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Application of a Graded Approach in Regulating the Safety of Radiation Sources

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APPLICATION OF A GRADED APPROACH IN REGULATING THE SAFETY OF RADIATION SOURCES

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INTERNATIONAL ATOMIC ENERGY AGENCY
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For further information on this publication, please contact:

Radiation Safety and Monitoring Section
International Atomic Energy Agency
Vienna International Centre
PO Box 100
1400 Vienna, Austria
Email: Official.Mail@iaea.org

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FOREWORD

The IAEA Safety Standards are designed to facilitate the safe use of nuclear technologies, including the use of radiation sources in medicine, industry, agriculture, education and research. The radiation risks to people and the environment that arise from the use of radiation sources need to be assessed and, if necessary, regulated.

To ensure effective regulatory control of a wide range of facilities and activities with radiation sources, it is necessary to apply a graded approach so that regulatory control is commensurate with the associated radiation risk. The higher the risk associated with a facility or activity, the more stringent the regulatory requirements. To ensure the efficient and effective use of its resources, it is essential that the regulatory body apply a graded approach to its regulatory functions, prioritizing its activities so that the resources are allocated in a manner that is commensurate with the radiation risks associated with the facilities and activities.

Some regulatory bodies, especially recently established ones, perform all regulatory functions in a uniform way. This means, for example, that there is one approach to authorization and all applications are processed and reviewed in the same way, or that low risk sources are inspected as frequently as high risk sources. As a result, the regulatory body is overloaded with work and then priority is often given to what is overdue, without considering the radiation risk associated with the facilities and activities.

The graded approach has been increasingly used within IAEA Safety Standards. Several IAEA Safety Standards establish requirements and provide recommendations on the application of a graded approach for different regulatory requirements but do not provide specific practical guidance on the implementation of regulatory functions in accordance with a graded approach.

This publication provides practical information on the application of a graded approach in regulating the safety of radiation sources; examples of this approach in several Member States are also included. The methodologies described promote a systematic and consistent approach to regulation in accordance with IAEA Safety Standards.

The IAEA wishes to express its gratitude to all those who contributed to this publication. The IAEA officers responsible for this publication were J. Bosnjak and V. Kamenopoulou of the Division of Radiation, Transport and Waste Safety.

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CONTENTS

1. INTRODUCTION

1.1. BACKGROUND

A properly established governmental, legal and regulatory framework for safety provides for the effective regulatory control of facilities and activities that give rise to radiation risks. An important aspect of a regulatory framework is to ensure that the implementation of the regulatory programme is commensurate and proportionate to the radiation risks associated with facilities and activities, in accordance with the graded approach. The concept of the graded approach in relation to the application of safety requirements is extensively covered within the IAEA safety standards.

Paragraph 3.24 of IAEA Safety Standards Series No. SF-1, Fundamental Safety Principles [1] states that: "The resources devoted to safety by the licensee, and the scope and stringency of regulations and their application, have to be commensurate with the magnitude of the radiation risks and their amenability to control."

Similarly, para. 4.3 of IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), Governmental, Legal and Regulatory Framework for Safety [2], states that: "The performance of regulatory functions shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach."

IAEA Safety Standards Series No. GSG-12, Organization, Management and Staffing of the Regulatory Body for Safety [3] provides recommendations on the organization and management of the regulatory body to ensure the effective performance of regulatory activities in accordance with the graded approach, taking account of the specific national circumstances.

IAEA Safety Standards Series No. GSG-13, Functions and Processes of the Regulatory Body for Safety [4] provides recommendations for meeting the requirements relevant to the regulatory body's functions and associated processes to implement those functions. The regulatory functions are required to be subject to a graded approach (see para. 4.3 of GSR Part 1 (Rev. 1) [2]) so that, while the descriptions of these functions are generic, the degree of application will differ with the magnitude and nature of radiation risks associated with the facilities and activities.

A regulatory system built in accordance with a graded approach contributes to the optimization of resources and increased efficiency and effectiveness of regulatory control and thus reduces the regulatory burden on authorized parties. The introduction of a graded approach is the opportunity to improve the transparency of regulatory processes, which is part of a growing expectation of the public that will contribute to the building and maintenance of trust in the authorities.

The application of a graded approach may be perceived as a challenge, especially for new regulatory bodies, because it involves a lot of judgement to be exercised by the regulatory body, and hence more competent and more experienced regulatory staff.

1.2. OBJECTIVE

The objective of this publication is to provide practical guidance on the application of the graded approach for the effective regulatory control of facilities and activities involving radiation sources. It describes possible approaches and specific considerations on the application of the graded approach including practical examples on the use of a graded approach to regulatory activities.

This publication is aimed at regulatory bodies with responsibilities for the safety of facilities and activities involving radiation sources.

1.3. SCOPE

This publication covers the application of the graded approach in regulating facilities and activities involving radiation sources in medicine, industry, agriculture, research and education, throughout the lifetime of facilities and the duration of the activities, and for the regulatory functions specified in GSR Part 1 (Rev. 1) [2] i.e. establishment of regulations and guides, authorization of facilities and activities, review and assessment of facilities and activities, inspection of facilities and activities, enforcement of regulatory requirements, communication and consultation with interested parties. Regulatory issues related to the interface of radiation safety with nuclear security are also discussed.

This publication does not address decommissioning and management of radioactive waste. Regulatory functions relevant to emergency preparedness and response are not included in the scope of this publication.

1.4. STRUCTURE

This publication consists of five sections and two appendices. Section 2 briefly summarizes the functions of a regulatory body that are subject to a graded approach. Section 3 describes the concept of a graded approach, including the various criteria to be considered for the development of a graded approach, and provides the examples of different methodologies for applying this approach. Section 4 describes the application of a graded approach to the regulatory functions of the regulatory body. Section 5 outlines issues to be considered in the application of a graded approach in relation to the organization, management and staffing of the regulatory body. Appendix I contains an example of the model that follows a step by step methodology on how to apply a graded approach in regulating the safety of radiation sources, while Appendix II provides an example of the use of a nomogram model in assessing the risk associated with facilities and activities. Finally, practical examples of the application of a graded approach in Member States are given in the Annexes.

2. REGULATORY FUNCTIONS FOR FACILITIES AND ACTIVITIES WITH RADIATION SOURCES

This section provides an introduction and brief description of the functions of a regulatory body for safety which are subject to a graded approach. While the functions are generic, the degree of application will differ in accordance with the risks associated with the facilities and activities under regulatory control. An integrated management system is fundamental to effectively apply a graded approach in the performance of its functions (see IAEA Safety Standards Series No. GSR Part 2, Leadership and Management for Safety [5]).

2.1. INTRODUCTION TO REGULATORY FUNCTIONS

The functions of a regulatory body in regulating the safety of radiation sources are described in GSR Part 1 (Rev. 1) [2] and further elaborated in GSG-13 [4]. These include the development of regulations that set out requirements for radiation safety; the development of supporting safety guides; the establishment of processes for notification and authorization of radiation sources; the review and assessment of facilities and activities; the performance of inspections; enforcement actions; and communication and consultation with interested parties.

2.1.1. Development of regulations and guides

Requirement 32 of GSR Part 1 (Rev. 1) [2] states that: "The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based."

The regulatory body needs to establish a system for developing, revising and promoting regulations and guides. Moreover, the regulatory body ensures that the development and implementation of regulations and guides is based on a graded approach commensurate with the radiation risks associated with the facility or activity.

The regulatory requirements for radiation safety will consider occupational, medical and public exposures, at all stages in the lifetime of a facility or duration of an activity. The guides (non-binding) aim to advise authorized parties on how to comply with laws and regulations, and on how to implement the regulatory requirements.

2.1.2. Notification and authorization, including the review and assessment of applications

Requirement 7 of IAEA Safety Standard Series No. GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Standards [6] 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.".

Requirement 23 of GSR Part 1 (Rev. 1) [2] states that: "Authorization by the regulatory body, including specification of the conditions necessary for safety, shall be a prerequisite for all those facilities and activities that are not either explicitly exempted or approved by means of a notification process."

The objective of a notification is to provide to the regulatory body initial information that a person or organization is intending to operate a facility or conduct an activity with radiation

sources. The regulatory body uses this information to decide on the level of regulatory control to be applied for this facility or activity.

The objective of granting authorizations by the regulatory body is to establish an effective regulatory control throughout the lifetime of a facility or duration of an activity in relation to safety. The authorization process ensures that the applicant complies with the relevant regulatory requirements.

Review and assessment of the applications for authorization are undertaken in order to enable the regulatory body to decide on the compliance of the facility or activity with the regulatory requirements and with the conditions specified in the authorization document. It is required that the depth and scope of the review and assessment be commensurate with the associated radiation risk, in accordance with a graded approach [2].

2.1.3. Inspection of facilities and activities

Requirement 27 of GSR Part 1 (Rev. 1) [2] states that: "The regulatory body shall carry out inspections of facilities and activities to verify that the authorized party is in compliance with the regulatory requirements and with the conditions specified in the authorization."

Requirement 29 states that: "Inspections of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach."

The regulatory body when developing and implementing a programme of inspections in accordance with a graded approach, takes into account the type, frequency and scope of inspections in conjunction with the risk level of the facility or activity to be inspected.

2.1.4. Enforcement

Requirement 30 of GSR Part 1 (Rev. 1) [2] states that: "The regulatory body shall establish and implement an enforcement policy within the legal framework for responding to non-compliance by authorized parties with regulatory requirements or with any conditions specified in the authorization."

Regulatory enforcement activities need to cover all areas of regulatory responsibilities. Enforcement actions may include documented verbal instructions, written notifications, the imposition of additional regulatory requirements and conditions, written warnings, civil penalties, prosecution, revocation of the authorization, and enforcing the cessation of activities or the closure of facilities. Those actions that are intended to correct or improve any aspect of the procedures and practices of the authorized party to ensure safety in accordance with regulatory requirements, need to be commensurate with the significance for safety of the non-compliance, in accordance with a graded approach.

2.1.5. Communication and consultation with interested parties

Requirement 36 of GSR Part 1 (Rev. 1) [2] states that: "The regulatory body shall promote the establishment of appropriate means of informing and consulting interested parties and the public about the possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body."

Coherent processes and procedures need to be established taking into account societal expectations and the expectations of interested parties. The regulatory body needs to have the authority and the responsibility to establish provisions for communication with interested parties, including the public, about the possible radiation risks associated with facilities and activities, as well as the regulatory decision making processes and regulatory decisions made. Informing and consulting interested parties need to be done by means of a transparent, open, consistent and ongoing communication process. This subject is addressed in detail in IAEA Safety Standards Series No. GSG-6, Communication and Consultation with Interested Parties by the Regulatory Body [7].

Interested parties include: the general public, such as people living in the vicinity of facilities; elected officials and governmental authorities at the national, regional and local levels; national and local non-governmental organizations; authorized parties and their employees; trade unions; suppliers; professional and academic organizations; news media; and other States, especially the neighbouring ones.

2.2. INTERFACE OF SAFETY WITH NUCLEAR SECURITY

Paragraph 2.40 of GSR Part 1 (Rev. 1) [2] states that: “Safety measures and nuclear security measures shall be designed and implemented in an integrated manner so that nuclear security measures do not compromise safety and safety measures do not compromise nuclear security.”

The safety and security of facilities and activities involving radiation sources have the same ultimate goal – to protect people and the environment from harmful effects of ionizing radiation. To accomplish this, safety is focused on achieving proper operating conditions, preventing accidents, mitigating those that do occur and providing protection from exposure to ionizing radiation. Nuclear security is oriented to prevent and detect malicious acts, including theft, sabotage and other criminal or intentional unauthorized acts that might lead to unacceptable radiological consequences or other adverse situations.

The safety and nuclear security measures implemented at radiation facilities help to ensure that adequate protection is achieved. Many design features and facility procedures contribute to both safety and security and offer opportunities for mutual enhancements. However, there are circumstances in which design features or facility procedures serve only one of the disciplines (safety or security) and in some cases can negatively affect the other. Moreover, modifications to the design or to the procedures related to safety or security might have unintended adverse effects on the one or the other. A properly managed interface between safety and security, as an element of both disciplines, is therefore essential for ensuring the protection of people and the environment from security related threats to, and radiological hazards associated with, radiation sources. It is important that the interface between safety and security is well understood and effectively managed to ensure that, the objectives of both are achieved as the disciplines continue to mature and when security measures are implemented at facilities involving radiation sources.

Use of a graded approach means that safety requirements and nuclear security recommendations are applied in a way that is commensurate with the potential hazards of facilities and activities involving radiation sources. The graded approach is applied to safety and security provisions covering all stages in the lifetime of a facility or duration of an activity with radiation sources.

Attention needs to be paid to the interface of safety with nuclear security during the development of criteria and methodologies for a graded approach. Some measures designed to provide safety, such as the use of interlocks and radiation detectors, will also provide a degree of security against the loss of a source or attempts to gain control over a source. Similarly, measures designed to prevent unauthorized access to sources will contribute to their safety by reducing the likelihood of misuse. Conversely, there could be situations in which, for example, measures intended to restrict access might adversely affect the safe use of a source. In the application of a graded approach, these aspects of safety and security may be considered together to avoid the possibility that application of a graded approach to safety requirements compromise security measures and vice versa.

3. THE CONCEPT OF A GRADED APPROACH

3.1. GENERAL CONSIDERATIONS REGARDING THE CONCEPT OF A GRADED APPROACH

A graded approach, as defined in the IAEA Safety Glossary [8] is:

(1) For a system of control, such as a regulatory system or a safety system, a process or method in which the stringency of the control measures and conditions to be applied is commensurate, to the extent practicable, with the likelihood and possible consequences of, and the level of risk associated with, a loss of control.
(2) An application of safety requirements that is commensurate with the characteristics of the facilities and activities or the source and with the magnitude and likelihood of the exposures.

The concept of the graded approach is based on the assessment of risk. Within SF-1 [1] the radiation risks are introduced as detrimental health effects of exposure to radiation (including the likelihood of such effects occurring), and any other safety related risks (including those to the environment) that might arise as a direct consequence of:

- Exposure to radiation;
- The presence of radioactive material or its release to the environment;
- A loss of control over radioactive source or any other source of radiation.

According to the IAEA Safety Glossary [8] risk is defined as a multi-attribute quantity expressing hazard, danger or chance of harmful or injurious consequences associated with exposures or potential exposures.

When applying the graded approach method:

(1) The characteristics of a facility or an activity in terms of the safety significance and complexity are determined;
(2) The potential impact of the facility or activity on health, safety and the environment are determined;
(3) The possible consequences, if an unanticipated event occurs or if an activity is improperly carried out, are taken into account.

The diversity of variables and factors that feed into the risk assessment process to determine the most likely consequence and the optimal course of action is core to the application of a graded approach in regulatory decision making.

As reported by Member States, most of the efforts in the application of a graded approach are associated with potential exposures and the risk associated with a loss of control over sources and the potential impacts on safety, health and the environment.

An objective risk assessment seeks to balance the application of safety measures while optimizing regulatory resources and effort without compromising safety or unduly limiting the operation of facilities or the conduct of activities that might give rise to radiation risks. Determining the most appropriate regulatory strategy to direct the regulatory body’s efforts

and optimize the use of its resources could present a challenge particularly in the early stages of implementing a graded approach.

From the regulators point of view, the application of the graded approach ensures that time, attention and resources are devoted to organization, functions, processes, activities and decisions that have a significant impact on regulatory effectiveness and efficiency, in view of the objective of protecting people and the environment from the harmful effects of ionizing radiation.

It is important to note that the use of a graded approach is a proportional application, not a relaxation of safety requirements.

Applying the graded approach does not mean any reduction on the regulatory requirements or control and does not relieve, the registrants or licensees form ensuring that:

(a) Regulatory requirements and licence conditions are met;
(b) The appropriate measures for protection and safety are implemented;
(c) Sufficient safety margins in the design, construction and operation of the facility are maintained;
(d) A multilevel (defence in depth) system of sequential, independent provisions for protection and safety is applied.

In order to apply the graded approach method in a systematic, consistent and transparent way, it is necessary to integrate it into the processes and procedures applied by the regulatory body and documented in the management system [9]. Within the process, the following are determined:

(a) Criteria for applying a graded approach compatible with the organization's objectives and activities;
(b) The optimum number of levels of risk that are to be defined within the application of the graded approach to encompass the identified criteria ('grading levels');
(c) Regulatory controls appropriate to each grading level.

The process is reviewed periodically to maintain the criteria and the respective controls that have been updated and adjusted.

3.2. DEVELOPING A GRADED APPROACH

The application of a graded approach in regulating the safety of facilities and activities involves a change in the regulatory decision making approach to overcome treating facilities and activities in the same way regardless of their risk. In order to successfully implement such changes, the commitment and support at a senior management level to the application of the graded approach is needed. The outcome and the lessons learned of this process could also lead to future changes in the regulatory provisions.

The development and implementation of a graded approach method to the regulatory functions, specified in section 2, contains the three main steps that are presented in detail in Figure 1:

(a) Step 1: Identification of the scope of the application of a graded approach.
(b) Step 2: Assessment of the risk associated with facilities and activities.
(c) Step 3: Application of a graded approach to regulatory functions.

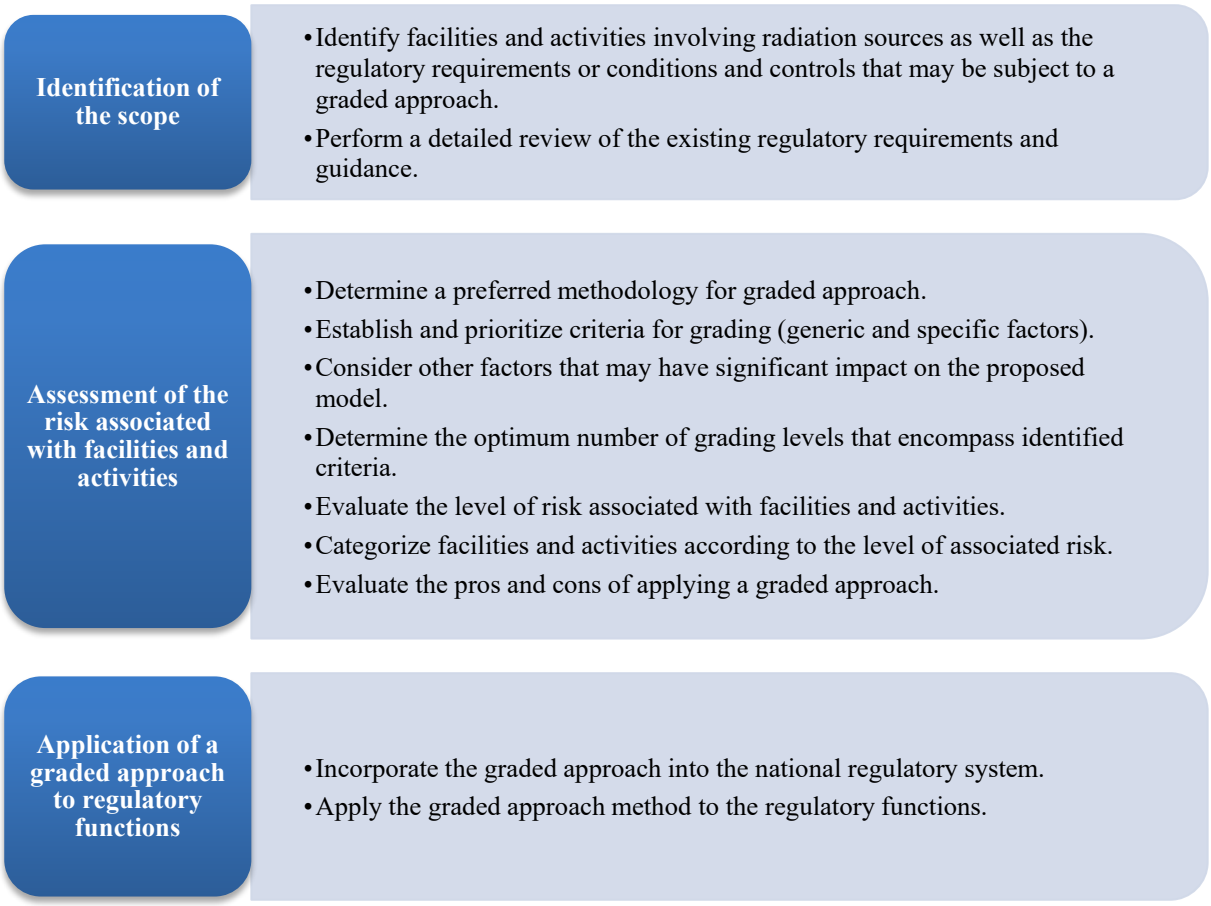

FIG. 1. Main steps in the development and implementation of the graded approach to regulatory functions

3.3. CRITERIA TO BE CONSIDERED FOR DEVELOPING A GRADED APPROACH

Paragraph 2.8 of GSG-13 [4] states:

> "The main factor to take into consideration in the application of a graded approach is that the application of the regulatory functions should be consistent with the magnitude of the possible radiation risks arising from the facility or activity. The approach should take into account any exposures to radiation, and discharges or releases of radioactive substances in normal operation, anticipated operational occurrences and accident conditions, as well as the possibility of events with a very low probability of occurrence, without neglecting very low probability events with potentially high consequences."

