their use and number; i.e. specify that survey meters used for industrial radiography are suitable and the applicant has a sufficient number of portable survey meters.
 - (c) Personnel monitoring devices. Demonstrate that personnel monitoring devices have been provided to all workers. Demonstrate that personal dosimetry devices with direct reading and alarm functions are available, if required. Specify all technical information and dosimetry services to be used.
 - (4) Safe and secure management and control of radiation sources once it has been decided to take them out of use, including financial provisions. Demonstrate that all disused sources, including depleted uranium, are managed in line with safety requirements, e.g. demonstrate that storage for disused sources is designed and controlled using optimization and dose limitations, and that management of the storage includes all safety and security precautions. Specify financial provisions for safe management of all disused sources, including depleted uranium.
-

TABLE II-4.6. APPLICATION FOR AUTHORIZATION — TECHNICAL INFORMATION FOR WELL LOGGING

- (1) Information on radiation sources.
 - (a) Information on well logging equipment, e.g. source container(s) or device(s) and well logging tools in which a radioactive source is to be used.

- (i) Manufacturer of the well logging equipment.
 - (ii) Supplier of the well logging equipment.
 - (iii) Model of the well logging equipment.
 - (iv) Serial number of the well logging equipment.
 - (v) Design, manufacturing and testing of the well logging tools. Demonstrate that source containers (i.e. used and spare containers, source holders, remote handling tools, shutters, safety mechanisms and housing systems, etc.) have been designed, manufactured and tested by an authorized manufacturer in accordance with the manufacturer's ISO 9001 quality assurance system (ISO 9001:2015). Provide relevant documentation, e.g. certificates, related fulfilment of international standards or national standards or requirements.
 - (vi) Demonstrate the existence of a locking mechanism to ensure that the source is safely retained in the storage container.
- (b) Information on radioactive sources (all non-exempt sources, including sources for checking equipment and calibration sources):
- (i) Radionuclide.
 - (ii) Manufacturer of the source.
 - (iii) Model.
 - (iv) Source serial number.
 - (v) Source activity and reference date.
 - (vi) Supplier of the source.
 - (vii) Special form certificate. Attach the special form certificate for the radioactive source.
 - (viii) Design, manufacturing and testing of the source. Demonstrate that the design, manufacturing and testing of the source were conducted in accordance with ISO 2919:2012 or another appropriate standard.
 - (ix) Leak test. Demonstrate that the leak test was conducted in accordance with ISO 9978:2020 or another appropriate standard.
 - (x) Working life of the source. Specify the recommended working life given by the manufacturer.
 - (xi) Certificate for sealed radioactive sources, according to ISO 2919:2012 or equivalent standard, specifying: source classification, model designation, serial number, content activity, leak test results according to ISO 9978:2020, radiation output, special form approval certificate number and recommended working life.

- (c) Details about depleted uranium used in well logging equipment, if any:
 - (i) Specify whether depleted uranium is used;
 - (ii) Specify the mass of the depleted uranium.
 - (d) Source changers and storage containers:
 - (i) Dose levels requirements and labelling requirements. Demonstrate that source changer(s) and storage container(s) meet dose level and labelling requirements for their safe use.
 - (ii) Safety of changer and storage container. Demonstrate the existence of a locking mechanism and that the source changer and storage container have been designed so that a source cannot fall out of the container.
- (2) Description of the facility.
- (a) Radioactive source storage:
 - (i) Layout of the source storage facility. Demonstrate that the design of the storage enables optimization of radiation protection for workers and members of the public. The layout needs to be given using a scale enabling analysis of the storage characteristics, e.g. entrances, doors, roof, floors, penetrations and adjacent offices or buildings. Specify all construction materials, e.g. material type, thickness and density. Specify which existing sources and equipment will be stored in the storage area. Specify the maximum capacity of the storage.
 - (ii) Shielding calculation and assumptions used. Demonstrate that the design and shielding, as well as the assumptions used (e.g. workload and occupancy factor), took into account the radiation fields produced by all sources to be stored. Demonstrate that doses are below dose limits, dose constraints for workers and members of the public are established, and doses are optimized to be as low as possible. Demonstrate that a qualified expert was involved in the calculations.
 - (iii) Safety features. Specify the position of all technical safety systems, e.g. monitors, sensors, access control measures, barriers, detectors producing warning signals and notices. Describe the design and function of safety and warning systems. Demonstrate that the text of the notices is in a language understandable to the persons likely to be in the areas around the radioactive source storage.
 - (iv) Boundaries of controlled and supervised areas. Demonstrate that controlled and supervised areas are designated.

- (b) Calibration areas. Demonstrate that a specific area has been designated in the facility for calibrating the logging tools containing radiation sources. Specify in detail how calibration will be conducted, e.g. establishment of controlled and supervised areas, use of warning signals and notices in a language understood by persons at the location, establishment of all other precautions before and during calibration. Specify how people will be informed when calibrations are planned and performed. Demonstrate that radiation monitors are used. When calibration cannot be performed in the designated area, demonstrate that adequate cooperation with the client has been established and safety precautions are taken to minimize the exposure to personnel. Demonstrate that security is ensured.
- (c) Locations of site well logging works. Specify in detail how site well logging works are to be prepared, e.g. cooperation with the client, assessment of the location, preparation of time schedule, use of local rules and emergency preparedness, taking into account any additional risks at the site. Specify in detail how site well logging works are to be conducted, e.g. establishment of controlled areas, use of warning signals and notices in a language understood by persons at the location, establishment of other precautions before, during and after the works. Specify the use of logging tools containing radiation sources and any radiation sources to be available at the site, monitoring equipment, personal dosimeters and alarm dosimeters, warning signals and notices, and emergency kit. Demonstrate that radiation monitors are used. Demonstrate that security is ensured. Demonstrate that arrangements are in place for the transport of radioactive sources in line with SSR-6 (Rev. 1) [II-5]. Specify the safety training provided to the drivers, as well as data related to the vehicles to be used.
- (d) On-site radioactive source storage. Provide procedures requiring appropriate arrangements to be established with the site operator ensuring that the same level of protection as in the user's source storage is granted at the temporary on-site source storage in the operating organization's main base. Describe the basic elements of the layout of a typical temporary storage of radioactive sources in remote locations and specify the maximum capacity of the storage. Demonstrate that doses are to be kept below dose limits, dose constraints for workers and member of the public are established, and doses are optimized to be as low as possible. Demonstrate that controlled and supervised areas are to be designated. Demonstrate that a qualified expert was involved in the calculations. If the well logging vehicle is to be used as temporary storage of

radioactive sources, specify all safety and security systems, as well as the assumptions used in the assessment of exposures of workers and members of the general public. Demonstrate that controlled and supervised areas are to be designated. Demonstrate that security functions of detection, delay and response are ensured.

- (3) Information on radiation monitoring equipment.
 - (a) Portable survey meters. Provide technical information related to portable survey meters to be used. Demonstrate the suitability and calibration of portable survey meters and specify their use and number, i.e. specify that survey meters used for well logging are suitable and that the applicant has a sufficient number of portable survey meters.
 - (b) Personnel monitoring devices. Demonstrate that personnel monitoring devices have been provided to all workers. Demonstrate that personal dosimetry devices with direct reading and alarm functions are available, if required. Specify all technical information and dosimetry services to be used.
 - (4) Safe and secure management and control of radiation sources once it has been decided to take them out of use, including financial provisions. Demonstrate that all disused sources, including depleted uranium, are managed in line with safety requirements, e.g. demonstrate that storage for disused sources is designed and controlled using optimization and dose limitations and that management of the storage includes all safety and security precautions. Specify the financial provisions for safe management of all disused sources, including depleted uranium.
-

TABLE II-4.7. APPLICATION FOR AUTHORIZATION — TECHNICAL INFORMATION FOR NUCLEAR GAUGES

- (1) Information on radiation sources.
 - (a) Information on nuclear gauge(s) containing radioactive sources, i.e. the housing of radioactive sources:
 - (i) Manufacturer of the nuclear gauge.
 - (ii) Supplier of the nuclear gauge.
 - (iii) Model of the nuclear gauge.
 - (iv) Serial number of the nuclear gauge.

- (v) Design, manufacturing and testing of nuclear gauges. Demonstrate that nuclear gauges containing radioactive sources and ancillary equipment are obtained from an authorized manufacturer in accordance with the manufacturer's ISO 9001 quality assurance system (ISO 9001:2015) to ensure that the design safety features are reproduced consistently. Demonstrate that international or national standards are met; e.g. for gauges designed for permanent installation, ISO 7205:1986 applies.
- (b) Information on radioactive sources (all non-exempt sources, including sources for checking equipment and calibration sources):
 - (i) Radionuclide.
 - (ii) Manufacturer of the source.
 - (iii) Model.
 - (iv) Source serial number.
 - (v) Source activity and reference date.
 - (vi) Supplier of the source.
 - (vii) Special form certificate. Attach the special form certificate for the radioactive source.
 - (viii) Design, manufacturing and testing of the source. Demonstrate that the design, manufacturing and testing of the source were conducted in accordance with ISO 2919:2012 or another appropriate standard.
 - (ix) Leak test. Demonstrate that the leak test was conducted in accordance with ISO 9978:2020 or another appropriate standard.
 - (x) Working life of the source. Specify the recommended working life given by the manufacturer.
 - (xi) Certificate for sealed radioactive sources, according to ISO 2919:2012 or equivalent standard, specifying: source classification, model designation, serial number, content activity, leak test results according to ISO 9978:2020, radiation output, special form approval certificate number and recommended working life.
- (c) Details about depleted uranium used for gauges, sources changers and storage containers, if any:
 - (i) Specify whether depleted uranium is used;
 - (ii) Specify the mass of the depleted uranium.
- (d) Source changers and storage containers:
 - (i) Dose levels requirements and labelling requirements. Demonstrate that the source changers and storage containers meet dose level and labelling requirements to ensure safety.

- (ii) Safety of changers and storage containers. Demonstrate the existence of a locking mechanism and that the source changer and storage container have been designed so that a source cannot fall out of the container.
- (e) Information on X ray generator(s):
 - (i) Type of the X ray generator.
 - (ii) Manufacturer of the X ray generator.
 - (iii) Model of the X ray generator.
 - (iv) Serial number(s) of the X ray generator housing and panel.
 - (v) Supplier of the X ray generator.
 - (vi) Type, model and serial number of the tube.
 - (vii) Manufacturer of the tube.
 - (viii) Maximum voltage.
 - (ix) Maximum current intensity.
 - (x) Supplier of the tube.
 - (xi) Permanent and added filters. Provide information on the use of filters already installed in the equipment and filters installed by the user.
 - (xii) Collimators. Provide information on the use of collimators.
 - (xiii) Maximum leakage radiation. Specify the leakage radiation given by the manufacturer.
 - (xiv) X ray generator equipment. Demonstrate that appropriate labels are posted, e.g. on the control panel. Demonstrate that the control panel has safety features, e.g. emergency stop button, appropriate indicators of the status of the equipment and a lock to prevent unauthorized use, and that there is a signal indicating when irradiation is taking place.
- (2) Description of the facility.
 - (a) Radioactive source storage:
 - (i) Layout of the storage for nuclear gauges containing radioactive sources. Demonstrate that the design of the storage enables optimization of radiation protection for workers and members of the public. The layout needs to be given using a scale enabling analysis of the storage characteristics, e.g. entrances, doors, roof, floors, penetrations and adjacent offices or buildings. Specify all construction materials, e.g. material type, thickness and density. Specify which existing sources and equipment will be stored in the storage area. Specify the maximum capacity of the storage.
 - (ii) Shielding calculation and assumptions used. Demonstrate that the design and shielding, as well as the assumptions used (e.g. workload and occupancy factor), took into account the

radiation fields produced by all sources to be stored. Demonstrate that doses are below dose limits, dose constraints for workers and members of the public are established, and doses are optimized to be as low as possible. Demonstrate that a qualified expert was involved in the calculations.

- (iii) Safety features. Specify the position of all technical safety systems, e.g. monitors, sensors, access control measures, barriers, detectors producing warning signals and notices. Describe the design and function of safety and warning systems. Demonstrate that the text of the notices is in a language understandable to the persons likely to be in areas around the radioactive source storage.
 - (iv) Boundaries of controlled and supervised areas. Demonstrate that controlled and supervised areas are designated.
- (b) Facility with fixed, i.e. installed, nuclear gauges:
- (i) Layout of the facility. Demonstrate that the location of a fixed nuclear gauge enables optimization of radiation protection for workers and members of the public. The layout needs to be given using a scale enabling analysis of the characteristics of the facility and adjacent areas, e.g. workplaces and access paths to the gauge. Include details related to the control room, when applicable, and to all other adjacent offices or buildings. Specify all construction materials, e.g. material type, thickness and density. Specify which existing sources and equipment will be used in the areas and provide the process flow diagram for each area. Give the position(s) of all source(s) and equipment in the facility.
 - (ii) Shielding calculation and assumptions used. Demonstrate that, during the design of any required shielding barriers, the appropriate assumptions were used (e.g. use factor and occupancy factor), and the radiation fields produced by a gauge, including scattered radiation, were taken into account. Provide dose and dose rate calculations related to the exposure for workers (in particular those working in places adjacent to the nuclear gauges) and members of the public. Demonstrate that doses are below the dose limit, dose constraints for workers and members of the public are established, and doses are optimized to be as low as possible. Demonstrate that a qualified expert was involved in the calculations.
 - (iii) Safety features. Specify the position of all technical safety features and warning systems, e.g. use of key control, barriers,

protective cage and warning signals (i.e. acoustic and visual) and notices. Describe the design and function of safety and warning systems, including the independence, redundancy and diversity of safety systems. Demonstrate that the text of the notices is in a language understandable to the persons likely to be in areas around the installed gauge. Specify how fire protection manages hazards related to the existing radioactive sources. Demonstrate that good engineering practices are taken into account.

- (iv) Boundaries of controlled and supervised areas. Demonstrate that controlled and supervised areas are designated and attach a layout showing the controlled and supervised areas.
- (c) Locations for site works using nuclear gauges. Specify in detail how a work with portable gauges will be prepared, e.g. cooperation with the client, assessment of the location, preparation of time schedule, use of local rules and emergency preparedness procedures, taking into account any additional risks at the site. Specify in detail how work with portable gauges will be conducted, e.g. establishment of controlled areas, use of temporary shielding, use of warning signals and notices in a language understood by persons at the location, establishment of all other precautions before, during and after the use of a gauge. Specify the use of all sources and equipment to be available at the site, such as monitoring equipment, personal dosimeters and alarm dosimeters, warning signals and notices, and emergency kit. Demonstrate that radiation monitors are used. In particular, demonstrate that a radiation monitor is used after each exposure using radiation sources. Demonstrate that security is ensured. Demonstrate that arrangements are in place for the transport of radioactive sources. Specify the safety training provided to drivers, as well as data related to the vehicles to be used.
- (d) On-site radioactive source storage. In on-site works using nuclear gauges, provide procedures requiring appropriate arrangements to be established with the site operator ensuring that the same level of protection as in the user's source storage is granted at the temporary on-site source storage in the operating organization's main base. Describe the basic elements of the layout of a typical temporary storage of radioactive sources in remote locations and specify the maximum capacity of the storage. Demonstrate that doses are to be kept below dose limits, dose constraints for workers and member of the public are established, and doses are optimized to be as low as possible. Demonstrate that controlled and supervised areas are to be designated. Demonstrate that a qualified expert was involved in the

calculations. If the vehicle transporting nuclear gauges is to be used as temporary storage of radioactive sources, specify all safety and security systems, as well as the assumptions used in the assessment of exposures of workers and members of the general public. Demonstrate that controlled and supervised areas are to be designated.

- (3) Technical information of radiation monitoring equipment.
 - (a) Portable survey meters. Provide technical information related to portable survey meters to be used. Demonstrate the suitability and calibration of portable survey meters and specify their use and number, i.e. specify that survey meters used for nuclear gauges are suitable and the applicant has a sufficient number of portable survey meters.
 - (b) Personnel monitoring devices. Demonstrate that personnel dosimetry devices have been provided to workers, if required by the safety assessment. Demonstrate that personal dosimetry devices with direct reading and alarm functions are available, if required. Specify all technical information and dosimetry services to be used.
 - (4) Safe and secure management and control of radiation sources once it has been decided to take them out of use, including financial provisions, when appropriate. Demonstrate that all disused sources, including depleted uranium, are managed in line with safety requirements, e.g. demonstrate that storage for disused sources is designed and controlled using optimization and dose limitations and that management of the storage includes all safety and security precautions. When appropriate, specify financial provisions for the safe management of all disused sources, including depleted uranium.
-

II-5. SAFETY ASSESSMENT

The information on the safety assessment to be submitted by applicants for authorization has been prepared in accordance with IAEA Safety Standards Series Nos GSR Part 4 (Rev. 1), Safety Assessment for Facilities and Activities (Requirements 1-7, 20 and 21) [II-6], GSR Part 1 (Rev. 1), Governmental, Legal and Regulatory Framework for Safety (Requirement 24) [II-7] and GSG-13 (paras 3.98 and 3.102) [II-2].

TABLE II-5. APPLICATION FOR AUTHORIZATION — SAFETY ASSESSMENT FOR ALL PRACTICES

The safety assessment has to address the following aspects^a:

- (1) Expected doses (occupational, public and from medical exposure) arising from normal operation of the practice.
- (2) Estimation of the potential doses (occupational, public and from medical exposure) from anticipated operational occurrences and accident conditions (failures or internal or external events that challenge the safety of the facility or activity).
- (3) Identification of postulated accident initiating events, commensurate with the particular features of the practice.
- (4) Description of the severity of the potential consequences for workers, members of the public and patients associated with each of the accident initiating events. Provide an evaluation of the consequences for workers, members of the public and patients based on the potential effect that each accident initiating event could have without taking into account the safety measures or barriers envisaged.
- (5) Description, for each accident initiating event, of existing safety barriers aimed at preventing or mitigating accidents.
- (6) Risks associated with each accident initiating event. Risk needs to be expressed as a function of the frequency with which the initiating event occurs, the robustness of the safety barriers and the severity of the potential consequences associated with each initiating event. Risk may be classified following a prioritization principle to facilitate further decision making.
- (7) Conclusions. Include a programme of safety measures to be carried out for higher risk initiating events to ensure optimization of protection to the highest reasonably achievable safety level.
- (8) Independent verification. Attach the results of an independent verification of the safety assessment.
- (9) Review of safety assessment. Demonstrate that regular and documented reviewing of the safety assessment is in place.

^a For certain practices in X ray imaging radiology (e.g. bone densitometry and stomatology), a generic safety assessment is sufficient.

II-6. PROTECTION OF WORKERS

The information on the protection of workers to be submitted by applicants for authorization has been prepared in accordance with GSR Part 3 (Requirements 4, 7, 9, 12, 13, 21, 24–26) [II-1] and GSG-13 (paras 3.98 and 3.102) [II-2].

TABLE II-6. APPLICATION FOR AUTHORIZATION — PROTECTION OF WORKERS IN ALL PRACTICES

- (1) Education and training of workers. Specify names, qualification, education, training and retraining of workers. Describe how staff^a (including assistants and trainees) are trained and qualified. Specify how the radiation protection officer was designated and whether the radiation protection officer complies with the criteria established by the regulatory body, e.g. education, training and experience. If the applicant uses a qualified expert, provide information on the certification (formal recognition), education and experience of the qualified expert.
- (2) Personal dosimetry. Specify the authorized or approved dosimetry service and the arrangements related to the monitoring of personal doses. Provide the results of the reviews of past occupational doses. Provide the records of past occupational exposure of workers (including itinerant), if not already recorded in the registry of occupational doses.
- (3) Workers' health surveillance. Specify programmes for health surveillance.
- (4) Itinerant workers. Describe the allocation and documentation of the responsibilities of the employer and the applicant for the safety and protection of itinerant workers.
- (5) Arrangements for the radiation protection programme. Demonstrate that all of the following elements of the radiation protection programme are in place:
 - (a) Assignment of responsibilities for the radiation protection programme.
 - (b) Designation of controlled or supervised areas. Specify the designation of controlled and supervised areas using a safety assessment and measured dose rates in working rooms/areas and storages. Demonstrate the appropriate management of labels, marks and notices.
 - (c) Practice specific local rules^b. Demonstrate that local rules applicable for workers are prepared for all processes and that an adequate number of workers is involved in the practice. In particular, specify the roles and responsibilities of workers and demonstrate that processes are

supervised. Demonstrate that rules, labels and notices are written in a language understood by those for whom they are intended. Provide a workplace and area monitoring programme. Demonstrate that the necessary radiation monitoring equipment is available. Provide the technical specification, selection, calibration, maintenance, testing and use of radiation monitoring equipment. Demonstrate that the monitoring programme takes into account all processes of the applicant, e.g. use and maintenance of radiation equipment, accepting packages with new radioactive sources and preparing packages for transport^c.

- (d) Personal protective equipment. Demonstrate that the need to rely on administrative control and personal protective equipment for protection and safety is minimized, giving priority to engineering controls. Demonstrate that appropriate personal protective equipment is provided and arrangements are made for its proper use, testing and maintenance.
- (e) Recording and reporting of information. Describe the system for recording and reporting all information related to exposure control, decisions regarding measures for occupational radiation protection and safety, as well as individual radiation monitoring.
- (f) Audit and review of the radiation protection programme and the security programme^c. Specify methods for periodic auditing and review of the implementation of the radiation protection and security programmes^c.

^a ‘Staff’ includes: for medical practices — medical physicists of various specialties (e.g. radiation therapy, nuclear medicine, diagnostic radiology and other medical and paramedical professionals) and radiation technologists; for industrial practices — operators of radiation sources (e.g. industrial irradiators, nuclear gauges, industrial radiography and well logging devices) and their assistants.

^b See below for local rules for industrial practices.

^c Not applicable to X ray imaging in radiology.

Local rules for industrial practices (Table II-6, 5(c)) have to include the following:

- (a) Industrial irradiators:
Demonstrate that operating procedures, rules or instruction have been provided in line with international recommendations and the recommendations of the manufacturer. Such procedures include: operation (e.g. access control, including the use of a portal monitor when entering the irradiation room, startup and shutdown procedures); maintenance, loading and unloading of

radioactive sources; transport of radioactive sources; individual monitoring; training; leakage testing of radioactive sources; testing of radiation monitors; routine checks by a radiation protection officer; audits and safety assessments by a qualified expert; response to visual and acoustic alarms; incident reporting and investigation; and emergency response.

(b) Industrial radiography:

- (i) Irradiation room. Demonstrate that local rules include, among others, periodic control of the facility, periodic tests of equipment, key control, startup sequence, labelling and posting, use of radiation monitors, stop sequence, security and control of records.
- (ii) Radioactive source storage and on-site radioactive source storage. Demonstrate that local rules include, among others, key control; use of survey meters and dosimeters; record keeping; control of labels, marks and notices; communication with the client; control of environmental impact; movement of sources within the applicant's or client's premises; and periodical source inventory control.
- (iii) Site radiography. Demonstrate that local rules and procedures include the acquisition of radiation survey meters, dosimeters, emergency kit, alarms, labels, marks and notices before going on-site; acquisition of sources from the storage; transport of sources; site management (including cooperation with the client); preparation of site radiography (including selection of barriers, marking and posting, and ensuring that at least two radiographers are involved); control of controlled areas and management of supervised areas (managing exposure of workers and members of the public) and of the positions of sources; and informing workers not occupationally exposed. Demonstrate that an adequate number of workers is involved for each procedure, e.g. for site radiography, at least two radiographers must be involved.

(c) Well logging:

- (i) Use of well logging techniques. Demonstrate that local rules and procedures include the acquisition of radiation survey meters, dosimeters, emergency kit, alarms, labels, marks and notices before going on-site; acquisition of sources from the storage; transport of sources; site management (including cooperation with the client); preparation of the well logging site (including selection of barriers, marking and posting and ensuring that at least two operators are involved); control of the controlled area and management of the supervised area (managing exposure of workers and members of the public) and of the position of sources; and informing workers not occupationally exposed. Demonstrate that an adequate number of workers is involved for each procedure, e.g. for well logging, at least two operators must be involved.

- (ii) Radioactive source storage and on-site radioactive source storage. Demonstrate that local rules include, among others, key control; use of survey meters and dosimeters; record keeping; control of labels, marks and notices; communication with the client; control of environmental impact; movement of sources within the applicant's or client's premises; and periodical source inventory control.
 - (iii) Other applicant activities related to well logging, e.g. exchange of new and spent sources, maintenance of equipment, calibration and tests of well logging equipment. Demonstrate that for all activities local rules exist to ensure safe management of radiation sources.
- (d) Nuclear gauges
- (i) Use of gauges. Demonstrate that local rules include, among others, the installation or dismantling of fixed gauges, maintenance and periodic leak testing of radioactive sources, periodic maintenance and testing of equipment, labelling and posting, use of radiation monitors, security and control of records. Demonstrate that for all activities local rules exist to ensure safe management of radiation sources.
 - (ii) Radioactive source storage and on-site radioactive source storage. Demonstrate that local rules include, among others, key control; use of survey meters and dosimeters; record keeping; control of labels, marks and notices; communication with the client; control of environmental impact; movement of sources within the applicant's or client's premises; and periodical source inventory control.
 - (iii) Use of gauges on-site. Demonstrate that local rules and procedures include the acquisition of radiation survey meters, dosimeters, emergency kit, alarms, labels, marks and notices before going on-site; acquisition of sources from the storage; transport of sources; site management (including cooperation with the client); preparation of the site where gauges will be used (including selection of barriers, marking and posting); control of the controlled area and management of the supervised area (managing exposure of workers and members of the public); control of the position of sources; and informing workers not occupationally exposed.