Requirement 6 of IAEA Safety Standards Series No. GSR Part 4 (Rev. 1), Safety Assessment for Facilities and Activities [10] states that "The possible radiation risks associated with the facility or activity shall be identified and assessed."

The term "possible radiation risks" relates to the maximum possible radiological consequences to people and environment that could occur from the facility or the activity, with no credit being taken for the safety systems or protective measures in place to prevent this [10].

The primary criteria for the assessment of risk associated with facilities and activities is based on the assessment of actual and potential radiation exposures (separately for occupational and public exposures) associated with facilities and activities in order to:

(a) Estimate, to the extent practicable, radiation exposures arising from normal operation;

(b) Estimate, to the extent practicable, the probabilities and magnitude of potential exposures, from anticipated operational occurrences and accident conditions (failures or internal or external events have occurred that challenge the safety of the facility or activity).

Radiation exposure to workers and the public might occur during normal operation of facilities or performance of activities or as a consequence of an anticipated operational occurrence or accident conditions. Changes in normal operation might result in exposures that could affect the public, workers or (for a medical exposure) patients.

A potential exposure is not certain to occur or, more specifically, is an exposure caused by some deviation from normal operation. The occurrence and magnitude of a potential exposure are both matters of probability and need to be considered and controlled.

Medical exposure differs from occupational and public exposure in that persons (primarily patients) are deliberately, directly and knowingly exposed to radiation for their benefit. However, a risk from a normal operation or from an accident exist, but its concept is different than the one in occupational or public exposure.

Factors that might have significant impact on the assessment of risk associated with facilities and activities are:

(a) Factors specific to the radiation source, such as:
    (i) For radioactive sources: the activity, the half-life, the dispersibility of the radioactive material, the physical and chemical properties of the source and characteristics of ionizing radiation;
    (ii) For X ray generators, linear accelerators and cyclotrons: factors specific to the equipment, such as the beam energy, the beam current and other characteristics of ionizing radiation.
(b) Factors specific to the facility and activity, such as:
    (i) Purpose of the use of radiation sources (e.g. medical use of radiation, non-medical human imaging, production of radionuclides, industrial applications).
    (ii) Complexity of activities, operating procedures, training requirements for staff, conditions of use (e.g. whether the radiation source remains within or is removed from a shielded container when in use).
    (iii) Design of facilities and equipment, and shielding devices (e.g. whether the safety can largely be ensured by the design of facilities and equipment).
    (iv) Site characteristics (e.g. use on the field or use in a fixed facility).

There are several additional factors that may also impact the level of regulatory control and the application of regulatory requirements for an individual facility or activity, such as:

(a) The maturity of the facility or activity;
(b) The knowledge and expertise of the authorized party’s staff;

(c) The compliance history of the facility or activity;
(d) The level of safety culture existing in the organizations;
(e) The adequacy of financial and human resources related to safety.

For regulatory bodies that are planning or reviewing the graded approach model, it is important to compare both the factors for different types of facilities as well as the respective factors of facilities of the same type. The process is summarized in Figure 2.

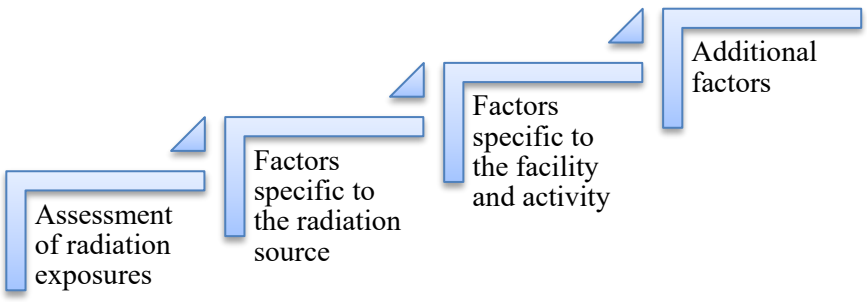

FIG. 2. Flow of criteria for developing a graded approach

3.4. NUMBER OF GRADING LEVELS

In order to define the optimum number of grading levels the following need to be taken into consideration:

- Setting too few levels might lead to a loss of transparency of the system for applying a graded approach, resulting in the potential for inconsistent approaches to similar issues and thus to the non-application of a graded approach.
- Setting too many levels might imply a degree of complexity and precision that would be difficult to justify. Having too many levels might, furthermore, lead to difficulties in the application of the graded approach and discourage its use.

Typically, between 3 and 5 grading levels are considered sufficient. The higher the grading level, the more stringent the controls applied.

3.5. EXAMPLES OF METHODOLOGIES

This section provides selected examples of methodologies for the application of a graded approach to regulatory functions. Annexes I-V provide specific examples of how the methodologies are applied to the regulatory functions in some Member States.

In selecting a methodology to apply a graded approach, the regulatory body may choose to apply one or a combination of methods depending on the level of development or maturity of the regulatory body.

The development and implementation of a graded approach might be challenging for regulatory bodies in the early stages of establishing the radiation safety infrastructure (see section 3.6).

The development of a more systematic and complex graded approach involves substantial regulatory experience and staff competence, both for the regulatory body and for operating organizations. In some models, the analysis of normal exposures and potential exposures is performed by the operating organization as a part of the safety assessment, which involves more competence and experience. Some models need historical data of doses to members of the public and workers in the analysis of normal exposures and potential exposures, analysis of operational feedback and inspection findings, as well as the capability (where needed) to carry out measurement campaigns to evaluate patient doses.

In certain graded approach models, the focus of the regulatory body is placed on the individual facilities and activities. The relevant factors, such as the level of maturity of the facility or activity, the knowledge and expertise of the personnel of the operating organization, the regulatory compliance history, the level of safety culture existing in the organization and the adequacy of financial and human resources, are taken into account in the identification of risks and their likelihood of occurrence, the assessment of implications and consequences, the identification of potential risk reduction options, and in the selection of course of actions.

3.5.1. Graded approach based on the categorization of radiation sources

This methodology uses the categorization of radiation sources as the main criterion for assessing the risk associated with the facility or activity. More specifically, the factors that need to be considered are:

(a) Categorization of sealed radioactive sources and some unsealed sources (based on IAEA Safety Standards Series No. RS-G-1.9, Categorization of Radioactive Sources [11]);
(b) The activity level of unsealed sources compared to the exemption levels specified in Schedule I of GSR Part 3 [6];
(c) For X ray generators, the peak tube potential (in kVp) and the maximum beam current (in mA or mAs);
(d) For linear accelerators and cyclotrons, the nominal energies and beam current.

The aggregation of radioactive sources and X ray generators and associated types of procedures, as well as their complexity, are taken into account in the development of this method.

This method may provide the regulatory body with an efficient and effective tool for the development of processes, procedures, work instructions as well as guidance for the applicants. It can be applied easily at the early stages of development of the regulatory control system as well as at later stages.

3.5.2. Graded approach based on levels of exposure

This methodology is based on the assessment of exposures, as the assessment of exposure is closely related to the assessment of radiation risk. The categorization of occupational and public exposures[1], including both normal and potential exposures, is used for targeting regulatory requirements and defining priorities within regulatory functions.

[1] In some Member States medical exposure during medical practice is also considered (see Annex I).

The levels of exposure used in the application of a graded approach may be defined in relation to radiation protection concepts such as dose constraints, dose limits, or the designation of areas. Several levels of exposure can be used; however, three levels for each exposure category (occupational, public, medical) have been found to be sufficient.

The benefit of this method is that the analysis of the normal exposures and potential exposures is a part of the safety assessment performed by an operating organization. The results of this analysis can be utilized for regulatory purposes in a transparent way; the operating organization can thus easily understand the basis for applying the graded approach to regulatory control.

3.5.3. Graded approach based on a risk informed method

This method uses a risk index in order to quantify the risk, and to rank the activities based on the amount of effort needed to regulate them. In general, the higher the risk of an activity, the more effort is needed to ensure safety. A risk index is a semi-quantitative measure of risk which is an estimate derived from a scoring approach using ordinal scales. Risk indices can be used to rate a series of risks using similar criteria so that they can be compared. These criteria are chosen by the regulatory body in order to establish the risk index approach. Examples of criteria used by Member States can be found in the annexes of this publication.

For each criterion chosen, the risk is estimated as a product of the probability of non-compliance and the impact of non-compliance on health and safety. The risk index approach allows the aggregation of several contributing factors to an overall risk ranking. The risk ranking of each activity is meant to provide a relative ranking of risk compared to other activities in order to determine the amount of regulatory effort that needs to be applied to each activity. The calculated value has no inherent meaning and is not an absolute measure of risk. Examples on how to apply this approach, are given in Annexes II-IV.

The use of the regulatory activities record keeping system, collecting and analysing operational and regulatory feedback, experience and the extensive competencies of the regulatory staff in designing and implementing this system of applying a graded approach are key parameters in the whole process. This system, which involves several steps, reduces the regulatory and administrative burden for both the regulatory body and operating organizations.

3.6. THE GRADED APPROACH FOR NEW REGULATORY BODIES

The application of a graded approach may be perceived as a challenge for new regulatory bodies, because it involves a lot of judgement to be exercised by the regulatory body and hence more competent and experienced regulatory staff.

Most decisions for applying a graded approach are not complex or time consuming; typically, they are simple, logical and intuitive. However, in some cases, the application of a graded approach needs a deep and broad knowledge of the scope of the regulatory system, a more mature regulatory system, additional judgement and assessment to be exercised by the regulatory body and experienced regulatory staff to be involved. Therefore, for a newly established regulatory body it is advisable to start with a simpler application of the graded approach, which allows it to prioritize its regulatory activities and gradually improve the regulatory system so that the resources are allocated in a manner commensurate with radiation risks.

The authorization and inspection processes, when established for the first time, sometimes follow a uniform (‘one size fits all’) approach. For example, there is a single approach to authorization and all applications are processed and reviewed in the same way, or activities with low risk sources are inspected as frequently as activities with high risk sources. However, for a newly established regulatory body not all necessary resources and competences might be available at the start. Therefore, it is advisable that the regulatory body prioritizes its needs, based on the importance to safety and the organizational risks to the regulatory body (e.g. the regulatory body’s inspection effort will be directed to those facilities and activities that present the most significant risks, such as those involving higher category radioactive sources).

With regard to the development of regulations, it is advisable for a newly established regulatory body to establish or adopt a basic set of performance-oriented regulations following the requirements established in GSR Part 3 [6] as a starting point. Subsequently, when practical regulatory experience is gained, in order to strengthen the regulatory requirements, a set of supplementary prescriptive regulations could be established, if considered necessary. The need for and the extent of the prescriptive regulations strongly depends on the availability of technical expertise in the State and on the national approach to regulation. In some States, for example, detailed guidance might be preferred over prescriptive regulations.

As a regulatory body matures and gains a better understanding of the regulatory programme, it might be able to further optimize its efforts to address key problems and issues for facilities and activities that cannot be dealt with purely through traditional compliance monitoring and enforcement approaches.

3.7. FURTHER DEVELOPMENT OF THE GRADED APPROACH

The models for applying a graded approach discussed in this section provide clarity on how regulatory bodies may redistribute limited resources between high risk and low risk facilities and activities. However, for moderate risk facilities and activities, there might be a disproportionate amount of resource being spent depending on the risk management approach adopted by the regulatory body. Regulatory bodies with a risk averse culture may treat moderate risk facilities and activities as high risk while those with a more risk tolerant culture may treat them as low risk.

Regulatory bodies may need to take a systematic wide view to identify and prioritize widespread non-compliance in facilities and activities. This process could be called ‘regulating smarter’. This is a process by which the regulatory body identifies significant problems and their root cause and implements a wide range of regulatory strategies to rectify them. For example, widespread non-compliance issues in the oil and gas industries or in industrial radiography may be resolved in close consultation with each industry with regulatory effort focused on the root cause of the problems, i.e. why there are repeat non-compliances. The underlying causes may be due to inadequate training of personnel, or a lack of clarity about regulatory requirements. These issues may be addressed in a collaborative manner between the industry and the regulatory body to improve regulatory compliance.

Another example on optimizing the regulatory control, is the authorization of large hospitals or universities where there are many facilities, radiation sources and transient users that produce a high potential for non-compliance. To ensure appropriate systems and processes to monitor and maintain compliance, the regulatory body may issue a broad scope single authorization that requires appropriate organizational governance, safety procedures and planned internal controls by the authorized party including periodic safety reports to the

regulatory body. Consideration may also be given to new technologies whether the justification of the practice is recent, to account for the experience of the operating organization and the regulatory body in the new technology.

While such an arrangement may be initially time consuming, it has the potential for reducing the time and effort of the regulatory body in the medium to long term.

Regulatory bodies need to continually examine their management systems and processes including resource allocation, training, safety culture and other issues to identify and resolve internal systemic issues impacting the regulatory programme. It may also be necessary for regulatory bodies to review and update the regulatory framework, including the regulations and the guides to better address risks from emerging technologies and new operating methods.

4. IMPLEMENTATION OF A GRADED APPROACH

Requirement 1 of GSR Part 1 (Rev. 1) [2] states:

> "The government shall establish a national policy and strategy for safety, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities, to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamentals."

Requirement 2 of GSR Part 1 (Rev. 1) [2] states that: "The government shall establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are clearly allocated."

Furthermore, GSR Part 1 (Rev. 1) [2] requires that the regulatory functions (see Section 2) are subject to a graded approach so that, while the descriptions of these functions are generic, the degree of application will differ in accordance with the facility or activity and the radiation sources involved.

4.1. ESTABLISHMENT OF REGULATIONS AND GUIDES

Paragraph 4.62. of GSR Part 1 (Rev. 1) [2] states:

> "The regulations and guides shall provide the framework for the regulatory requirements and conditions to be incorporated into individual authorizations or applications for authorization. They shall also establish the criteria to be used for assessing compliance. The regulations and guides shall be kept consistent and comprehensive and shall provide adequate coverage commensurate with the radiation risks associated with the facilities and activities, in accordance with a graded approach."

The legal hierarchy, that exists in most States, by itself follows a graded approach and usually consists of three basic levels: statutory law enacted by a parliament at the top level; regulations (or so-called subsidiary legislation) promulgated by appropriate governmental bodies as a second level; and non-binding guides or codes of practice as a third level.

Because of the very technical nature of safety regulation, it has seemed reasonable to frame legislation in more general terms and to leave more technical requirements to subsidiary legislation (regulations). Such an approach allows for a more efficient and timely adjustment to changes in circumstances, including technological developments or new directions in a national programme for the use of nuclear energy and ionizing radiation. Irrespective of the degree to which the government or regulatory body has developed prescriptive regulations, the regulatory body will give consideration to supplementing its regulations with non-binding supporting guides on how to comply with regulations, where appropriate [4].

4.1.1. Specific factors to be considered for use of a graded approach for regulations and guides

In addition to the factors described in Section 3.2, the following specific factors may be considered by the regulatory body when developing the regulation and guides in accordance with a graded approach:

(a) The need for new or updated regulations or guides in a specific area;

(b) The scope of the regulations and guides;
(c) The priorities for the development of regulations and guides;
(d) The necessary resources for the development of regulations and guides.

4.1.2. Graded approach to the development of regulations and guides

The structure and content of regulations and guides are subject to a graded approach. The development of any regulations for the control of radiation sources is balanced between two differing approaches:

(a) Performance oriented approach (regulatory requirements are more general and simply specify the overall radiation safety requirement and basic operational parameters);
(b) Prescriptive approach (regulatory requirements are more specific and state how to achieve radiation safety).

Typically, in practice, regulations are based on a combination of both approaches.

The development and update of regulations to adequately address all facilities and activities within the mandate of the regulatory body may take considerable time and place a high demand on the regulatory body's resources. Setting priorities for its activities and directing efforts to develop and revise regulations taking into account radiation risk is an area where a graded approach plays a significant role, so that regulations governing facilities and activities of higher risk have higher priority.

When establishing regulations and guides, States are encouraged to develop their own national regulations and guides based on the IAEA safety standards. During this process, the national circumstances (e.g. available expertise, number of a particular type of facilities and activities, radiation risk associated with regulated facilities and activities) are to be considered.

Regulations and guides are living documents that need to be amended periodically. Review and revision of national regulations and guides is an on-going process that can benefit from a graded approach. The need for any revision of the regulations and guides is to be carefully evaluated, as the reasons for the revision may be different, for example:

(a) New developments in technology, research and development, and operational lessons learned (e.g. new International Commission on Radiological Protection (ICRP) recommendations);
(b) New developments in international safety standards and industry standards (e.g. new IAEA safety standards);
(c) Changes in national circumstances (e.g. revised law, new application of radiation technology);
(d) Feedback and lessons learned from the regulatory and operational experience.

The need to revise regulations and guides may be obvious, but it might not be necessary immediately. Often, a significant regulatory effort is needed to make changes, and this needs to be carefully weighed against the benefit to safety that their change will bring. Sometimes, interim measures such as regulatory guides or licence conditions may be used.

The implementation of regulations is usually supported by practice-specific prescriptive documents (e.g. codes of practice or guides) describing how to meet the specific regulatory expectations.

The legal and regulatory framework contains several administrative requirements, which establish a basis for the application of a graded approach in regulatory control of radiation sources [6], such as:

(a) Exclusion (not feasible to control, e.g. K-40 in the body, or cosmic radiation at the surface of the Earth);
(b) Exemption (facilities or activities exempted from some or all the regulatory requirements);
(c) Clearance (sources, including materials and objects, within notified or authorized practices, cleared from regulatory control);
(d) Notification;
(e) Authorization by registration;
(f) Authorization by licensing.

Appendix I (I.2.3.1 Regulations and guides) provides an example illustrating how these administrative requirements may be structured.

4.2. NOTIFICATION AND AUTHORIZATION

The regulatory body determines which facilities or activities are exempted from notification or authorization, using as the basis for this determination the criteria for exemption specified in Schedule I of GSR Part 3 [6] or any exemption levels specified based on these criteria. For the non-exempted practices, the notification or authorization are applied.

The concepts of notification or authorization by registration, and authorization by licensing, broadly represent a graded approach to regulatory control based upon the levels of risk or the nature of the facility or activity (see Figure 3).

Paragraph 3.7 of GSR Part 3 [6] states: “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.”

Where notification alone is insufficient for a facility or activity (e.g. exposures expected to be associated with the facility or activity have the potential to exceed the small fraction of the limit specified by the regulatory body) an application for authorization needs be submitted to the regulatory body. The application for authorization may also serve as notification [4]. The regulatory body clarifies which types of facility and activity are eligible for notification only and for which types of facility and activity authorization is required, by providing criteria or lists of types of facility and activity [4].

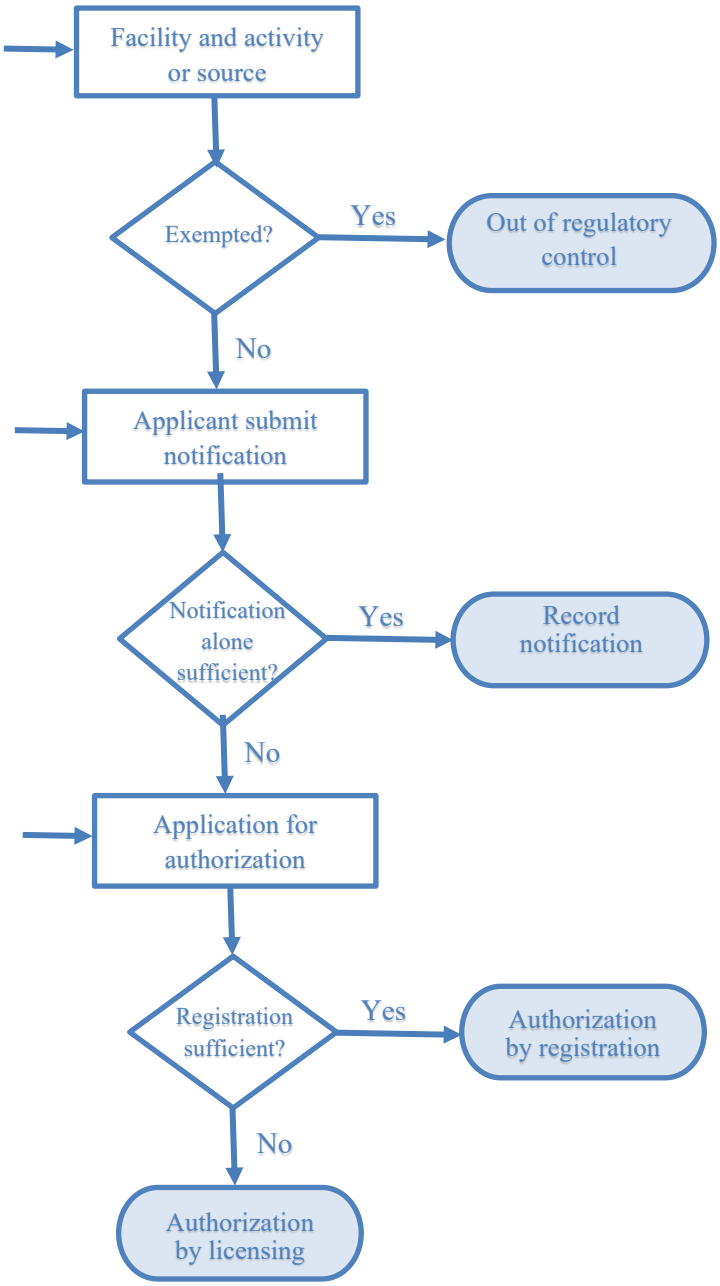

FIG. 3. The notification and authorization process

4.2.1. Notification

Requirement 7 of GSR Part 3 [6] 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."

Paragraph 3.74 of GSG-13 [4] states that: "The notification and, as appropriate, the application for authorization should be submitted on forms prescribed by the regulatory body with information that is commensurate with the level of radiation risk associated with operating the facility or conducting the activity."

The regulatory bodies could use the option of 'notification alone' which may be sufficient for facilities and activities associated with low radiation risk, for which normal exposures are expected to be very small and the likelihood and magnitudes of potential exposures are negligible (e.g. low activity sources in an analytical laboratory or calibration sources in Category 5).

For facilities and activities associated with a moderate or higher radiation risk, it may be appropriate for the regulatory body to consider authorization (by registration or licensing).

4.2.2. Specific factors to be considered when applying a graded approach to authorization

Regulatory bodies need to consider which form of authorization is appropriate for a given type of facility and activity: authorization by registration or authorization by licensing. Authorization by registration applies to facilities and activities of lower risk that the authorization by licensing. Coupled with the type of authorization is the level of complexity of the documentation to be submitted to the regulatory body prior to the authorization or subsequent renewals. This includes the degree of detail in the safety assessment. The duration for which the authorization is granted is another consideration for the regulatory body; more complex facilities and activities would warrant a more frequent renewal process.

In addition to the factors described in Section 3.2, the following specific factors may be considered by the regulatory body when developing a model for authorization of facilities and activities in accordance with a graded approach:

(a) The design of the facilities and equipment to ensure protection and safety;
(b) The human resources and competence of the staff;
(c) The operating procedures to follow;
(d) The experience obtained in operations;
(e) The dependence of operations on human performance.

4.2.3. Graded approach to authorization

If the risk corresponding to a facility or an activity is low or moderate, authorization by registration can be used by the regulatory body. Authorization by licensing is issued by the regulatory body following an application and review process, and it is required for all activities deemed to represent a significant radiation risk [6]. In other words, the extent of the regulatory control applied is commensurate with the potential magnitude and nature of the hazard.

4.2.3.1. Authorization by registration

Registration is "a form of authorization for facilities and activities of low or moderate risks whereby the person or organization responsible for the practice has, as appropriate, prepared and submitted a safety assessment of the facilities and equipment to the regulatory body" [8]. Typical practices that are suitable for registration are those for which:

(a) Safety can largely be ensured by the design of the facilities and equipment;
(b) The operating procedures are simple to follow;
(c) The training requirements for safety are minimal;
(d) There is no history of problems relating to safety in operations.

Registration is best suited to those practices for which operations do not vary significantly [See footnote 19 of Ref [6]].

For some simple forms of diagnostic radiology, such as dental radiography and Dual-energy X ray Absorptiometry (DXA), authorization through registration may be acceptable [12]. Registration is appropriate for: low activity sealed sources (Cat. 4 and 5) and the distribution of consumer products.

4.2.3.2. Authorization by licensing

Authorization by licensing is required by the regulatory body for all facilities and activities, other than those to which an exemption applies, and they are not otherwise designated as suitable for notification alone or for authorization by registration. In principle, a licence is necessary for the higher risk or more complex facilities and activities, including those for which the radiation safety depends significantly on human performance, such as some medical applications (e.g. radiotherapy) and industrial radiography.

The graded approach is further reflected in the authorization of complex facilities or activities, where a multi-stage authorization may be appropriate. This means that different types of authorization are issued at the different stages in the lifetime of the facility or duration of the activity (e.g. radiotherapy). Some of the stages in the lifetime of a facility or the duration of an activity may include specific hold points at which separate authorizations are necessary (e.g. construction licence, operation licence).

Licensing is appropriate for most types of facility and activity with radiation sources (e.g. industrial radiography, industrial irradiators, high-activity gauges, use of unsealed sources, manufacturing of sources, storage of radioactive material). It is a common practice that licensing is necessary for medical facilities and activities such as radiotherapy, nuclear medicine, image guided interventional radiology and for most diagnostic radiology facilities and activities [12].

The documentation to be submitted in support of an application for authorization (and described in guidance on the format and content of the documents issued by the regulatory body) need to follow the graded approach. The detail of the documents submitted depends on the type of radiation sources and the perceived radiation hazard. This may range from the use of low risk dental X ray equipment to the significant hazards that can arise in radiotherapy, industrial radiography, well logging or irradiators. For example, the demonstration of safety for industrial radiography needs to be much more detailed and comprehensive than the one submitted for the authorization of a dental X ray device.

The regulatory body may attach conditions to an authorization and may suspend or revoke it in the event of a violation of its conditions or in any circumstances in which the regulatory body determines that continued activity would pose an unacceptable risk to health, safety and the environment. Conditions or limitations imposed on the authorization by the regulatory body are also subject to a graded approach; for example, more detailed and/or specific conditions for high risk facilities or activities compared to low risk facilities or activities where specific conditions are not often used.

Appendix I (I.2.3.2 Notification and authorization) provides typical examples of facilities and activities eligible for authorization by registration or by licencing.

4.2.3.3. Duration of the authorization

The duration of an authorization may be subject to a graded approach. Authorizations may be granted for a specific time period (e.g. 3, 5 or 10 years). Usually, the duration is shorter for high risk facilities and activities (e.g. radiotherapy, industrial radiography), whereas in the case of low risk, the duration of authorization (usually in the form of registration) is longer.

In some Member States, authorization by registration is granted for an indefinite period of time (permanent authorization). This can significantly reduce the regulatory burden associated with renewals. However, in such a case, an authorization is issued under certain conditions and a mechanism needs to be in place to ensure that the authorized party responsible for the facility or activity complies with the authorization conditions and informs the regulatory body if conditions have changed. This practice does not exclude these facilities or activities from being inspected.

There are also examples from several Member States in which the government establishes a generic authorization process, to simplify the process and introduce transparency and uniformity in all government institutions. Therefore, the different processes in authorization such as registration and licensing are not recognized, and also specific time limits for authorization duration are not allowed. In this case, applying a graded approach to regulatory control is limited to the strengthening of existing regulatory controls by imposing licensing conditions which reflect specific situation.

4.2.3.4. Review and assessment of an application for authorization

Application of a graded approach in the review and assessment of an application for authorization, including for subsequent renewals, is reflected in the scope and depth of the analysis of documents; it depends on the complexity of the facility and activity and the associated radiation risks. In order to optimize the review and assessment processes, the methodologies described in Section 3 may be used in order to categorize facilities or activities based on radiation risk.

The regulatory body needs to specify timeframes for reviewing and assessing applications in accordance with a graded approach. The time specified will depend on the complexity of the application including the safety assessment and might range from a few weeks for the authorization of low risk facilities (e.g. dental radiography) to several months, for, example, for a nuclear medicine therapy facility.

For sources that pose a significant risk, unusual or complex facilities and activities, the regulatory body is advised to verify the contents of the documents submitted by means of inspection (see Section 4.3) of the site where the radiation sources are or are to be installed or used.

Other relevant factors, such as the maturity or complexity of the facility or activity, need to be taken into account in applying a graded approach to review and assessment. The consideration of maturity relates to: the use of proven practices and procedures and proven designs; data on operational performance of similar facilities or activities; uncertainties in the performance of the activity or operation of a facility; and the continuing and future availability of experienced manufacturers and constructors. Complexity relates to the extent and difficulty of the efforts needed to construct a facility or to implement an activity; the number of related processes for which control is necessary; the extent to which radioactive material has to be handled; the

reliability and complexity of systems and components; the accessibility of structures, systems and components for maintenance, inspection, testing and repair.

4.3. INSPECTION

Paragraph 4.50 of GSR Part 1 (Rev. 1) [2] states:

> "The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections) and shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach."

4.3.1. Specific factors to be considered for the use of a graded approach for inspections

A graded approach may be applied in deciding which types of inspection for specific types of facility and activity will be implemented. Inspections may be conducted by individuals or teams and may be announced or unannounced for both programmed and reactive inspections. Inspections may be of full or reduced scope with specific objectives. The number of inspectors can be graded as well, depending on the type of the facility or activity as well as on the type of inspection to be performed. The extent to which inspections are performed in the regulatory process will depend on the potential magnitude and nature of the risk associated with the facility or activity.

In addition to the factors described in Section 3.2, the following specific factors may be considered in establishing an inspection programme of facilities and activities in accordance with the graded approach:

(a) Regulatory body resources;
(b) Priority and frequency of inspections;
(c) Methods of inspection;
(d) Types of regulatory inspection;
(e) General national legislation.

Paragraph 3.218 of GSG-13 [4] states that: "The priority and frequency of inspections should reflect the risk associated with the radiation source and the complexity of the facility or activity, as well as possible consequences of an accident and the type and frequency of any regulatory non-compliances found by inspections."

The type and frequency of non-compliances identified during inspections is an important parameter that has an influence on the prioritization of inspections.

The inspection frequency defines the minimum number and type of inspections to be carried out in a facility and is also subject to the regulatory body's available resources. If resources are limited, facilities and activities associated with high risk are to be prioritised.

Methods of inspections may vary significantly in accordance with a graded approach. The simplest inspection applicable for low risk activities could be just an examination of procedures, records and documentation. More comprehensive inspection procedures

incorporate and use a method such as monitoring and direct observation of working practices and equipment, providing to the inspector an opportunity to discuss and interview personnel of the authorized party. In addition, in some inspections, verification tests and measurements may be conducted at fixed points of special interest using the equipment of the regulatory body.

With a view to further improve the inspection process, some regulatory bodies allocate resources towards compliance promotion, in order to reduce demands on the regulatory body and promote voluntary review. In such cases, the regulatory body requires that the authorized parties perform their own self-assessment and report the results to the regulatory body. Experience shows that such self-assessment contributes to safety performance and facilitates the inspectors to focus on areas of specific interest.

4.3.2. Graded approach to inspection activities

This subsection describes a proposed methodology for applying the graded approach to the inspection of facilities and activities involving radiation sources, which is step 3 in the graded approach methodology (see Appendix I). In this step, the graded approach would be used in developing a baseline inspection programme for different facilities and adjusting the inspection programme in consideration of the general and specific factors described above.

At this point, it is expected that the first two steps in the development of the method for applying the graded approach (identification of the need to apply a graded approach, and development of a model) have already been completed. However, if additional adjustments specific to inspection activities are noted (e.g. number of grading levels), this can be done in this step as well.

Implementation of a graded approach is related to the development or review of an overall programme for the inspection of facilities and activities, which includes the following steps:

(a) Establish a list of all facilities and activities that are to be authorized by registration or licensing;
(b) Categorize these facilities and activities on the basis of the associated risk;
(c) Identify priorities and safety significant goals for the programme ensuring that all applicable factors are considered (scope and objectives are defined and the method to fulfil these scope and objectives is determined, e.g. announced or unannounced inspections; priority and frequency; on-site inspections and desktop questionnaires , depth of inspections, single inspector or team);
(d) 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;
(e) Develop annual inspection plan from this baseline inspection programme (may need to be adjusted based on available resources).

Following an inspection, the review of the implementation of corrective actions can also be based on a graded approach. Inspection reports will indicate what is to be corrected; however, the severity of the non-compliances will dictate the time frame for corrective actions. For non-compliances associated with high risk, the corrective actions need to be implemented immediately, while for non-compliances that pose low radiation risk the inspector may set a reasonable deadline for implementing the corrective actions.

In some States, with a large number of facilities and activities authorized by registration (e.g. dental practice, fixed gauges), it is difficult to assign a specific frequency of inspection. Inspections of these facilities and activities can be conducted through targeted inspections (campaigns), or through random inspections or with inspections of a smaller frequency, appropriate to the associated risks.

Appendix I (II.2.3.3 Inspection) suggests a range of minimum inspection frequencies for the radiation facilities and activities based on the assessment of the safety risks.

4.4. ENFORCEMENT

Paragraph 4.54 of GSR Part 1 (Rev. 1) [2] states that: "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."

The regulatory body needs to develop and implement an enforcement policy compatible with the existing national legal framework. The enforcement policy is usually made publicly available so that registrants and licensees are informed of enforcement actions for non-compliances.

The enforcement process may vary according to the national legislative framework, but generally it consists of three steps, as follows (more information on the enforcement process can be found in GSG-12 [3]):

(a) Evaluate the significance of a non-compliance;
(b) Determine the appropriate enforcement action;
(c) Apply enforcement using an associated procedure for the selected enforcement action and with clear documentation of the facts, findings and the basis for the enforcement action.

There are numerous enforcement tools and statutory enforcement powers that can be utilized in accordance with a graded approach. In general, items of non-compliance that pose a significant safety risk, or uncorrected items of non-compliance from previous inspections are subject to enforcement action.

4.4.1. Specific factors to be considered for use of the graded approach for enforcement

When elaborating an enforcement policy, the graded approach may be taken into account by the regulatory body when assessing the significance of a non-compliance. The following aspects to design and implement a graded approach to enforcement actions may be considered:

(a) Significance for safety of the non-compliance, taking into account the possible effects and consequences on safety and security, health and environment;
(b) Actual and/or potential safety consequences of the non-compliance and the complexity of the corrective action;
(c) The national legal infrastructure provisions in terms of enforcement actions;

(d) The focus of the enforcement action (corrective or punitive) and the complexity of the process for applying it by means of administrative or legal procedures;
(e) To whom the enforcement actions will be applied (organization and/or individuals);
(f) If special measures (i.e. in case of a serious and imminent risk) are needed immediately;
(g) The time of response and the level of follow-up by the regulatory body related to the non-compliance;
(h) The nature of the regulatory approach (prescriptive or performance based).

Aspects related to the historic performance of the authorized party and human factors need to be considered to direct and/or refine the option for the enforcement action to be applied based on safety significance. The following items are to be taken into consideration when selecting an enforcement action:

(a) The recurrence of a particular non-compliance;
(b) The past safety performance of the authorized party and the performance trend;
(c) The duration of non-compliances;
(d) The circumstances that lead to non-compliances;
(e) Whether or not the authorized party identified and/or reported non-compliances;
(f) Conduct of the operating organization after the discovery of a non-compliance;
(g) Whether there have been intentional non-compliances, and the respective degree;
(h) Whether non-compliances impacted the ability of the regulatory body to perform its regulatory oversight function;
(i) The total number of non-compliances.

4.4.2. Graded approach to enforcement actions by the regulatory body

A graded approach can be applied by using the following enforcement actions (recommendations on enforcement methods are provided in GSG-13 [4]):

(a) Verbal or written notification of non-compliance;
(b) Written warnings and/or imposition of additional regulatory requirements;
(c) Penalties through application of fines;
(d) Restriction or suspension of activities;
(e) Modification, suspension or revocation of the authorization.

To ensure consistency in its decision making the regulatory body needs to develop procedures about how to use each of the enforcement tools.

Experience in some Member States, in line with their national legal framework, suggests that imposing penalties on the operating organization rather than on individual workers is preferable and is more likely to lead to improved safety performance. However, it is necessary not to lose sight of a clear separation between what is acceptable and not acceptable in terms of individual behaviours.

The official communication of enforcement actions, especially the suspension or revocation of the authorization, to interested parties and/or to the public by means of the website of the regulatory body improves the effectiveness of the enforcement actions and reinforce the commitment of the operating organization to take the necessary corrective actions.

4.5. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

Communication and consultation are strategic instruments that support a regulatory body in performing its regulatory functions, enabling it to make informed decisions and to develop awareness for safety and safety culture among interested parties. To achieve this, the regulatory body needs to develop a communication strategy. The factors that the regulatory body needs to consider when developing its communication strategy are:

- The strategic goal and priorities included in the policy and strategy for safety;
- The facilities and activities with radiation sources in the country;
- National circumstances (e.g. public concerns, safety culture, neighbouring countries);
- The available resources for implementing this strategy.