II-7. PROTECTION OF THE PUBLIC

The information on the protection of the public to be submitted by applicants for authorization has been prepared in accordance with GSR Part 3 (Requirements 13, 30–32, 44 and 45) [II-1] and GSG-13 (paras 3.98 and 3.102) [II-2].

TABLE II-7. APPLICATION FOR AUTHORIZATION — PROTECTION OF THE PUBLIC FOR ALL PRACTICES

System of protection and safety for members of the public:

- (1) Describe a system of protection and safety for members of the public. Demonstrate that optimization of radiation protection of the public is in place.
 - (2) Demonstrate that assessment, control and surveillance of the external exposure of the public are implemented, i.e. use of dose constraints for members of the public. Provide the assumptions used to assess the external exposure of the public.
 - (3) Describe the training of personnel having functions relevant to the protection and safety of members of the public. Demonstrate that a monitoring programme and management of records are in place.
 - (4) Describe the use of signs, labels, marks and notices addressing members of the public. Confirm that these are in a language understood by members of the public.
-

II-8. PROTECTION OF PATIENTS

The information on the protection of patients to be submitted by applicants for authorization has been prepared in accordance with GSR Part 3 (Requirements 9, 36-39, 41 and 42) [II-1] and GSG-13 (paras 3.98 and 3.102) [II-2].

The information to be provided by applicants for authorization includes the following (see Tables II-8.1 to II-8.3):

- (1) Responsibilities;
- (2) Justification;
- (3) Optimization;
- (4) Quality assurance.

TABLE II-8.1. APPLICATION FOR AUTHORIZATION — PROTECTION OF RADIOTHERAPY PATIENTS

- (1) Responsibilities.
Specify how radiological medical practitioners ensure that protection and safety are justified and optimized for each medical exposure and who is responsible for that, e.g. the chief oncologist. Specify who is the responsible medical physicist, e.g. the chief physicist.
- (2) Justification.
 - (a) Specify who can prescribe a treatment (e.g. oncologist or gynaecologist for a gynaecological brachytherapy).
 - (b) Specify how the patient is verified not to be pregnant. Describe the procedure used to justify treatment for pregnant patients, if any.
 - (c) Procedure for patient identification. Describe how each individual is identified before a justified and optimized medical exposure.
- (3) Optimization.
 - (a) Procedures for most common treatments. Describe briefly the most common treatment procedures and how optimization is ensured.
 - (b) Patient records (information of the treatment). Describe how patient records are kept and what kind of treatment information is recorded.
 - (c) Follow-up of treatments. Describe how radiological reviews of treatments are carried out, including an investigation and critical review of the current practical application of the radiation protection principles used for the justification and optimization of the treatments that are performed in the medical radiation facility.
- (4) Quality assurance.
 - (a) Technical quality control:
 - (i) At the time of acceptance and commissioning of the equipment, prior to its clinical use on patients: measurements of the physical parameters of medical radiological equipment made by, or under the supervision of, a medical physicist. Describe the tests, responsibilities for performing the tests and approving the results, criteria for the tests and used standards, e.g. a reference to a standard procedure of acceptance testing.
 - (ii) Quality control programme. Measurements of the physical parameters of medical radiological equipment made by, or under the supervision of, a medical physicist periodically, after any major maintenance procedure that could affect the protection and safety of patients, and after any installation of new software or modification of existing software that could

affect the protection and safety of patients. Describe the tests, responsibilities of performing the tests and approving the results, established tolerance limits, and implementation of corrective actions if the measured values of the physical parameters are outside established tolerance limits. Testcategories include the following:

- Mechanical tests.
 - Dosimetry. Periodic checks of the calibration and conditions of operation of dosimetry equipment and monitoring equipment.
 - Other. Emergency buttons, interlocks, signs, warning lights and communication system with the treatment room.
- (iii) Independent dosimetry audit. Describe how calibrations of radiation therapy units are subject to prior independent verification.
- (iv) Maintenance. Describe how adequate maintenance of the therapy and imaging equipment has been arranged.
- (v) Acceptance and commissioning of the computerized treatment planning systems. Describe the tests, responsibilities for performing the tests and approving the results, criteria for the tests and used standards, e.g. with reference to a standard procedure of acceptance testing.
- (b) Other quality assurance:
- (i) Treatment procedures:
 - Treatment planning. Describe the qualifications and training of planners and instructions for planning, e.g. used guidelines or ‘cook books’.
 - Responsibilities. Describe responsibilities for dose planning, verification and approval. Describe the procedure for approval, e.g. assignment of the treatment plan.
 - Procedure for the verification of appropriate physical and clinical factors used in treatment procedures. Describe the treatment verification system before clinical implementation of the treatment, especially for the verification of complex treatments.
 - Records. Describe how records of relevant procedures and results are maintained.
 - (ii) Reporting and learning systems. Describe how the results of the investigation of unintended exposures are used to improve patient safety and protection.

- (iii) Regular and independent audits. Describe how regular and independent audits are performed for the quality assurance programme for radiotherapy.
 - (iv) Procedures for carers and comforters. Describe the optimization of protection for carers and comforters and the established dose constraints.
-

TABLE II-8.2. APPLICATION FOR AUTHORIZATION — PROTECTION OF NUCLEAR MEDICINE PATIENTS

- (1) Responsibilities.
Specify how radiological medical practitioners ensure that protection and safety are justified and optimized for each medical exposure and who is responsible for that, e.g. chief nuclear medicine physician. Specify who is the responsible medical physicist e.g. the chief physicist.
- (2) Justification.
 - (a) Specify who can prescribe a nuclear medicine procedure, e.g. a physician or oncologist.
 - (b) Specify how the patient is verified not to be pregnant or breastfeeding. Describe a procedure to justify medical exposure for a pregnant or breastfeeding patient. Describe procedures to inform the patient on precautions to protect the infant after receiving radionuclides.
 - (c) Procedure for patient identification. Describe how each individual is identified before a justified and optimized medical exposure.
- (3) Optimization.
 - (a) Procedures for most common nuclear medicine procedures and treatments. Describe briefly the most common imaging and treatment procedures and how optimization has been ensured. Describe the implementation of diagnostic reference levels.
 - (b) Patient records (information of medical exposure). Describe how patient records are kept and what kind of medical exposure information is recorded.
 - (c) Follow-up of procedures. Describe how radiological reviews of diagnostic imaging and treatments are carried out, including an investigation and critical review of the current practical application of radiation protection principles for the justification and optimization of procedures performed in the medical radiation facility.

- (4) Quality assurance.
- (a) Technical quality control:
- (i) At the time of acceptance and commissioning of the equipment, prior to its clinical use on patients: measurements of the physical parameters of medical radiological equipment made by, or under the supervision of, a medical physicist. Describe the tests, responsibilities for performing the tests and approving the results, criteria for the tests and used standards, e.g. a reference to a standard procedure of acceptance testing.
 - (ii) Quality control programme. Measurements of the physical parameters of medical radiological equipment and activity calibrator made by, or under the supervision of, a medical physicist periodically, after any major maintenance procedure that could affect the protection and safety of patients, and after any installation of new software or modification of existing software that could affect the protection and safety of patients. Perform tests to verify the quality of radiopharmaceuticals. Describe the tests, responsibilities for performing the tests and approving the results, established tolerance limits, and implementation of corrective actions if the measured values of the physical parameters are outside established tolerance limits.
 - (iii) Maintenance. Describe how adequate maintenance of the imaging equipment has been arranged.
- (b) Other quality assurance:
- (i) Imaging and treatment procedures:
 - Treatment planning. Describe the qualifications and training of planners and the instructions for planning, e.g. used guidelines or ‘cook books’.
 - Responsibilities. Describe the responsibilities for dose planning, verification and approval. Describe the procedure for approval, e.g. assignment of the treatment plan.
 - Records. Describe how records of relevant procedures and results are maintained.
 - (ii) Reporting and learning systems. Describe how the results of the investigation of unintended exposures are used to improve safety and patient protection.
 - (iii) Regular and independent audits. Describe how regular and independent audits are performed for the quality assurance programme for nuclear medicine.

- (iv) Procedures for carers and comforters. Describe the optimization of protection for carers and comforters and the established dose constraints.
-

TABLE II-8.3. APPLICATION FOR AUTHORIZATION — PROTECTION OF PATIENTS IN X RAY IMAGING IN RADIOLOGY

- (1) Responsibilities.
Specify how radiological medical practitioners ensure that protection and safety is justified and optimized for each medical exposure and who is responsible for that, e.g. the chief radiologist. Specify who is the responsible medical physicist e.g. the chief physicist.
- (2) Justification.
 - (a) Specify who can prescribe an X ray imaging procedure, e.g. a physician.
 - (b) Specify how the patient is verified not to be pregnant. Describe a procedure to justify medical exposure for a pregnant patient.
 - (c) Procedure for patient identification. Describe how each individual is identified before a justified and optimized medical exposure.
- (3) Optimization.
 - (a) Procedures for most common X ray imaging procedures. Describe briefly the most common imaging procedures and how optimization has been ensured. Describe the implementation of diagnostic reference levels.
 - (b) Patient records (information of the medical exposure). Describe how patient records are kept and what kind of medical exposure information is recorded.
 - (c) Follow-up of the procedures. Describe how radiological review of diagnostic imaging is carried out, including an investigation and critical review of the current practical application of the radiation protection principles for the justification and optimization of the procedures that are performed in the medical radiation facility.
- (4) Quality assurance.
 - (a) Technical quality control:
 - (i) At the time of acceptance and commissioning of the equipment, prior to its clinical use on patients: measurements of the physical parameters of medical radiological equipment made by, or

- under the supervision of, a medical physicist. Describe the tests, responsibilities for performing the tests and approving the results, criteria for the tests and used standards, e.g. a reference to a standard procedure of acceptance testing.
- (ii) Quality control programme. Measurements of the physical parameters of medical radiological equipment made by, or under the supervision of, a medical physicist periodically, after any major maintenance procedure that could affect the protection and safety of patients, and after any installation of new software or modification of existing software that could affect the protection and safety of patients. Describe the tests, responsibilities for performing the tests and approving the results, established tolerance limits, and implementation of corrective actions if the measured values of the physical parameters are outside established tolerance limits.
 - (iii) Maintenance. Describe how adequate maintenance of the imaging equipment has been arranged.
- (b) Other quality assurance:
- (i) Records of imaging procedures. Describe how records of relevant procedures and results are maintained.
 - (ii) Reporting and learning systems. Describe how the results of the investigation of an unintended exposure are used to improve safety and patient protection.
 - (iii) Regular and independent audits. Describe how regular and independent audits are performed for the quality assurance programme for X ray imaging.
 - (iv) Procedures for carers and comforters. Describe the optimization of protection for carers and comforters and the established dose constraints.
-

II-9. SECURITY OF SOURCES

The information on the security of sources to be submitted by applicants for authorization has been prepared in accordance with IAEA Nuclear Security Series Nos 14, Nuclear Security Recommendations on Radioactive Material and Associated Facilities [II-8], and 11-G (Rev. 1), Security of Radioactive Material in Use and Storage and of Associated Facilities [II-9].

The regulatory body may require the information in Table II-9 to be presented in a security plan submitted with the application for authorization. Whether submitted in the licence application form or in a security plan, some of the information may be security sensitive and may need to be protected accordingly.

TABLE II-9. APPLICATION FOR AUTHORIZATION — SECURITY SYSTEM AND SECURITY MANAGEMENT MEASURES FOR PRACTICES WITH SECURITY LEVEL A, B OR C RADIOACTIVE MATERIAL

- (1) Assignment of radioactive material to a category and a security level. Identify and explain the basis for the categorization of each radioactive material and its associated security level according to [article of applicable regulations].
- (2) Site description. Describe the physical features of the site where the practice is conducted and its surrounding environment, including diagrams and scale floor and building drawings and photographs. This information must include:
 - (a) The location and layout of the site, particularly indicating areas accessible to the public, roads and parking areas; nearest public thoroughfares, the central security office, building and site perimeter, access points and physical barriers.
 - (b) The site's surrounding environment, such as industrial, commercial, residential or other areas; distances to nearest police stations and other response services; proximity to other buildings and roads; and other features of security or operational interest, such as other facilities with hazardous materials.
- (3) Operational description. Describe site operations in relation to the practice, including working and non-working hours; the number and type of staff involved in the site's operations; and the typical number, type and frequency of other people (such as visitors, public, patients, customers, service personnel or contractors) who may be at the site during scheduled operations or at any other time.
- (4) Security roles and responsibilities. Document the assignment of all roles and responsibilities with respect to the security of radioactive material, including the roles and responsibilities of the following:
 - (a) Site leadership, management and supervisors.
 - (b) Positions directly responsible for the security of radioactive material.
 - (c) Positions with responsibility for regulatory matters, including any positions prescribed by the regulatory authority, such as the licensee, radiation safety officer, security personnel, advisers, guards and other

security related positions specifically required by regulation. Provide an organization chart showing the staffing structure with lines of authority and supervision to demonstrate how the security organization and responsibilities fit within the overall site organization.

- (5) Security training and qualification. Provide the following information:
 - (a) Requirements for qualification of staff with security responsibilities.
 - (b) Training to be provided to each individual, including the required initial, specialized, advanced or refresher training for each position with security responsibilities; security awareness training for all staff; and other relevant, specific, on the job training, such as procedures and work instructions.
 - (c) Provider(s) of the identified training and how frequently each part of the training must be conducted.
 - (d) How training records that document satisfactory completion of all security related training are established and maintained.
- (6) Access authorization. Describe the process used for authorizing personnel who need unescorted access to radioactive source locations, secured areas and/or security sensitive information in order to perform their duties (which may or may not be directly related to security), including how the following functions are performed:
 - (a) Identification of the positions requiring unescorted access;
 - (b) Verification that individuals holding the identified positions are trustworthy;
 - (c) Verification that individuals holding the identified positions have the necessary training;
 - (d) Timely withdrawal of access for individuals who no longer require it;
 - (e) Periodic review and re-evaluation for particular circumstances, such as withdrawing access authorization when personnel or positions no longer need unescorted access, transfer of job responsibilities or termination of employment;
 - (f) Maintain up to date records of personnel authorized for unescorted access.
- (7) Trustworthiness evaluation. Describe the process for evaluating the trustworthiness and reliability of personnel to determine whether they may be granted unescorted access to radioactive material, secured areas and/or security sensitive information, including the following:
 - (a) Basis for identifying individuals whose trustworthiness must be evaluated for access authorization;
 - (b) Requirements regarding trustworthiness in applicable regulations or elsewhere, including any requirements that vary depending on security level or other factors;

- (c) Method by which each individual is evaluated;
 - (d) Requirements for periodic review and any re-evaluation for particular circumstances;
 - (e) Maintenance of records to document trustworthiness evaluations.
- (8) Information protection. Describe the measures for protecting information the unauthorized disclosure of which could compromise the security of radioactive material, including the following:
- (a) The information that needs protection;
 - (b) How the protected information is identified, such as the use of markings or other designators that will ensure that all users of this information recognize it as requiring protection;
 - (c) The forms of protected information, such as paper documents, electronic media or video recordings;
 - (d) Where the protected information is stored and who has custody of it;
 - (e) Who has access to sensitive information and how that access is determined (e.g. required to perform job, appropriate level of trustworthiness);
 - (f) The protection measures in place to prevent unauthorized access when the information is being used or stored (e.g. physical protection, encryption);
 - (g) The requirements in place for preventing unauthorized access when protected information is being reproduced or transmitted inside or outside of the site;
 - (h) How protected information is destroyed when no longer needed to prevent recovery, including who is authorized to destroy it and by what means the various forms will be destroyed.
- (9) Maintenance programme. Describe the programme for maintaining security equipment to ensure continuous and reliable operation.
- (10) Budget and resource planning. Describe how financial resources are allocated to the security of radioactive material.
- (11) Evaluation for compliance and effectiveness. Describe the process used by the site to independently verify that the site is in compliance with all applicable security requirements, and for assessing the effectiveness of the security system in identifying any weaknesses that need to be corrected and any opportunities for continuous improvement, including arrangements for performance testing.
- (12) Threat information. Describe the types of threat information provided, and how it is provided.
- (13) Security assessment methodology. Describe the process or methodology used to design the security system and assess its vulnerabilities, taking into account the threat information provided.

- (14) Security system design. Describe how the security system has been designed to provide the level of protection required, taking into account the graded approach and principles of defence in depth and balanced protection. Indicate how each secured area and associated radioactive material are protected by detection, delay and response measures in an integrated and balanced way. Identify the types of equipment and systems installed and their location.
- (15) Access control. Describe the physical measures for controlling access, including the following:
 - (a) How personnel are physically controlled at each control point to limit access only to authorized persons according to the access authorization procedure and to prevent unauthorized access;
 - (b) Specific media used to authenticate the identity of authorized persons, such as key card, personal identification number, biometric device or a combination;
 - (c) Procedures to be followed by authorized persons to access a secured area, including application of the two-person rule, where relevant.
- (16) Detection, assessment, and delay measures. For each controlled or secured area, describe the following:
 - (a) Means of detection, including intrusion detection systems and observation by site personnel;
 - (b) Method of assessment, including people and equipment supporting the assessment;
 - (c) Delay measures used to increase adversary task time relative to response time.
- (17) Procedures for routine, off-shift and emergency operations. Describe how assigned personnel, such as staff and contractors, operate security systems and discharge their other security related responsibilities during the following periods:
 - (a) Business hours;
 - (b) Non-business hours (off-shift or after hours, when staff are not ordinarily present, generally at nights, on weekends and during holidays);
 - (c) Emergency operations.
- (18) Procedures for opening and closing secured areas. Describe the procedures for opening and closing each secured area within the site, particularly activities such as unlocking and locking doors and other barriers, as well as communication with the alarm monitoring station to deactivate and activate detection systems. Identify who in the organization is responsible for opening and closing these areas, and include actions to validate that other delay mechanisms (e.g. cages) have been appropriately secured.

- (19) Procedures for key and lock control. Describe the procedures used for the control of all keys, locks, combinations, passwords and related measures used to control access to secured areas and security systems. Identify who is responsible for changing access control measures and the specific conditions that require them to be changed, such as the compromise of a combination or password, loss of a security key or termination of a staff member's access.
 - (20) Procedures for accounting and inventory. Describe how the site performs periodic accounting for radioactive material, including the following:
 - (a) Verification method used, such as a physical check, remote video monitoring, examination of seals or other tamper indicating devices, or radiation measurements.
 - (b) Records indicating the results of each verification, as well as when, by whom and by what method the verification was conducted.
 - (c) Requirements for corrective actions and reporting whether the presence of radioactive material cannot be verified. In addition, describe how the site establishes and maintains an inventory of its radioactive material.
 - (21) Procedures for receipt and transfer of radioactive material. Describe the procedures for ensuring that security and control of a radioactive source are maintained when it is being received from outside the site and when it is transferred to another authorized person.
 - (22) Response to a nuclear security event. Describe the arrangements with local law enforcement or other designated response authority for responding to a security event, including attempted or actual theft or sabotage of a radioactive source or device.
 - (23) Communications. Describe the communication methods used to summon a response.
 - (24) Security event reporting. Describe how security events are reported to the operator's security organization. Describe how events are documented, who is responsible to document the event, and subsequent external reporting requirements.
 - (25) Security during emergencies and contingencies. Summarize arrangements and actions to be taken during non-security emergencies or other contingency situations to ensure that the protection of the radioactive material is maintained.
 - (26) Increased threat level. Describe how notifications of an increased threat level are addressed.
-

REFERENCES TO ANNEX II

- [II-1] EUROPEAN COMMISSION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014).
- [II-2] INTERNATIONAL ATOMIC ENERGY AGENCY, Functions and Processes of the Regulatory Body for Safety, IAEA Safety Standards Series No. GSG-13, IAEA, Vienna (2018).
- [II-3] INTERNATIONAL ATOMIC ENERGY AGENCY, Leadership and Management for Safety, IAEA Safety Standards Series No. GSR Part 2, IAEA, Vienna (2016).
- [II-4] INTERNATIONAL ATOMIC ENERGY AGENCY, IAEA Safety Glossary: 2018 Edition, IAEA, Vienna (2019).
- [II-5] INTERNATIONAL ATOMIC ENERGY AGENCY, Regulations for the Safe Transport of Radioactive Material, IAEA Safety Standards Series No. SSR-6 (Rev. 1), IAEA, Vienna (2018).
- [II-6] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety Assessment for Facilities and Activities, IAEA Safety Standards Series No. GSR Part 4 (Rev. 1), IAEA, Vienna (2016).
- [II-7] INTERNATIONAL ATOMIC ENERGY AGENCY, Governmental, Legal and Regulatory Framework for Safety, IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), IAEA, Vienna (2016).
- [II-8] INTERNATIONAL ATOMIC ENERGY AGENCY, Nuclear Security Recommendations on Radioactive Material and Associated Facilities, IAEA Nuclear Security Series No. 14, IAEA, Vienna (2011).
- [II-9] INTERNATIONAL ATOMIC ENERGY AGENCY, Security of Radioactive Material in Use and Storage and of Associated Facilities, IAEA Nuclear Security Series No. 11-G (Rev. 1), IAEA, Vienna (2019).

Annex III

EXAMPLE OF GUIDANCE ON THE REVIEW AND ASSESMENT OF APPLICATIONS FOR AUTHORIZATION



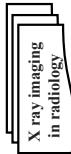

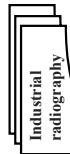
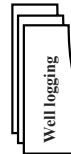
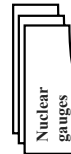
Information provided in this annex is intended to be used by regulatory bodies as a reference when establishing and implementing a national system for the review and assessment of applications for authorization prepared in accordance with Annex II. Regulatory bodies need to adapt this annex to be consistent with their national legislation and regulations.

Examples have been developed to illustrate the application of the IAEA safety standards to various practices. They include the use of radiotherapy, nuclear medicine, X ray imaging in radiology, industrial irradiators, industrial radiography, well logging and nuclear gauges. Material related to security, based on IAEA Nuclear Security Series publications, is presented separately, according to the security level. Review and assessment guidance has been grouped into the following nine elements:

- (1) General information;
- (2) Administrative information;
- (3) Integrated management system;
- (4) Technical information;
- (5) Safety assessment;
- (6) Protection of workers;
- (7) Protection of the public;
- (8) Protection of patients (applicable only to medical practices);
- (9) Security of sources.

Elements (1) to (3), (5) to (7) and (9) consist of a single table with guidance on the review and assessment of applications for authorization by regulatory bodies. Tables III-1 to III-3, III-5 to III-7 and III-9 are applicable to all practices, subject to the clarifications in their footnotes. Elements (4) and (8) are addressed in practice specific Tables III-4.1 to III-4.7 and III-8.1 to III-8.3.

Figure III-1 illustrates the use of the tables in this annex as applied to the review of applications for different practices.

	General information (Table III-1)	Administrative information (Table III-2)	Integrated management system (Table III-3)	Technical information (Tables III-4.1 to III-4.7)	Safety assessment (Table III-5)	Occupational protection (Table III-6)	Public protection (Table III-7)	Patient protection (Tables III-8.1 to III-8.3)	Security (Table III-9)
	✓	✓	✓	Table III-4.1	✓	✓	✓	Table III-8.1	✓
	✓	✓	✓	Table III-4.2	✓	✓	✓	Table III-8.2	N/A *
	✓	✓	✓	Table III-4.3	✓	✓	✓	Table III-8.3	N/A
	✓	✓	✓	Table III-4.4	✓	✓	✓	N/A	✓
	✓	✓	✓	Table III-4.5	✓	✓	✓	N/A	✓
	✓	✓	✓	Table III-4.6	✓	✓	✓	N/A	✓
	✓	✓	✓	Table III-4.7	✓	✓	✓	N/A	✓ *

* Nuclear gauges incorporating low activity radioactive sources and nuclear medicine should be subject to prudent security management practices.

FIG. III-1. Developing practice specific review and assessment guidance. N/A: not applicable.

III-1. GENERAL INFORMATION

TABLE III-1. REVIEW AND ASSESSMENT OF APPLICATIONS FOR AUTHORIZATION — GENERAL INFORMATION FOR ALL PRACTICES

Verify that the required information has been provided.