Defining goals and priorities for communication is particularly important, as communication often also needs to be subject to a graded approach, and actions scaled in order of urgency or safety significance.

Para 2.15 of GSG-6 [7] states:

> "The regulatory body should adapt its methods for communication and consultation to the objectives and the expected interested parties, and in accordance with a graded approach. The methods should be used in accordance with national circumstances, and with the concerns and interests of interested parties."

With regard to providing information to the public, para 4.69 of GSR Part 1 (Rev.1) [2] states that: "Public information activities shall reflect the radiation risks associated with facilities and activities, in accordance with a graded approach."

A graded approach might be a new concept to interested parties, which needs proactive communication and dialogue on the rationale behind the approach. Such communication might support the practical implementation of the graded approach and help operating organizations to understand the process and the responsibilities corresponding to it.

Ultimately, communication needs to be an integral part supporting the application of a graded approach, helping all stakeholders to understand their roles and responsibilities. To choose the appropriate method of communication based on a graded approach, the regulatory body need to identify:

(a) The interested parties;
(b) The types of information to be provided to the interested parties;
(c) The communication channels and tools to convey the information.

Various tools and channels may be used, either general or targeted to specific audiences. The number and type of tools depend on the message, audience, timing, resources as well as legal and regulatory requirements. Moreover, in choosing the most appropriate tool, the national context needs to be taken into account, e.g. what channel is used more by young people or what percentage of the public has access to internet.

Examples of information that may be of interest to be communicated to the interested parties are:

- Legal and regulatory requirements for safety;
- Conclusions from reviews and assessments, including critical comments;
- Findings of inspections;
- Regulatory decisions;
- Policy, strategies, guides and procedures;
- Events that might affect safety;
- Comprehensive picture of the national safety infrastructure;
- Actual status of safety;
- Information on regulatory activities, decisions and judgements.

Regulatory bodies need to strive for a high level of transparency and openness. This helps to build the public's trust in its independence, competence, integrity and impartiality. Members of the public usually have incomplete knowledge and a great deal of uncertainty when it comes to issues involving safety. This directly influences their perception of the risk associated with the use of radiation sources. The graded approach might be used to establish a proactive communication with and early involvement of interested parties even before formal regulatory activities have been launched, to demonstrate the willingness of the regulatory body to listen and respond to a broad variety of concerns.

More information is available on the Nuclear Communicator's Toolbox section on the IAEA website.

4.6. APPLICATION OF GRADED APPROACH TO OTHER REGULATORY ACTIVITIES

4.6.1. Technical and administrative support

4.6.1.1. Administrative functions

The organizational structure of the regulatory body includes departments and units that may be further divided into specific small structures to support the regulatory functions. The risk based graded approach applied to the regulatory functions is automatically reflected within the organization of the regulatory body and affects the administrative functions and the number and size of the departments and units. The recruitment and training of regulatory staff, as well as the knowledge management, are administrative activities in which the graded approach may be reflected.

Irrespective of the organizational structure, the regulatory body needs to have units or individuals dedicated to various administrative activities supporting the routine operations of the regulatory body (e.g. finance, management of documents and records, purchasing and control of equipment).

The regulatory body may employ its own administrative staff to carry out the administrative functions, or it may rely on the administrative staff of a parent organization to carry out these functions (if the regulatory body is part of a bigger organization, e.g. a government ministry), or it may need to subcontract some of these functions to an external organization.

The application of the graded approach in administrative functions will optimize the allocation of human resources. The number and the size of the units as well as the number of individuals that perform administrative tasks primarily depends on the size of the regulatory programme.

4.6.1.2. Legal support

The regulatory body often needs legal support for performing some functions, such as the drafting of legislation, regulations and guidance and their review for compatibility with other relevant laws. Legal support is also needed in the authorization process and proposed enforcement actions. The application of a graded approach to the provision of legal support needs to consider the risks associated with the existing facilities and activities to be regulated (including potential future practices), in accordance with the policy and strategy of the State.

Legal support can be in-house or provided by another organization (e.g. a relevant government ministry). A graded approach can be also followed in choosing among those options, depending on the size of the regulatory programme and the available resources.

4.6.1.3. External expert support

The regulatory body may choose to seek advice or assistance from an external expert support organization in the technical or functional areas necessary to discharge its responsibilities. External expert support can be provided by legal organizations, standards organizations, certified testing and analytical services and advisory bodies. The regulatory body may choose to formulate a dedicated process by which the external expert support is sought and provided in accordance with the policy of the regulatory body.

The graded approach in the provision of external expert support can be applied to the following:

(a) The level of expertise necessary to perform the work;
(b) The deliverables expected from the external experts;
(c) The expected time frames.

Administrative and technical support functions need to be represented in the processes covered by the regulatory body's management system in which the graded approach is addressed. Recommendations on using technical and administrative support are provided in GSG-12 [3].

4.6.2. Transport of radioactive material

Requirements for the transport of radioactive material (by all modes on land, water, or air) are established in IAEA Safety Standards Series No. SSR-6 (Rev. 1), Regulations for the Safe Transport of Radioactive Material [13]. In SSR-6 (Rev. 1) [13], a graded approach is applied on the basis of three different conditions of transport, as follows:

(a) Routine conditions of transport (incident free);
(b) Normal conditions of transport (minor mishaps);
(c) Accident conditions of transport.

The application of the graded approach in the transport of radioactive material needs to be based on the nature of transport activities in the State and on the consequences of a failure of the package to meet the requirements established in SSR-6 (Rev. 1), especially in relation to contents limits for packages and conveyances and in the performance standards applied to package designs. Implicitly, this means that in developing national transport regulations based on SSR-6 (Rev. 1) [13], the graded approach is applied by basing these regulations on the transport activities within the country (e.g. there is no need to include in national regulations

the transport of fissile material if fissile material is not transported in the country or not foreseen to be transported in the near future).

In this regard, the competent authority for the transport of radioactive material may at least include in the core processes the following:

- Formulating regulations based on the package type, conveyances and package designs;
- Classifying packages based on packaging components;
- Reviewing the relevant documentation;
- Drafting an inspection plan based on risk analysis taking into account the consequences of failure and the transport plan of the carrier.

More guidance on transport activities and the application of the graded approach is given in Annex IX of Ref. [9].

4.6.3. Research and development

Regulatory activities rely on state of the art scientific and technical knowledge obtained from national and international research and development programmes. In this context, research and development is the supporting function of the regulatory body which is used to assess and evaluate the technical basis of the regulatory decisions.

In applying the graded approach in research and development the following, inter alia, may be considered:

- National policy and strategy for safety;
- National priorities in research and development related to the radiation safety;
- Specific national needs for regulating safety;
- Relevant safety areas discussed in national and international fora;
- New technological developments;
- Operating experience;
- Unresolved issues on safety.

The application of a graded approach in research and development may be reflected in the resources devoted such as the number of staff involved, time frame, training programme, administrative burden, and the infrastructure to be used.

5. THE ORGANIZATION, MANAGEMENT AND STAFFING OF THE REGULATORY BODY

5.1. ORGANIZATION

Requirement 16 of GSR Part 1 (Rev. 1) [2] states that: "The regulatory body shall structure its organization and manage its resources so as to discharge its responsibilities and perform its functions effectively; this shall be accomplished in a manner commensurate with the radiation risks associated with facilities and activities."

The organization of the regulatory body may vary widely from State to State, largely depending on the national circumstances. The structure and size of the regulatory body depends mostly on the size of the regulatory programme (type, kind and number of facilities and activities to be regulated). As such, when establishing the legal and regulatory framework for safety (including the regulatory body), it is essential to know the type, kind and number of sources in the country (pictured in the national register of sources) to be regulated.

Other important factors, local conditions and demands, that need to be considered are:

(a) The national legal framework;
(b) The involvement of several regulatory authorities in the regulatory system;
(c) The nature of the regulatory approach (prescriptive or performance based);
(d) The human and financial resources of the regulatory body;
(e) The geographic distribution of facilities and activities.

Additional factors that have an impact are:

(a) The workload, determined by the size, the number, the type, and the stage in the lifetime of the existing facilities and activities to be regulated;
(b) Future plans (e.g. new facilities and activities to be constructed or introduced, new technologies).

To ensure that the functions of the regulatory body are performed efficiently and effectively, a methodology for applying a graded approach needs to be adopted, commensurate with the risks associated with the facilities and activities and taking into account the existing national radiation infrastructure and circumstances.

When developing the structure of the regulatory body, consideration needs to be given to whether to organize it according to regulatory processes or according to the types of facility or activity to be regulated. In larger regulatory bodies, regulatory staff may be assigned to perform only within a specific functional area (e.g. review and assessment of applications for authorization). Alternatively, based on the experience from some States regulatory staff may specialize in particular practices (e.g. radiotherapy) and consequently their work assignments would cover more than one functional area in the organizational structure (e.g. assessing applications for authorization and conducting inspections of radiotherapy facilities).

To optimize the allocation of its resources and to discharge its responsibilities and perform its functions effectively, the regulatory body may consider establishing a sufficiently flexible and adaptable organizational structure. Attention needs to be paid to have a well balanced ratio between technical staff and administrative staff.

There are several factors that need to be taken into account when the country decides whether the regulatory body need to be organized through a single central headquarters model or if additional offices located in different regions in the State are needed. The most important factors for this decision are the number and geographical spread of facilities and activities with radiation sources, the size of the country, the associated cost of traveling and the accessibility to facility locations.

In order to confirm that the organizational structure meets its expectations, there is a need for its periodic review by the regulatory body.

5.2. MANAGEMENT SYSTEM

Requirement 19 of GSR Part 1 (Rev. 1) [2] states that: "The regulatory body shall establish, implement, and assess and improve a management system that is aligned with its safety goals and contributes to their achievement."

The application of the management system may be subject to a graded approach that takes into account significance to safety and possible consequences in case of failure. Grading will enable resources and attention to be targeted at the activities of greater significance and identify activities of lesser significance. This can result in minimizing total costs while improving safety.

Development and implementation of a graded approach to the management system will contribute to increasing efficiency and effectiveness in reaching an organization's (a regulatory body or any other organization) objectives through the adoption of appropriate controls and optimized use of resources. This includes, among others, the optimized use of supporting functions like human resources, financial resources, information technology resources, equipment and technological resources, use of advisory committees, international cooperation.

The regulatory body needs to define the scope of its activities, which is important when designing and establishing a systematic method for applying a graded approach. The management system of the regulatory body needs to have the flexibility to prioritize and to direct its efforts.

5.3. STAFFING AND COMPETENCE

Requirement 18 of GSR Part 1 (Rev. 1) [2] states that: "The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities."

The management system of an organization includes competence matters and is graded to assess, plan and deploy appropriate resources with adequate competences for any activity and process related to safety. The graded approach is to be applied to the products and activities of the competence management processes.

It is necessary that the regulatory body have staff with expertise in a wide range of technical matters, as well as in human and organizational factors. The human resource plan (number, skills and competence) of the regulatory body will also depend on decisions about the tasks that are to be carried out by the regulatory body itself and those which could be referred to external experts, advisory committees or technical support organizations [14].

For the newly established regulatory bodies there might be a need to prioritize their needs based on radiation risk (see Section 3.6).

Reference [15] provides practical guidance on developing adequate competence management and introducing the quadrant competence areas typically needed for regulatory functions. It proposes a graded approach to these competencies for each competence area (regulatory function). Three different levels of competence are proposed:

(a) Basic: General competence in the area concerned;
(b) Medium: A competence level sufficient in routine cases;
(c) High: A competence level necessary for more complex cases or at the strategic level within the regulatory body.

More information on this topic is available in Ref. [16].

APPENDIX I

EXAMPLE OF A GRADED APPROACH MODEL FOR REGULATING THE SAFETY OF RADIATION SOURCES

I.1 INTRODUCTION

A systematic method for applying the graded approach is critical to ensure consistency, minimize subjectivity and to reduce the likelihood of assigning an incorrect grading level to facilities and activities. Risk analysis is fundamental to the development of a graded approach and is defined as the process of identifying and analysing potential radiation risks and other risks associated with normal operation and possible accidents involving radiation sources.

An example of a graded approach model is provided in this Appendix. The model covers all phases, from identification of the need to the assessment of risk associated with a facility or activity to the implementation of a graded approach. It combines methods from IAEA publications and used in Member States and seeks to provide a simple approach that may be easily implemented by regulatory bodies.

This model uses the relative ranking of risk to determine the appropriate level of regulatory control.

It is important to note that this model is an example based on experience and it is not the only way to implement IAEA safety requirements and recommendations in relation to applying a graded approach in the national regulatory framework.

I.2 DEVELOPING A GRADED APPROACH

Before the development of a graded approach model begins, the regulatory body needs to have detailed information of the current radiation safety infrastructure in the State, in particular the details of existing facilities and activities (including an inventory of radiation sources) and future plans.

In this example, the methodology used is given in Section 3.2.

I.2.1 Step 1: Identification of the scope of application of a graded approach

In this step, the scope of the application of a graded approach is determined. The regulatory functions to be considered are:

(a) Development of regulations and guides;
(b) Notification and authorization, including review and assessment;
(c) Inspection of facilities and activities;
(d) Enforcement;
(e) Communication and consultation with interested parties.

Facilities and activities commonly used in medical and industrial field are used as an example to develop a graded approach model commensurate with radiation risks.

I.2.2 Step 2: Assessment of risk associated with facilities and activities

This step contains several sub-steps which specify key elements in the process of developing a model for a graded approach.

At first, the appropriate methodology for the development of a graded approach needs to be determined. In this example, a new methodology will be proposed, which uses some of the elements from the examples outlined in section 3.

In order to categorize facilities and activities according to the level of associated risk (high, moderate or low), in the following subchapters the radiation risk will be evaluated based on the assessment of:

- Level of exposure;
- Factors specific to the radiation source;
- Facility and activity specific factors.

Finally, a matrix comprising the results of these three criteria needs to be developed to provide the overall relative ranking of the radiation risk associated with facilities and activities (see Table 4).

Section 3.5 contains examples of three alternative methodologies already in use in Member States.

I.2.2.1 Assessment of the level of exposure

The assessment of normal exposures (that is when the facility is operating under normal conditions or the activity is being carried out under normal conditions) and potential exposures (in which failures or internal or external events could occur that might challenge the safety of the facility or activity) is closely related to the assessment of the level of risk associated with facility and activity. Based on this assessment, the exposures will be categorized for each type of facility and activity separately. More specifically, the categorization of occupational exposures and public exposures, taking into account both normal exposures and potential exposures will be used for targeting regulatory requirements and prioritizing regulatory actions. An example is given in Annex I.

Table 1 presents an example of grading levels for occupational exposures and public exposures. In terms of the optimum number of grading levels, three levels for each type of exposure are considered as sufficient. Level 1 corresponds to the highest and level 3 to the lowest exposure.

TABLE 1. LEVEL OF EXPOSURES

Exposure	**Grading level**		
	1 (high)	2 (moderate)	3 (low)
Occupational	Effective dose > 6 mSv per year or equivalent dose of an organ > 3/10 of dose limit	Effective dose ≤ 6 mSv per year	Effective dose ≤ 1 mSv per year
Public	Effective dose > 0.3 mSv per year	Effective dose ≤ 0.3 mSv per year	Effective dose ≤ 0.1 mSv per year

I.2.2.2 Factors specific to the radiation source

Additional factors and criteria that have a significant impact on the assessment of risk associated with facilities and activities are specific to the radiation sources, such as:

(a) Categorization of sealed sources based on the IAEA categorization [11];
(b) Categorization of some unsealed sources based on the IAEA categorization [11] and comparison of the activity level of the unsealed sources with the exemption levels specified in Schedule I of GSR Part 3 [6];
(c) Categorization of radiation generators based on the nominal energies.

(a) Categorization of sealed sources

RS-G-1.9 [11] establishes a categorization system of radioactive sources. The categorization system is based on the potential for radioactive sources to cause deterministic health effects, as shown in Table 2. This potential is due partly to the physical properties of the source, especially its activity, and partly to the way in which the source is used.

TABLE 2. CATEGORIES OF RADIOACTIVE SOURCES

Source Category	**Risk in being close to an individual source**	**Possible health effects/exposure time**	**Typical application**
1	Extremely dangerous to the person	Permanent injury to fatality in a few minutes to an hour	Radioisotope thermoelectric generators (RTGs), Irradiators, Teletherapy sources, Fixed, multi-beam teletherapy (e.g. gamma knife) sources
2	Very dangerous to the person	Permanent injury to fatality in a period of hours to days	Industrial gamma radiography sources, High/medium dose rate brachytherapy sources
3	Dangerous to the person	Permanent injury, but unlikely to be fatal in a period of days to weeks	Fixed industrial gauges that incorporate high activity sources, Well logging gauges
4	Unlikely to be dangerous to the person	Temporary injury possible in many weeks of exposure	Low dose rate brachytherapy sources (except eye plaques and permanent implants), industrial gauges that do not incorporate high activity sources, Bone densitometers, Static eliminators
5	Most unlikely to be dangerous to the person	No permanent injury	Low dose rate brachytherapy eye plaques and permanent, implant sources, XRF devices, Electron capture devices, PET check sources

Sources in Categories 1–3 are generally capable, if not properly controlled, of causing severe deterministic effects. Therefore, for the purpose of relative ranking in this methodology, sources in these categories are ranked as of high potential to cause deterministic health effects.

Category 4 sources, if not properly controlled, are unlikely to be dangerous. Sources from this category are ranked as of moderate potential to cause deterministic health effects.

Category 5 sources are most unlikely to be dangerous and are ranked as of low potential to cause deterministic health effects.

(b) Categorization of some unsealed sources

RS-G-1.9 [11] states that the principles of the categorization system for sealed sources may be also applied to determine categories for unsealed sources.

For unsealed sources, a case by case categorization based on the activity (A) of the radioactive material in sources and D value (see Annex II of RS-G-1.9 [11]) for specific radionuclide can be used. Then the calculated A/D values are used to provide an initial ranking of relative risk for sources, which are then categorized after consideration of other factors such as the physical and chemical forms, the type of shielding or containment employed, and the circumstances of use and accident case histories.

In accordance with the examples provided in RS-G-1.9 [11], most common types of unsealed source used in nuclear medicine, such as 131-I and Tc-99m, are in Categories 4 or 5.

In some States, the exemption levels specified in GSR Part 3 [6] are used as a basis for the development of that categorization system of unsealed sources. One example of such a methodology is provided in Annex I, Table I-2.

(c) Categorization of radiation generators

There is no formal international system of categorization for X ray generators and particle accelerators that is equivalent to the categorization system for radioactive sources proposed in RS-G-1.9 [11]. There is a wide variation in the type of radiation generators in use, considering the complexity of the design, generator power, control systems and operating procedures, especially for those used in medical radiation facilities.

The ranking of a radiation generator using a systematic method based on factors specific to the equipment, will ensure consistency and minimize subjectivity in the application of the graded approach in regulating radiation safety. This is especially important given that the use of ionizing radiation in medicine is the most widespread application of ionizing radiation in Member States.

General criteria for establishing grading levels, as discussed in Section 3, that could be considered when performing an initial review include factors intrinsic to the X ray generators, linear accelerators and cyclotrons, and factors specific to the equipment, such as the beam energy, the beam current, dose rates and other characteristics. The first step in the development of a categorization scheme for radiation generators is the collection of data on the typical operating parameters for various generators and practices, such as the peak tube potential, tube current, exposure time and power output.