III-2. ADMINISTRATIVE INFORMATION

TABLE III-2. REVIEW AND ASSESSMENT OF APPLICATIONS FOR AUTHORIZATION — ADMINISTRATIVE INFORMATION FOR ALL PRACTICES

Verify that all required information has been provided. The following may be taken into account:

- (1) Verify that the natural or legal person of the company or organization is accredited;
 - (2) Specify the address where the sources are to be located or the practice carried out, if different from the address of the company or organization;
 - (3) Verify that the application is duly signed by the applicant;
 - (4) Verify whether premises or sources are being rented by another duly authorized entity.
-

III-3. INTEGRATED MANAGEMENT SYSTEM

TABLE III-3. REVIEW AND ASSESSMENT OF APPLICATIONS FOR AUTHORIZATION — INTEGRATED MANAGEMENT SYSTEM FOR ALL PRACTICES

- (1) Management structure and responsibilities.
 - (a) Confirm that protection and safety^a and security^b are effectively incorporated into the overall management system of the licensee.
 - (b) Confirm that responsibilities for radiation safety and security^b have been assigned to competent people. Responsible parties could include, as appropriate, the radiation protection officers, persons responsible for security^b, workers and itinerant workers, radiation safety committee and clients. This particularly concerns^c the responsibility of medical staff for the protection of patients and the responsibility of experts qualified in medical physics for ensuring dosimetry^c and quality aspects of diagnosis and treatments, as applicable. Confirm that responsibilities related to cooperation and consultation have been clearly defined.
- (2) Monitoring for verification of compliance. Check that the documentation covers the performance of regular assessments of radiation protection, safety and security^b, such as a quality control programme and plans for regular reviews.
- (3) Confirm that the following procedures and programmes have been submitted to the regulatory body:
 - (a) Radiation source inventory, supply of sources, prior assessment of the radioactive sources and radiation generators, and inventory of disused sources^d;
 - (b) Pay attention to control of a full life cycle of a source, i.e. cradle to grave^b;
 - (c) Education, training and competence of staff and their training, retraining and informing;
 - (d) Testing, routine and periodic examination and maintenance, and quality assurance programme^c;
 - (e) Investigation of incidents and accidents;
 - (f) Emergency preparedness and response;
 - (g) Review whether training and exercises have been included;
 - (h) Control of modification(s) of facilities, equipment and activity;
 - (i) Management of disused sources and depleted uranium, if applicable^b;
 - (j) Safe transport of radioactive material^b;

- (k) Import and export of radioactive sources^b;
- (l) Control of visitors;
- (m) Release of patients after radionuclide therapy^c;
- (n) Programme for the improvement of the integrated management system.

^a As defined in the IAEA Safety Glossary¹.

^b Not applicable to X ray imaging in radiology.

^c Applicable to radiotherapy, nuclear medicine and X ray imaging in radiology.

^d For nuclear medicine, include inventory of radioactive waste and discharges. For X ray imaging in radiology, consider only radiation generators.

^e Applicable to nuclear medicine.

III-4. TECHNICAL INFORMATION

The information to be evaluated by the regulatory body includes the following:

- (1) Information on radiation sources;
- (2) Information on measuring instruments for quality control (only for radiotherapy, nuclear medicine and X ray imaging in radiology);
- (3) Information on the facilities;
- (4) Description of the activity (only for industrial uses);
- (5) Information of radiation monitoring equipment;
- (6) Safe and secure (except for X ray imaging in radiology) management and control of radiation sources once it has been decided to take them out of use, including financial provisions (except for X ray imaging in radiology);
- (7) Technical patient protection systems (only for radiotherapy).

The information to be considered for the items above is provided for each practice in Tables III-4.1 to III-4.7.

¹ INTERNATIONAL ATOMIC ENERGY AGENCY, IAEA Safety Glossary: 2018 Edition, IAEA, Vienna (2019).

TABLE III-4.1. REVIEW AND ASSESSMENT OF APPLICATIONS FOR AUTHORIZATION — TECHNICAL INFORMATION FOR RADIOTHERAPY

- (1) Information on radiation sources.
 - (a) Information on radiotherapy equipment using radioactive sources.
 - (i) Verify that the information includes the manufacturer, supplier, model and serial number of the radiotherapy device;
 - (ii) Verify that the main safety features of the device have been made available.
 - (b) Information on the radiotherapy sources, check sources and other than category 1–2 sealed sources. Verify that the information includes at least the following:
 - (i) Radionuclide, activity, reference date, serial number, model, serial number of any associated equipment or container, manufacturer, category of source, intended use and location;
 - (ii) Information on all non-exempt sources, including sources for checking equipment and calibration sources;
 - (iii) All source activities are provided in SI units, with the date on which the activity was determined.
 - (c) Details about depleted uranium, if any. Verify that the required information has been provided, if applicable.
 - (d) Information on linear accelerator. Verify that the information includes at least the following: type of linear accelerator, manufacturer, supplier, model, serial number of the linear accelerator and nominal beam energies, separately for different beam qualities.
 - (e) Information on simulator or imaging device. Verify that the information includes at least the following: type of equipment, model, year of manufacture, panel and equipment serial number, type of radiation emitted, maximum power (maximum voltage, maximum current intensity), manufacturer, supplier, intended use and location.
- (2) Information on measuring instruments for quality control. Verify that the dosimetry instrumentation (chamber and electrometer), in addition to being traceable, is to be calibrated at appropriate intervals (every two years).
- (3) Description of the facility.
 - (a) Verify whether a general plan of the facility has been provided, including the following:
 - (i) Work areas for the practice, including the boundaries of the controlled and supervised areas and adjacent areas;
 - (ii) Operations to be carried out in each area;

- (iii) Process flow and location of the sources;
 - (iv) Shielding penetrations, ventilation and electrical ducts;
 - (v) Description of safety features;
 - (vi) Description of structural and portable shielding, including the calculation demonstrating that the shielding is sufficient to satisfy the dose constraints for the practice;
 - (vii) Description of construction materials and the materials used to finish the surfaces in the work areas, as necessary.
- (b) Verify the results of the shielding and dose calculations and whether the calculations have been performed by an authorized qualified expert.
 - (c) Verify whether the radiological survey report is satisfactory.
 - (d) Verify that the design of the facility, depending on its declared purpose, addresses the following: sufficient treatment and simulation rooms, console areas, moulds room, in-patient rooms, waiting rooms, changing rooms, planning, reception, passages used by staff and patients and adjacent areas, source storage room and consulting rooms.
 - (e) Important aspects to take into account are the following:
 - (i) The shielding in treatment rooms and in-patient rooms for patients with implants, and in rooms for storage of brachytherapy sources, are to be calculated by qualified experts;
 - (ii) Appropriate positioning of patient monitoring and control panels;
 - (iii) Distribution of areas in such a way as to facilitate concentration and attention and prevent interference and distractions;
 - (iv) Attention to applying lessons learned from accidental exposures.
- (4) Technical information of radiation monitoring equipment.
- (a) Verify that the technical characteristics of portable survey meters and personnel monitoring devices (e.g. energy response) are appropriate for the specific radiation monitoring situation at the workplace in question;
 - (b) Verify that the dosimeters used for routine radiation monitoring are designed to quantify the maximum potential exposure that may be reasonably foreseen, in accordance with the results of the safety assessments.
- (5) Safe and secure management and control of radiation sources once it has been decided to take them out of use, including financial provisions. Verify that procedures take into account all possible options for the future management of disused sealed sources, such as the following:
- (a) Return to the manufacturer or supplier, as the preferred solution;

- (b) Transfer to some other authorized organization when the source meets requirements for its safe use;
 - (c) Temporary storage at the facility itself until the management path has been decided;
 - (d) Transfer to an authorized facility for temporary or prolonged storage.
- (6) Technical patient protection systems. Verify that the required information has been provided.
-

TABLE III-4.2. REVIEW AND ASSESSMENT OF APPLICATIONS FOR AUTHORIZATION — TECHNICAL INFORMATION FOR NUCLEAR MEDICINE

- (1) Information on radiation sources.
 - (a) Information on unsealed sources:
 - (i) Verify that the inventory includes at least the following: radionuclide, maximum activity at a specific time, reference date, physical form, intended use and location;
 - (ii) Verify that information has been provided on all non-exempt sources;
 - (iii) Verify that all source activities have been provided in SI units, with the date on which the activity was determined.
 - (b) Information on sealed sources:
 - (i) Verify that the inventory includes at least the following: radionuclide, activity, reference date, serial number, model, manufacturer, category of source, intended use and location;
 - (ii) Verify that information has been provided on all non-exempt sources, including sources for checking equipment and calibration sources;
 - (iii) Verify that all source activities have been provided in SI units, with the date on which the activity was determined.
 - (c) Information on imaging devices with a radiation source. Verify that the inventory includes at least the following: type of equipment, model, year of manufacture, panel and equipment serial number, type of radiation emitted, maximum power (maximum voltage and maximum current intensity), manufacturer and supplier.

- (2) Information on measuring instruments for quality control. Activity calibrator. Verify that the inventory includes at least the manufacturer, model, serial number and supplier of the device.
- (3) Description of the facility.
 - (a) Verify that a general plan of the nuclear medicine laboratory, radioactive source storage, temporal storage for radioactive waste and adjacent areas has been provided, including the following:
 - (i) Work areas for the practice, including the boundaries of the controlled and supervised areas and adjacent areas;
 - (ii) Operations to be carried out in each area;
 - (iii) Process flow and location of the sources;
 - (iv) Shielding penetrations and ventilation and electrical ducts;
 - (v) Description of safety features;
 - (vi) Description of structural and portable shielding, including the calculation demonstrating that the shielding is sufficient to satisfy the dose constraints for the practice;
 - (vii) Description of construction materials and the materials used to finish the surfaces in the work areas, as necessary.
 - (b) Verify the results of the shielding and dose calculations and whether the calculations have been performed by an authorized qualified expert.
 - (c) Verify that the radiological survey report is satisfactory.
 - (d) Pay attention to applying lessons learned from accidental exposures.
 - (e) Specific aspects to verify in the design of nuclear medicine facilities include the following:
 - (i) Provision of sufficient space to accommodate areas at least for the following: source preparation and storage; administration of radiopharmaceuticals; separate waiting rooms and bathrooms for patients before and after administration; imaging rooms; in-patient rooms for therapy; radioactive waste storage; and decontamination facilities;
 - (ii) Use of impermeable surface coatings, sealed joints, and designs that are easy to decontaminate for work surfaces, walls and floors;
 - (iii) Areas in which radioactive gases or aerosols are expected to be generated have ventilation systems with the possibility for hoods or glove boxes;
 - (iv) In-patient rooms for patients treated with high activity substances (e.g. ^{131}I) have special bathrooms, washbasins and showers for each patient and, according to the workload, decay tanks for contaminated bodily fluids;

- (v) The layout of the facility places the areas where activities are higher as far as possible from public access areas;
 - (vi) Waiting rooms and bathrooms used by patients before the administration of the radioactive material are separated from those used after the administration of the radiopharmaceutical;
 - (vii) Waiting rooms for patients who have been administered ^{18}F for PET studies, and those whose treatments involve ^{131}I , may require structural shielding in walls, floor and ceiling for the protection of the public;
 - (viii) The routes used for internal transport of radioactive material (within the hospital) are minimized and, to the extent possible, kept away from public areas.
- (4) Technical information of radiation monitoring equipment.
- (a) Verify that the technical characteristics (e.g. energy response) of the portable survey meters for monitoring external exposure, air contamination and surface contamination and of personnel monitoring devices are appropriate for the specific radiation monitoring situation at the workplace in question;
 - (b) Verify that the dosimeters used for routine radiation monitoring are designed to quantify the maximum potential exposure that may be reasonably foreseen, in accordance with the results of the safety assessments.
- (5) Safe and secure management and control of radioactive waste and radiation sources once it has been decided to take them out of use, including financial provisions. Verify that the procedures take into account all possible options for the future management of disused sealed sources, such as the following:
- (a) Return to the manufacturer or supplier, as the preferred solution;
 - (b) Transfer to some other authorized organization when the source meets requirements for its safe use;
 - (c) Temporary storage at the facility itself until the management path has been decided;
 - (d) Transfer to an authorized facility for temporary or prolonged storage.
-

TABLE III-4.3. REVIEW AND ASSESSMENT OF APPLICATIONS FOR AUTHORIZATION — TECHNICAL INFORMATION FOR X RAY IMAGING IN RADIOLOGY

- (1) Information on radiation sources.
 - (2) Information on imaging devices with a radiation source. Verify that the inventory of imaging devices with radiation sources includes at least the following: type of equipment, model, year of manufacture, panel and equipment serial number, maximum power (maximum voltage and maximum current intensity), manufacturer, supplier, intended use and location.
 - (3) Description of the facility.
 - (a) Verify that a general plan of the facility has been provided and is satisfactory, including the following:
 - (i) Work areas for the practice, including the boundaries of controlled and supervised areas and adjacent areas;
 - (ii) Procedures to be carried out in each area;
 - (iii) Location of the X ray equipment;
 - (iv) Steps in the shielding and ventilation and electrical ducts;
 - (v) Description of safety features;
 - (vi) Description of structural and portable shielding, including the calculation demonstrating that the shielding is sufficient to satisfy the dose constraints for the practice;
 - (vii) Description of construction materials used.
 - (b) Verify the results of the shielding and dose calculations and whether the calculations have been performed by an authorized qualified expert.
 - (c) Verify whether the radiological survey report is satisfactory.
 - (4) Technical information of radiation monitoring equipment.
 - (a) Verify that the technical characteristics of the portable survey meters and personnel monitoring devices (e.g. energy response) are appropriate for the specific radiation monitoring situation at the workplace in question;
 - (b) Verify that the dosimeters used for routine radiation monitoring are designed to quantify the maximum potential exposure that may be reasonably foreseen, in accordance with the results of the safety assessments.
-

TABLE III-4.4. REVIEW AND ASSESSMENT OF APPLICATIONS FOR AUTHORIZATION — TECHNICAL INFORMATION FOR INDUSTRIAL GAMMA IRRADIATORS

- (1) Information on radiation sources.
 - (a) Verify that an inventory of radiation sources has been provided together with the characteristics of each source.
 - (b) Verify that for sealed sources the inventory includes at least the following: radionuclide, activity, reference date, serial number, model, serial number of any associated equipment or container, manufacturer, category of source, intended use and location.
 - (c) Confirm that information has been provided on all non-exempt sources, including sources for checking equipment and calibration sources.
 - (d) Verify that all source activities have been provided in SI units, with the date on which the activity was determined.
 - (e) Verify the following:
 - (i) Sealed sources must comply with the provisions of ISO 2919:2012;
 - (ii) The radioactive material is insoluble in water;
 - (iii) The outer capsule material of sealed sources is such that corrosion is negligible when the source is in the storage position in the pool;
 - (iv) Account must be taken of the thermal fatigue to which the material may be subjected.
- (2) Description of the facility.
 - (a) Verify that a detailed description of the facility has been provided and that it includes the irradiation room and any available source storage.
 - (b) Verify that the following information has been provided:
 - (i) General plan of the facility, including the following:
 - Classification of the irradiator type by design, and accessibility and shielding of the radiation source;
 - Work areas for the practice, including plans of source storage(s) and boundaries of the controlled and supervised areas and adjacent areas;
 - Operations to be carried out in each area;
 - Process flow diagram and location of the sources;
 - Penetrations in the shielding to allow the passage of ventilation and electrical ducts.
 - (ii) Description of safety features.

- (iii) Description of structural and any portable shielding to be used, including the calculation demonstrating that the shielding is sufficient to satisfy the dose constraints for the practice.
 - (iv) Description of any source storage, including the shielding and dose calculation demonstrating that the applicable dose constraints for the practice have been observed.
 - (v) Description of construction materials and the materials used to finish the surfaces in the work areas, as necessary.
 - (vi) Description of the emergency power supply system to supply services essential for safety, such as emergency lighting, instrumentation and control.
 - (vii) Description of the fire detection and extinguishing system that protects the integrity of the irradiation source and mechanisms, equipment, systems and safety systems.
- (c) Verify the results of the shielding and dose calculations and whether the calculations have been performed by an authorized qualified expert.
- (3) Technical information of radiation monitoring equipment.
- (a) Verify that the technical characteristics (e.g. energy response) of the portable and stationary survey meters for monitoring external exposure and contamination of water at the pool and of personnel monitoring devices are appropriate for the specific radiation monitoring situation at the workplace in question;
 - (b) Verify that the dosimeters used for routine radiation monitoring are designed to quantify the maximum potential exposure that may be reasonably foreseen, in accordance with the results of the safety assessments.
- (4) Safe and secure management and control of radiation sources once it has been decided to take them out of use, including financial provisions. Verify that the procedures take into account all possible options for the future management of disused sealed sources, such as the following:
- (a) Return to the manufacturer or supplier, as the preferred solution;
 - (b) Transfer to some other authorized organization when the source meets the requirements for its safe use;
 - (c) Temporary storage at the facility itself until the management path has been decided;
 - (d) Transfer to an authorized facility for temporary or prolonged storage.
-

TABLE III-4.5. REVIEW AND ASSESSMENT OF APPLICATIONS FOR AUTHORIZATION — TECHNICAL INFORMATION FOR INDUSTRIAL RADIOGRAPHY

- (1) Information on radiation sources.
 - (a) Verify that the inventory of radiation sources has been provided together with the characteristics of each source.
 - (b) Verify that the inventory includes at least the following:
 - (i) For sealed sources: radionuclide, activity, reference date, serial number, model, serial number of any associated equipment or container, manufacturer, category of source, intended use and location;
 - (ii) For containers: manufacturer, model, capacity and serial number, type of package in accordance with IAEA Safety Standards Series No. SSR-6 (Rev. 1), Regulations for the Safe Transport of Radioactive Material², and container certification;
 - (iii) For radiation generator equipment: type of equipment, model, year of manufacture, panel and equipment serial number, type of radiation emitted, maximum power (maximum voltage and maximum current intensity), manufacturer, supplier, intended use and location;
 - (iv) Information has been provided on all non-exempt sources, including sources for checking equipment and calibration sources, as well as crawler control sources;
 - (v) All source activities have been provided in SI units, with the date on which the activity was determined;
 - (vi) Sealed source certificates have been provided in line with ISO 2919: 2012.
- (2) Description of the facility.
 - (a) Verify that a detailed description of the facility has been provided and that it includes the source storage and any available irradiation room(s), as well as the locations for site radiography and on-site source storage(s).
 - (b) Verify that the following information has been provided:

² INTERNATIONAL ATOMIC ENERGY AGENCY, Regulations for the Safe Transport of Radioactive Material, IAEA Safety Standards Series No. SSR-6 (Rev. 1), IAEA, Vienna (2018).

- (i) General plan of the facility, including the following:
 - Work areas for the practice, including plans of the source storage and of any available irradiation room(s), as well as the boundaries of the controlled and supervised areas and adjacent areas;
 - Operations to be carried out in each area;
 - Process flow diagram and location of the sources;
 - Penetrations in the shielding to allow the passage of ventilation and electrical ducts;
 - (ii) Description of the safety features.
 - (iii) Description of structural and any portable shielding to be used, including the calculation demonstrating that the shielding is sufficient to satisfy the dose constraints for the practice.
 - (iv) Description of construction materials and the materials used to finish the surfaces in the work areas, as necessary.
 - (v) Description of any source storage, including the shielding and dose calculation demonstrating that the applicable dose constraints for the practice have been observed.
 - (vi) Description of on-site source storage and locations where on-site industrial radiography work is carried out, including dose calculations and all the necessary safety mechanisms to control access to the sources.
- (c) Verify the results of shielding and dose calculations and whether the calculations have been performed by an authorized qualified expert.
- (3) Technical information of radiation monitoring equipment.
- (a) Verify that the technical characteristics of the portable and any stationary survey meters for monitoring external exposure and personnel monitoring devices are appropriate for the specific radiation monitoring situation at the workplace in question;
 - (b) Verify that the dosimeters used for routine radiation monitoring are designed to quantify the maximum potential exposure that may be reasonably foreseen, in accordance with the results of the safety assessments.
- (4) Safe and secure management and control of radiation sources once it has been decided to take them out of use, including financial provisions. Verify that the procedures take into account all possible options for the future management of disused sealed sources, such as the following:
- (a) Return to the manufacturer or supplier, as the preferred solution;
 - (b) Transfer to some other authorized organization when the source meets requirements for its safe use;

- (c) Temporary storage at the facility itself until the management path has been decided;
 - (d) Transfer to an authorized facility for temporary or prolonged storage.
-

TABLE III-4.6. REVIEW AND ASSESSMENT OF APPLICATIONS FOR AUTHORIZATION — TECHNICAL INFORMATION FOR WELL LOGGING

- (1) Information on radiation sources.
 - (a) Verify that the inventory of radiation sources has been provided together with the characteristics of each source.
 - (b) Verify that the inventory includes at least the following:
 - (i) For sealed sources: radionuclide, activity, reference date, serial number, model, serial number of any associated equipment or container, manufacturer, category of source, intended use and location, fluence rate or nominal emission (e.g. number of neutrons per second), ISO certification or other recognized by the regulatory body of the country of origin;
 - (ii) For containers: manufacturer, make, model, capacity and serial number, type of package in accordance with SSR-6 (Rev. 1)² and container certification;
 - (iii) When neutron generator equipment is to be used, verify: type of equipment, model, year of manufacture, panel and equipment serial number, type of radiation emitted, characteristics of tritium radiation source, maximum voltage, fluence rate or nominal emission (e.g. number of neutrons per second), manufacturer, supplier, intended use and location.
 - (c) Verify that information has been provided on all non-exempt sources, including sources for checking equipment and calibration sources, as well as radioactive tracers, if they are to be used.
 - (d) Confirm that all source activities have been provided in SI units, with the date on which the activity was determined.
 - (e) Verify that the sealed source certificates have been provided in line with ISO 2919: 2012.
- (2) Description of the facility.
 - (a) Verify that a detailed description of the facility has been provided and that it includes the source storage and any calibration areas available,

as well as the locations for well logging works and the on-site source storage.

- (b) Verify whether the following information has been provided:
 - (i) General plan of the facility, including the following:
 - Work areas for the practice, including plans of the source storage and of any calibration areas available, as well as the boundaries of the controlled and supervised areas and adjacent areas;
 - Operations to be carried out in each area;
 - Process flow diagram and location of the sources;
 - Penetrations in the shielding to allow the passage of ventilation and electrical ducts.
 - (ii) Description of safety features.
 - (iii) Description of structural and any portable shielding, including the calculation demonstrating that the shielding is sufficient to satisfy the dose constraints for the practice.
 - (iv) Description of any source storage, including the shielding and dose calculation demonstrating that the applicable dose constraints for the practice have been observed.
 - (v) Description of construction materials and the materials used to finish the surfaces in the work areas, as necessary.
 - (vi) Description of on-site source storages and locations where well logging work is carried out, including dose calculations and all the necessary safety mechanisms to control access to the sources.
 - (c) Verify the results of shielding and dose calculations and whether the calculations have been performed by an authorized qualified expert.
- (3) Information on radiation monitoring equipment.
- (a) Verify that the technical characteristics (e.g. energy response) of the portable radiation survey meters for monitoring external exposure, as well as personnel monitoring devices, are appropriate for the specific radiation monitoring situation at the workplace in question;
 - (b) Verify that the dosimeters used for routine radiation monitoring are designed to quantify the maximum potential exposure that may be reasonably foreseen, in accordance with the results of the safety assessments.
- (4) Safe and secure management and control of radiation sources once it has been decided to take them out of use, including financial provisions. Verify that the procedures take into account all possible options for the future management of disused sealed sources, such as the following:
- (a) Return to the manufacturer or supplier, as the preferred solution;

- (b) Transfer to some other authorized organization when the source meets requirements for its safe use;
 - (c) Temporary storage at the facility itself until the management path has been decided;
 - (d) Transfer to an authorized facility for temporary or prolonged storage.
-

TABLE III-4.7. REVIEW AND ASSESSMENT OF APPLICATIONS FOR AUTHORIZATION — TECHNICAL INFORMATION FOR NUCLEAR GAUGES

- (1) Information on radiation sources.
 - (a) Verify that the inventory of radiation sources has been provided together with the characteristics of each source.
 - (b) Verify that the inventory includes at least the following:
 - (i) For sealed sources: radionuclide, activity, reference date, serial number, model, serial number of the head containing the source or of the equipment, manufacturer, category of source, intended use and location;
 - (ii) For containers: manufacturer, make, model, capacity and serial number, type of package in accordance with SSR-6 (Rev. 1)²;
 - (iii) For radiation generator equipment: type of equipment, model, year of manufacture, panel and X ray head serial number, maximum power (maximum voltage and maximum current intensity), manufacturer, supplier, intended use and location.
 - (c) Confirm that information has been provided on all non-exempt sources, including sources for checking equipment and calibration sources.
 - (d) Verify that all source activities have been provided in SI units, with the date on which the activity was determined.
 - (e) Confirm that the sealed source certificates have been provided in line with ISO 2919: 2012.
- (2) Description of the facility.
 - (a) Verify that a detailed description of the facility has been provided and that it includes the source storage and fixed (i.e. installed) nuclear gauges, as well as the locations for site works using nuclear gauges and on-site source storages.