An example of categorization of radiation generators is used in the metrology relating to the calibration of ionization chambers for radiation therapy. [17]. This basic categorization of the generators is based on the energy they produce, as follows:

- Low energy X rays (with potentials below and up to 100 kV);
- Medium energy X rays (with potentials above 100 kV);
- High energy photons and electron beams (with energies above 1 MeV).

A proposed categorization of generators on the basis of operating parameters is given in Table 3.

TABLE 3. PROPOSED CATEGORIZATION OF RADIATION GENERATORS

Radiation generator	**Typical range of tube potentials or beam energies**[*)]	**Energy category**
Dental radiography (Intraoral)	50 - 70kV	low
Dual-energy X- ray absorptiometry (DXA)	40 - 140kV	low/medium
Dental radiography (OPG)	55 - 125kV	low/medium
Mammography	24 - 40 kV	low
Mobile radiography	50 - 125 kV	medium
Veterinary radiography	45 - 125 kV	medium
CBCT (Cone beam computed tomography)	70 - 120 kV	medium
General radiography	50 - 150 kV	medium
Fluoroscopy	50 -150 kV	medium
Computed tomography (CT)	50 - 140 kV	medium
Interventional radiology	50 -150 kV	medium
Radiation therapy (accelerators)	4 - 25 MeV	high
Proton and ion beam therapy	50 - 250 MeV	high
X ray fluorescence	20 - 60 kV	low
X ray security systems	40 - 320 kV	medium
Industrial radiography (generators)	150 - 400 kV	medium

[*)] The values used in the table are for information purposes only and may differ significantly depending on the equipment manufacturer and the technology used.

Radiation generators do not emit radiation until power is applied to the unit. Low and medium energy X rays are produced by X ray generators. X ray generator power rating vary considerably, the highest power up to 120kW is used in interventional radiology and in computed tomography (CT) scanning up to 100kW and for the other diagnostic radiology modalities, the power is lower. With large radiation doses delivered in a short time, deterministic effects including skin injury or hair loss can occur. However, deterministic effects are impossible in conventional radiology and might only occur in the lengthiest procedures involving complex interventional processes and are extremely unlikely to occur in CT scanning or any other diagnostic procedures. High energy (megavoltage) photon and electron beams (produced by linear accelerators) and protons and ion beams (produced by cyclotrons or synchrotrons) are capable of causing severe deterministic effects.

I.2.2.3 Facility and activity specific factors

The following facility and activity specific factors, already described in Section 3.3, could be used to further assess the associated radiation risk:

(a) Purpose of the use (e.g. medical use of radiation, non-medical human imaging, production of radionuclides, industrial applications).
(b) Complexity of activities, operating procedures, training needs for staff, conditions of use (e.g. whether the radiation source remains within or is removed from a shielded container when in use).

(c) Design of facilities and equipment, and shielding devices (e.g. whether the safety can largely be ensured by the design of facilities and equipment).
(d) Site characteristics (e.g. use on the field or use in a fixed facility).

Based on these factors, a series of questions were developed that could be applied to determine the categorization of risk associated with a specific facility and activity:

- Can safety be largely ensured by the design of the facilities and equipment?
- What is the level of competence that is needed to ensure safety?
- Is safety significantly dependent on human performance?
- Are operating procedures simple to follow?
- Are operations relatively constant over time?
- Is there a history of problems relating to safety in operations?

For each question, the impact on safety of facility and activity needs to be assessed and a corresponding ranking (high, moderate or low) assigned. This ranking is used to determine the overall relative risk rank for a given facility or activity, as presented in Table 4.

I.2.2.4 Matrix for evaluation of the radiation risk associated with facilities and activities involving radiation sources

In order to make an initial ranking of relative radiation risk associated with facilities and activities, an example of a matrix comprising of pre-established criteria has been developed (see Table 4). To apply these criteria to individual facilities or activities, regulatory experience and judgement are to be used. In this particular example, three levels for relative ranking radiation risk have been chosen (high, moderate and low).

The proposed relative ranking may be used in determining the appropriate level of regulatory control to be applied for each kind of authorized facilities and activities. In general, the higher the risk, the more effort is needed to ensure the safety of the specific facility and activity.

The application of a graded approach to medical uses of radiation is complex due to the wide variation in the complexity of medical radiation facilities and in the design of facilities and equipment. Several specific factors are considered in developing the system for applying a graded approach, such as the patient dose, especially in high-dose practices (e.g. CT examinations) and in new practices (e.g. tomosynthesis in mammography). The occupational and medical exposure can be high in image guided and interventional procedures. The complexity of the practice as well as levels of occupational exposure and medical exposure in brachytherapy and in nuclear medicine therapy practices.

Industrial radiography with radioactive sources produces high dose rates and hence the radiation risks arising from routine use, together with the probability and magnitude of potential exposures arising from incidents, is to be taken into account.

Under normal circumstances, sealed radioactive sources used in well logging will remain encapsulated throughout their working life. However, well logging sources could give rise to significant external exposures, particularly while they are being manipulated routinely out of their shielded containers or during a removal of the source.

An example of the application of criteria for a low risk facility and activity, as used in Table 4:

- Protection is optimized such that occupational and public exposures are not significant, and it would be unlikely that the doses received exceed grading level 3 in Table 1;
- The health effects of exposure to radiation (including the likelihood of such effects occurring) is considered minimal;
- Safety can largely be ensured by the design of the facilities and equipment;
- Operating procedures are simple to follow, and the training needs are minimal;
- Historically there have been few problems with safety in operations.

The criteria for determining the overall risk associated with facilities and activities is primarily based on the assessment of level of exposure (see I.2.2.1). Other factors, such as those specific to radiation sources (see I.2.2.2) as well as factors specific to the facility and activity (see I.2.2.3) may influence the primary factor by increasing the overall risk for one category.

TABLE 4. RELATIVE RANKING OF RISK ASSOCIATED WITH FACILITIES AND ACTIVITIES

Facilities and activities	**Level of exposure** (see I.2.2.1)	**Factors specific to radiation source** (see I.2.2.2)	**Factors specific to facility and activity** (see I.2.2.3)	**Overall relative risk**
Dental radiography (Intraoral)	low	low	low	low
Dental radiography (OPG)	low	low/moderate	low	low
DXA (bones densitometry)	low	low/moderate	low	low
Mammography	low	low	low	low
Mobile radiography	low	moderate	moderate	moderate
Veterinary radiography	low	moderate	moderate	moderate
CBCT	low	moderate	moderate	moderate
General radiography	low	moderate	moderate	moderate
Fluoroscopy (diagnostic)	moderate	moderate	moderate	moderate
Computed tomography (CT)	moderate	moderate	moderate	moderate
Interventional radiology	high	moderate	high	high
Radiation therapy (accelerators)	moderate/high	high	high	high
Radiation therapy (Co-60)	high	high	high	high
Gamma knife	moderate/high	high	high	high
Protons and ion beams therapy	high	high	high	high
Cyclotron – radioisotope production	high	high	high	high
High dose rate (HDR) brachytherapy	high	high	high	high
Low dose rate (LDR) brachytherapy	moderate	moderate	high	moderate
Superficial X ray therapy	high	moderate	high	high
Nuclear medicine – therapy	moderate/high	moderate	high	high
Nuclear medicine – diagnosis	moderate	moderate	high	moderate/high
Radioimmunoassay	low	low	low	low

TABLE 4. RELATIVE RANKING OF RISK ASSOCIATED WITH FACILITIES AND ACTIVITIES, cont.

Facilities and activities	Level of exposure	Factors specific to radiation source	Factors specific to facility and activity	Overall relative risk
Fluorescence using X ray	low	low	low	low
Fluorescence with radioactive sources	low	low	low	low
X ray security systems	low	moderate	low	low
Container with accelerators (customs inspection)	low	high	moderate	moderate
Industrial gamma radiography	high	high	high	high
Industrial radiography (X ray)	high	moderate	moderate	high
Irradiators with source	moderate	high	high	high
Irradiators with X ray (blood)	low	moderate	moderate	moderate
Calibration with sources	moderate	high/moderate	moderate	moderate/high
Calibration with X ray	low	moderate	moderate	moderate
Fixed industrial gauges cat 3	low	high	low	moderate
Fixed industrial gauges cat 4	low	moderate	low	low/moderate
Mobile industrial gauging	moderate	moderate	moderate	moderate
Radioactive lightning rods	low	low/moderate	low	low
Well logging devices	low	high	moderate	moderate
Electron capture devices	low	low	low	low
Calibration check sources	low	low	low	low

I.2.3 Step 3: Application of a graded approach to the regulatory functions

The regulatory body needs to apply a graded approach to the regulatory control of facilities and activities, based on the relative risk ranking. In addition to considering the risk posed by the regulated facility or activity, specific information from operational experience, licensee performance, safety assessments, and regulatory experience might be considered in applying the graded approach method.

The relative ranking of risk for commonly used facilities and activities may be used as the basis for the application of a graded approach to the regulatory functions. An example of the application of such a graded approach is the notification, and authorization by registration or by licensing.

The level of regulatory control to be applied to facilities and activities associated with very high and very low risk is straightforward and there is a high level of consensus among regulatory bodies on how to regulate them. This does not apply to moderate risk facilities and activities, as some regulatory bodies prefer to treat moderate risk items as high risk items, while others prefer to treat moderate risk items as low risk items.

I.2.3.1 Regulations and guides

The national legal and regulatory framework includes the administrative as well as the regulatory requirements for protection and safety of workers, the public and patients.

Annex II of Ref. [18] provides an example of using a graded approach in relation to the content of applications for authorization for radiotherapy, nuclear medicine, X-ray imaging in radiology, industrial irradiators, industrial radiography, well logging, and nuclear gauges.

Reference [19] provides model provisions, as an example of the regulatory framework, that may be considered by national authorities in developing administrative requirements as part of regulatory control.

Regulatory requirements may be applied in a graded manner, commensurate with the risk posed by the regulated facility and activity. Examples of appropriate regulations covering all aspects of the use of radiation sources and the safe management of the associated radioactive waste are provided in Ref. [19]. These examples illustrate possible ways to develop administrative requirements for the application of a graded approach in regulatory matters as exclusion, exemption, clearance, notification, authorization by registration, authorization by licensing, inspection and enforcement.

I.2.3.2 Notification and authorization

After determining that a facility or activity with radiation sources needs to be subject to regulatory control, the first step is notification, which provides initial information to the regulatory body about the possession of a source and the intention to conduct an activity with it.

For the authorization of medical facilities or activities, in some regulatory systems the initially assigned risk category is increased (e.g. low risk to moderate, or moderate to high risk). This will mean that medical radiation facilities and activities will always be authorized either by registration or by licensing, Article 27 of Ref. [20].

Examples of facilities and activities where "notification alone" might apply

In the case of non-exempted facilities and activities associated with low radiation risk, for which normal exposures are unlikely to exceed a small fraction, and the likelihood and magnitudes of potential exposures are negligible, notification alone may be sufficient.

An electron capture detector used in a gas chromatograph (e.g. containing a Ni-63 source of activity 185 MBq), in accordance with the previous analysis is categorized as low risk. This is a Category 5 source with a small quantity of radioactive substance emitting low energy beta particles, and notification alone is considered sufficient.

X ray fluorescence analysers are mainly used for industrial quality control purposes. Exposures from normal operation and the possibility of accidental exposure during routine operation are negligible, and notification alone is considered sufficient.

Examples of facilities and activities where authorization by registration might apply

Several medical applications listed in Table 4, such as dental radiography (intraoral), DXA (Dual-energy X ray absorptiometry) and mammography are categorized as low risk, which implies that notification alone is a sufficient level of control. However, usually the use of sources for medical exposures or for non-medical imaging purposes always needs to be authorized. For all those applications authorization by registration will be applied.

The same approach could be used for unsealed sources of low activity used for diagnostic purposes, such as radioimmunoassay (RIA) examinations involving less than 37 MBq of I-125.

X ray systems used for security screening are ranked as of low risk, however, in cases where the devices emit X rays up to 320 kVp, authorization by registration is considered as a more appropriate choice.

Authorization by registration is appropriate for facilities and activities associated with a moderate radiation risk, such as fixed industrial gauges containing Category 4 sources.

Other facilities and activities where authorization by registration might be appropriate include the following:

- Dental radiography (intraoral);
- DXA (Dual-energy X ray Absorptiometry);
- Mammography;
- Veterinary radiography;
- X ray Irradiators;
- Radioactive lightning rods[2].

Examples of facilities and activities where authorization by licencing might apply

For facilities and activities associated with a moderate or higher radiation risk, it may be appropriate for the regulatory body to consider authorization by licensing.

Medical radiation facilities mostly belong to this group. In medical uses of ionizing radiation, patient exposure depends a lot on human performance; radiation protection and safety are not only ensured by facility design, but also significant emphasis is on knowledge, training and skills of the operating personnel conducting the activity. Authorization by licensing is typically used for radiation therapy facilities, nuclear medicine facilities, facilities performing image guided interventional procedures and most of the diagnostic radiology facilities.

All facilities and activities involving radioactive sources of Categories 1–3 are ranked as of high potential to cause deterministic health effects and need to be authorized by licensing.

Duration of the authorization

The regulatory body authorization is granted for a certain period of time and the authorized parties need to seek re-approval after that time or when any significant change is to be made. The period of time for the authorization may be based on an assessment of the kind and level

[2] In many States this is no longer considered a justified practice

of risk or complexity associated with the facilities and activities. In the case of low risk applications, authorization in the form of registration may be granted for a longer time period (e.g. up to 10 years). The licence duration for high risk facilities and activities may be up to 5 years (e.g. radiotherapy 3 years, industrial radiography 3 years, nuclear medicine 5 years, diagnostic radiology 5 years).

If the regulatory system does not recognize the fixed term of validity of the authorization, this can be achieved by other means, such as authorizations issued under certain conditions and mechanisms that allow the regulatory body to request updating of the key documents and safety assessment necessary for authorization within specified time limits (e.g. every 5 years).

I.2.3.3 Inspection

The steps in the application of a graded approach to inspection activities are described in Section 4.3.

In order to have a comprehensive inspection programme that includes all facilities and activities with radiation sources and have a clear picture of the inspection frequency, it is advisable to design an inspection programme that covers a period of 5 years. This will also help to estimate with greater precision and assign human and financial resources for the purpose of regulatory inspections.

The primary focus of the annual inspection plan will be on facilities and activities with high and moderate risk, that present the most significant risk to both workers and the public. These include hospitals (i.e. using radiotherapy and nuclear medicine sources), pipeline and large metal fabrication companies (i.e. using industrial radiography sources), and oil exploitation companies (i.e. using well logging sources). Some inspections of registered applications may also be included in the programme each year.

When developing an annual inspection plan additional factors (e.g. State specific) might be taken into account.

A higher priority is assigned to the inspections of facilities and activities:

- Which include radiation sources of higher risk;
- In which the result of their safety assessment shows that there is higher likelihood of accidental exposure;
- That have a greater number of non-compliances from the inspections previously carried out;
- That have repeated follow up investigations.

Table 5 gives an example of the risk categorization and the inspection frequency.

TABLE 5. MINIMUM INSPECTION FREQUENCY

Risk categorization	**Inspection frequency (years)**
high	1–2
moderate	3–4
low	5

The regulatory body needs to consider that, regardless of the existence of annual inspection plan, it is very likely that during the course of the year there will be a need to perform inspections (mostly reactive) not included in the plan.

Specific factors such as methods and the number of inspectors needed to conduct an inspection may vary significantly in accordance with the risk. These factors need to be taken into account when designing the annual inspection programme.

I.2.3.4 Enforcement

In general, items of non-compliance that pose a significant safety risk, or uncorrected items of non-compliance from previous inspections are subject to enforcement action. The regulatory body needs to develop a system, based on a graded approach, to evaluate the severity of every non-compliance and to have a commensurate enforcement policy and programme taking safety, societal, economic and environmental factors into account.

Section 4.4 provides details about the enforcement process, including the specific factors to be considered for the use of a graded approach in enforcement actions. The enforcement process consists of three steps:

(a) Evaluate the significance of a non-compliance by considering specific factors;
(b) Determine the appropriate enforcement action;
(c) Apply enforcement using an associate procedure for the selected enforcement action and with clear documentation of the facts, findings and the basis for the enforcement action.

It is important to highlight that the regulatory body within its enforcement policy may develop its own graded approach based on the actual or potential safety consequences of the violations being assessed, and in accordance with the national legislation. Determination of the appropriate enforcement action strongly depends on the legal system of the State.

Table 6 provides an example of determining the significance of the non-compliances.

TABLE 6. SIGNIFICANCE OF NON-COMPLIANCES

Grading Level	Consequences of non-compliances	Possible actions
Grade 1	Operations are considered unsafe. Resulted in or could have resulted in serious safety consequences.	The regulatory body may consider suspending or restricting the facility's operations and, where practicable, may consider confiscating the radiation sources.
Grade 2	Potential risk to health and safety exists. Resulted in or could have resulted in moderate safety consequences.	The regulatory body may decide to suspend or restrict the facility's operations until regulatory infractions or safety conditions are corrected.
Grade 3	No immediate threat to health and safety. Resulted or could have resulted in low safety consequences.	Informal or formal instructions may be given to correct the non-compliance (however, written instructions need to follow oral instructions or directions); Facility operations may continue while corrective measures are taken.

Non-compliances of grade 1 may be considered for strong enforcement actions. This designation reflects the level of regulatory concern associated with the non-compliance and

usually involves actions with actual or high potential to have serious consequences on workers, the public, the patients or the environment. Examples of grade 1 non-compliances are failure to promptly notify the regulatory body of lost or missing radioactive sources or when the presence of a radioactive source (e.g. Category 1-3) is not verified at the necessary intervals.

For non-compliances of grade 2, a partial suspension of authorization might apply, for example, to a company authorized to perform well logging but which fails to satisfactorily comply with its own radiation protection programme while using sealed radioactive sources. Oher examples of grade 2 non-compliances are when radioactive source and its container are not properly marked, or when quality control tests are not performed at regular intervals.

Although grade level 3 non-compliances are not as significant based on risk, assigning this grading level does not mean that the non-compliances have no risk significance. Some examples of different categories of grade 3 non-compliances are when inventory records are not present in designated location or when training records are not kept up to date. This involves issues that do not prevent the licensee from being able to take appropriate actions on safety related matters.

The repetition of non-compliances (of all grading levels) are to be considered when deciding for the enforcement action or the renewal of the authorization.

APPENDIX II

RISK ASSESSMENT USING THE NOMOGRAM MODEL

II.1 RISK ASSESSMENT NOMOGRAM

A risk assessment nomogram (RAN) is a tool to support objective and transparent application of a graded approach by the regulatory body. It involves an assessment of the likelihood and consequence of failures in the application of safety and control measures for a facility or activity. The failures may be added to provide a total risk score. A comparison of risk scores may be used to assess the relative risk at a facility or an activity level.

To obtain the maximum benefit from this model, the regulatory body may need to have a good understanding of vulnerabilities or failures that are likely to occur in the normal operation of a practice. For example, industrial radiography is vulnerable to security risks during field operations and to equipment malfunction. Vulnerabilities in a nuclear medicine application arise a result of handling unsealed sources increasing the risk of spills and occupational exposure. This level of knowledge and understanding is usually gained as a result of conducting review and assessments or inspections over a period of time. The total risk score may be used to compare the relative risk between different radiation applications or at the facility or activity level. It may also be used to asses and compare compliance between operating organizations conducting the same type of activity. For example, to undertake comparison between nuclear medicine and diagnostic radiography facilities or between two operating organizations undertaking the same activity.

The benefits of this model are as follows:

(a) To strengthen the graded approach to further categorise practices (low, moderate and high risk) based on operational performance. This information may be used, for example to assign inspection frequencies or the frequency of renewal of authorizations.
(b) To gain insights to focus on poorly performing operating organizations.

II.2 APPLICATION OF A RISK ASSESSMENT NOMOGRAM

Template nomogram

The template for a risk assessment nomogram is provided in Figure 4. By entering known variables (i.e. the likelihood of a radiation hazard occurring as a result of a failure in safety measure and the potential consequence in terms of radiation exposure) on the nomogram, it is possible to determine a risk score. The range of risk scores may be set at any value and may vary, i.e. 0 to 100, 0 to 50 or 0 to 10. To ensure consistent outcomes, the template nomogram has not to be varied or changed between risk assessments as it will distort the risk scores.

The following information is relevant to using the nomogram:

(a) The safety and control measures are imposed by the regulatory body as part of the authorization process to mitigate potential hazards that might arise in the normal operation of a facility or the conduct of an activity. The first step is to identify the safety and control measures applicable to the practice being assessed.
(b) A list of topics for which commonly applicable safety and control measures are applied by regulatory bodies is provided below. These may be modified or added to as needed:

- Skills, competence and training for operating personnel;
- Safety culture within the operating organization;
- Nuclear security;
- Personal protective equipment and safety devices;
- Manual handling of sources;
- Exposure to a radiation source during normal use;
- Failure or malfunction of radiation source;
- Contamination of the environment;
- Exposure during diagnostic or therapeutic medical procedures;
- Unauthorized access to sources.

(c) The list of safety and control measures cannot be changed between the same type of facilities or activities. For example, the same list of safety and control measures needs to be used in the risk assessment of all diagnostic radiography facilities. Likewise, for industrial radiography facilities.

(d) The potential for failures or areas of vulnerability need to be considered based on previous performance or knowledge of the practice. Safety and control measures s need to be used as criteria for the assessment.

(e) For each safety and control measure the following ned to be assessed:
- The probability of the potential failures (e.g. almost certain, very likely, unusual but possible, remotely possible, conceivable but unlikely, practically impossible);
- Assess the risk of radiation exposure as a result of the vulnerability or failure (e.g. whether it would be continuous, frequent, occasional, infrequent or rare);
- Estimate the occupational exposure and public exposure, as appropriate, as a result of the failure. If available, use existing information from records of individual monitoring;
- Link the information on the nomogram (see the examples in II.3) to identify the risk score, ensuring that the two lines intersect at the tie line.

Individual risk scores for each safety and control measures for the practice are summed to develop the overall risk score.

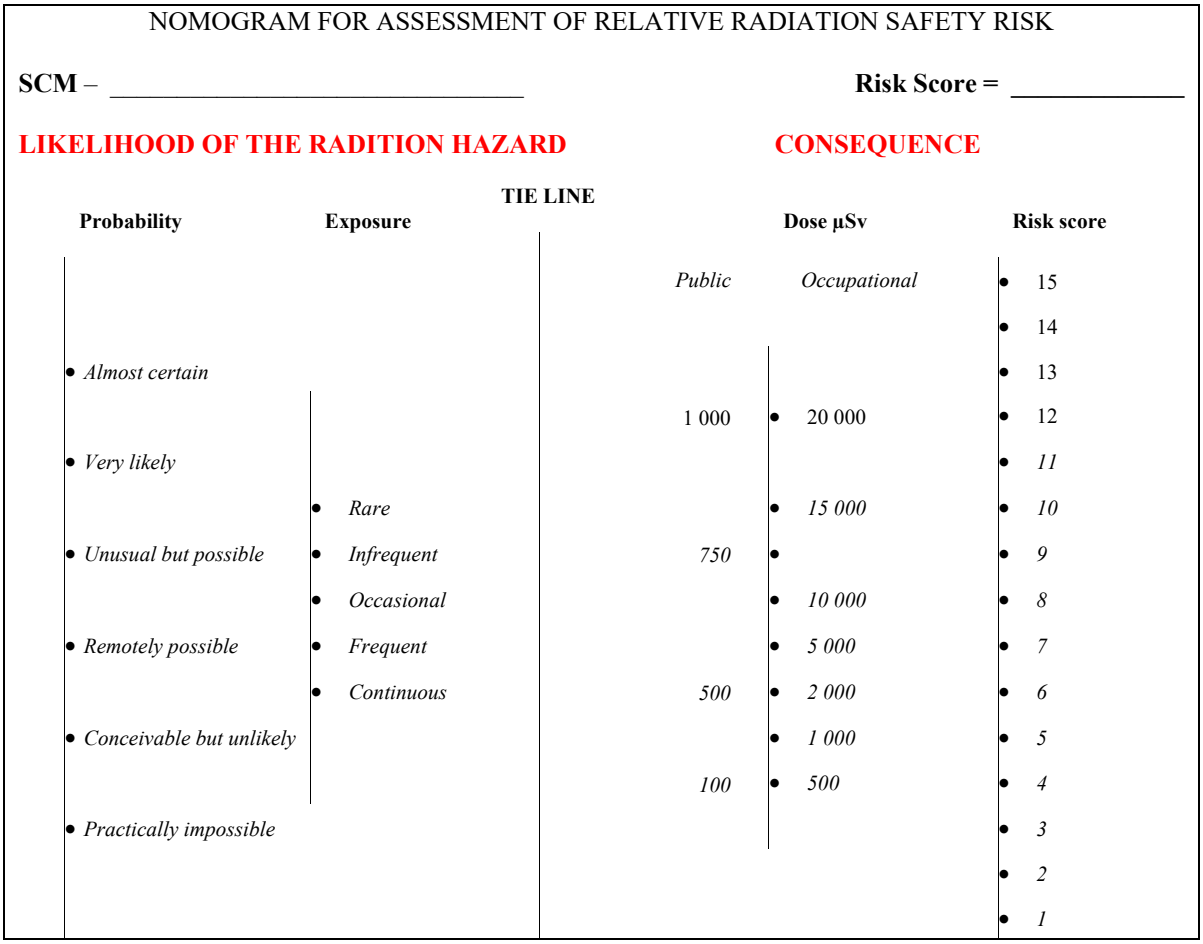

FIG. 4. Template Risk Assessment Nomogram

II.3 EXAMPLES TO DEMONSTRATE THE USE OF THE RISK ASSESSMENT NOMOGRAM

II.3.1 Example 1 - Industrial radiography

Based on knowledge of industrial radiography practices including known consequences of actual incidents, identify the safety and control measures used for regulatory control in the conduct of this practice. Example of how this may be done is provided below.

Note: these are subjective assessments and may vary between regulatory bodies.

Applicable safety and control measures (SCM) for industrial radiography facilities are:

1. Safety culture within the operating organization;
2. Personal protective equipment and safety devices;
3. Exposure to radiation sources during normal use;
4. Manual handling of sources;
5. Failure or malfunction of equipment;
6. Unauthorized access to a source;
7. Loss or theft of a source.

SCM1 - Safety culture and / skills, competencies and training of users: Safety culture could be seen as area of high vulnerability in industrial radiography facilities. Risk taking behaviour is unusual but possible. This might result in radiation exposure occurring in a continuous manner during the conduct of the activity by the worker. The consequence of this exposure could result in an effective dose of 15 mSv to the worker. Marking these points on the nomogram and extrapolating to the fourth line produces a risk score of 12, as shown in Figure 5.

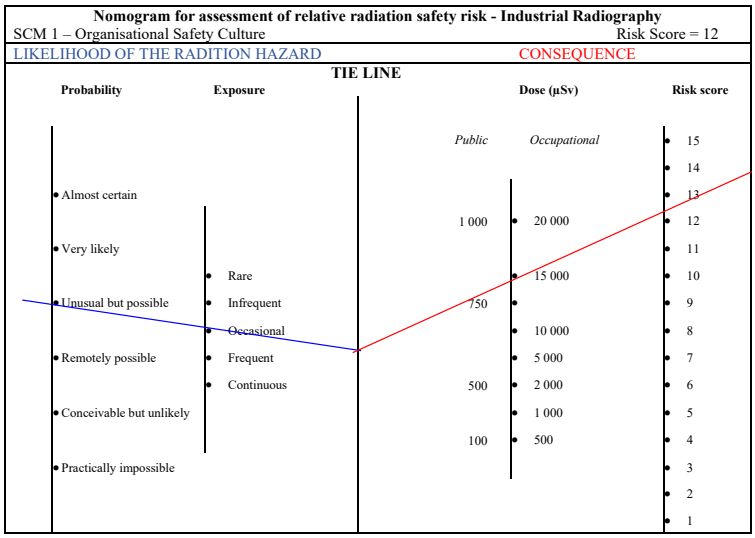

FIG. 5. Example nomogram for safety culture and skills, training and competencies

SCM2 - Personal protective equipment and safety devices: The reliance on manual operation of industrial radiography sources, especially outside of fixed facilities, means that safety devices are critical for the safe conduct of this activity. For example, inadequate safety culture might mean that a collimator is not always used, resulting in radiographers being occasionally exposed during the conduct of field based activities. This could result in an effective dose of about 10 mSv to the worker. This produces a risk score of 9, as shown in Figure 6.

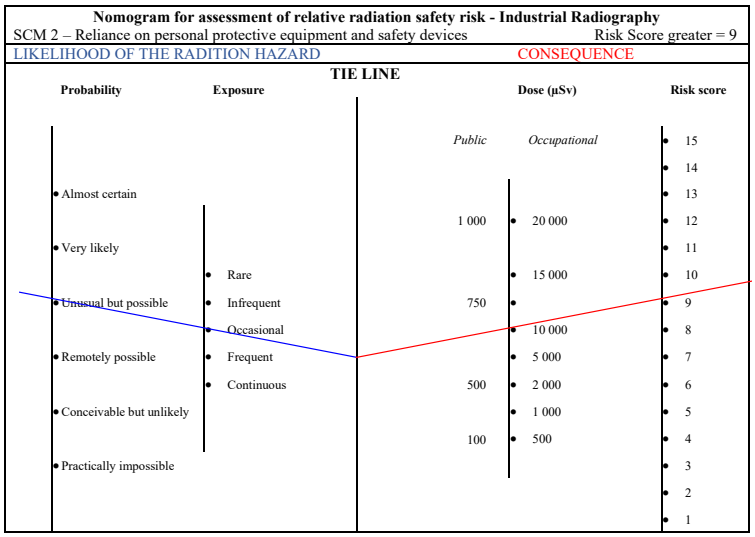

FIG. 6. Example nomogram for reliance on safety devices

SCM3 – Exposure to radiation sources during normal use: Due to the high activity of the source which is typically used outside of a radiography facility and the reliance on safety devices, there is high likelihood of the worker being exposed to radiation during normal use. The annual radiation dose could be at the order of 5 mSv. This produces a risk score of 13, as shown in Figure 7.

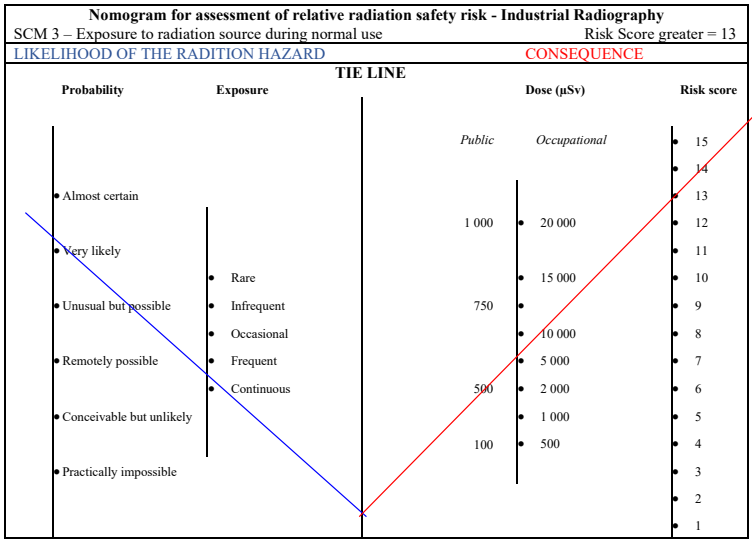

FIG. 7. Nomogram for exposure to radiation source during normal use

SCM4 – Need for manual handling of the source: In mobile industrial radiography there is high need for manual handling of the source container as it gets moved from site to site. The source set up arrangements for radiography on site also involves manual handling of the source container and associated equipment. This could result in the worker getting a dose of 5 mSv per annum. This produces a risk score of 13, as shown in Figure 8.

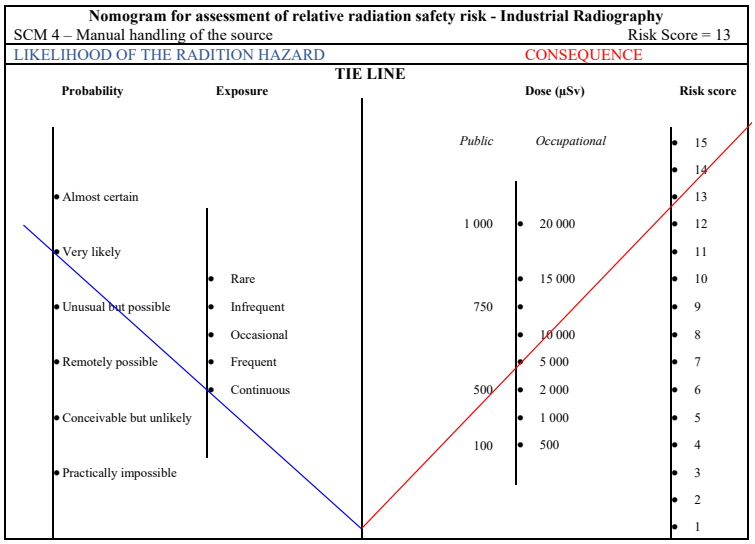

FIG. 8. Nomogram for manual handling of the source

SCM5 – Failure or malfunction of equipment: In industrial radiography incidents are not uncommon, for example a source failing to return into the container or a source becoming disconnected from the exposure mechanism and needing to be manually retrieved. Under such scenarios the exposure to the operating personnel might occur on an intermittent basis and the

resulting radiation dose could be about 10 mSv. This produces a risk score of 9, as shown in Figure 9.

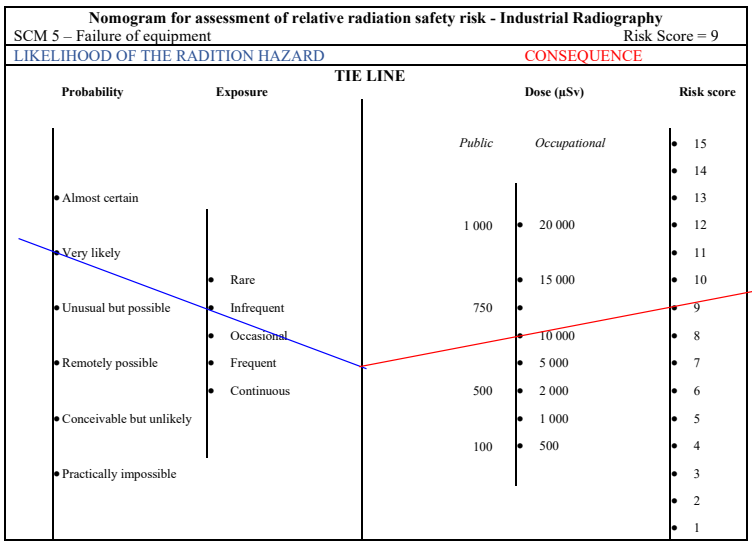

FIG. 9. Nomogram for failure or malfunction of equipment

SCM6 – Unauthorized access to a source: Unauthorized access to the source might occur as a result of a failure to properly demarcate a controlled area. This might, for example, result in a dose of 100 µSv dose to members of public. This produces a risk score of 1, as shown in Figure 10.

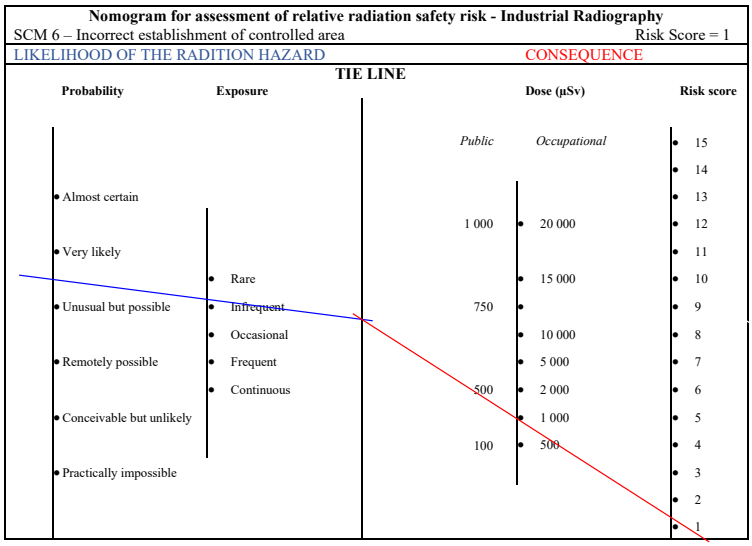

FIG. 10. Nomogram for unauthorized access to the source

SCM7 – Loss or theft of a source: Industrial radiography sources are vulnerable to loss or theft due to the mobile nature of the practice. It is common for the sources to be locked in transport vehicles or placed in temporary storage facilities. The members of public are most likely at risk if the sources are stolen and might, for example, receive a dose of about 500 µSv i.e. from the sources in their transport containers. This produces a risk score of 8, as shown in Figure 11.

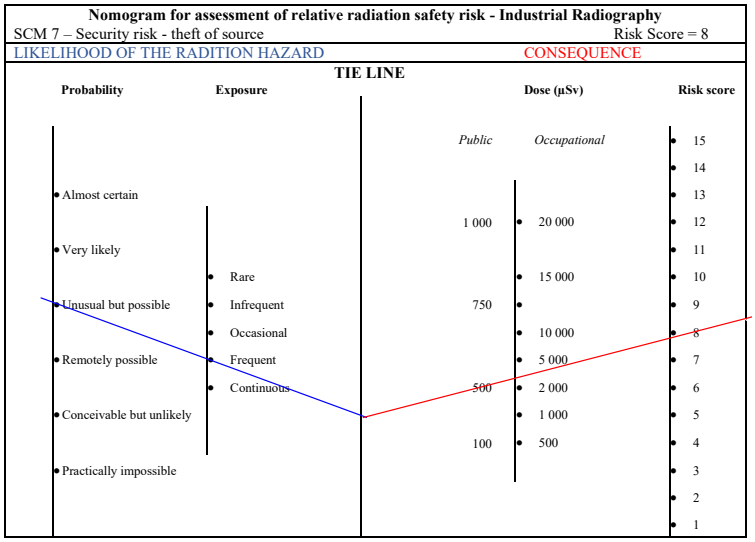

FIG. 11. Nomogram for loss or theft of a source

The total risk score is shown in Table 7.

TABLE 7. EXAMPLE TOTAL RISK SCORE FOR INDUSTRIAL RADIOGRAPHY

Potential vulnerabilities in SCM	**Risk Score**
Lack of safety culture or the necessary skills, competencies or training	12
Reliance on personal protective equipment and safety devices	9
Need for manual handling of sources	13
Exposure to radiation sources during normal use	13
Unauthorized access to a source	1
Failure or malfunction of equipment	9
Loss or theft of a source	8
Total Score	65

II.3.2 Example 2 – Nuclear Medicine

Applying a similar process to that described for industrial radiography in Section II.3.1, the risk assessment nomogram may be used to identify the total risk score for a nuclear medicine facility. An example of the output of this process is shown in Table 8.