- (b) Verify whether the following information has been provided:
 - (i) General plan of the facility, including:
 - Work areas for the practice, including plans of the source storage and any fixed (i.e. installed) nuclear gauges, as well as the boundaries of the controlled and supervised areas and adjacent areas;
 - Operations to be carried out in each area;
 - Process flow diagram and location of the sources;
 - Penetrations in the shielding to allow the passage of ventilation and electrical ducts.
 - (ii) Description of the safety features.
 - (iii) Description of structural and any portable shielding, including the calculation demonstrating that the shielding is sufficient to satisfy the dose constraints for the practice.
 - (iv) Description of any source storage, including the shielding and dose calculation demonstrating that the applicable dose constraints for the practice have been observed.
 - (v) Description of construction materials and the materials used to finish the surfaces in the work areas, as necessary.
 - (vi) Description of on-site source storages and locations where on-site works using nuclear gauges are carried out, including dose calculations and all the necessary safety mechanisms to control access to the sources.
 - (c) Verify the results of shielding and dose calculations and whether the calculations have been performed by an authorized qualified expert.
- (3) Technical information of radiation monitoring equipment.
- (a) Verify that the technical characteristics (e.g. energy response) of the portable radiation survey meters for monitoring external exposure, as well as personnel monitoring devices, are appropriate for the specific radiation monitoring situation at the workplace in question;
 - (b) Verify that the dosimeters used for routine radiation monitoring are designed to quantify the maximum potential exposure that may be reasonably foreseen, in accordance with the results of the safety assessments.
- (4) Safe and secure management and control of radiation sources once it has been decided to take them out of use, including financial provisions. Verify that the procedures take into account all possible options for the future management of disused sealed sources, such as the following:
- (a) Return to the manufacturer or supplier, as the preferred solution;
 - (b) Transfer to some other authorized organization when the source meets the requirements for its safe use;

- (c) Temporary storage at the facility itself until the management path has been decided;
 - (d) Transfer to an authorized facility for temporary or prolonged storage.
-

III-5. SAFETY ASSESSMENT

TABLE III-5. REVIEW AND ASSESSMENT OF APPLICATIONS FOR AUTHORIZATION — SAFETY ASSESSMENT FOR ALL PRACTICES

- (1) Verify that the safety assessment has been carried out following a graded approach^a.
- (2) Verify that a safety assessment has been provided and it includes:
 - (a) A demonstration that the doses (both occupational and public) expected from the normal operation of the practice do not exceed any relevant dose limits and restrictions.
 - (b) A detailed description of the scenarios used for the estimation of the potential doses (both occupational and public).
 - (c) A justification for the selection of the postulated accident initiating events, considering all reasonable occurring human errors, equipment failures and external events or combinations thereof, which could potentially lead to an accident, as well as the lessons learned from previous events. The details on the identification of initiating events can be provided using standard methods for identifying hazards, such as failure modes and effects analysis (FMEA), hazard and operability analysis (HAZOP), preliminary hazard analysis and expert criteria, specifying whether lessons learned from accident or incident situations have been taken into account.
 - (d) A description of the severity of the potential consequences associated with each accident initiating event, specifying the consequences for workers and members of the public based on the potential effect that each accident initiating event could have without taking into account the safety measures or barriers envisaged.
 - (e) Evidence that barriers and procedures to control the hazard include safety interlocks, safety warnings or alarms, and safety and emergency procedures.

- (f) A demonstration that the risks associated with each initiating event are classified based on qualitative, semi-quantitative or quantitative criteria and following a prioritization principle to facilitate further decision making.
- (g) Conclusions on whether an adequate level of safety, in compliance with the relevant regulations, has been achieved.
- (h) Identification of any necessary improvements and additional measures to be taken for optimization of protection.
- (i) A demonstration that procedures are in place for updating the documented safety assessment as necessary. The safety assessment report has to be retained until the facility has been fully decommissioned and dismantled or the activity has been terminated and released from regulatory control.
- (j) Evidence that the independent verification has been performed by suitably qualified and experienced individuals, or a group, different from those who carried out the safety assessment.

^a For certain practices in X ray imaging radiology (e.g. bone densitometry and stomatology), it is sufficient that a generic safety assessment exists.

III-6. PROTECTION OF WORKERS

TABLE III-6. REVIEW AND ASSESSMENT OF APPLICATIONS FOR AUTHORIZATION — PROTECTION OF WORKERS FOR ALL PRACTICES

- (1) Education and training of workers.
 - (a) Verify that the following information is provided for all occupationally exposed workers^a:
 - (i) Given names and surnames;
 - (ii) Qualifications;
 - (iii) Training;
 - (iv) Psychological and physical fitness.
 - (b) Verify that the number and qualifications of the staff involved are in proper relation to the expected workload.
 - (c) Verify the documentary evidence showing that the qualifications and psychological and physical fitness of the staff are accredited by competent organizations recognized by the regulatory body. National

regulations might require documented acknowledgement by the relevant authority that staff have the qualifications and expertise needed for the conduct of the authorized activity.

- (2) Personal dosimetry.
 - (a) Verify that all persons requiring it have access to individual radiation monitoring, and ensure that no unauthorized staff are receiving personal dosimetry;
 - (b) Verify that dosimeters are used correctly and staff are notified of their individual doses;
 - (c) It needs to be noted that, to ensure the necessary accuracy and precision, personal dosimetry needs to be implemented by an approved dosimetry service.
- (3) Workers' health surveillance.
 - (a) Verify whether the description of the health surveillance programme covers the following:
 - (i) Performance of medical examinations of occupationally exposed workers in accordance with the general principles of occupational medicine.
 - (ii) Performance of examinations prior to starting work with radiation and subsequent periodic examinations to assess workers' initial and ongoing fitness for the tasks to which they are assigned.
 - (iii) Specific advice provided by an occupational health specialist, sometimes supported by other specialists, for the following categories of workers:
 - Women who are or may be pregnant;
 - Individuals who have been or may have been exposed to doses considerably in excess of the limits;
 - Workers who may have concerns with respect to their exposure to radiation;
 - Other workers requesting such advice.
 - (iv) Formal plans for managing situations in which workers may be overexposed, specifying the measures that need to be taken and the resources for carrying out these actions.
- (4) Itinerant workers. Verify that appropriate managerial and practical arrangements establishing a clear allocation of responsibilities among the relevant parties, including the itinerant worker, the employer of that worker, and the management of the facility at which the work is occurring, exist and are implemented.

- (5) Arrangements for the radiation protection programme.
- (a) Verify that the radiation protection programme is scaled to the needs of the operating organization and covers the following, among others:
 - (i) Assignment of responsibilities for the radiation protection programme;
 - (ii) Designation of controlled or supervised areas using warning symbols, such as that recommended by the International Organization for Standardization, and appropriate instructions at access points and other appropriate locations within the areas;
 - (iii) Local rules to be followed by workers and supervision of work;
 - (iv) Arrangements for radiation monitoring of workers and workplaces, including acquisition and maintenance of monitoring equipment and personal protective equipment, if necessary;
 - (v) System for recording and reporting all information related to exposure control, decisions regarding measures for occupational radiation protection and safety, as well as individual radiation monitoring;
 - (vi) Methods for periodic auditing and review of implementation of the radiation protection programme and the security programme^b.
 - (b) Verify whether the description of the workplace radiation monitoring programmes specifies the following:
 - (i) The magnitudes to be measured;
 - (ii) Where, when and how often the measurements are to be taken;
 - (iii) The most appropriate measurement methods and procedures;
 - (iv) The reference levels, and the measures to be taken if these levels are exceeded.

^a ‘Staff’ includes the following: for medical practices — medical physicists of various specialties (e.g. radiation therapy, nuclear medicine, diagnostic radiology and other medical and paramedical professionals), medical physicists and radiation technologist; for industrial practices — operators of radiation sources (e.g. industrial irradiators, nuclear gauges, industrial radiography and well logging devices) and their assistants.

^b Not applicable to X ray imaging in radiology.

III-7. PROTECTION OF THE PUBLIC

TABLE III-7. REVIEW AND ASSESSMENT OF APPLICATIONS FOR AUTHORIZATION—PROTECTION OF THE PUBLIC FOR ALL PRACTICES

- (1) Verify that a radiation monitoring programme has been provided for the facility that includes at least the following:
 - (a) Procedures for restricting public exposure;
 - (b) Description of control of visitors, including physical barriers and instructions for access to controlled and supervised areas;
 - (c) Estimation of the dose to the public;
 - (d) Records system.
 - (2) Verify that applicants ensure compliance with dose limits and constraints for the public.
 - (3) Verify that the monitoring programme takes into account the assessment of external exposure of the public.
 - (4) Verify that account is taken of the maintenance of appropriate records of the results of the monitoring programme and of the estimation of the dose to the public.
 - (5) Verify whether the procedure for the control of visitors to controlled and supervised areas takes into account the following:
 - (a) Visitors are accompanied by persons with a knowledge of protection and safety measures;
 - (b) Provision of adequate information and instructions to visitors prior to entering the controlled or supervised area, and ensuring the protection and safety of visitors and other individuals who may be affected by their actions;
 - (c) Use of signs in controlled and supervised areas.
-

III-8. PROTECTION OF PATIENTS

The information to be evaluated by the regulatory body includes the following:

- (1) Responsibilities;
- (2) Justification;
- (3) Optimization;
- (4) Quality assurance.

The information to be considered for the items above is provided for each practice in Tables III-8.1 to III-8.3.

TABLE III-8.1. REVIEW AND ASSESSMENT OF APPLICATIONS FOR AUTHORIZATION — PROTECTION OF PATIENTS IN RADIOTHERAPY

- (1) Responsibilities. Verify the institutional commitment to ensure that no patient undergoes medical exposure unless the following is true:
 - (a) The registrant or licensee has stipulated that treatment will not be delivered without a documented medical referral;
 - (b) Overall responsibility for protection of the patient has been assigned to a radiotherapy medical practitioner or other specialist medical practitioner (dermatologist, ophthalmologist, neurologist, etc.) duly qualified for dose prescription;
 - (c) Responsibility for calibration, clinical dosimetry and physical aspects of quality assurance has been assigned to a medical physicist with specific competence in these areas, with the support of a dosimetrist;
 - (d) Responsibility for delivery of treatment in line with the plan has been assigned to radiotherapy technologists;
 - (e) The medical practitioners have informed the person undergoing exposure, as appropriate, of the expected benefits and risks.
- (2) Justification.
 - (a) Verify the institutional commitment to ensuring that the justification of the individual medical exposure for each patient is carried out through consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate, taking into account the following, in particular for pregnant and paediatric patients:
 - (i) The appropriateness of the prescription;
 - (ii) The urgency of the procedure;
 - (iii) The characteristics of the medical exposure;

- (iv) The characteristics of the specific patient;
 - (v) Relevant information on prior radiological procedures performed on the patient.
 - (b) Verify that the entity has and uses national or international medical protocols.
 - (c) Verify whether provisions have been made to place signs in appropriate languages in public places, waiting rooms for patients and other places, and that other means of communication are also used, as necessary, to request that female patients who are to undergo radiotherapy procedures notify the medical practitioner in the event that they are or might be pregnant.
 - (d) Verify whether there are procedures for ascertaining the gestational status of a female patient of reproductive capacity before the performance of any radiotherapy procedure that could result in a significant dose to the embryo or foetus, so that this information can be considered in the justification of the radiotherapy procedure and in the optimization of protection and safety.
 - (e) Verify that procedures for patient identification include recognized patient/client identifiers.
- (3) Optimization.
- (a) Procedures for most common treatments. Verify that any radiotherapy treatment procedure has been established on the basis of approved national or international clinical protocols.
 - (b) Patient records (information of the treatment). Verify that the prescription of the treatment is recorded in writing and includes all data on the patient and the treatment needed to implement the various stages of the radiotherapy process. The treatment data sheet includes:
 - (i) Description of the planning target volume;
 - (ii) Dose to the centre of the planning target volume, and the maximum and minimum doses delivered to the planning target volume;
 - (iii) Doses to other relevant organs and dose fractionation;
 - (iv) The overall treatment times;
 - (v) The data collection and record sheets to be elaborated taking into account national and international experience.
 - (c) Follow-up of the treatments. Verify that provision has been made for review of the clinical development of the patient during treatment, at the intervals stipulated in the clinical protocols, and review of completion of the treatment data sheet.

- (4) Quality assurance.
- (a) Technical quality control:
- (i) Verify that, after radiotherapy equipment has been installed, acceptance tests are performed to verify that the equipment meets the manufacturer's technical specifications. The responsibilities of suppliers to address any non-conformities identified need to be regulated on a contractual basis. Verify that the acceptance tests on installed equipment are supervised and signed off by the medical physicist.
 - (ii) Verify that the commissioning tests are performed by the medical physicist and the volume of testing is as established in a nationally or internationally recognized protocol (e.g. TRS-398). Verify that the results of the tests were formally recorded and signed off by the medical physicist and are included in the commissioning report.
 - (iii) Verify that the results of the commissioning tests were verified independently by another medical physicist. This independent verification includes redundant measurement of critical parameters such as the dose rate under reference conditions, using different dosimetric equipment (chamber and electrometer).
 - (iv) Verify that, for cobalt teletherapy and high dose rate brachytherapy equipment, the results of the commissioning tests on the unit (e.g. yield) match the information given by the manufacturer in the source certificate.
 - (v) Verify whether dosimeters calibrated for photon and electron beams of the energies that will be used by the entity are available, as well as dosimeters for measuring microbeams, if appropriate.
 - (vi) Verify that the calibration procedures ensure the traceability of the measurements, the independent verification of calibration data and frequency, and recalibration after any maintenance that could affect the radiation beams.
 - (vii) Verify that the report with the results of the acceptance and commissioning tests has been provided.
 - (viii) Verify that the image acquisition, storage and transmission equipment for treatment planning has been subjected to acceptance and commissioning tests in line with nationally or internationally recognized protocols.
 - (ix) Verify that the treatment planning system has been subjected to acceptance and commissioning tests in line with applicable national and international protocols.

- (x) Verify that the report on the commissioning tests includes the following:
 - The protocol used for commissioning, specifying possible differences from the tests performed and their implications from a physical and clinical point of view;
 - The results of direct measurements taken, based on the forms established in the protocols;
 - The measuring instruments used, specifying their technical characteristics, and copies of the certificates for their most recent verification;
 - The results of the calculations performed and comparison of the results with the tolerances or acceptance limits of the parameters;
 - The conclusions regarding the suitability of the equipment for use in patient treatment, signed off by the medical physicist;
 - The results of the commissioning of the computerized treatment planning system, comparing the results from the planning of test cases with direct measurements performed for these cases.
- (b) Other quality assurance:
 - (i) Verify that the quality management programme for medical exposures covers the following:
 - Possible critical organs involved in the treatment.
 - For all treatments, performance of the initial treatment verification or first positioning of the patient with the participation of the medical physicist, technician and radiotherapy medical practitioner who ultimately approves the commencement of the treatment.
 - All changes made to an ongoing treatment must be approved by the radiotherapy medical practitioner.
 - Acquisition and review of portal images during the initial verification of the treatment or first positioning of the patient, and periodically during treatment. For teletherapy, it is recommended that images be taken and reviewed on a weekly basis.
 - In brachytherapy, for each application, image acquisition has to be ensured for the purposes of correct reconstruction of the applicator and adjacent structures.
 - Use of in vivo dosimetry is recommended during the initial verification of the treatment or first positioning of the patient, to verify and document the doses received by

critical structures, in the case of treatment plans requiring this. Any radiotherapy treatment must be prescribed on the basis of approved clinical protocols. It is recommended that, at the planning meeting for new patients at which the radiotherapy medical practitioner, the medical physicist, the dosimetrist and the technician be present, the specifics of the treatment to be delivered to each patient be clarified and the probability of errors of interpretation be reduced. These protocols may be reinforced by instructions and procedures which are posted in a visible location, or which are at least accessible to the operators.

- Proper positioning and immobilization of the patient, thus allowing the treatment position to be reliably reproduced during dose delivery.
 - Provision of suitable equipment for image and patient data acquisition, thus facilitating accurate definition of the planning target volume to be estimated and compared with that given in the treatment plan.
- (ii) Verify that provisions have been made to maintain for the period stipulated by the regulatory body, and make available, the following records:
- Records of any delegation of responsibilities by any of the principal parties;
 - Records of training of personnel in radiation protection;
 - Results of acceptance and commissioning tests on equipment;
 - Records of the results of quality controls performed (safety, mechanical and dosimetric parameters);
 - Records of maintenance of relevant equipment;
 - Patient clinical dosimetry;
 - Records associated with the quality assurance programme;
 - Reports on investigations of unintended and accidental medical exposures.
- (iii) Verify that there are mechanisms in place for internal reporting and analysis of incidents.
- (iv) Verify whether the procedure for investigating any unintended or accidental medical exposure covers the following:
- Calculation or estimation of the doses received and the dose distribution in the patient.
 - Indication of the corrective actions required to prevent the recurrence of such unintended or accidental medical exposures.

- Implementation of all the corrective actions that are under own responsibility.
 - Production and maintenance, as soon as possible after the investigation or as otherwise required by the regulatory body, of a written record that states the cause of the unintended or accidental medical exposure and includes the information specified in the first three bullet points above, as relevant, and any other information as required by the regulatory body. For significant unintended or accidental medical exposures, or as otherwise required by the regulatory body, prompt submission of this written record to the regulatory body and to the relevant health authority, if appropriate.
 - Ensuring that the radiotherapy medical practitioner informs the patient or the patient's legal representative of the unintended or accidental medical exposure.
- (v) Verify that the prevention programme incorporates lessons learned from accidental exposures and it is reflected in quality assurance programmes and in work procedures.
- (vi) Verify whether provisions have been made for periodic reviews to be performed by the radiotherapy medical practitioners, in cooperation with the paramedical staff and medical physicists. The review has to include an investigation and critical review of the radiation protection principles of justification and optimization for the treatments performed. In addition, verify whether provisions have been made to perform systematic and independent audits of the quality assurance programme for medical exposures, and that their frequency is commensurate with the complexity of the procedures performed and the associated risks. It is recommended that the quality management programme for medical exposures be subjected to external audits. It is recommended that the teletherapy equipment of the service be included in postal dosimetry audits.
- (vii) Verify whether provisions have been made for optimized procedures and the necessary means to ensure compliance with the dose constraints for persons providing care to patients.
- (viii) Verify whether the procedures take into account the criteria specifying which persons may be allowed to help patients, for example friends and family members, except pregnant women, and that they are informed of the risks.
-

TABLE III-8.2. REVIEW AND ASSESSMENT OF APPLICATIONS FOR AUTHORIZATION — PROTECTION OF PATIENTS IN NUCLEAR MEDICINE

- (1) Responsibilities.
 - (a) Verify the documentation of the institutional commitment to ensure that no patient, whether symptomatic or asymptomatic, undergoes medical exposure unless the following is true:
 - (i) The diagnostic or therapeutic procedure has been prescribed by a medical practitioner and sufficient information on the clinical context has been provided, or the patient is part of an approved programme of biomedical research;
 - (ii) The diagnostic or therapeutic procedure has been justified through consultations between the specialist in nuclear medicine and the referring medical practitioner, or is part of an approved programme of biomedical research;
 - (iii) A specialist in nuclear medicine has assumed responsibility for the radiation protection and safety of the patient;
 - (iv) The patient or the patient's authorized legal representative has been informed, as appropriate, of the diagnostic or therapeutic benefits, as well as the radiation risks.
 - (b) Verify that the medical physicists' information is available, their qualifications are duly accredited and that they assume their responsibilities in writing or else hold an individual licence.
 - (c) Verify that any delegation of responsibilities is properly documented.
- (2) Justification.
 - (a) Verify the institutional commitment to ensuring that the justification of the individual medical exposure for each patient is carried out through consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate, taking into account the following, in particular for pregnant and paediatric patients:
 - (i) The appropriateness of the prescription;
 - (ii) The urgency of the procedure;
 - (iii) The characteristics of the medical exposure;
 - (iv) The characteristics of the specific patient;
 - (v) Relevant information on prior radiological procedures performed on the patient.

- (b) Verify the institutional commitment regarding the following:
 - (i) Diagnostic or therapeutic procedures bear the signature of the specialist in nuclear medicine, who may also be the one making the referral;
 - (ii) Informed consent is obtained following provision of information at a level of detail commensurate with the radiation risks of the procedure.
 - (c) Verify that procedures for patient identification include recognized patient/client identifiers.
- (3) Optimization.
- (a) Procedures for most common treatments:
 - (i) Verify that provisions are made for pharmaceuticals to be supplied by authorized suppliers who guarantee the quality thereof;
 - (ii) Verify that methods are used to achieve diagnostic and therapeutic efficacy with the minimum dose;
 - (iii) Verify that the procedures ensure that the prescribed activity is administered in all cases;
 - (iv) Verify that estimates are made of typical doses for the most common diagnostic studies and of absorbed doses to the tissues or organs of relevance for individual patients;
 - (v) Verify whether provisions have been made to analyse typical activities administered to patients and compare them with reference levels;
 - (vi) Verify that provisions have been made to comply with the procedures for managing cadavers containing radioactive material established by the regulatory body in consultation with health authorities;
 - (vii) Analyse the procedures with regard to the following:
 - Dose optimization for protection of the foetus (administering lower activities and increasing acquisition times, preferential use of ^{99m}Tc , recommending hydration for frequent emptying of the patient's bladder when using radiopharmaceuticals that are metabolized renally, etc.);
 - Estimation of foetal dose in studies requiring the use of iodine or gallium;
 - Ensuring, in the case of treatment involving radionuclides, that information is provided to patients of reproductive age to avoid pregnancy until the pharmaceutical has been eliminated and, when iodine treatment is necessary in

- pregnant patients, that information is provided concerning the risks to the foetus;
- Male patients who have received therapeutic doses of ^{131}I using ^{32}P and ^{89}Sr need to be warned not to have unprotected sexual relations for periods of at least four months (significant amounts of the radionuclide can appear in sperm).
- (viii) Verify whether provision is made for the protection of patients who are breastfeeding. Verify that the protocols cover the following:
- Asking the patient whether she is breastfeeding before the study or treatment, and clinical review by a medical practitioner;
 - Availability of information material, such as folders and posters/signs in waiting rooms;
 - Recommending interruption of breastfeeding for appropriate periods, depending on the radionuclide (three weeks for diagnostic studies using ^{131}I and ^{201}Tl , and 12 hours for studies using $^{99\text{m}}\text{Tc}$).
- (b) Patient records (information of the medical exposure):
Check that provisions have been made to maintain for the period stipulated by the regulatory body, and make available, the patient records, incorporating, among others, the study or treatment, date, radiopharmaceuticals and activity and any other information, allowing retrospective assessment.
- (c) Follow-up of the procedures/treatment:
- (i) Verify that provision has been made for review of the clinical development of the patient during treatment, at the intervals stipulated in the clinical protocols, and review of completion of the treatment data sheet;
 - (ii) Verify that radiological review of diagnostic imaging procedures and treatments are to be carried out periodically.
- (4) Quality assurance.
- (a) Technical quality control:
- (i) Verify that there are one or more activity meters (activity calibrators), with calibration traceable to secondary standards for the various radionuclides employed;
 - (ii) Verify the existence of procedures ensuring that the activity to be administered is measured and recorded at the time of administration. For $^{99\text{m}}\text{Tc}$ studies, it is appropriate to verify the Mo/Tc ratio for each elution of the generator to rule out toxicity;

- (iii) Verify that the imaging equipment is calibrated using nationally or internationally accepted protocols.
- (b) Other quality assurance:
 - (i) Verify that there are written protocols for the various diagnostic studies that cover the following, among others:
 - Analysis of information from prior examinations;
 - Activity reference levels for the various diagnostic studies;
 - Protocols that ensure selection of the appropriate radiopharmaceutical and activity, with particular attention to the requirements of pregnant patients and paediatric patients;
 - Use of methods to block absorption by organs not under study and to accelerate excretion after the study, in cases where this is relevant;
 - Written instructions and information for managing the patient as a mobile source;
 - Operation of imaging equipment in accordance with the instructions in an operating manual in the local language and with the licence conditions;
 - Data acquisition conditions — such as collimator type and angulation, energy window, matrix size, acquisition time, SPECT (single photon emission computed tomography) or PET (positron emission tomography) parameters and zoom factor, and the number of frames and time interval in dynamic studies — have been chosen so as to achieve optimal image quality with the least possible dose;
 - Application of a programme of preventive maintenance and monitoring of equipment that prevents degradation of image quality and the need for unnecessarily high activities or repetition of studies to compensate for lower quality;
 - For therapeutic procedures, it has been ensured that the activity administered is absorbed primarily by the organ(s) being treated and that exposure to the rest of the body is minimized.
 - (ii) Verify that provisions have been made to maintain for the period stipulated by the regulatory body, and make available, the following records:
 - Records of any delegation of responsibilities that affect the protection of patients;