TABLE 8. EXAMPLE TOTAL RISK SCORE FOR NUCLEAR MEDICINE

Potential vulnerabilities in SCM	**Risk score**
Lack of safety culture or of necessary skills, competencies or training	9
Reliance on personal protective equipment and safety devices	10
Need for manual handling of sources	10
Exposure to radiation sources during normal use	9
Unauthorized access to source	3
Failure or malfunction of equipment	5
Contamination of the environment	7
Unnecessary exposure during diagnostic procedures	7
Total Score	60

II.4 CATEGORIZATION OF FACILITIES AND ACTIVITIES (LOW, MODERATE AND HIGH) USING THE RISK ASSESSMENT NOMOGRAM

The risk assessment nomogram may be used to assess the relative risks of all radiation facilities and activities. The risk scores may vary depending on the expertise and judgement of the risk assessor. The scores will also depend upon the safety culture and general standard of protection and safety in member states. The risk scores may be grouped to further categorise facilities and activities into low moderate and high risk. An example of such a categorization is provided in Table 9; however, the risk category may vary depending upon the spread of risk scores.

TABLE 9. EXAMPLE CATEGORIZATION OF FACILITIES AND ACTIVITIES USING THE RAN

Facility and activity	**Total Risk score**	**Risk Category**
Industrial radiography	65	high
Nuclear medicine (both diagnostic and therapeutic)	60	high
Interventional radiology	53	high
Veterinary radiotherapy	41	moderate
Well logging	38	moderate
Computed tomography	37	moderate
Diagnostic radiography –film	25	moderate
Nuclear gauges	20	low
Intraoral dental radiography	15	low

REFERENCES

[1] EUROPEAN ATOMIC ENERGY COMMUNITY, FOOD AND AGRICULTURE ORGNIZATION 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).

[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, Leadership and Management for Safety, IAEA Safety Standards Series No. GSR Part 2, IAEA, Vienna (2016).

[6] EUROPEAN ATOMIC ENERGY COMMUNITY, FOOD AND AGRICULTURE ORGNIZATION 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).

[7] INTERNATIONAL ATOMIC ENERGY AGENCY, Communication and Consultation with Interested Parties by the Regulatory Body, IAEA Safety Standards Series No. GSG-6, IAEA, Vienna (2017).

[8] INTERNATIONAL ATOMIC ENERGY AGENCY, IAEA Safety Glossary: Terminology Used in Nuclear Safety and Radiation Protection, 2018 Edition, IAEA, Vienna (2018).

[9] INTERNATIONAL ATOMIC ENERGY AGENCY, Use of a Graded Approach in the Application of the Management System Requirements for Facilities and Activities, IAEA-TECDOC-1740, IAEA, Vienna (2014).

[10] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety Assessment for Facilities and Activities, IAEA Safety Standards Series No. GSR Part 4 (Rev. 1), IAEA, Vienna (2016).

[11] INTERNATIONAL ATOMIC ENERGY AGENCY, Categorization of Radioactive Sources, IAEA Safety Standards Series No. RS-G-1.9. IAEA, Vienna (2005).

[12] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Protection and Safety in Medical Uses of Ionizing Radiation, IAEA Safety Standards Series No. SSG-46. IAEA, Vienna (2018).

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

[14] INTERNATIONAL ATOMIC ENERGY AGENCY, Establishing the Infrastructure for Radiation Safety, IAEA Safety Standards Series No. SSG-44. IAEA, Vienna (2018).

[15] INTERNATIONAL ATOMIC ENERGY AGENCY, Managing Regulatory Body Competence, Safety Reports Series No. 79, IAEA, Vienna (2013).

[16] INTERNATIONAL ATOMIC ENERGY AGENCY, Methodology for the Systematic Assessment of the Regulatory Competence Needs (SARCoN) for Regulatory Bodies of Radiation Facilities and Activities, IAEA-TECDOC-1860, IAEA, Vienna (2019).

[17] INTERNATIONAL ATOMIC ENERGY AGENCY, Absorbed Dose Determination in External Beam Radiotherapy, IAEA Technical Reports Series No. 398, IAEA, Vienna, (2000).

[18] INTERNATIONAL ATOMIC ENERGY AGENCY, Notification, Authorization, Inspection and Enforcement for the Safety and Security of Radiation Sources, IAEA Technical Report Series No. 1002, IAEA, Vienna (2020).

[19] INTERNATIONAL ATOMIC ENERGY AGENCY, Model Regulations for the Use of Radiation Sources and for the Management of the Associated Radioactive Waste, IAEA-TECDOC-1732, IAEA, Vienna (2013).

[20] Council Directive 2013/59/Euratom of 5 December 2013, laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, Official Journal of the European Communities No. L 13, Office for Official Publications of the European Communities, Luxembourg (2014).

ANNEX I

PRACTICAL EXAMPLE OF APPLYING THE GRADED APPROACH IN ESTABLISHING REGULATIONS AND GUIDES

I–1. FINLAND

The Finnish Radiation Act and Decrees were revised in 2018. Using a graded approach, the STUK (Radiation and Nuclear Safety Authority) regulations were issued after that based on the Radiation Act. The legislation and regulations on ionizing radiation consist of the following:

- Radiation Act 859/2018;
- Government Decree on ionizing radiation 1034/2018;
- Decree of Ministry of Social Affairs and Health on ionizing radiation 1044/2018;
- STUK Regulations:
    - SY/1/2018 on exemption and clearance levels;
    - S/1/2018 on the investigation, assessment and monitoring of occupational exposure;
    - S/2/2018 on a plan for radiation safety deviations and actions during and after radiation safety deviations;
    - S/3/2018 on security of radiation sources licenced upon the Radiation Act;
    - S/4/2018 the use of high-power laser equipment;
    - S/5/2018 on the use of non-ionizing radiation in a cosmetic or other comparable procedure;
    - S/6/2018 on radiation measurements;
    - S/2/2019 on the radioactive waste and discharges of radioactive substances in the use of unsealed sources;
    - S/3/2019 on the practice exposing to natural radiation;
    - S/4/2019 on the justification and optimization of medical exposure;
    - S/5/2019 on safety of radiation sources during the practice;
    - S/6/2019 on obligations of undertakings.

Finnish regulations can be found at Finlex and at the STUK webpage www.stuk.fi.

I–1.1 Example of the application of a graded approach in Finnish legislation and regulations

Categorization of exposures and radiation sources

Decree on ionizing radiation 1034/2018 Section 16:

The categorizations concerning radiation practices referred to in section 27 of the Radiation Act have to be carried out separately for occupational exposure, public exposure and medical exposure. The categorization requires an assessment of the radiation exposure attributable to normal operations and the potential exposure attributable to radiation safety incidents.

In addition, any unsealed sources in laboratories, discharges of radioactive substances, sealed sources and waste to be disposed of in the form of mounding are also subject to a categorization based on radiation sources.

The category of the radiation exposure and radiation source may be 1, 2 or 3. Category 1 is equivalent to the highest and category 3 to the lowest radiation exposure, activity of the radiation source or amount of waste or activity concentration. If the practice in question does not include a radiation exposure or radiation source functioning as a basis for the categorization, the category of the radiation exposure or radiation source is E. The categorizations of radiation exposures and radiation sources are provided in Tables I–1 and I–2.

TABLE I–1. CATEGORIES OF EXPOSURES

Exposure	**Category**			**To be noted**
	3	**2**	**1**	
Occupational exposure	Effective dose ≤ 1 mSv a year *)	Effective dose ≤ 6 mSv a year	Effective dose > 6 mSv a year or equivalent dose of an organ > 3/10 of dose limit	The effective dose is the annual dose to a worker.
Public exposure	Effective dose ≤ 0.1 mSv a year**)	Effective dose ≤ 0.3 mSv a year	Effective dose > 0.3 mSv a year	The effective dose is the annual dose to a representative person. In the categorization, the exposure of a wrong patient as a radiation safety incident is comparable to medical exposure.
Medical exposure	Effective dose ≤ 0.1 mSv a year, and the practice does not result in deterministic effects to the patient.	Effective dose ≤ 100 mSv a year, and the practice does not result in deterministic effects to the patient.	Effective dose > 100 mSv, or local or an organ's absorbed dose > 10 Gy, or the practice may result in effects to the patient.	Concerns the dose to the patient from one examination, procedure or treatment session.

*) The category is 3 when the practice results in occupational exposure which is nevertheless so low that the workers are not categorized as radiation workers.
**) The category is 3 when the practice results in minor public exposure.

TABLE I–2. CATEGORIES OF RADIATION SOURCES

Radiation sources	**Category**			**To be noted**
	3	**2**	**1**	
Unsealed sources in a laboratory	Activity ≤ k × 10 × exemption value	Activity ≤ k × 10,000 × exemption value	Activity > k × 10,000 × exemption value	The activity is the highest activity of an unsealed source handled at any time.
	The factor k is determined according to the practice: particularly high-risk work: k = 0.1, handling by conventional chemical methods: k =1, simple handling: k = 10 and storage: k = 100.			
Sealed sources	Activity ≤ the activity value of a high-activity sealed source	Activity ≤ 1,000 × the activity value of a high-activity sealed source.	Activity > 1,000 × the activity value of a high-activity sealed source.	The activity value of a sealed source means the activity value provided under section 75, subsection 5 of the Radiation Act.

Exemption

Radiation Act 859/2018:

Section 49

(Practices exempt from a safety licence)

A safety licence is not required for:

(a) The use of non-ionizing radiation;
(b) The use of such a radiation source compliant with the justification principle in which the exposure is insignificant due to the amount of the radioactive substance or the safety features of the radiation appliance;
(c) A practice in which the radioactive substance derives from a permitted discharge of a radioactive substance and from radioactive waste or a radioactive material which has been reused, recycled, utilized or disposed of in a manner specified under section 84;
(d) The shipment of a radiation source;
(e) The export of a radiation source which does not contain a radioactive substance;
(f) The transport of radioactive substances, excluding the road or rail transport of high-activity sealed sources;
(g) The holding of healthcare or veterinary medicine X ray equipment, provided that the holder has a safety licence for the use of same equipment in the field of healthcare or veterinary medicine or for the installation, maintenance or remediation of such equipment;
(h) Such remediation or maintenance work of a radiation appliance which does not concern the appliance's parts producing radiation or shielding from radiation or any equivalent parts in a way that impacts safety;

Other practices which meet the criteria for an exemption from a safety licence pursuant to section 50, subsection 1.

Further provisions on practices exempted from a safety licence as referred to in subsection 1, paragraph 9 are given by government decree.

STUK issues more detailed regulations for the implementation of European Union directives in terms of the insignificant amount of radioactivity (exemption value) and an appliance's safety features as referred to in subsection 1, paragraph 2.

Section 50

(Exemption from safety licence under a decision by the Radiation and Nuclear Safety Authority)

STUK may exempt radiation practices other than those referred to Chapter 13 (Medical exposure) or 14 (Non-medical human imaging) from a safety licence, provided that exemption is the most appropriate alternative and that:

(a) The radiation exposure and potential exposure due to the practice is insignificant enough not cause a health detriment;
(b) The practice has been demonstrated to be justified;
(c) The practice is safe in principle.

The decision may include conditions necessary for ensuring safety.

The decision may be withdrawn if the prerequisites for exemption are not met or if the conditions for exemption have not been complied with and the deficiencies are not remedied within a prescribed period of time despite a request to do so.

Further provisions on the prerequisites for exemption from a safety licence are given by government decree for the purpose of implementing European Union legislation.

Government Decree on Ionizing radiation 1034/2018:

Section 27

(Practices exempt from a safety licence)

Under section 49, subsection 1, paragraph 9 of the Radiation Act, a safety licence is not required for:

(a) The use, manufacture, trade, installation, possession, safekeeping, import, shipment or storage of an appliance which produces ionizing radiation electrically, provided that the appliance operates with a maximum voltage of 30 kilovolts and does not cause, within a ten centimetre distance of the appliance's accessible surfaces, a higher dose rate than 1 μSv per hour;
(b) The use of fire alarms and fire detectors containing radioactive Am-241 in the purpose they have been designed for or their resale and use or the possession, retention, storage, installation, maintenance or repair related to their use and resale; new fire alarms may nevertheless contain a maximum of 40 kBq of Am-241;
(c) For the use of a sealed source with radiation safety properties meant for educational use which produces ionizing radiation electrically and contains a maximum of 40 kBq of Am-241, Sr-90 or Cs-137 as a teaching aid in schools, vocational schools and comparable institutions, provided that the educational institution has appointed a person in charge of radiation safety;

(d) The use of lamps and lighters containing a maximum activity equal to the exemption value of a radioactive substance in the purpose they have been designed for or their resale and use or the possession, retention, storage, installation, maintenance or repair related to their use and resale.

Section 28

(Conditions for exemption from a safety licence)

The practice is in principle safe as referred to in section 50, subsection 1, paragraph 3 of the Radiation Act if the workers do not need to be categorized as radiation workers and the effective dose of a member of the public is at most, excluding unlikely radiation safety incidents, of the magnitude of:

- 10 μSv a year from artificial radioactive substances;
- 1 mSv a year from naturally occurring radioactive materials.

The effective dose to a member of the public in unlikely radiation safety incidents may not be higher than 1 mSv a year in a practice referred to in subsection 1, paragraph 1.

An assessment of a dose arising from naturally occurring radioactive materials is to be considered in addition to the dose due to the existing local background radiation.

Example: Use of medical physics expert

Government Decree on Ionizing radiation 1034/2018:

Section 19

(Use of a medical physics expert)

The responsible party have to ensure that a medical physics expert is *closely involved* in radiotherapy practices, excluding established radionuclide therapy.

A medical physics expert *has to be used* in any radionuclide therapy other than that referred to in subsection 1 as well as in interventional radiology, computerized tomography and other practices causing high medical exposure.

In practices other than those referred to in subsection 1 and 2, a medical physics expert *has to be used at the commencement of* the practice and the expert has to be available during the practice.

By way of derogation from what is provided in subsection 3, dental X ray imaging in health care by using panoramic tomography X ray equipment, cephalostats or dental X ray equipment for imaging with an intraoral imaging receptor are subject to the use of a medical physics expert, provided that advice is required in some matter referred to in section 20.

Any imaging as referred to in Chapter 14 (*Non-medical human imaging)* of the Radiation Act with a health care equipment subject to subsection 3 and 4.

Use of radiation protection expert (equals to qualified expert in the GSR Part 3)

Government Decree on Ionizing radiation 1034/2018:

Section 17

(Use of a radiation safety expert)

The responsible party has to ensure that the radiation safety expert is:

(a) closely involved in the radiation practice if the category of the occupational or public exposure referred to in section 16 is 1 or 2;
(b) available for the radiation practice when the category of the occupational or public exposure is 3.

A radiation safety expert has also to be used:

(a) at the commencement of a new radiation practice;
(b) when changing a radiation practice in such a way that the class of the occupational or public exposure can change;
(c) in the event of a problem detected in the radiation protection of workers or members of the public;
(d) in connection to the discontinuation of a radiation practice which involves the handling of radioactive substances when it pertains to a matter referred to in section 18, subsection 12 or 13.

By way of derogation from what is provided in subsection 1 and 2, a radiation safety expert at least has to be used when advice is required in a matter referred to in section 18:

(a) in dental X ray imaging by using panoramic tomography X ray equipment, cephalostats or dental X ray equipment for imaging with an intraoral imaging receptor;
(b) in veterinary X ray examinations conducted with dental X ray equipment;
(c) the use of shielded X ray equipment in industry;
(d) in an aviation practice requiring a safety licence.

ANNEX II

PRACTICAL EXAMPLES OF APPLYING THE GRADED APPROACH IN THE AUTHORIZATION PROCESS

II–1 GREECE

The practices subject to authorization need to be justified first. A general flowchart for the authorization is shown in figure II–1. The methodology used in order to identify the practices that need to be registered or licensed or remain at the notification level is the one described in section 3.5.1.

More specifically, practices involving sources of category 5 are subject to registration. Sources in categories 1–4 are subject to licensing. X ray units used for non-medical exposure with tube potential less than 500 kV are registered while the ones with tube potential higher that 500 kV fall into the licensing regime. For unsealed sources the activity is used as a criterion for their classification. Taking the above into consideration the practices that are registered or licensed are shown in Tables II–1 and II–2. In the same Tables specific examples falling within the context of each row are given.

Following this classification, specific procedures have been developed for granting the authorizations (registration certificate or license). These procedures follow a graded approach the outline of which is shown in Table II–3. Specific detailed procedures have also been developed for each of the practices subject to registration or licensing.

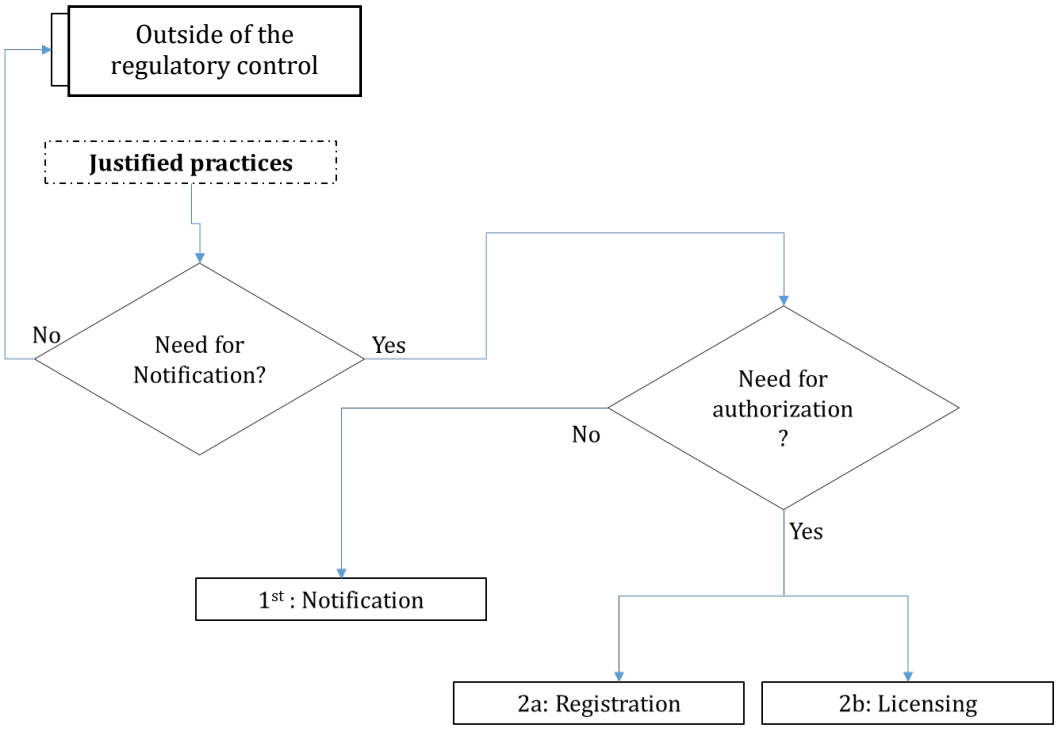

FIG. II–1. Flowchart for the authorization of justified practices

TABLE II–1. PRACTICES SUBJECT TO REGISTRATION

1	X ray generators used for medical exposure involving mammography, dental applications and bone densitometry and simple X ray radiography. Examples: – Intraoral, cephalometric or panoramic examinations – Dental CBCT examinations – Simple X ray examinations using fixed equipment in a clinic or hospital – Simple X ray examinations using portable equipment in a hospital (outside medical imaging departments) or in houses – Mammography inside a hospital or clinic – Mammography for screening purposes using portable equipment
2	Use of unsealed sources with activity up to 37 MBq for medical exposure and/or in vitro diagnostic examinations. Examples: – Immunoradiometric assays (IRMA) and conventional radioimmuno assays (RIA)
3	X ray generators (with tube potential <500 kV) used for non-medical purposes and more specifically for research, veterinary, industrial, educational and security purposes. Examples: – Use of X rays for animal diagnosis – Use of X rays for cargo screening – Use of X rays for the quality control of products in industry – Non-Destructive Testing (NDT) in industrial radiography inside or outside a facility – XRF/XRD analysis
4	Use of radioactive sealed sources of category 5 and unsealed sources with activity up to 37 MBq for non-medical purposes and more specifically for research, veterinary, industrial, educational and security purposes. Examples: – Use of sealed sources Category 5 for calibration purposes of imaging equipment – Use of Category 5 sources for measuring parameters such as density or thickness – Used of unsealed sources up to 37 MBq for research purposes

TABLE II–2. PRACTICES SUBJECT TO AUTHORIZATION

1	X ray generators (including accelerators) used for medical exposure and exposure for non-medical imaging (except those of point 1 subject to registration). Examples: – Computed Tomography – Mammography tomosynthesis – Image guided procedures for diagnostic or interventional purposes (implantation of pacemakers, defibrillation, ablation, PTCA, embolization) – Image guided procedures for diagnostic or interventional purposes outside the imaging department (orthopaedics, ERCP, lithotripsy) – Simulation for radiotherapy – External radiotherapy using X rays or electron beams – Intensity-modulated radiation therapy (IMRT), Image-guided radiation therapy (IGRT), Stereotactic radiosurgery (SSR), Stereotactic body radiation therapy (SBRT) using X ray beams – Total body irradiation – Brachytherapy using X rays

TABLE II–2. PRACTICES SUBJECT TO AUTHORIZATION, cont.