- Records of results of calibrations and periodic verifications of measurement and imaging equipment, and other records associated with the quality assurance programme;
 - Dosimetry of patients;
 - Records of local assessments made with regard to reference levels;
 - Records of the information necessary for retrospective assessment of doses, including the radionuclide and activity administered;
 - Records of exposure information for volunteers subjected to medical exposure as part of a programme of research;
 - Reports on investigations of unintended and accidental medical exposures.
- (iii) Verify that there are mechanisms in place for internal reporting and analysis of incidents.
- (iv) Verify that consideration is given to preventing the following situations:
- Wrong patient;
 - Wrong pharmaceutical;
 - Wrong activity;
 - Wrong route of administration;
 - Repetition of studies owing to deficient quality of equipment;
 - Undiscovered pregnancy;
 - Failure to detect a breastfeeding situation.
- (v) Verify that the prevention programme incorporates lessons learned from accidental exposures and this is reflected in quality assurance programmes and in work procedures.
- (vi) Verify whether provisions have been made for periodic radiological reviews to be performed by the nuclear medicine medical practitioners, in cooperation with the paramedical staff and medical physicists. The radiological review has to include an investigation and critical review of the radiation protection principles of justification and optimization for the procedures performed. In addition, verify whether provisions have been made to perform systematic and independent audits of the quality assurance programme for medical exposures, and that their frequency is commensurate with the complexity of the radiological procedures performed and the associated risks.
- (vii) Verify whether provisions have been made for optimized procedures and the means required to ensure compliance with

- dose constraints for persons providing care to patients and for volunteers participating in programmes of biomedical research.
- (viii) Verify whether the procedures take into account the criteria specifying which persons may be allowed to help patients, for example friends and family members, except pregnant women, and that they are informed of the risks.
-

TABLE III-8.3. REVIEW AND ASSESSMENT OF APPLICATIONS FOR AUTHORIZATION — PROTECTION OF PATIENTS IN X RAY IMAGING IN RADIOLOGY

- (1) Responsibilities.
- (a) Verify the institutional commitment to ensure that no patient, whether symptomatic or asymptomatic, undergoes medical exposure unless the following is true:
- (i) The radiological procedure has been requested and prescribed by a medical practitioner and information on the clinical context has been provided, or it is part of an approved health screening programme;
- (ii) The procedure has been justified through consultations, as appropriate, between the radiological medical practitioner and the referring medical practitioner, or it is part of an approved health screening programme;
- (iii) A radiological medical practitioner has assumed responsibility for radiation protection and safety in the planning and delivery of the medical exposure;
- (iv) The patient or the patient's authorized legal representative has been informed, as appropriate, of the expected diagnosis as well as the radiation risks.
- (b) Verify whether the responsibilities of the medical physicist for diagnostic radiology are available and documented.
- (c) Verify that any delegation of responsibilities is properly documented.
- (2) Justification.
- (a) Verify the institutional commitment to ensuring that the justification of the individual medical exposure for each patient is carried out through consultation between the radiological medical practitioner and the

referring medical practitioner, as appropriate, taking into account the following, in particular for pregnant and paediatric patients:

- (i) The appropriateness of the prescription;
 - (ii) The urgency of the procedure;
 - (iii) The characteristics of the medical exposure;
 - (iv) The characteristics of the specific patient;
 - (v) Relevant information on prior radiological procedures performed on the patient.
- (b) Verify that the entity has and uses national or international medical protocols.
 - (c) Verify whether provisions have been made to place signs in appropriate languages in public places, waiting rooms for patients and other places, and that other means of communication are also used, as necessary, to request that female patients who are to undergo diagnostic procedures notify the medical practitioner in the event that they are or might be pregnant.
 - (d) Verify that procedures for patient identification include recognized patient/client identifiers.
- (3) Optimization.
- (a) Procedures for most common treatments:
 - (i) Verify that any diagnostic procedure has been established on the basis of approved national or international clinical protocols.
 - (ii) Verify the use, when appropriate, of the following techniques to avoid delivering unnecessary doses to patients:
 - Reduction of the size of the irradiation field;
 - Protection of organs in the body that might be affected (gonads, lens, etc.);
 - The source–skin or source–imaging system distance is not smaller than the recommended value;
 - The total filtration is not less than the recommended value;
 - Use of anti-diffusion grids made of carbon fibre materials;
 - Control of irradiation times;
 - Where possible, intensifying screens containing high efficiency phosphorescent materials, such as rare earths, barium and tantalum, are used;
 - Control of (dispersed) radiation using, where possible, anti-diffusion grids between the patient and the imaging system;
 - Correct processing of radiography films;
 - Reduction of the number of repeat irradiations;
 - Establishment of quality assurance programmes.

- (b) Patient records. Check that provisions have been made to maintain for the period stipulated by the regulatory body, and make available, the patient records, including at least the study, date and any other information allowing retrospective assessment.
 - (c) Follow-up of the procedures. Verify that radiological review of diagnostic imaging procedures and treatments are to be carried out periodically.
- (4) Quality assurance.
- (a) Technical quality control:
 - (i) Verify that the medical physicist has ensured the following:
 - Calibration of equipment using internationally or nationally accepted protocols;
 - Performance of calibrations at the time of commissioning of a unit, prior to its clinical use, after any procedure that could affect the dosimetry and at intervals approved by the regulatory body;
 - Traceability of the calibration of all dosimeters used for patient dosimetry and for source calibration to a standards dosimetry laboratory, for the energies used in diagnostic radiology.
 - (ii) Verify that a report has been submitted with the results of the acceptance and commissioning testing or quality control testing conducted within the last year.
 - (b) Other quality assurance:
 - (i) Verify that optimization measures are in place, such as:
 - Internal policies, guidance, procedures and visual signs supporting the programme (examples of visual signs are written statements, exposure tables or posters providing information on methods);
 - Protocols covering all types of normal radiological procedure for all equipment used;
 - Staff training.
 - (ii) Take into consideration that the use of the following techniques avoids delivering unnecessary doses to patients:
 - Reduction of the size of the irradiation field;
 - Protection of organs in the body that might be affected (gonads, lens, etc.);
 - The source–skin or source–imaging system distance is not smaller than the recommended value;
 - The total filtration is not less than the recommended value;
 - Use of anti-diffusion grids made of carbon fibre materials;

- Control of irradiation times;
 - Where possible, intensifying screens containing high efficiency phosphorescent materials, such as rare earths, barium and tantalum, is used;
 - Control of (dispersed) radiation using, where possible, anti-diffusion grids between the patient and the imaging system;
 - Correct processing of radiography films;
 - Reduction of the number of repeat irradiations;
 - Establishment of quality assurance programmes.
- (iii) Verify that provisions have been made to maintain for the period stipulated by the regulatory body, and make available, the following records:
- Records of any delegation of responsibilities by any of the principal parties;
 - Records of training of personnel in radiation protection;
 - Records of the results of the calibrations and periodic checks of the physical parameters;
 - Patient records, incorporating, among others, the study, date, equipment and technical parameters used, including the number of exposures and the duration of fluoroscopic radiological procedures, allowing retrospective assessment;
 - Records of local assessments and reviews made with regard to diagnostic reference levels;
 - Records associated with the quality assurance programme;
 - Exposure records for volunteers subjected to medical exposure as part of a programme of medical research;
 - Reports on investigations of unintended and accidental medical exposures.
- (iv) Verify whether provisions have been made to report and investigate unintended or accidental exposures should they occur. Examples include the following:
- Devices that end the exposure when slices have been taken and that may fail;
 - Exposure of the wrong person, or the wrong tissue in a patient;
 - Any exposure that is substantially greater than foreseen;
 - Any inadvertent exposure of the embryo or foetus during a radiological procedure.

- (v) Verify that the prevention programme incorporates lessons learned from accidental exposures and that this is reflected in quality assurance programmes and in work procedures.
 - (vi) Verify whether provisions have been made for periodic radiological reviews to be performed by the radiological medical practitioners, in cooperation with the paramedical staff and medical physicists. The radiological review has to include an investigation and critical review of the radiation protection principles of justification and optimization for the procedures performed and an analysis of rejection of clinical images, in particular in digital radiology, where analysis of rejection is even more important, as it is easier to delete an image and repeat the examination than physically to reject a film. In addition, verify whether provisions have been made to perform systematic and independent audits of the quality assurance programme for medical exposures, and that their frequency is commensurate with the complexity of the radiological procedures performed and the associated risks.
 - (vii) Verify whether provision has been made for optimized procedures and the means required to ensure compliance with dose constraints for persons providing care to patients and for volunteers participating in programmes of biomedical research.
 - (viii) Verify whether the procedures take account of the criteria specifying which persons may be allowed to help patients, for example friends and family members except pregnant women, and that they are informed of the risks
-

III-9. SECURITY OF SOURCES

TABLE III-9. REVIEW AND ASSESSMENT OF APPLICATIONS FOR AUTHORIZATION — SECURITY SYSTEM AND SECURITY MANAGEMENT MEASURES FOR PRACTICES WITH SECURITY LEVEL A, B OR C RADIOACTIVE MATERIAL

(1) Assignment of radioactive material to category and security levels.
Verify that the application properly assigns the operator’s radioactive material to category and security level, including:

- Correctly identifies the regulatory basis for categorization YES NO
- Correctly takes into account aggregation, if applicable YES NO
- Assigns radioactive material to the correct category YES NO
- Assigns radioactive material to correct security level YES NO

Comments:

(2) Site description.
Verify that the application provides an adequate physical description, including:

- Site layout YES NO
- Site’s surrounding environment YES NO

Comments:

(3) Operational description.

Verify that the application provides an adequate operational description, including:

- Working and non-working hours YES NO
- Number and type of staff YES NO
- Number, type and frequency of other persons who may be present at the site YES NO

Comments:

(4) Roles and responsibilities.

Verify that the application adequately describes roles and responsibilities, including:

- Staff with security responsibilities, by position YES NO
- The nature of those security responsibilities YES NO
- Organization chart YES NO

Comments:

(5) Security training and qualification.

Verify that the application adequately describes training and qualification, including:

- Each staff position and required security qualifications YES NO
- Required training and frequency for each position YES NO
- Training provider YES NO
- How training records are maintained YES NO

Comments:

(6) Access authorization.

Verify that the application adequately describes the access authorization process, including:

- Basis for identifying persons with authorized access YES NO
- Process for verifying that persons who need authorized access have received trustworthiness verification and required training YES NO
- Review, re-evaluation and withdrawal of access YES NO
- Maintenance of access authorization records YES NO

Comments:

(7) Trustworthiness evaluation.

Verify that the application adequately describes how the operator verifies trustworthiness, including:

- Basis of identifying persons whose trustworthiness must be evaluated YES NO
- Applicable requirements regarding trustworthiness YES NO
- Arrangements and methods for trustworthiness evaluation YES NO
- Maintenance of records YES NO

Comments:

(8) Information protection.
Verify that the application adequately describes information protection measures, including:

- Types of information requiring protection YES NO
- Process for identifying persons requiring access to such information YES NO
- Means of protecting against unauthorized access YES NO

Comments:

(9) Maintenance programme.
Verify that the application adequately describes the operator's maintenance programme.

YES NO

Comments:

(10) Budget and resource planning.
Verify that the application adequately describes the operator's budget and resource planning process, as it relates to the security of radioactive material.

YES NO

Comments:

(11) Evaluation for compliance and effectiveness.
Verify that the application adequately describes the operator's process of evaluation for compliance and effectiveness.

YES NO

Comments:

(12) Threat information.

Verify that the application adequately describes what threat information is provided to the site and how it is provided.

YES NO

Comments:

(13) Security assessment methodology.

Verify that the application adequately describes the methodology used to design the security system and assess its vulnerabilities.

YES NO

Comments:

(14) Security system design.

Verify that the application adequately describes the overall design of the security system, including:

- How each secured area is protected to the required level of protection YES NO
- Types and location of security equipment for detection, delay and response YES NO

Comments:

(15) Access control. Describe the physical measures for controlling access.

Verify that the application adequately describes access control measures, including:

- Means of physically controlling access YES NO
- Media used to authenticate the identity of authorized persons YES NO
- Procedures for authorized persons to obtain access YES NO

Comments:

(16) Detection, assessment and delay measures.

For each secured area, verify that the application adequately describes security measures, including:

- Detection measures YES NO
- Assessment measures YES NO
- Delay measures YES NO

Comments:

(17) Procedures for routine, off-shift and emergency operations.

Verify that the application adequately describes security procedures during:

- Business hours YES NO
- Non-business hours YES NO
- Emergency operations YES NO

Comments:

(18) Procedures for opening and closing of secured areas.

Verify that the application adequately describes procedures for opening and closing each secured area.

YES NO

Comments:

(19) Procedures for key and lock control.

Verify that the application adequately describes procedures for key and lock control.

YES NO

Comments:

(20) Procedures for accounting and inventory.
Verify that the application adequately describes procedures for accounting and inventory, including:

- Means and frequency of verifying the presence of each radioactive source YES NO
- Maintenance of verification measures YES NO
- Steps to be taken when source presence cannot be verified YES NO
- Maintenance of radioactive source inventory YES NO
- Annual inventory verification YES NO

Comments:

(21) Procedures for receipt and transfer of radioactive material.
Verify that the application adequately describes receipt and transfer procedures.

YES NO

Comments:

(22) Response to a nuclear security event.
Verify that the application adequately describes arrangements for responding to a nuclear security event.

YES NO

Comments:

(23) Communications.
Verify that the application adequately describes the communication methods used to summon a response.

YES NO

Comments:

(24) Security event reporting.

Verify that the application adequately describes security event reporting, including procedures for:

- Reporting security events to the site security organization YES NO
- Documentation of security events YES NO
- External reporting of security events YES NO
- Evaluation of security events and, if necessary, revision of the security plan YES NO

Comments:

(25) Security during emergencies and contingencies.

Verify that the application adequately describes arrangements for maintaining security during emergencies and contingencies.

YES NO

Comments:

(26) Increased threat level.

Verify that the application adequately describes how notifications of an increased threat level are addressed.

YES NO

Comments:

Annex IV

EXAMPLE OF CERTIFICATE FORM FOR AUTHORIZATION

AUTHORIZATION FOR PRACTICES AND SOURCES WITHIN PRACTICES

AUTHORIZED PERSON FOR THE PRACTICE AND THE USE OF
RADIATION SOURCES WITHIN THE PRACTICE:

Note: In this part, the address, telephone, fax and email address of the authorized person for the practice and the use of sources within the practice (i.e. the licensee or legal person) is provided.

RADIATION PROTECTION OFFICER:

QUALIFIED EXPERT (if applicable):

PURPOSE OF AUTHORIZATION:

LOCATION OF THE PREMISES:

Note: In this part, the address of the premises where the practice and sources within the practice are located is provided.

RADIOACTIVE SOURCES AND APPARATUS CONTAINING RADIOACTIVE
SUBSTANCES (APPROVED FOR USE)

Manufacturer	Model	Serial number	Radionuclide	Activity (Bq)	Activity date	Use	Location

ELECTRICAL DEVICES PRODUCING IONIZING RADIATION (IONIZING RADIATION GENERATORS)

Manufacturer	Model	Serial number	Maximum power (e.g. maximum radiographic kVp, mA)	Use	Location

LICENCE CONDITIONS

Note: In this part, the authorized person is directed to:

- Comply with regulations (specifying the paragraph numbers);
- Ensure that any person who may subsequently be engaged to operate, install, maintain or otherwise perform activities in the practice and with sources within the practice on the premises has approved training, in accordance with the criteria stated in the radiation protection programme;
- Provide prior written notification to the regulatory body of any intension to sell, relocate, install or dispose of radiation sources (i.e. by any means), or plans to modify the structure of the premises in any way that may significantly impact radiation safety, and nominate a replacement of the qualified expert or radiation protection officer;
- Ensure that the installation, service or maintenance of the practice and the use of sources within the practice on the premises is performed only by personnel authorized by the regulatory body;
- Ensure compliance with any other specific conditions that the regulatory body will require, as necessary.

The authorized person is approved: _____

Note: Not valid unless signed by an authorized officer of the regulatory body.

Date: _____

Regulatory body: _____

Note: In this part, the address, telephone and fax numbers and email address of the regulatory body are provided.

LICENCE NUMBER:

EXPIRY DATE:

Note: This authorization is to be displayed in a prominent public location in the authorized premises for the practice and use of sources within the practice.

Annex V



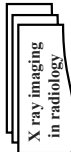
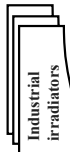
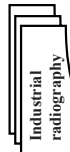


EXAMPLE OF GUIDANCE ON REGULATORY INSPECTIONS

Information provided in this annex is intended to be used by regulatory bodies as a reference when establishing and implementing inspection programmes commensurate with the radiation safety and security risks associated to the facility or activity. Regulatory bodies need to adapt this annex to make it consistent with their national legislation and regulations. Examples have been developed to illustrate the application of the IAEA safety standards to various practices. They include the use of radiotherapy, nuclear medicine, X ray imaging in radiology, industrial irradiators, industrial radiography, well logging and nuclear gauges. Material related to security, based on IAEA Nuclear Security Series publications, is presented separately, according to the security level. Inspection guidance has been grouped into the following nine elements:

- (1) General information;
- (2) Administrative information;
- (3) Integrated management system;
- (4) Technical information;
- (5) Safety assessment;
- (6) Protection of workers;
- (7) Protection of the public;
- (8) Protection of patients (applicable only to medical practices);
- (9) Security of sources.

Elements (1) to (3) and (5) to (7) consist of a single table with guidance on regulatory inspections of facilities and activities. Tables V-1 to V-3, V-5 to V-7 and V-9.1 to V-9.5 are applicable to all practices, subject to the clarifications in their footnotes. Elements (4) and (8) are addressed in practice specific Tables V-4.1 to V-4.7 and V-8.1 to V-8.3.

Figure V-1 illustrates the use of tables in this annex as applied to regulatory inspection guidance.

	General information (Table V-1)	Administrative information (Table V-2)	Integrated management system (Table V-3)	Technical information (Tables V-4.1 to V-4.7)	Safety assessment (Table V-5)	Occupational protection (Table V-6)	Public protection (Table V-7)	Patient protection (Tables V-8.1 to V-8.3)	Security (Tables V-9.1 to V-9.5)
	✓	✓	✓	Table V-4.1	✓	✓	✓	Table V-8.1	✓
	✓	✓	✓	Table V-4.2	✓	✓	✓	Table V-8.2	N/A *
	✓	✓	✓	Table V-4.3	✓	✓	✓	Table V-8.3	N/A
	✓	✓	✓	Table V-4.4	✓	✓	✓	N/A	✓
	✓	✓	✓	Table V-4.5	✓	✓	✓	N/A	✓
	✓	✓	✓	Table V-4.6	✓	✓	✓	N/A	✓
	✓	✓	✓	Table V-4.7	✓	✓	✓	N/A	✓ *

* Nuclear gauges incorporating low activity radioactive sources and nuclear medicine should be subject to prudent security management practices.

FIG. V-1. Developing practice specific inspection guidance. N/A: not applicable.

When using the information provided here, special attention has to be paid to the following key elements for the inspection:

- (1) Implementation of an integrated management system appropriate for the scope of use, which ensures that:
 - (a) Responsibilities for protection and safety are defined and implemented;
 - (b) Human factors such as ergonomic principles are taken into account to prevent human and organizational failures;
 - (c) Protection and safety are not compromised, e.g. by following all the procedures or safety measures or by taking other business decisions;
 - (d) Assessments of past performance, present conditions and future needs are performed, and appropriate actions are taken when needed.
- (2) Control of the use of radiation sources and facilities is ensured to avoid any loss.
- (3) Optimization of protection and safety is ensured, e.g. patient protection is implemented, and the likelihood and magnitude of unintended and accidental medical exposures are restricted by means of measures for preventing accidents.
- (4) Radiation detection instrumentation technically appropriate for the practice is provided in sufficient number.
- (5) Implementation of classification of areas, local rules and monitoring of the workplace.
- (6) Measurement and recording of radiation doses received by workers as a result of the authorized practice.
- (7) Periodic reviews of measures for protection and safety, including independent verification, if necessary.
- (8) The workers are:
 - (a) Knowledgeable in planned and emergency exposure situations, e.g. trained and retrained in radiation protection and safety related to the authorized practice, including site specific instructions;
 - (b) Empowered to implement the radiation safety measures.
- (9) Implementation of measures to keep public exposure as low as reasonably achievable by monitoring, assessing and recording radiation doses received by members of the public as a result of the authorized practice.
- (10) Implementation of patient protection:
 - (a) By assuming responsibilities for ensuring protection and safety;
 - (b) By ensuring that medical exposures are justified and the protection and safety of the patient are optimized.
- (11) In line with the regulatory framework in the State, security needs to be considered, as appropriate, but only for radioactive sources.

V-1. GENERAL INFORMATION

TABLE V-1. INSPECTION GUIDANCE — GENERAL INFORMATION FOR ALL PRACTICES

Verify that the licensee holds the licence (official document issued by the regulatory body), and that it is still valid.

V-2. ADMINISTRATIVE INFORMATION

TABLE V-2. INSPECTION GUIDANCE — ADMINISTRATIVE INFORMATION FOR ALL PRACTICES

Confirm that the representative of the legal person, the radiation protection officer and the qualified expert are the same as provided in the licence.

V-3. INTEGRATED MANAGEMENT SYSTEM

TABLE V-3. INSPECTION GUIDANCE — INTEGRATED MANAGEMENT SYSTEM FOR ALL PRACTICES

- (1) Management structure and responsibilities.
 - (a) Confirm that the overall organizational system in place ensures that requirements for safety and security are established and applied coherently with other requirements, so that neither safety nor security is compromised by the need to meet other requirements or demands.
 - (b) Confirm that responsibilities for radiation safety and security^a, as authorized in the licence, are implemented. Confirm that responsibilities related to cooperation and consultation are in place.

- (2) Monitoring for verification of compliance.
- (a) Check that the licensee performs regular assessment of radiation protection, safety and security^a, such as a quality control programme, and plans for regular reviews.
 - (b) Confirm that the following procedures and programmes are in place and are fully implemented. Include consideration of security procedures and programmes^a for each of the following items, if necessary:
 - (i) Source inventory, supply of sources, prior assessment of the sources and equipment, and inventory of disused sources^b. Pay attention to the control of a full life cycle of a source, i.e. cradle to grave^a.
 - (ii) Education, training, retraining and competence of the staff.
 - (iii) Testing, routine and periodic examination and maintenance, and quality assurance programme.
 - (iv) Investigation of incidents and accidents.
 - (v) Emergency preparedness and response. In particular, check whether training and exercises are performed.
 - (vi) Control of modification(s) of facilities, equipment and activity.
 - (vii) Management of disused sources and depleted uranium, if applicable^b.
 - (viii) Safe transport of radioactive material^a.
 - (ix) Import and export of radioactive sources, if applicable^a.
 - (x) Control of visitors.
 - (xi) Release of patients after radionuclide therapy^c. Verify that procedures and guidelines exist.
 - (xii) Programme for the improvement of the integrated management system.

^a Not applicable to X ray imaging in radiology.

^b For nuclear medicine, include the inventory of radioactive waste and discharges. For X ray imaging in radiology, consider only radiation generators.

^c Applicable to nuclear medicine.

V-4. TECHNICAL INFORMATION

TABLE V-4.1. INSPECTION GUIDANCE — TECHNICAL INFORMATION FOR RADIOTHERAPY

- (1) Information on radiation sources.
 - (a) Radiotherapy equipment using radioactive sources, radiotherapy sources, check sources, and sources other than category 1–2 sealed sources:
 - (i) Verify that the licensee possesses only sources and devices authorized in the licence;
 - (ii) Confirm that the control panel has safety features, e.g. emergency stop button, appropriate indicators of status of the equipment, and a lock to prevent unauthorized use;
 - (iii) Confirm that periodic leak testing of radiotherapy sources is performed.
 - (b) Depleted uranium. Verify that the licensee possesses only sources and devices authorized in the licence.
 - (c) Linear accelerator:
 - (i) Confirm that beam energies and other information are as in the licence;
 - (ii) Confirm that the control panel has safety features, e.g. emergency stop button, appropriate indicators of status of the equipment, and a lock to prevent unauthorized use.
 - (d) Simulator or imaging device. Confirm that the information of the device is as in the licence.
- (2) Information on measuring instruments for quality control. Equipment for beam calibration:
 - (a) Confirm that the information of the device is as in the licence;
 - (b) Check functionality, calibration and availability.
- (3) Description of the facility. Radiotherapy room, adjacent areas and storages:
 - (a) Confirm that the design and layout of the facility are as described in the licence.
 - (b) Check arrangements related to adjacent offices or buildings. During inspection of the radiotherapy room, check arrangements related to the control room. During inspection of a storage, check that stored sources do not exceed the specified maximum capacity of the storage.
 - (c) Check whether assumptions used for the shielding calculation, e.g. use factor, occupancy factor and workload, are still valid.

- (d) Confirm that safety and security features are in place and function as described by the user in the documentation supporting the application for authorization.
 - (e) Confirm the position of all technical safety and security features and warning systems, such as emergency cord or button, radiation monitor(s) (e.g. dose rate monitor in the room), door interlocks, use of key control, sensors, access control measures, barriers, monitors and warning signals (i.e. acoustic and visual) and notices.
 - (f) Verify the function of safety and warning systems, including the independence and redundancy of interlock systems.
 - (g) Verify that the text of the notices is in a language understandable to the persons likely to be in areas around the irradiation room(s).
 - (h) Check the boundaries of controlled and supervised areas.
 - (i) Verify that controlled and supervised areas are designated.
- (4) Technical information of radiation monitoring equipment.
- (a) Through observations, confirm that a sufficient amount of radiation monitoring equipment is available, suitable for this practice and properly calibrated.
 - (b) Installed radiation monitor(s). Check whether installed radiation monitors are in line with the technical information provided in the application for authorization. Check functionality and calibration.
 - (c) Portable survey meters. Check whether portable survey meters are in line with the technical information provided in the application for authorization. Check functionality, calibration and availability.
 - (d) Personnel monitoring devices. Check that personnel monitoring devices have been provided to all workers, as described in the licence application. Check that personal dosimetry devices with direct reading and alarm functions are available, if required.
- (5) Safe and secure management and control of radiation sources once it has been decided to take them out of use, including financial provisions.
- (a) Confirm that all disused sources, including depleted uranium, are managed in line with safety requirements, e.g. check that storage for disused sources is designed and controlled using optimization and dose limitations and that management of the storage includes all safety and security precautions;
 - (b) Check whether financial provisions for the safe management of all disused sources, including depleted uranium, are in place;
 - (c) Check that the licensee possesses only radiation sources that have been approved in the authorization i.e. check for any sources without regulatory control. Verify that the sources are stored and controlled in a safe manner.

- (6) Check how patient protection has been optimized using technical systems such as treatment planning systems, image guiding systems, treatment verification systems, immobilization devices, and visual and acoustic communication systems between the control room and the treatment room.
-

TABLE V-4.2. INSPECTION GUIDANCE — TECHNICAL INFORMATION FOR NUCLEAR MEDICINE

- (1) Information on radiation sources.
 - (a) Verify that the licensee possesses only sources and devices authorized in the licence.
 - (b) Information on sealed sources. Confirm that periodic leak testing of nuclear medicine sources is performed.
 - (c) Information on imaging devices with a radiation source. Confirm that the information of the device is as in the licence.
- (2) Information on measuring instruments for quality control. Confirm that the information of the activity calibrator is as in the licence.
- (3) Description of the facility. Nuclear medicine laboratory and adjacent areas and storages:
 - (a) Confirm that the design and layout of the facility are in place as described in the licence.
 - (b) Check arrangements related to adjacent offices or buildings.
 - (c) Check whether the assumptions used for the shielding calculation, e.g. use factor, occupancy factor and workload, are still valid.
 - (d) Confirm that safety and security features are in place and function as described by the user in the documentation supporting the application for authorization.
 - (e) Confirm the position of all technical safety and security features and warning systems.
 - (f) Verify that the text of the notices is in a language understandable to the persons likely to be in areas around the irradiation room(s).
 - (g) Check the boundaries of controlled and supervised areas. Demonstrate that controlled and supervised areas are designated.

- (4) Technical information of radiation monitoring equipment.
 - (a) Through observations, confirm that a sufficient amount of radiation monitoring equipment is available, suitable for this practice and properly calibrated.
 - (b) Installed radiation monitors. Check whether installed radiation monitors are in line with the technical information provided in the application for authorization. Check functionality and calibration.
 - (c) Portable survey meters. Check whether portable survey meters are in line with the technical information provided in the application for authorization. Check functionality, calibration and availability.
 - (d) Personnel monitoring devices. Check that personnel monitoring devices have been provided to all workers, as described in the licence application. Check that personal dosimetry devices with direct reading and alarm functions are available, if required.
 - (5) Safe and secure management and control of radiation sources once it has been decided to take them out of use, including financial provisions.
 - (a) Confirm that all disused sources are managed in line with safety requirements, e.g. check that storage for disused sources is designed and controlled using optimization and dose limitations and that management of the storage includes all safety and security precautions.
 - (b) Check whether financial provisions for the safe management of all disused sources are in place.
 - (c) Check that the licensee possesses only radiation sources that have been approved in the authorization i.e. check for any sources without regulatory control. Verify that the sources are stored and controlled in a safe manner.
-

TABLE V-4.3. INSPECTION GUIDANCE — TECHNICAL INFORMATION FOR X RAY IMAGING IN RADIOLOGY

- (1) Information on radiation sources.
 - (a) Verify that the licensee possesses only sources and devices authorized in the licence.
 - (b) Information on imaging devices with a radiation source. Confirm that the information of the device is as in the licence.

- (2) Description of the facility. X ray imaging room and adjacent areas.
 - (a) Confirm that information on the room is as in the licence.
 - (b) Confirm that the design and layout of the facility are as described in the licence.
 - (c) Check arrangements related to adjacent areas.
 - (d) Check whether the assumptions used for the shielding calculation, e.g. use factor, occupancy factor and workload, are still valid.
 - (e) Confirm that safety features are in place and function as described by the user in the documentation supporting the application for authorization.
 - (f) Confirm the position of all technical safety features and warning systems.
 - (g) Verify that the text of the notices is in a language understandable to the persons likely to be in areas around the irradiation room.
 - (h) Check the boundaries of the controlled and supervised areas, as appropriate. Demonstrate that controlled and supervised areas are designated.
 - (3) Technical information of radiation monitoring equipment.
 - (a) Through observations, confirm that a sufficient amount of radiation monitoring equipment is available, suitable for this practice and properly calibrated.
 - (b) Portable survey meters. Check whether portable survey meters are in line with the technical information provided in the application for authorization. Check their functionality, calibration and availability.
 - (c) Personnel monitoring devices. Check that personnel monitoring devices have been provided to all radiation workers, as described in the licence application. Check that personal dosimetry devices with direct reading and alarm functions are available, if required.
-

TABLE V-4.4. INSPECTION GUIDANCE — TECHNICAL INFORMATION FOR INDUSTRIAL GAMMA IRRADIATORS

- (1) Information on radiation sources.
 - (a) Verify that the licensee possesses only sources and devices authorized in the licence.

- (b) Radioactive sources for irradiation, for checking equipment, calibration sources and control sources. Confirm that periodic leak testing of sources is performed.
 - (c) Storage containers. Check that storage containers meet the dose level and labelling requirements.
- (2) Description of the facility.
- (a) Irradiation room(s) and any source storage:
 - (i) Confirm that the design and layout of the facility are as described in the licence.
 - (ii) Check arrangements related to the irradiation room, adjacent rooms and adjacent offices or buildings. During inspection of the gamma irradiator, check arrangements related to the control room. During inspection of the storage, check that stored sources do not exceed the specified maximum capacity of the storage.
 - (iii) Check whether the assumptions used for the shielding calculation, e.g. use factor and occupancy factor, are still valid.
 - (iv) Confirm that safety and security features are in place and function as described by the user in the documentation supporting the application for authorization.
 - (v) Confirm the position of all technical safety and security features and warning systems, such as emergency cord or button, radiation monitor(s) (e.g. dose rate monitor in the room), door interlocks, use of key control, sensors, access control measures, barriers, monitors, warning signals (i.e. acoustic and visual) and notices.
 - (vi) Verify the function of safety and warning systems, including the independence and redundancy of interlock systems.
 - (vii) Verify that the text of the notices is in a language understandable to the persons likely to be in areas around the irradiation room(s).
 - (viii) Check the boundaries of controlled and supervised areas.
 - (ix) Confirm that controlled and supervised areas are designated.
 - (b) Control panel. Verify that the irradiator control panel is in line with the technical description of the licence and has the following safety systems: mechanisms for safe operation, light signals for safety mechanisms and for operation of the irradiator, emergency shutdown button, single control and access key for the irradiator and viewing screen for the product transport system.
 - (c) Source holder and rack. Verify in detail the design and the characteristics and manufacturing conditions of the sources, source holders and rack. In particular, check the operational procedures for leak and contamination tests of radiation sources.

- (d) Safety mechanisms of the gamma irradiator:
- (i) Check the operational procedures to assess the following safety mechanisms: safety chain in the maze; electric lock on the access door; internal emergency exit mechanism on the irradiator access door; irradiator actuation key attached to the portable survey meter; fixed radiation survey meters for the access door, irradiation room, ionization system and product exit; personal alarm monitor; portable radiation survey meter with irradiator key attached; irradiator access door; anti-collision system; entrance door locking system; system for locking and lowering the source in the maze (internal safety buttons or cable); photoelectric cell system for the personnel access door, product entry and exit port; high/low water level control system for the pool; ionization system; ventilation or extraction disconnection system; earthquake detection system; stored source detection system; smoke detection system; temperature detection system; 'roof plug open' detection system; emergency power supply system for the irradiator; automatic or manual fire extinguishing system; malfunction interlock system; emergency shutdown system on the control panel; automatic or manual water loss replacement system; pool water cooling system; protective plates for the source; sound and light signals in the control room, on the control panel and in the irradiator.
 - (ii) Confirm that security is in line with the security plan submitted in the application.
- (e) Operation of the gamma irradiator. Check whether the following rules or instructions for the operation of the irradiator are in line with the licence: written instructions for commencing and ending operation; written instructions regarding the requirement to verify safe conditions, as indicated by the visual indicators of the control panel and the irradiator, before entering the irradiation room; written instructions regarding the requirement to use a portable radiation survey meter before entering the irradiation room and to verify that the survey meter is working with the help of a radiation source; written instructions to ensure that the irradiator is maintained as prescribed by the manufacturer, with particular attention paid to ensuring that all components of the product positioning system, product boxes and carriers continue to meet design specifications; written instructions covering actions to be taken in the event of malfunctions; and simple emergency response instructions posted visibly in the control room.

- (3) Technical information of radiation monitoring equipment.
 - (a) Through observations, confirm that a sufficient amount of radiation monitoring equipment is available, suitable for this practice and properly calibrated.
 - (b) Installed radiation monitors. Check whether installed monitors are in line with the technical information provided in the application for authorization. Check functionality and calibration.
 - (c) Portable survey meters. Check whether portable survey meters are in line with the technical information provided in the application for authorization. Check their functionality, calibration and availability.
 - (d) Personnel monitoring devices. Check that personnel monitoring devices have been provided to all workers, as described in the licence application. Check that personal dosimetry devices with direct reading and alarm functions are available, if required.
 - (4) Safe and secure management and control of radiation sources once it has been decided to take them out of use, including financial provisions.
 - (a) Confirm that all disused sources, including depleted uranium, are managed in line with safety requirements, e.g. check that storage for disused sources is designed and controlled using optimization and dose limitations and that management of the storage includes all safety and security precautions.
 - (b) Check whether financial provisions for the safe management of all disused sources, including depleted uranium, are in place.
 - (c) Check that the licensee possesses only radiation sources that have been approved in the authorization i.e. check for any sources without regulatory control. Verify that the sources are stored and controlled in a safe manner.
-

TABLE V-4.5. INSPECTION GUIDANCE — TECHNICAL INFORMATION FOR INDUSTRIAL RADIOGRAPHY

- (1) Information on radiation sources.
 - (a) Verify that the licensee possesses only sources and devices authorized in the licence.
 - (b) Radiography sources and radioactive sources for checking equipment, calibration sources and control sources e.g. as a part of the pipe crawler

- equipment. Confirm that periodic leak testing of radiography sources is performed.
- (c) Depleted uranium used for exposure devices, source changers, storage containers and collimators:
 - (i) Source changers and storage containers;
 - (ii) Check that the source changers and storage containers meet the dose level and labelling requirements.
 - (d) X ray generator:
 - (i) Confirm that appropriate labels are posted, e.g. on the control panel;
 - (ii) Confirm that the control panel has safety features, e.g. emergency stop button, appropriate indicators of status of the equipment and a lock to prevent unauthorized use;
 - (iii) Confirm that the length of the X ray tube connection cable is at least 20 m for X ray generators of up to 300 kV and longer for higher energy equipment.
- (2) Description of the facility.
- (a) Source storage and irradiation room:
 - (i) Confirm that the design and layout of the facility are as described in the licence.
 - (ii) Check arrangements related to adjacent offices or buildings. During inspection of the irradiation room, check arrangements related to the control room. During inspection of the storage, check that stored sources do not exceed the specified maximum capacity of the storage.
 - (iii) Check whether the assumptions used for the shielding calculation, e.g. use factor and occupancy factor, are still valid.
 - (iv) Confirm that safety and security features are in place and function as described by the user in the documentation supporting the application for authorization.
 - (v) Confirm the position of all technical safety and security features and warning systems, such as emergency cord or button, radiation monitor(s) (e.g. dose rate monitor in the room), door interlocks, use of key control, sensors, access control measures, barriers, monitors, warning signals (i.e. acoustic and visual) and notices.
 - (vi) Verify the function of safety and warning systems, including the independence and redundancy of interlock systems.
 - (vii) Verify that the text of the notices is in a language understandable to the persons likely to be in areas around the irradiation room(s).
 - (viii) Check the boundaries of controlled and supervised areas.

- (b) Locations for site radiography works:
- (i) Verify whether site radiography is performed as specified in the licence, e.g. cooperation with the client, assessment of the location, preparation of the time schedule, use of local rules and emergency preparedness, taking into account any additional risks at the site.
 - (ii) Verify how site radiography is conducted, e.g. establishment of controlled areas, use of warning signals and notices in a language understood by persons at the location, establishment of all other precautions before, during and after irradiation.
 - (iii) Confirm that all safety features (e.g. alarms and lights) are in place and are functional.
 - (iv) Check whether all sources and equipment are available at the site, such as X ray exposure devices, collimators, guide tubes, control cables, monitoring equipment, personal dosimeters and alarm dosimeters, warning signals and notices, and emergency kit.
 - (v) Check whether all radiation monitors are functional. In particular, check whether a portable radiation monitor is used after each exposure using radiation sources.
 - (vi) Confirm that at least two workers are performing on-site radiography for each radiography source.
 - (vii) Perform an independent radiation survey using the appropriate measurement technique and compare the results with the licensee's measurements regarding controlled and supervised areas.
 - (viii) Through observation, verify that the licensee transports gamma exposure devices properly. Examine packages for appropriate labelling and review the associated certification documentation. Examine whether shipping containers are properly fixed in the vehicles. Verify that shipping papers are complete and available. Survey packages and vehicles to verify compliance with transport regulations.
 - (ix) Confirm that security is in line with the security plan submitted in the application.
- (c) On-site source storage. Confirm that safety and security measures are in place when a specific location (or the radiography vehicle) is used as on-site source storage in the operating organization's main base. Confirm the implementation of all safety systems, as well as the assumptions used in the assessment of exposures of workers and members of the general public.

- (3) Technical information of radiation monitoring equipment.
 - (a) Through observations, confirm that a sufficient number of radiation monitoring equipment is available, suitable for this practice and properly calibrated.
 - (b) Installed radiation monitors. Check whether installed monitors are in line with the technical information provided in the application for authorization. Check functionality and calibration.
 - (c) Portable survey meters. Check whether portable survey meters are in line with the technical information provided in the application for authorization. Check their functionality, calibration and availability.
 - (d) Personnel monitoring devices. Check that personnel monitoring devices have been provided to all workers, as described in the licence application. Check that personal dosimetry devices with direct reading and alarm functions are available, if required.
 - (4) Safe and secure management and control of radiation sources once it has been decided to take them out of use, including financial provisions.
 - (a) Confirm that all disused sources, including depleted uranium, are managed in line with safety requirements, e.g. check that storage for disused sources is designed and controlled using optimization and dose limitations, and that management of the storage includes all safety and security precautions.
 - (b) Check whether financial provisions for the safe management of all disused sources, including depleted uranium, are in place.
 - (c) Check that the licensee possesses only radiation sources that have been approved in the authorization i.e. check for any sources without regulatory control. Verify that the sources are stored and controlled in a safe manner.
-

TABLE V-4.6. INSPECTION GUIDANCE — TECHNICAL INFORMATION FOR WELL LOGGING

- (1) Information on radiation sources.
 - (a) Verify that the licensee possesses only sources and devices authorized in the licence.

- (b) Well logging radioactive sources, including sources for checking equipment and calibration sources:
 - (i) Verify whether there have been changes in the inventory of sources and whether records are maintained in that regard;
 - (ii) Verify for each type of source the location and serial number, and whether there has been any unauthorized movement of sources;
 - (iii) Confirm that periodic leak testing of radioactive sources is performed.
- (c) Source storage containers:
 - (i) Check that the source changers and storage containers meet the dose level and labelling requirements;
 - (ii) Confirm that a locking mechanism is in place.
- (2) Description of the facility.
 - (a) Source storage and calibration areas:
 - (i) Confirm that the design and layout of the source storage and calibration area are as described in the licence.
 - (ii) Check arrangements related to adjacent offices or buildings. During inspection of a storage, check that stored sources do not exceed the specified maximum capacity of the storage.
 - (iii) Check whether assumptions used for the shielding calculation, e.g. use factor and occupancy factor, are still valid.
 - (iv) Confirm that safety and security features are in place and function as described by the user in the documentation supporting the application for authorization.
 - (v) Confirm the position of all technical safety and security features and warning systems, such as emergency devices, radiation monitor(s) (e.g. dose rate monitor in the room), door interlocks, use of key control, sensors, access control measures, barriers, monitors, warning signals (i.e. acoustic and visual) and notices.
 - (vi) Verify the function of safety and warning systems, including the independence and redundancy of interlock systems.
 - (vii) Verify that the text of the notices is in a language understandable to the persons likely to be in areas around the well logging operation area.
 - (viii) Check the boundaries of controlled and supervised areas.
 - (b) Locations for site well logging works:
 - (i) Verify whether the operation is performed as specified in the licence, e.g. cooperation with the client, assessment of the location, preparation of the time schedule, use of local rules and emergency preparedness, taking into account any additional risks at the site.

- (ii) Verify how the operation is conducted, e.g. establishment of controlled areas, use of warning signals and notices in a language understood by persons at the location, establishment of all other precautions before, during and after irradiation.
 - (iii) Confirm that all safety features (e.g. alarms and lights) are in place and are functional.
 - (iv) Check whether all sources and equipment are available at the site, such as monitoring equipment, personal dosimeters and alarm dosimeters, warning signals and notices, and emergency kit.
 - (v) Check whether all radiation monitors are functional. In particular, check whether a portable radiation monitor is used to confirm that the source is shielded.
 - (vi) Confirm that at least two workers perform the well logging operation.
 - (vii) Perform an independent radiation survey using the appropriate measurement technique and compare the results with the licensee's measurements regarding controlled and supervised areas.
 - (viii) Through observation, verify that the licensee transports well logging radioactive sources and devices properly. Examine packages for proper labelling and review the associated certification documentation. Examine whether shipping containers are properly fixed in the vehicles. Verify that shipping papers are complete and available. Survey packages and vehicles to verify compliance with transport regulations.
 - (ix) Confirm that security is in line with the security plan submitted in the application.
- (c) On-site source storage. Confirm that safety and security measures are in place when a specific location (or the well logging vehicle) is used as on-site source storage in the operating organization's main base. Confirm the implementation of all safety systems, as well as the assumptions used in the assessment of exposures of workers and members of the general public.
- (3) Technical information of radiation monitoring equipment.
- (a) Through observations, confirm that a sufficient amount of radiation monitoring equipment is available, suitable for this practice and properly calibrated.
 - (b) Portable survey meters. Check whether portable survey meters are in line with the technical information provided in the application for authorization. Check their functionality, calibration and availability.

- (4) Personnel monitoring devices. Check that personnel monitoring devices have been provided to all workers, as described in the licence application. Check that personal dosimetry devices with direct reading and alarm functions are available, if required.
 - (5) Safe and secure management and control of radiation sources once it has been decided to take them out of use, including financial provisions.
 - (a) Confirm that all disused sources, including depleted uranium, are managed in line with safety requirements, e.g. check that storages for disused sources are designed and controlled using optimization and dose limitations and that management of the storages includes all safety and security precautions.
 - (b) Check whether financial provisions for the safe management of all disused sources, including depleted uranium, are in place.
 - (c) Check that the licensee possesses only radiation sources that have been approved in the authorization i.e. check for any sources without regulatory control. Verify that the sources are stored and controlled in a safe manner.
-

TABLE V-4.7. INSPECTION GUIDANCE — TECHNICAL INFORMATION FOR NUCLEAR GAUGES

- (1) Information on radiation sources.
 - (a) Verify that the licensee possesses only sources and devices authorized in the licence.
 - (b) Nuclear gauge devices. Check radioactive sources, sources for checking equipment and calibration sources. Confirm that periodic leak testing of radioactive sources is performed.
 - (c) Depleted uranium used for nuclear gauge devices. Check source changers and source storage containers. Check that the source changers and storage containers meet the dose level and labelling requirements.
 - (d) Nuclear gauges that use an X ray generator:
 - (i) Confirm that appropriate labels are posted;
 - (ii) Confirm that the X ray generator has safety features, e.g. emergency stop button, appropriate indicators of status of the equipment and a lock to prevent unauthorized use.

- (2) Description of the facility.
- (a) Source storages and facilities with fixed (i.e. installed) nuclear gauge(s):
- (i) Confirm that the design and layout of the source storage and the facility with fixed (i.e. installed) nuclear gauge(s) are as described in the licence.
 - (ii) Check arrangements related to adjacent offices or buildings. During inspection of a storage, check that stored sources do not exceed the specified maximum capacity of the storage.
 - (iii) Check whether the assumptions used for the shielding calculation (e.g. use factor and occupancy factor) are still valid.
 - (iv) Confirm that safety and security features are in place and function as described by the user in the documentation supporting the application for authorization.
 - (v) Confirm the position of all technical safety and security features and warning systems, such as emergency cord or button, radiation monitors (e.g. dose rate monitor in the room), door interlocks, use of key control, sensors, access control measures, barriers, monitors, warning signals (i.e. acoustic and visual) and notices.
 - (vi) Verify the function of safety and warning systems, including the independence and redundancy of interlock systems.
 - (vii) Verify that the text of the notices is in a language understandable to the persons likely to be in areas around the irradiation room(s).
 - (viii) Check the boundaries of controlled and supervised areas.
- (b) Locations for site works using nuclear gauges:
- (i) Verify that the operation is performed as specified in the licence, e.g. cooperation with the client, assessment of the location, preparation of time schedule, use of local rules and emergency preparedness, taking into account any additional risks at the site.
 - (ii) Check operation with mobile nuclear gauges. Verify how the operation is conducted, e.g. establishment of controlled areas, use of warning signals and notices in a language understood by persons at the location, establishment of all other precautions before, during and after irradiation.
 - (iii) Confirm that all safety features (e.g. alarms and lights) are in place and are functional.
 - (iv) Check whether all sources and equipment are available at the site, such as monitoring equipment, personal dosimeters and alarm dosimeters, warning signals and notices, and emergency kit.

- (v) Check whether all radiation monitors are functional. In particular, check whether a portable radiation monitor is used after each exposure using radiation sources.
 - (vi) Confirm that at least two workers perform procedures using mobile nuclear gauges with each source.
 - (vii) Perform an independent radiation survey using the appropriate measurement technique and compare the results with the licensee's measurements regarding controlled and supervised areas.
 - (viii) Through observation, verify that the licensee transports mobile nuclear gauges properly. Examine packages for appropriate labelling and review the associated certification documentation. Examine whether shipping containers are properly fixed in the vehicles. Verify that shipping papers are complete and available. Survey packages and vehicles to verify compliance with transport regulations.
 - (ix) Confirm that security is in line with the security plan submitted in the application.
- (c) On-site source storage. Confirm that safety and security measures are in place when a specific location (or the well logging vehicle) is used as on-site source storage in the operating organization's main base. Confirm the implementation of all safety systems, as well as the assumptions used in the assessment of exposures of workers and members of the general public.
- (3) Technical information of radiation monitoring equipment.
- (a) Through observations, confirm that a sufficient amount of radiation monitoring equipment is available, suitable for this practice and properly calibrated.
 - (b) Portable survey meters. Check whether portable survey meters are in line with the technical information provided in the application for authorization. Check their functionality, calibration and availability.
 - (c) Personnel monitoring devices. Check that personnel monitoring devices have been provided to all workers, as described in the licence application. Check that personal dosimetry devices with direct reading and alarm functions are available, if required.
- (4) Safe and secure management and control of radiation sources once it has been decided to take them out of use, including financial provisions.
- (a) Confirm that all disused sources, including depleted uranium, are managed in line with safety requirements, e.g. check that storage for disused sources is designed and controlled using optimization and dose limitations and that management of the storage includes all safety and security precautions.

- (b) Check whether financial provisions for the safe management of all disused sources, including depleted uranium, are in place.
 - (c) Check that the licensee possesses only radiation sources that have been approved in the authorization i.e. check for any sources without regulatory control. Verify that the sources are stored and controlled in a safe manner.
-

V-5. SAFETY ASSESSMENT

TABLE V-5. INSPECTION GUIDANCE — SAFETY ASSESSMENT FOR ALL PRACTICES

- (1) Confirm that the licensee has implemented and documented regular reviews of the safety assessment^a, and the safety assessment is up to date;
 - (2) Confirm that the licensee has independent verification of the safety assessment.
-

^a For certain practices in X ray imaging radiology, e.g. bone densitometry and stomatology, it is sufficient that a generic safety assessment exists.

V-6. PROTECTION OF WORKERS

TABLE V-6. INSPECTION GUIDANCE — PROTECTION OF WORKERS FOR ALL PRACTICES

- (1) Education and training of workers.
 - (a) Confirm that the staff (including assistants and trainees) are trained and qualified in accordance with the license. Check access authorization measures and security training^a.
 - (b) Confirm that radiation protection officers understand their responsibilities, including informing the senior management of the licensee on the performance of protection safety and security measures^a.
 - (c) Confirm that qualified experts understand their responsibilities and exercise their duties.

- (2) Personal dosimetry.
 - (a) Confirm that the licensee uses an authorized or approved dosimetry service, and check arrangements related to monitoring of personal doses;
 - (b) Confirm that the licensee has maintained and reviewed past occupational doses for all workers (including itinerant). Verify how the licensee maintains dose records and informs the workers about their doses. Verify the use of investigation levels.
- (3) Workers' health surveillance. Check whether the specified programme for health surveillance is in place.
- (4) Itinerant workers. Confirm that the licensee has control of allocation and documentation of the responsibilities of the employer, and the safety and protection of itinerant workers are ensured. Check access authorization measures and security training^a.
- (5) Arrangements for the radiation protection programme and the security programme^a.
 - (a) Confirm that elements of the radiation protection programme and the security programme^a are in place.
 - (b) Designation of controlled, supervised and protected areas for security^a purposes:
 - (i) Confirm by observation and independent measurements that the classification of controlled and supervised areas is appropriate, i.e. in line with the radiation protection programme;
 - (ii) Confirm that the designation of protected areas is in line with the security programme^a;
 - (iii) Verify that labels, signs and notices are in place as appropriate;
 - (iv) Confirm that audits and reviews of the radiation protection programme and the security programme^a are carried out periodically.
 - (c) Practice specific local rules^b:
 - (i) Check the implementation of local rules applicable for workers for all processes of the licence.
 - (ii) Check that an adequate number of workers is involved in the practice. In particular, check roles, responsibilities and the supervision of processes.
 - (iii) Check that rules, labels and marks are in a language understood by those for whom they are intended.
 - (iv) Check the appropriateness and use of radiation monitoring equipment and protective equipment.
 - (v) Check that the licensee's reliance on administrative control and personal protective equipment for protection and safety is

- minimized, giving priority to engineering controls. Check that local rules related to security^a are in place.
- (vi) Check that local rules for irradiation rooms in radiotherapy, industrial gamma irradiators and industrial radiography, and for working areas in nuclear medicine, as applicable, include periodic control of the facility, periodic tests of equipment, key control, startup sequence, labelling and posting, use of radiation monitors, stop sequence, security^a and control of records. Check that the local rules are implemented.
 - (vii) Check^a that local rules for radioactive source storage and temporary storage of disused sources and radioactive waste in nuclear medicine include key control, use of survey meters and dosimeters, record keeping, control of labels, marks and notices, movement of sources within the applicant's premises, security and periodical source inventory control. Check that the local rules are implemented.
- (d) Workplace and area monitoring programme:
- (i) Check that selection, calibration, maintenance, testing and use of equipment to measure radiation dose rates are appropriate.
 - (ii) Check that the monitoring programme takes into account all processes within the practice, e.g. use and maintenance of radiation equipment, accepting packages with new radioactive sources and preparing packages for transport^a.
 - (iii) Check that the programme establishes the use of at least one operational dose rate meter for each source during use. Check that this is implemented.
 - (iv) Check that the programme includes the use of at least one operational dose rate meter^c during the practice. Check that this is implemented.

^a Not applicable to X ray imaging in radiology.

^b See below for additional checks for industrial practices.

^c For each source when on-site radiography is performed, for each kind of well logging operation, and for each kind of the nuclear gauges.

For industrial practices (Table V–6, 5(c)), verify in addition the following:

(a) Site radiography:

Check that local rules and procedures include the transport and use of the radioactive source storage and on-site radioactive source storage; acquisition of radiation survey meters, dosimeters, emergency kit, alarms, labels, marks and notices before going on-site; acquisition of sources from the storage; transport of sources; site management (including cooperation with the client); preparation of site radiography (including selection of barriers, marking and posting, assuring that at least two radiographers are involved); control of the controlled area and management of the supervised area (managing exposure of workers and members of the public); and control of the position of sources, informing workers not occupationally exposed. Check that for each procedure an adequate number of workers is involved, e.g. for site radiography at least two radiographers must be involved. Check that local rules and procedures include security. Check that the local rules are implemented.

(b) Well logging:

(i) Specific requirements for well logging:

- Check the compliance of the design of well logging equipment incorporating radiation sources, including radiation source containers, source holders, shielding, shutters, safety mechanisms and housing systems for detectors, with the requirements laid down in the international standard (ISO 7205:1986);
- Check that compliance of the design of the remote handling tools is such that operators cannot expose their hands or another part of their body to the radiation while the source is transferred from the container to the well logging tool;
- Check whether the source is safely retained in the container after the source is withdrawn from the tool;
- Check whether the presence of radiation sources is indicated by signs such as labels, warnings and alert signals;
- Check whether the radiation source is leak-tight and free of contamination (ISO 9978:2020).

(ii) Specific requirements for the calibration and testing area of well logging tools:

Check whether the operation base area is used especially for this purpose and is classified as a controlled area; the radioactive sources are handled only with the help of remote handling tools, which need to be available for this purpose in the premises; light and sound signals are in place to indicate the start and finish of the calibration and testing activities; the presence of radiation sources is indicated by signs such

as labels, warnings and alert signals; the access control area is only for unauthorized persons while calibrations are being carried out; the radioactive sources are monitored after being taken out of and placed into the container with the remote handling tool to confirm that the sources are shielded.

(iii) Well logging operation:

Check that local rules and procedures include the transport and use of radioactive source storage and on-site radioactive source storage; acquisition of radiation survey meters, dosimeters, emergency kit, alarms, labels, marks and notices before going on-site; acquisition of sources from the storage; transport of sources; site management (including cooperation with the client); preparation for well logging (including selection of barriers, marking and posting, ensuring that at least two workers are involved); control of the controlled area and management of the supervised area (managing exposure of workers and members of the public); and control of the position of a source, informing workers not occupationally exposed. Check that for each procedure an adequate number of workers is involved, e.g. for site well logging operation at least two workers must be involved. Check that local rules and procedures include security. Check that the local rules are implemented.

(c) Nuclear gauges:

(i) Specific requirements for nuclear gauges:

- Check the compliance of the design of the nuclear gauge equipment incorporating radiation sources, including the radiation source containers, source holders, shielding, shutters, safety mechanisms and housing systems for the detectors, with the requirements laid down in the international standard (ISO 7205:1986);
- Check whether nuclear gauges with a collimated beam have a shutter which, in the closed position, prevents exposure to the radiation beam at the exit port;
- Check whether backscatter nuclear gauges have any means of intercepting secondary (or dispersed) radiation;
- Check whether there is a signal indicating when irradiation is taking place (for X rays);
- Check whether the detector container prevents operators from exposing their hands or another part of the body to the useful beam while the electronic mechanisms are being adjusted;
- Check whether the source is safely retained in the container after irradiation;

- Check whether the presence of radiation sources is indicated by signs such as labels, warnings and alert signals;
 - Check whether the radiation source is leak-tight and free of contamination (ISO 9978:2020);
 - For X ray nuclear gauge equipment, check whether the control panel is appropriately labelled and whether the following items are functioning properly: lock to prevent unauthorized use, signals to show the status of the equipment, automatic exposure blocking mechanism (for fixed or stationary equipment) and emergency shutdown button.
- (ii) Mobile nuclear gauge operation:
 Check that local rules and procedures include the transport and use of radioactive source storage and on-site radioactive source storage; acquisition of radiation survey meters, dosimeters, emergency kit, alarms, labels, marks and notices before going on-site; acquisition of sources from the storage; transport of sources; site management (including cooperation with the client); preparation of site irradiation (including selection of barriers, marking and posting, ensuring that at least two workers are involved); control of the controlled area and management of the supervised area (managing exposure of workers and members of the public); and control of the position of a source, informing workers not occupationally exposed. Check that for each procedure an adequate number of workers is involved. Check that local rules and procedures include security. Check that the local rules are implemented.

V-7. PROTECTION OF THE PUBLIC

TABLE V-7. INSPECTION GUIDANCE — PROTECTION OF THE PUBLIC FOR ALL PRACTICES

- (1) Confirm that assessment, control and surveillance of external and internal exposure of public are in place, i.e. use of dose constraints for the members of the public.
- (2) Check the assumptions used to assess the exposure of the public.
- (3) Check the training of personnel having functions relevant to the protection and safety of members of the public.
- (4) Verify that a monitoring programme and management of records are in place.

- (5) Check the use of signs, labels, marks and notices addressing members of the public. Check that they are in a language understood by members of the public.
 - (6) Check that the procedure for the protection of visitors is applied.
-

V-8. PROTECTION OF PATIENTS

TABLE V-8.1. PROTECTION OF PATIENTS IN RADIOTHERAPY

- (1) Responsibilities. Check that responsibilities are still as defined in the application.
- (2) Justification.
 - (a) Check that prescriptions exist and that they are given by authorized persons as described in the application.
 - (b) Check that procedures for verifying that the patient is not pregnant or, in case of radionuclide therapy, breastfeeding are in line with the licence. Check whether a pregnant patient has had radiotherapy and whether the procedure to justify treatment of a pregnant patient was followed and special attention was given to the protection of the foetus.
- (3) Optimization.
 - (a) Procedures for most common treatments. Check that the most common treatment procedures are as described in the application and that optimization has been ensured in practice.
 - (b) Patient records (information of the treatment). Check that recording of patient data is according to the licence.
 - (c) Follow-up of treatments. Check that radiological review of treatments is performed as described in the application.
- (4) Quality assurance.
 - (a) Technical quality control:
 - (i) Check that acceptance testing and commissioning of the equipment prior to its clinical use on patients has been carried out as described in the application;
 - (ii) Check that the quality control programme is in line with the licence and has been implemented;
 - (iii) Check that an independent dosimetry audit has been performed prior to clinical use;
 - (iv) Check that maintenance is in line with the licence.

- (b) Other quality assurance — treatment procedures:
 - (i) Check that identification of the patients is in line with the licence;
 - (ii) Check that the qualifications and training of planners are in line with the licence, and instructions for the planning of most common treatments exist;
 - (iii) Check that responsibilities for dose planning, verification and approval are in line with the licence, and the procedure for approval has been implemented;
 - (iv) Check that the procedure for verification of the appropriate physical and clinical factors used in treatment procedures has been implemented;
 - (v) Check that records of relevant procedures and results have been maintained;
 - (vi) Check that the results of the investigation of an unintended exposure have been used to improve safety and patient protection;
 - (vii) Check that regular and independent audits have been performed for the quality assurance programme for radiotherapy;
 - (viii) Check that dose constraints for the optimization of protection for careers and comforters have been used.
-

TABLE V-8.2. INSPECTION GUIDANCE — PROTECTION OF PATIENTS IN NUCLEAR MEDICINE

- (1) Responsibilities. Check that responsibilities are still as defined in the application.
- (2) Justification.
 - (a) Check that prescriptions exist and that they are given by authorized persons as described in the application.
 - (b) Check that procedures to verify that a patient is not pregnant or breastfeeding are in line with the licence. Check that the procedure to justify medical exposure for a pregnant or breastfeeding patient has been implemented. Check that procedures to inform the patient on precautions to protect an infant after radionuclide therapy have been implemented.
- (3) Optimization.
 - (a) Procedures for most common imaging procedures and treatments: Check that the most common procedures are as described in the application and that optimization has been ensured in practice.

- (b) Patient records (information of the treatment). Check that recording of patient data is according to the licence.
 - (c) Follow-up of the imaging procedures and treatments. Check that a radiological review of imaging procedures and treatments is performed as described in the application.
- (4) Quality assurance.
- (a) Technical quality control:
 - (i) Check that acceptance testing and commissioning of the equipment prior to its clinical use on patients has been carried out as described in the application;
 - (ii) Check that the quality control programme is in line with the licence and has been implemented;
 - (iii) Check that maintenance is in line with the licence.
 - (b) Other quality assurance — imaging procedures:
 - (i) Check that identification of the patients is in line with the licence;
 - (ii) Check that the qualifications and training of planners are in line with the licence, and instructions for the planning of most common treatments exist;
 - (iii) Check that responsibilities for dose planning, verification and approval are in line with the licence, and the procedure for approval has been implemented;
 - (iv) Check that records of relevant procedures and results have been maintained;
 - (v) Check that the results of the investigation of an unintended exposure have been used to improve safety and patient protection;
 - (vi) Check that regular and independent audits have been performed for the quality assurance programme for nuclear medicine;
 - (vii) Check that dose constraints for the optimization of protection for carers and comforters have been used.
-

TABLE V-8.3. INSPECTION GUIDANCE — PROTECTION OF PATIENTS IN X RAY IMAGING IN RADIOLOGY

- (1) Responsibilities. Check that responsibilities are still as defined in the application.
- (2) Justification.
 - (a) Check that prescriptions exist and that they are given by authorized persons as described in the application.

- (b) Check that procedures to verify that the patient is not pregnant are in line with the licence. Check that the procedure to justify medical exposure for a pregnant patient has been implemented.
 - (3) Optimization.
 - (a) Procedures for most common imaging procedures: Check that the most common procedures are as described in the application and that optimization has been ensured in practice.
 - (b) Patient records (information of the medical exposure): Check that recording of patient data is according to the licence.
 - (c) Follow-up of the imaging procedures: Check that radiological review of imaging procedures is performed as described in the application.
 - (4) Quality assurance.
 - (a) Technical quality control:
 - (i) Check that acceptance testing and commissioning of the equipment prior to its clinical use on patients has been carried out as described in the application;
 - (ii) Check that the quality control programme is in line with the licence and has been implemented;
 - (iii) Check that maintenance is in line with the licence.
 - (b) Other quality assurance — X ray imaging procedures:
 - (i) Check that identification of the patients is in line with the licence;
 - (ii) Check that records of relevant procedures and results have been maintained;
 - (iii) Check that the results of investigations of unintended exposures have been used to improve safety and patient protection;
 - (iv) Check that regular and independent audits have been performed for the quality assurance programme for X ray imaging;
 - (v) Check that dose constraints for optimization of protection for carers and comforters have been used.
-

V-9. SECURITY OF SOURCES

TABLE V-9.1. INSPECTION GUIDANCE — DETECTION, DELAY AND RESPONSE MEASURES FOR SECURITY LEVEL A

Security function	Security measure	Yes	No	Corresponding security subgoal and evaluation criteria	Basis				Comments
					Records	Interview	Observation	Testing	
Detection	Electronic intrusion detection system and/or continuous surveillance by operator personnel			<ul style="list-style-type: none"> — Immediate detection of unauthorized access to locations in which radioactive material is present? — Immediate detection of attempted unauthorized removal of radioactive material, including removal by an insider? — For electronic detection system: <ul style="list-style-type: none"> • Appropriate choice of technology? • Properly configured? • In working order? • Properly maintained? • User competence? • Integration and compatibility with the overall security system? 					

TABLE V-9.1. INSPECTION GUIDANCE — DETECTION, DELAY AND RESPONSE MEASURES FOR SECURITY LEVEL A (cont.)

Security function	Security measure	Yes	No	Corresponding security subgoal and evaluation criteria	Basis				Comments
					Records	Interview	Observation	Testing	
Detection	Electronic intrusion detection system and/or continuous surveillance by operator personnel			— For continuous surveillance by operator personnel: <ul style="list-style-type: none"> • Procedures and training in place? — Operator personnel understand and follow procedures?					
Detection	Remote video monitoring or direct observation by operator or response personnel			— Immediate assessment of detection? — For remote video monitoring: <ul style="list-style-type: none"> • Appropriate choice of technology? • Properly configured? • In working order? • Properly maintained? • User competence? • Integration and compatibility with the overall security system? 					

TABLE V-9.1. INSPECTION GUIDANCE — DETECTION, DELAY AND RESPONSE MEASURES FOR SECURITY LEVEL A (cont.)

Security function	Security measure	Yes	No	Corresponding security subgoal and evaluation criteria	Basis				Comments
					Records	Interview	Observation	Testing	
Detection	Remote video monitoring or direct observation by operator or response personnel			— For direct observation by operator or response personnel: <ul style="list-style-type: none"> • Procedures and training in place? • Operator personnel understand and follow procedures? 					
Detection	Daily verification through physical checks, video monitoring, tamper indicating devices, etc.			— Detection of loss through verification? <ul style="list-style-type: none"> • Appropriate choice of detection means? • Documentation of verification? 					

TABLE V-9.1. INSPECTION GUIDANCE — DETECTION, DELAY AND RESPONSE MEASURES FOR SECURITY LEVEL A (cont.)

Security function	Security measure	Yes	No	Corresponding security subgoal and evaluation criteria	Basis				Comments
					Records	Interview	Observation	Testing	
Delay	System of at least two layers of barriers (e.g. walls, cages)			<p>— Sufficient delay measures to provide a high level of protection against unauthorized removal of radioactive material?</p> <ul style="list-style-type: none"> • Appropriate choice of barriers? • Balanced protection? • Integration with the overall security system? 					
Response	Rapid, dependable, diverse means of communication such as telephone and/or radio			<p>— Immediate communication to response personnel?</p> <ul style="list-style-type: none"> • Appropriate choice of technologies? • At least two means of communication? • Properly configured? • In working order? • Properly maintained? • User competence? • Integration and compatibility with the overall security system? 					

TABLE V-9.1. INSPECTION GUIDANCE — DETECTION, DELAY AND RESPONSE MEASURES FOR SECURITY LEVEL A (cont.)

Security function	Security measure	Yes	No	Corresponding security subgoal and evaluation criteria	Basis				Comments
					Records	Interview	Observation	Testing	
Response	Arrangements with a designated response force, including provision for sufficient personnel, equipment and training, documented in a response plan			<p>— Immediate response with sufficient resources to interrupt and defeat the adversary?</p> <ul style="list-style-type: none"> • Procedures and training in place? • Operator and designated response force understand and follow the response plan? 					

TABLE V-9.2. INSPECTION GUIDANCE — DETECTION, DELAY AND RESPONSE MEASURES FOR SECURITY LEVEL B

Security function	Security measure	Yes	No	Corresponding security subgoal and evaluation criteria	Basis				Comments
					Records	Interview	Observation	Testing	
Detection	Electronic intrusion detection equipment and/or continuous surveillance by operator personnel			<p>Corresponding security subgoal and evaluation criteria</p> <ul style="list-style-type: none"> — Immediate detection of any unauthorized access to locations where radioactive material is present? — For electronic intrusion detection equipment: <ul style="list-style-type: none"> • Appropriate choice of technology? • Properly configured? • In working order? • Properly maintained? • User competence? • Integration and compatibility with the overall security system? — For continuous surveillance by operator personnel: <ul style="list-style-type: none"> • Procedures and training in place? • Operator personnel understand and follow procedures? 					

TABLE V-9.2. INSPECTION GUIDANCE — DETECTION, DELAY AND RESPONSE MEASURES FOR SECURITY LEVEL B (cont.)

Security function	Security measure	Yes	No	Corresponding security subgoal and evaluation criteria	Basis				Comments
					Records	Interview	Observation	Testing	
Detection	Tamper detection equipment and/or periodic checks by operator personnel			<p>— Detection of any attempted unauthorized removal of radioactive material?</p> <p>— For tamper detection equipment:</p> <ul style="list-style-type: none"> • Appropriate choice of technology? • Properly configured? • In working order? • Properly maintained? • User competence? • Integration and compatibility with the overall security system? <p>— For periodic checks by operator personnel:</p> <ul style="list-style-type: none"> • Procedures and training in place? • Operator personnel understand and follow procedures? 					

TABLE V-9.2. INSPECTION GUIDANCE — DETECTION, DELAY AND RESPONSE MEASURES FOR SECURITY LEVEL B (cont.)

Security function	Security measure	Yes	No	Corresponding security subgoal and evaluation criteria	Basis				Comments
					Records	Interview	Observation	Testing	
Detection	Remote video monitoring and/or direct observation by operator or response personnel			<p>— Immediate assessment of detection?</p> <p>— For remote video monitoring:</p> <ul style="list-style-type: none"> • Appropriate choice of technology? • Properly configured? • In working order? • Properly maintained? • User competence? • Integration and compatibility with the overall security system? <p>— For assessment by operator personnel:</p> <ul style="list-style-type: none"> • Procedures and training in place? • Operator personnel understand and follow procedures? 					

TABLE V-9.2. INSPECTION GUIDANCE — DETECTION, DELAY AND RESPONSE MEASURES FOR SECURITY LEVEL B (cont.)

Security function	Security measure	Yes	No	Corresponding security subgoal and evaluation criteria	Basis				Comments
					Records	Interview	Observation	Testing	
Detection	Weekly verification through measures such as physical checks and tamper detection equipment			— Detection of loss through verification? • Appropriate choice of detection means? • Documentation of verification?					
Delay	System of two layers of barriers (e.g. walls, cages)			— Sufficient delay to provide an intermediate level of protection against unauthorized removal of radioactive material? • Appropriate choice of barriers? • Balanced protection? • Integration with the overall security system?					

TABLE V-9.2. INSPECTION GUIDANCE — DETECTION, DELAY AND RESPONSE MEASURES FOR SECURITY LEVEL B (cont.)

Security function	Security measure	Yes	No	Corresponding security subgoal and evaluation criteria	Basis				Comments
					Records	Interview	Observation	Testing	
Response	Rapid, dependable means of communication such as telephone and/or radio			<p>— Immediate communication to response personnel?</p> <ul style="list-style-type: none"> • Appropriate choice of technology? • Properly configured? • In working order? • Properly maintained? • User competence? • Integration and compatibility with the overall security system? 					
Response	Equipment and procedures to initiate immediate response			<p>— Immediate initiation of response to interrupt unauthorized removal?</p> <ul style="list-style-type: none"> • Arrangements with response personnel in place? • Procedures and training in place? • Operator and response personnel understand and follow procedures? 					

TABLE V-9.3. INSPECTION GUIDANCE — DETECTION, DELAY AND RESPONSE MEASURES FOR SECURITY LEVEL B (PORTABLE DEVICES WHEN USED IN THE FIELD)

Security function	Security measure	Yes	No	Corresponding security subgoal and evaluation criteria	Basis				Comments
					Records	Interview	Observation	Testing	
Detection	Visual observation by two operator personnel			<p>— Immediate detection of any unauthorized access to locations where radioactive material is present?</p> <p>— Detection of any attempted unauthorized removal of radioactive material?</p> <ul style="list-style-type: none"> • Procedures and training in place? • Operator personnel understand and follow procedures? 					
Detection	Observation by operator personnel			<p>— Immediate assessment of detection?</p> <ul style="list-style-type: none"> • Procedures and training in place? • Operator personnel understand and follow procedures? 					
Detection	Daily checks after field use			<p>— Detection of loss through verification?</p> <ul style="list-style-type: none"> • Appropriate choice of detection means? • Documentation of checks? 					

TABLE V-9.3. INSPECTION GUIDANCE — DETECTION, DELAY AND RESPONSE MEASURES FOR SECURITY LEVEL B (PORTABLE DEVICES WHEN USED IN THE FIELD) (cont.)

Security function	Security measure	Yes	No	Corresponding security subgoal and evaluation criteria	Basis				Comments
					Records	Interview	Observation	Testing	
Delay	Means of affixing the device to a stationary object, if possible			— Sufficient delay to provide an intermediate level of protection against unauthorized removal of radioactive material? <ul style="list-style-type: none"> • Appropriate choice of means? • Balanced protection? 					
Response	Two persons, each equipped with an independent mobile communication device			— Immediate communication to response personnel? <ul style="list-style-type: none"> • Appropriate choice of technology? • Properly configured? • In working order? • Properly maintained? • User competence? • Integration and compatibility with the overall security system? 					

TABLE V-9.3. INSPECTION GUIDANCE — DETECTION, DELAY AND RESPONSE MEASURES FOR SECURITY LEVEL B (PORTABLE DEVICES WHEN USED IN THE FIELD) (cont.)

Security function	Security measure	Yes	No	Corresponding security subgoal and evaluation criteria	Basis				Comments
					Records	Interview	Observation	Testing	
Response	Advance notification to local response force before deployment, and immediate communication after detection			<p>— Immediate initiation of response to interrupt unauthorized removal?</p> <ul style="list-style-type: none"> • Arrangements with response force in place? • Procedures and training in place? • Operator and response force understand and follow procedures? 					

TABLE V-9.4. INSPECTION GUIDANCE — DETECTION, DELAY AND RESPONSE MEASURES FOR SECURITY LEVEL C

Security function	Security measure	Yes	No	Corresponding security subgoal and evaluation criteria	Basis				Comments
					Records	Interview	Observation	Testing	
Detection	Observation by operator personnel			— Detection of unauthorized removal of radioactive material? <ul style="list-style-type: none"> • Procedures and training in place? • Operator personnel understand and follow procedures? 					
Detection	Monthly verification through physical checks, tamper detection equipment			— Detection of loss through verification? <ul style="list-style-type: none"> — For physical checks: <ul style="list-style-type: none"> • Appropriate choice of means? • Documentation of checks? — For tamper detection equipment: <ul style="list-style-type: none"> • Appropriate choice of technology? • Properly configured? • In working order? • Properly maintained? • User competence? • Integration and compatibility with the overall security system? 					

TABLE V-9.4. INSPECTION GUIDANCE — DETECTION, DELAY AND RESPONSE MEASURES FOR SECURITY LEVEL C (cont.)

Security function	Security measure	Yes	No	Corresponding security subgoal and evaluation criteria	Basis				Comments
					Records	Interview	Observation	Testing	
Delay	One barrier (e.g. cage, source housing) or presence of operator personnel			<p>— Sufficient delay to provide a baseline level of protection against unauthorized removal of radioactive material?</p> <p>— For barriers:</p> <ul style="list-style-type: none"> • Appropriate choice of barrier? • Balanced protection? <p>— For operator personnel:</p> <ul style="list-style-type: none"> • Procedures and training in place? • Operator personnel understand and follow procedures? 					

TABLE V-9.4. INSPECTION GUIDANCE — DETECTION, DELAY AND RESPONSE MEASURES FOR SECURITY LEVEL C (cont.)

Security function	Security measure	Yes	No	Corresponding security subgoal and evaluation criteria	Basis				Comments
					Records	Interview	Observation	Testing	
Response	Rapid, dependable means of communication such as telephone and/or radio			<p>— Prompt communication to response personnel?</p> <ul style="list-style-type: none"> • Appropriate choice of technology? • Properly configured? • In working order? • Properly maintained? • User competence? • Integration and compatibility with the overall security system? 					
Response	Procedures for identifying necessary actions in accordance with response plan			<p>— Appropriate action in the event of unauthorized removal of radioactive material?</p> <ul style="list-style-type: none"> • Procedures and training in place? • Operator understands and follows procedures in accordance with response plan? 					

TABLE V-9.5. INSPECTION GUIDANCE — SECURITY MANAGEMENT MEASURES

Security measure	Yes	No	Corresponding security subgoal and evaluation criteria	Basis				Comments
				Records	Interview	Observation	Testing	
Procedures for determining the individuals who need access, verifying that such individuals are trustworthy and reliable and have received necessary training, authorizing access, withdrawing access as appropriate and maintaining documentation			<p>— Established process for granting individuals authorized unescorted access to radioactive material and/or access to sensitive information?</p> <ul style="list-style-type: none"> • Identification of staff requiring unescorted access? • Verification that the individuals requiring unescorted access are reliable, trained and trustworthy? • Withdrawal of access authorization of individuals who no longer require access? • Records of personnel authorized for unescorted access? 					

TABLE V-9.5. INSPECTION GUIDANCE — SECURITY MANAGEMENT MEASURES (cont.)

Security measure	Yes	No	Corresponding security subgoal and evaluation criteria	Basis				Comments
				Records	Interview	Observation	Testing	
Background checks for all personnel authorized for unescorted access to radioactive material and/or to sensitive information			<p>— Checks ensure trustworthiness and reliability of authorized individuals?</p> <ul style="list-style-type: none"> • Defined process to assess trustworthiness? • Process applied in a consistent manner to all relevant staff? • Periodic re-evaluation? • Appropriate record keeping? 					

TABLE V-9.5. INSPECTION GUIDANCE — SECURITY MANAGEMENT MEASURES (cont.)

Security measure	Yes	No	Corresponding security subgoal and evaluation criteria	Basis				Comments
				Records	Interview	Observation	Testing	
Identification and verification measures			<p>— Access controls that effectively restrict unescorted access to radioactive material to authorized persons only?</p> <ul style="list-style-type: none"> • Physical measures for controlling access to limit access only to authorized persons? • Appropriate media used, such as key card, personal identification number, biometric device or a combination? • Procedures and training in place? • Procedures in place for escorting others? • Operator personnel understand and follow procedures? • Appropriate record keeping? 					

TABLE V-9.5. INSPECTION GUIDANCE — SECURITY MANAGEMENT MEASURES (cont.)

Security measure	Yes	No	Corresponding security subgoal and evaluation criteria	Basis				Comments
				Records	Interview	Observation	Testing	
Procedures to identify sensitive information and protect it from unauthorized disclosure			<p>— Identification and protection of sensitive information:</p> <ul style="list-style-type: none"> • Managed approach to protect sensitive information in accordance with national policies? • Identification of the types of information that need to be protected? • Specification of how the information needs to be protected in use, storage and transmission? • Methods for destruction of documents and other media? • Periodic re-evaluation? • Operator personnel understand and follow procedures? 					

TABLE V-9.5. INSPECTION GUIDANCE — SECURITY MANAGEMENT MEASURES (cont.)

Security measure	Yes	No	Corresponding security subgoal and evaluation criteria	Basis				Comments
				Records	Interview	Observation	Testing	
A security plan that addresses the required topics is submitted or made available to the regulatory body and is periodically exercised, evaluated and revised as appropriate			<p>— Security plan:</p> <ul style="list-style-type: none"> • Correspondence of plan and implementation? • Appropriately protected? • Periodically exercised? • Evaluated and revised as appropriate? 					
Assessment of necessary knowledge, skills and attitudes; provision of corresponding training; procedures for documenting and updating training			<p>— Training and qualifications of individuals with security responsibilities:</p> <ul style="list-style-type: none"> • Training and qualification requirements, including refresher training established for each position with security responsibilities? • Awareness training of all staff? • Training and qualifications of externally provided security staff? • Appropriate record keeping? 					

TABLE V-9.5. INSPECTION GUIDANCE — SECURITY MANAGEMENT MEASURES (cont.)

Security measure	Yes	No	Corresponding security subgoal and evaluation criteria	Basis				Comments
				Records	Interview	Observation	Testing	
Procedures and documentation for verifying the presence of radioactive material at prescribed intervals; establishment and maintenance of a radioactive material inventory			<p>— Accounting and inventory of radioactive material:</p> <ul style="list-style-type: none"> • Procedures in place? • Operator personnel understand and follow procedures? • Appropriate record keeping? 					
Process for verifying that all applicable security requirements are met and for assessing the effectiveness of the security system, using performance tests as appropriate			<p>— Evaluation of compliance and effectiveness, including performance testing:</p> <ul style="list-style-type: none"> • Procedures in place? • Evaluations periodically conducted in accordance with procedures, including evaluation frequency? • Identified deficiencies tracked and corrected? • Appropriate record keeping? 					

TABLE V-9.5. INSPECTION GUIDANCE — SECURITY MANAGEMENT MEASURES (cont.)

Security measure	Yes	No	Corresponding security subgoal and evaluation criteria	Basis				Comments
				Records	Interview	Observation	Testing	
Response plan addressing security related scenarios and procedures for timely reporting of security events			<p>— Capability to manage and report security events?</p> <ul style="list-style-type: none"> • Response arrangements for all types of security event, including references to emergency plans and emergency response actions? • Implementation of defined roles and responsibilities of on-site security or facility personnel and external response forces (if required) during security events? • Independent communication methods used by response forces? • Procedures for investigating, reporting and follow-up of security events? 					

Annex VI

EXAMPLE OF A CODE OF CONDUCT FOR INSPECTORS

- Before an inspection is carried out, inspectors need to be thoroughly prepared for the task. The competence and preparation of staff is a key element in achieving effective inspections results.
- The type of preparation depends on the type (planned or reactive, announced or unannounced, individual or team) and method of inspection.
- Inspectors will have no direct or indirect interest in facilities and activities being inspected, beyond the interest necessary for regulatory purposes.
- Inspectors will ensure that regulatory inspections cover all areas of responsibility of the regulatory body and that the manner, extent and frequency of inspections are in accordance with a graded approach.
- Where an inspection involves two or more officers, the supervisor will determine which officer will take the lead role in discussions and interviews.
- Inspectors will refrain from any public display of disagreement with each other.
- Inspectors will identify themselves by showing their identification card or other appropriate credential.
- Inspectors will present a professional appearance and demeanour.
- Inspectors will adopt a firm but courteous attitude at all times.
- Where practicable, inspectors may discuss issues as they arise.
- Inspectors will avoid open criticism of individuals.
- Inspectors will remain focused on performing their functions in relation to safety and security, irrespective of any personal views.
- Inspectors need to operate professionally and within their remit in relation to safety and security.
- Inspectors will ensure that regulatory inspections do not diminish the prime responsibility for safety and security of the authorized party, for example by exercising control, supervision or verification activities that are the responsibility of the authorized party.
- Inspection staff do not need to act as consultants on means of achieving regulatory requirements. However, in countries where there is limited radiation protection or security expertise, inspectors may appropriately provide advice on practical implementation, particularly if written guidance has not yet been developed by the regulatory body. However, they need to stress that the authorized party retains the responsibility for safety and security.

- Inspectors may, as appropriate, communicate directly with the authorized party's personnel responsible for supervising and performing the activities being inspected. This is especially important in follow-up investigations in which inspectors are involved in reconstructing events and assessing the authorized party's response.
- Inspectors will conduct inspections only in accordance with an approved inspection programme, plan, guidelines, procedures and checklists. They will also ensure that the techniques utilized for the inspections are commensurate with the inspection requirements and the activity or area being inspected. Certain activities may require inspectors to avoid immediate discussions with the personnel performing the activity, and some inspections may not provide the opportunity for direct observations.
- Inspectors will seek feedback from the authorized party about the conduct of inspection.

Annex VII

EXAMPLE OF A MEMORANDUM OF UNDERSTANDING BETWEEN THE REGULATORY BODY AND THE DEPARTMENT OF CUSTOMS

(1) Rationale

Several incidents have taken place around the world that highlight the potential for significant health and safety concerns when high activity radioactive materials are improperly transported, stored, handled or used. A number of radiation workers and the public have suffered severe radiation injuries as a result of some of these incidents. Deaths have also been reported. Persons who received a radiation dose but who have survived the more serious short term effects of radiation exposure also have a significantly increased risk of developing cancer in later life.

To minimize the risk of such incidents, it is essential to have rigorous import controls in place to ensure that radiation sources entering the country are released only to authorized persons and only for authorized purposes. Portal radiation detectors may also be desirable to detect attempts by persons to smuggle radioactive substances into the country

(2) Purpose

The purpose of this memorandum of understanding is to state the roles and responsibilities of the regulatory body and the department of customs in relation to the import and export of radiation sources and to establish clear working guidelines on the actions to be taken by the respective parties.

(3) Scope

For the purpose of this memorandum of understanding, 'radiation sources' means:

(a) All radioactive substances; and

- (b) All devices that are capable of producing ionizing radiation when electrically energized¹, other than those exempted² by the regulatory body under the radiation control legislation.

Note: Some products, such as consumer devices, individually may contain exempt quantities of a radioactive substance. However, importation in bulk (e.g. by a wholesaler) may nevertheless require authorization from the regulatory body. The regulatory body undertakes to inform the department of customs of any such restrictions.

The Harmonized System³ for radiation sources is given in Supplement A.

The regulatory body administers the radiation control legislation and the related regulations, which create an offence for a person to possess, use, manufacture, store, transport, dispose of, or otherwise deal with non-exempt radiation sources unless they do so under an authorization issued by the regulatory body.

The department of customs administers the customs legislation³ and related regulations and is responsible for controlling the country's imports and exports in accordance with this legislation.

- (4) Governmental agencies not exempt from compliance

It is noted that all governmental agencies are bound by the radiation control legislation and subject to the prescribed penalties for non-compliance.

- (5) General agreement

- (a) The department of customs agrees that it shall not permit the importation of any radiation source unless the person to whom the radiation source is consigned can produce an Authority to Import⁴ certificate issued by the regulatory body. In the event that the authorization cannot be produced,

¹ For example, X ray equipment, linear and particle accelerators.

² The regulations in the radiation control legislation state the exempt activity of specific radioactive substances, whether as discrete sources or in bulk, and identify exempt electrical devices.

³ The Harmonized Commodity Description and Coding System, or Harmonized System of tariff nomenclature, is an internationally standardized system of names and numbers to classify traded products, developed and maintained by the World Customs Organization. See <http://www.wcoomd.org/en/topics/nomenclature/instrument-and-tools/hs-nomenclature-2022-edition/hs-nomenclature-2022-edition.aspx>

⁴ The purpose of this certificate is to signify the regulatory body's approval that importation may proceed, subject to any other requirements that may be imposed by the department of customs.

the department of customs agrees that it will hold the shipment in an area approved by the regulatory body and immediately notify the regulatory body of the details of the shipment.

- (b) The department of customs agrees that it shall not permit the export of any radioactive substance unless the consignor can produce an Authority to Export⁵ certificate issued by the regulatory body.

It is further agreed that where a situation arises that is not dealt with by this agreement, no action will be taken by either party without first consulting with the other.

(6) Informing the regulatory body

Notwithstanding point (5), the department of customs agrees to promptly notify the regulatory body of the details of all imported radiation sources, including the name and contact details of the importer and the date of importation. The agreed form for this purpose is given in Supplement B.

(7) Informing the department of customs

The regulatory body agrees to promptly notify the department of customs of any changes to the legislation, or of any other decision taken by the regulatory body, that has a bearing on the importation, storage or transport of radiation sources.

The regulatory body will also provide on at least a quarterly basis a list of those operators with routine authority to import radiation sources.

(8) Training of department of customs personnel

The regulatory body agrees that it will provide radiation safety training to all department of customs officers designated by the department of customs and will provide additional support as may be necessary from time to time. However, the department of customs may obtain the services of an approved⁶ qualified expert for these purposes if it so wishes.

⁵ The purpose of this certificate is to signify the regulatory body's approval that a radioactive substance may be exported, subject to any other requirements that may be imposed by the department of customs. It does not signify that the substance has been packaged in accordance with the transport regulations. That is the responsibility of the consignor.

⁶ Approved by the regulatory body.

(9) Opening packages or containers

To ensure the health and safety of its workers, the department of customs agrees that its officers will not open any package or container bearing the internationally recognized radiation warning symbol, or any package or container that its officers have reason to believe may contain a radioactive source, unless an officer of the regulatory body (or an approved⁶ qualified expert) is present to direct and supervise radiation safety procedures.

(10) Portal radiation detection equipment

The regulatory body and the department of customs agree that they will discuss with their respective ministers the need for the installation and operation of portal radiation detection equipment at designated⁷ points of entry into the country.

(11) Contact persons

Until otherwise notified in writing, the contact person for the regulatory body is: [name, title, position held and contact telephone number] and for the department of customs is: [name, title, position held and contact telephone number].

This memorandum of understanding takes effect from the date it is signed by both parties.

DIRECTOR

CHIEF CUSTOMS OFFICER

REGULATORY BODY

DEPARTMENT OF CUSTOMS

Date _____

Date _____

⁷ Designated by the Government.

Supplement A

REFERENCE

NUMBER GOODS

28.44	Radioactive chemical elements and radioactive isotopes (including the fissile or fertile chemical elements and isotopes)^a and their compounds; mixtures and residues containing these products
2844.10	Natural uranium and its compounds; alloys, dispersions (including cermet), ceramic products and mixtures containing natural uranium or natural uranium compounds
2844.20	Uranium enriched in ²³⁵ U and its compounds; plutonium and its compounds; alloys, dispersions (including cermet), ceramic products and mixtures containing uranium enriched in ²³⁵ U, plutonium or compounds of these products
2844.30	Uranium depleted in ²³⁵ U and its compounds; thorium and its compounds; alloys, dispersions (including cermet), ceramic products and mixtures containing uranium depleted in ²³⁵ U, thorium or compounds of these products
2844.40	Radioactive elements and isotopes and compounds other than those of 2844.10, 2844.20 or 2844.30; alloys, dispersions (including cermet), ceramic products and mixtures containing these elements, isotopes or compounds; radioactive residues
2844.50	Spent (irradiated) fuel elements (cartridges) of nuclear reactors
2845	Isotopes other than those of 2844; compounds, inorganic or organic, of such isotopes, whether or not chemically defined

^a Heading 2844 applies only to:

- (1) Technetium (atomic number 43), promethium (atomic number 61), polonium (atomic number 84) and all elements with an atomic number greater than 84;
- (2) Natural or artificial radioactive isotopes, whether or not mixed together;
- (3) Compounds, inorganic or organic, of these elements or isotopes, whether or not

- chemically defined, whether or not mixed together;
- (4) Alloys, dispersions (including cermets), ceramic compounds and mixtures containing these elements or isotopes, or inorganic or organic compounds thereof, and having a specific radioactivity exceeding 74 Bq/g;
 - (5) Spent (irradiated) fuel elements (cartridges) of nuclear reactors;
 - (6) Radioactive residues, whether or not usable.

The term 'isotopes' in this note and for headings 2844 and 2845 refers to individual radionuclides, excluding those existing in nature in the monoisotopic state, or mixtures of isotopes of one and the same element, enriched in one or several of the said isotopes, that is, elements of which the natural isotopic composition has been artificially modified.

REFERENCE

NUMBER GOODS

90.22	Apparatus based on the use of X rays or of alpha, beta or gamma radiations, whether or not for medical, surgical, dental or veterinary uses, including radiography or radiotherapy apparatus, X ray tubes and other X ray generators, high tension generators, control panels and desks, screens, examination or treatment tables and chairs
9022.1	Apparatus based on the use of X rays, whether or not for medical, surgical or veterinary uses, including radiography or radiotherapy apparatus
9022.12	Computed tomography apparatus
9022.13	Other, for dental uses
9022.14	Other, for medical, surgical or veterinary uses
9022.19	For other uses
9022.2	Apparatus based on the use of alpha, beta or gamma radiations, whether or not for medical, surgical, dental or veterinary uses, including radiography or radiotherapy apparatus
9022.21	For medical, surgical, dental or veterinary uses
9022.29	For other uses

9022.30	X ray tubes
9022.90	Other, including parts and accessories

REFERENCE

NUMBER GOODS

84.01 Nuclear reactors; fuel elements (cartridges), non-irradiated for nuclear reactors, machinery and apparatus for isotopic separation

8401.10 Nuclear reactors

8401.20 Machinery and apparatus for isotopic separation, and parts thereof

8401.30 Fuel elements (cartridges), non-irradiated

8401.40 Parts of nuclear reactors

REFERENCE

NUMBER GOODS

85.43 Electrical machines and apparatus having individual functions not specified or included elsewhere in chapter 85 of the World Customs Organization Harmonized System

8543.10 Particle accelerators

8543.11 Ion implanters for doping semiconductor materials

8543.19 Other

Note: The codes and goods descriptions shown in Supplement A need to be confirmed with the country's customs department or agency.

Supplement B

IMPORTATION OF NON-EXEMPT RADIATION SOURCES

NOTIFICATION TO THE REGULATORY BODY

To be completed by the consignee or their authorized agent.

Original has to be retained by the customs department. copy to the consignee.

PORT OF ENTRY	
DATE OF ENTRY	
IDENTIFICATION NUMBER (i.e. customs department identification)	
IMPORT AUTHORITY CERTIFICATE NUMBER (i.e. issued by the regulatory body)	
IMPORTING AGENT	
ADDRESS	
TELEPHONE NUMBER	
CONSIGNEE'S NAME	
ADDRESS	
TELEPHONE NUMBER	
FAX NUMBER	
RADIATION SOURCE TYPE	Radioactive Other

RADIOACTIVE SUBSTANCES	
RADIONUCLIDE (e.g. ⁶⁰ Co, ¹⁹² Ir, ²³⁵ U)	
ACTIVITY (Bq and its decimal multiples, e.g. MBq, GBq, TBq)	
PHYSICAL FORM	
INTENDED USE	

OTHER RADIATION SOURCES	
MANUFACTURER	
MODEL	
SERIAL NUMBER	
INTENDED USE	

CONSIGNEE'S SIGNATURE (i.e. or that of the authorized agent)	
PRINT NAME	
DATE	

For additional information, contact the regulatory body on [telephone number].

CUSTOMS DEPARTMENT: Immediately fax a copy of this form to the regulatory body on [fax number].

CONTRIBUTORS TO DRAFTING AND REVIEW

Assi, M.	Lebanese Atomic Energy Commission (LAEC), Lebanon
Attan, H.B.	Atomic Energy Licensing Board (AELB), Malaysia
Betancourt, A.	International Atomic Energy Agency
Betancourt Hernandez, L.	International Atomic Energy Agency
Bly, R.	Radiation and Nuclear Safety Authority (STUK), Finland
Bokov, D.	Federal Environmental, Industrial and Nuclear Supervision Service (Rostekhnadzor), Russian Federation
Bosnjak, J.	International Atomic Energy Agency
Da Silva, A.D.	National Nuclear Energy Commission (CNEN), Brazil
Englefield, C.	Environment Agency, United Kingdom
Goldberg, P.	Nuclear Regulatory Commission (NRC), United States of America
Janzekovic, H.	Slovenian Nuclear Safety Administration (SNSA), Slovenia
Morris, F.	Pacific Northwest National Laboratory (PNNL), USA
Pacheco Jimenez, R.	International Atomic Energy Agency
Quevedo, J.	National Center for Nuclear Safety, Cuba
Schlee, R.	International Atomic Energy Agency
Shaffer, M.	Nuclear Regulatory Commission (NRC), United States of America
Warsi, N.I.	Pakistan Nuclear Regulatory Authority (PNRA), Pakistan
Waseem, M.	International Atomic Energy Agency

Zubair, M.

Pakistan Nuclear Regulatory Authority (PNRA),
Pakistan

Consultants Meetings

Vienna, Austria: 7–10 March 2016, 18–22 July 2016, 14–18 August 2017,
25–29 September 2017, 15–19 January 2018, 21–15 January 2019



IAEA

International Atomic Energy Agency

No. 26

ORDERING LOCALLY

IAEA priced publications may be purchased from the sources listed below or from major local booksellers.

Orders for unpriced publications should be made directly to the IAEA. The contact details are given at the end of this list.

NORTH AMERICA

Bernan / Rowman & Littlefield

15250 NBN Way, Blue Ridge Summit, PA 17214, USA

Telephone: +1 800 462 6420 • Fax: +1 800 338 4550

Email: orders@rowman.com • Web site: www.rowman.com/bernan

REST OF WORLD

Please contact your preferred local supplier, or our lead distributor:

Eurospan Group

Gray's Inn House

127 Clerkenwell Road

London EC1R 5DB

United Kingdom

Trade orders and enquiries:

Telephone: +44 (0)176 760 4972 • Fax: +44 (0)176 760 1640

Email: eurospan@turpin-distribution.com

Individual orders:

www.eurospanbookstore.com/iaea

For further information:

Telephone: +44 (0)207 240 0856 • Fax: +44 (0)207 379 0609

Email: info@eurospangroup.com • Web site: www.eurospangroup.com

Orders for both priced and unpriced publications may be addressed directly to:

Marketing and Sales Unit

International Atomic Energy Agency

Vienna International Centre, PO Box 100, 1400 Vienna, Austria

Telephone: +43 1 2600 22529 or 22530 • Fax: +43 1 26007 22529

Email: sales.publications@iaea.org • Web site: www.iaea.org/publications



IAEA

International Atomic Energy Agency

RELATED PUBLICATIONS

**THE NUCLEAR SAFETY AND NUCLEAR SECURITY INTERFACE:
APPROACHES AND NATIONAL EXPERIENCES**

IAEA Technical Reports Series No. 1000

STI/DOC/010/1000 (59 pp.; 2021)

ISBN 978-92-0-121920-6

Price: €30

**MANAGING THE INTERFACE BETWEEN SAFETY AND SECURITY
FOR NORMAL COMMERCIAL SHIPMENTS OF RADIOACTIVE
MATERIAL**

IAEA Technical Reports Series No. 1001

STI/DOC/010/1001 (80 pp.; 2021)

ISBN 978-92-0-106121-8

Price: €46

**ADVISORY MISSION ON REGULATORY INFRASTRUCTURE FOR
RADIATION SAFETY AND NUCLEAR SECURITY**

IAEA Services Series No. 45

IAEA-SVS-45 (54 pp.; 2022)

**CODE OF CONDUCT ON THE SAFETY AND SECURITY OF
RADIOACTIVE SOURCES**

Non-serial Publications

IAEA/CODEOC/2004 (122 pp.; 2004)

This publication has been developed to assist IAEA Member States in establishing and maintaining regulatory control through notification, authorization, inspection and enforcement in relation to facilities and activities with radiation sources, in order to achieve the fundamental safety and security objectives. The publication addresses the implementation of the requirements for safety and security in a harmonized way, taking into account differences in the requirements and the regulatory infrastructures of different States. For example, in some States the same regulatory body is responsible for the control of safety and security, while in others, safety and security are controlled by separate regulatory bodies. A harmonized approach for notification, authorization, inspection and enforcement is intended to improve the efficiency and effectiveness of regulatory control through concurrent inspection for safety and security.