2	Use of radioactive sources for medical purposes and in vitro diagnostic exposure (except those of point 2 subject to registration). Examples: – External radiotherapy using sources in categories 1–4 – RIA and IRMA with total activity higher than 37 MBq – Stereotactic body radiation therapy using Co-60 – Brachytherapy HDR, MDR, seeds
3	Administration of radioactive substances to persons and animals for medical and veterinary purposes (diagnosis and therapy). Examples: – Imaging procedures in nuclear medicine SPECT/PET – Use of α, β, γ sources for therapeutic purposes in nuclear medicine therapy
4	Administration of radioactive substances in the production or manufacture of consumer products or other products, including medicinal products, and the import of such products. Examples: – Labelling and tracing of radiopharmaceuticals or other products for research purposes
5	X ray generators (with tube potential higher than 500 kV) and particle accelerators with particle energies less than 10 MeV used for purposes of research, veterinary, industrial, educational, sterilization and safety, excluding practices involving medical exposure. Examples: – Sterilization of medical and other products using X rays – Operation of X rays for container or vehicle control – External radiotherapy for animals
6	Use of radioactive sources in categories 1–4 for research, veterinary, industrial, educational, sterilization and safety purposes, excluding practices involving medical exposure. Examples: – Industrial radiography – Use of sources for metrology purposes
7	Production of radionuclides using particle accelerators and accelerators using energies higher than 10 MeV for research and industry purposes. Examples: – Linear accelerators for research purposes – Use of category 1 sources for sterilization purposes – Cyclotrons for radiopharmaceuticals production

TABLE II–3. BASIC OUTLINE OF THE PROCEDURES USED FOR THE REGISTRATION AND AUTHORIZATION

	Registration	**Authorization**
Information to be submitted:	- List of exposed workers - List of practices and relevant equipment - RPO per practice - Design features of the installation (including shielding features) - Radiological and safety report including (where applicable): • expected occupational exposures and public exposures and radiation protection measures; • maintenance, testing and regular inspection of equipment and operating conditions in general; • operational limits and dose constraints; • management of disused sources; • brief summary of the management of the radioactive waste produced, measures to dispose of such waste, accident analysis and emergency procedures.	- List of exposed workers - List of practices and relevant equipment - RPO per practice and Medical Physics expert if the practices involve medical exposure - Design features of the installation (including shielding features) - Radiological and safety report prepared by a radiation protection expert, including: • operational limits, dose constraints • radiological environmental impact study, where applicable; • expected occupational exposures and public exposures and radiation protection measures • individual monitoring and workplace monitoring programmes; • a programme of maintenance, testing and regular inspection of equipment and operating conditions in general; • radioactive waste management, including patient discharges, and measures to dispose of such waste where radioactive sources are used; • management of disused sources and measures to prevent any loss, material leakage, theft or unauthorized use of radioactive sources and materials; • accident analysis and emergency procedures; • probabilities and magnitude of potential exposures; • ways in which potential exposures or accidental and unintended medical exposures could occur; • quality assurance programme; • radiation protection measures and description of administrative procedures (in particular procedures relating to pregnant or breast-feeding workers); • records and record keeping procedures, especially for practices using unsealed and sealed sources.
Authorization period	Up to 10 years	Up to 5 years

TABLE II–3. BASIC OUTLINE OF THE PROCEDURES USED FOR THE REGISTRATION AND AUTHORIZATION, cont.

Authorization documentation include	– Regulatory requirements; – Authorized party's data; – List of sources and X ray units; – Dates of approval and deadline; – General reference to approval of the state of radiological protection and safety of the facility.	– Regulatory requirements; – Authorized party's data; – List of sources and X ray units; – Date of approval and deadline; – Specific conditions and reference to requirements in national legislation; – Reference to approval of the state of radiological protection and safety of the facility regarding: • shielding studies; • radiological and environmental impacts and radioactive waste management; • existence of necessary safety measures and warning devices; • education, information and training of exposed workers; • the existence of emergency procedures; • record keeping.

II–2 IRELAND

In Ireland there are two bodies that regulate practices and activities involving ionizing radiation. The Environmental Protection Agency (EPA) is responsible for the protection of workers and members of the public from harmful effects of ionizing radiation. Responsibility for protection of patients during the use of ionizing radiation rests with the Health Information and Quality Authority (HIQA).

A risk-based approach to authorization has been developed in Ireland which recognises the differing risks associated with activities involving sources of ionising radiation and reduces the regulatory and administrative burden for regulatory staff and those being regulated. The aim of the graded approach has been to ensure that the regulatory focus (e.g. in review and inspection) is placed on higher risk activities without compromising safety and security.

It was decided that higher risk applications will continue to be subject to licensing, with associated safety-related conditions, targeted inspection and a licensing period of ten years. Registration is associated with a less stringent level of control than licensing and is associated with lower risk practices that require less specific controls. A Certificate of Registration is issued indefinitely.

II–2.1 Model for Graded Approach to Authorization

Figure II–2 illustrates both the scope of notification (and the difference between generic and specific exemption in this regard) and the variation in types of authorization, as the magnitude and likelihood of exposures increase.

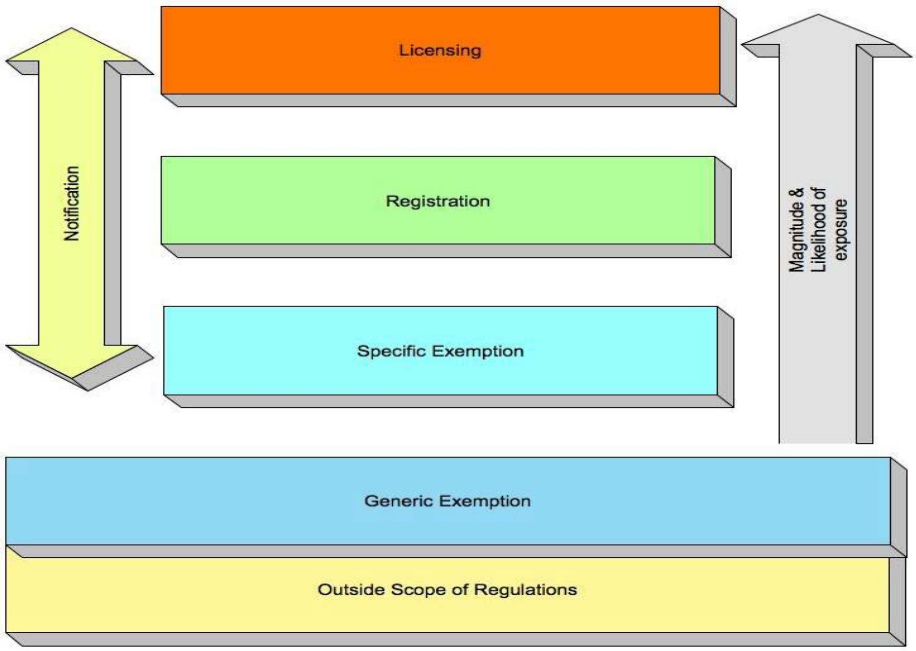

FIG.II–2. Illustration of the relationship between components of a graded approach to authorization

Generic exemption is considered, in this context, to apply to those practices that meet the activity concentration exemption levels specified in Schedule I of IAEA Safety Standard Series No. GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Standards [II–1], for which no notification is required.

Specific exemptions apply to practices that have been assessed by the regulatory body to be suitable for exemption, on the basis of the dose and risk criteria for exemption specified in Schedule I of GSR Part 3 [II–1].

II–2.1.1 Decision criteria for licensing

In order to determine whether licensing might be appropriate to practices other than those specifically defined in national legislation, an approach based on IAEA Safety Standards Series No. RS-G-1.9, Categorization of Radioactive Sources [II–2] was explored. Such an approach has been recommended as a possible approach for determining a graded approach to authorization. The categorization of sources is based on the potential danger posed to a person over given periods of time, for the purpose of making risk-informed decisions on the regulatory control of radioactive sources for the purposes of safety and security.

It was recognised that other factors might also influence whether practices need to be licensed, such as disposal considerations for sources no longer in use. However, this approach considered sealed sources only, and it was recognised that it might not be appropriate to apply such categorization to unsealed sources.

II–2.1.2 Evidence based analysis

The collection and analysis of evidence to determine whether there was a case for releasing a number of existing applications from some of the requirements for licensing was used in the development of a graded approach to authorization.

Specific analyses were undertaken for the purpose of decision-making and the structure of the evidence based papers were designed to provide the necessary information on the risks, control and regulatory measures for making decisions on the level of authorization that would be appropriate. A series of evidence-based analyses of the risks associated with the following applications was undertaken: Dental radiography; Veterinary radiography; DEXA; Cabinet X ray; and General and mobile X ray.

These analyses addressed the following pre-defined issues:

(a) Identification of the risks (both under normal operation and in the event of inadvertent exposures)
(b) Exposed groups (staff and members of the public)
(c) Magnitude and likelihood of exposures;
(d) Control measures in place to minimise risk (room design, training, PPE)
(e) Possibility and probability of accidental exposures
(f) Availability of Codes of Practice and other guidance
(g) Historical data and dosimetry
(h) Effectiveness of regulatory control (in reducing exposures further or improving safety of installations).

Example: Evidence Based Analysis of Risks for DXA Scanners

1. Application

DXA: This modality is used for measuring bone mineral density (BMD). DXA scanners can be categorised into two types: Central scanners and peripheral scanners.

Central Scanners: These scanners measure the BMD of the spine and hip. Central scanners can be further subdivided in accordance to the shape of the scanning X ray beam. These include, Pencil Beam, Narrow Angle Fan Beam, Wide Angle Fan Beam, Flash Beam and Cone beam scanners.

Peripheral Scanners: These scanners are small portable units which measure BMD in the forearm or heel. In general, it is to be noted that in addition to regulatory requirements for radiological protection, general health and safety legislation also applies and provides for employer and employee responsibilities and duties of care, and compilation of risk assessments and safety statements.

2. Description of source of ionising radiation

The units range in energy from 40kV to 140kV. Units designed solely for measuring BMD in a forearm or foot have energy range of 40–60kV, while the large units used for spines have an energy range of 80–140 kV.

The size of the X ray beam can be either a pencil, fan or cone beam. The pencil beam is older technology using a single detector while fan beam units use any array of detectors to image the object. Modern cone beam units utilise 2D digital radiographic detectors.

Scan times using a fan beam DXA scanner range from 30 to 60 seconds. DXA scanners using a pencil beam have scan times of 5–10 minutes. Cone beam scans take 1–2 seconds.

3. Persons at risk

Staff Members: Licensed DXA units in Ireland are in use in hospitals and private medical centres. Staff involved in carrying out DXA examinations may not normally receive any significant radiation dose provided normal radiation protection measures are employed. As well as good working procedures, these measures include a consideration by the Radiation Protection Adviser (RPA) of room design, size and layout, shielding and policies relating to the wearing of lead aprons and personal dosimeters, if necessary. Staff members typically include radiographers, radiologists, health care personnel and porters.

Members of the Public: All general X ray rooms have to be designed to ensure that the design dose constraint (0.3 mSv/year) is not exceeded. That is, that no member of the public can receive a dose in excess of 0.3 mSv in a year noting that the dose limit for a member of the public is 1mSv. Under the current regulatory framework, general X ray rooms have to be assessed for suitability by an approved RPA. In this assessment RPAs take account of the projected workloads of the X ray units, distances to boundaries, boundary materials, beam direction and occupancy of adjoining areas. The assessment is used to identify any additional shielding or procedures needed in order to ensure safety.

4. Identification of risks

A summary of the risks associated with DXA scanners is shown in Table II–4.

TABLE II–4. RISKS ASSOCIATED WITH DXA SCANNERS

Hazard	**Persons at risk**	**Method of reducing risk from hazard (Control Measures)**	**Residual Risk from Hazard***
Exposure from primary and scattered radiation	Staff in adjacent rooms	Adequate training in radiation protection. Training provided from the manufacturer and/or supplier in the correct use of the DXA scanner. Maximising distance between source of radiation and staff. The controlled area is clearly defined. Use of protective lead screens where necessary e.g. in small rooms where the operator of the scanner cannot be outside the controlled area when taking an exposure. Appropriate design of facility. RPA consulted at planning stages of facility. Adherence to the design code of practice and Radiation Safety Procedures (if necessary) Appropriate design of facility	Low**
Exposure due to inadvertent entry into controlled area	Staff and members of the public	Signage and warning lights, where appropriate Room access controlled during exposure Staff training	Low
Exposure due to inadequate design of facility	Staff and members of the public	Consultation with RPA at design stage and before any major modifications of the room	Low
Exposure due to equipment error	Staff and members of the public	This is not a foreseeable occurrence. Regular in-house quality control programme implemented to ensure quality of performance. In-built software needed a daily calibration check to be passed before the unit can be used.	Low
Prevention of loss or theft of equipment	Members of the public	Security of premises. Peripheral scanners will only be used in designated locations where a risk assessment has been conducted.	Low

* Note the residual risk considered for reasonably foreseeable hazards under normal operation once the control measures have been implemented.
** Low risk definition: Where the detrimental *health effects* of *exposure* to *radiation* (including the likelihood of such effects occurring) is considered minimal. In general terms a low risk scenario is one where protection is optimized such that occupational risks may no longer be significant. In terms of dose it would be unlikely that any of the hazards identified with control measures in place would result in a dose in excess of 1 mSv.

5. Historical dosimetry data

The regulations do not require the operators of DXA scanners to use personal dosimetry. It has been deemed unnecessary due to the low scatter doses associated with this type of practice. The occupational exposure to the scanner operator depends upon the type of scanner, the workload and the relative position of the operator to the scanning table. Dose monitoring has been conducted by a number of licence holders of DXA scanners using TLDs positioned at the operator table. All results from these studies have shown that there have been no recorded doses on these TLDs. In addition, where personal monitoring has been performed on staff using these scanners, no doses were recorded.

It has been reported that the scatter dose rates at 1m from the central axis of the patient table range from a few tenths of a μSv/h to 5 μSv/h depending on the scanner model. From these values, recent studies indicate that the annual effective dose for an average workload (20

patients/day) at 1m from the scanner will be between 0.1 and 1.5 mSv depending on the model of the scanner.

In practical terms, the scanner operators' desk needs to be positioned at least 1m away from a pencil beam, and at least 2m from a fan beam scanner. Some older models, that are not now common, need a distance of 3.5 m. In the case of fan beam and cone beam configurations or if the distances above cannot be accommodated, the use of protective screens may be considered.

Further to a review of the reportable doses submitted by authorized parties from 2006 to 2012 it was noted that there have been no reported doses to staff directly involved with the use of DXA scanners.

6. Availability of Codes of Practice and other guidance

There is no specific Code of Practice for the use of DXA scanners, and one is not expected to be produced. A guidance document will be issued by the EPA to provide guidance on the development of radiation safety procedures and a radiation risk assessment. It will also include practical elements of radiation protection which would include consideration of the ALARA principle and the use of distance to determine the optimum operator position. The guidance document will include reference to the following EPA documents:

- "Design Code for Diagnostic Medical Facilities where Ionising Radiation is used" (2009);
- "Guidelines for reporting radiological incidents to the Radiological Protection Institute of Ireland" (2009).

The applicant also has to have simple local rules which will cover operational procedures including use of mobile lead screen if necessary.

7. Regulatory requirements for registration

The EPA's "Design Code for Diagnostic Medical Facilities where Ionising Radiation is used" (2009) is to be followed.

The EPA's "Guidelines for reporting radiological incidents to the Radiological Protection Institute of Ireland" (2009) is to be followed.

Consultation with the RPA is required during the design stage of the facility. There is no need for full-time appointment of an RPA.

EPA to be notified of any proposals to change any aspects of the registration prior to these changes taking effect.

The regulations contained in Statutory Instrument No. 125 of 2000 and the Radiological Protection (Amendment) Act, 2002 are to be complied with.

8. Conclusions

Although the practice of DXA scanning could probably be considered as a candidate for notification only, it has been decided that it is more appropriate for this practice to be authorized by registration. The regulatory body has conducted 11 inspections – of DXA practices between 2009 and 2011 and there have been no concerns raised over radiation safety. This confirms that the use of DXA units is very low risk and supports the decision for authorization by registration.

The regulatory body has given consideration to this evidence based analysis of risks for DXA scanners and has approved this assessment.

9. Effectiveness of regulatory control

Considering the low doses associated with the use of DXA scanners and the details contained within this analysis, it is difficult to see that doses would increase or that the safety of installations be compromised by changing from authorization by licensing to authorization by registration. A similar approach was taken with remaining ionising radiation applications and a regulatory decision was made as to whether these applications continued to be authorized by licensing or were subject to registration.

II–2.1.3 Decision criteria for registration

A series of questions that could be applied as high level criteria for authorization by registration were developed, as follows:

- Does the facility and/or equipment design ensure safety?
- Are operating procedures simple to follow?
- Are the safety training requirements minimal?
- Is there a history of few problems with safety in operation?
- Is safety largely/significantly independent of human activity?
- Could the application be addressed in generic risk assessment?

These criteria were used to perform an initial screening review of the range of applications that take place in Ireland to determine whether the criteria helped to identify those applications that might be candidates for a less rigorous level of authorization under a graded approach to authorization. The additional issues of security and the mandatory provisions of Ref. [II–3] for the licensing of some practices were taken into account.

These initial criteria were further developed into a series of more specific questions. These questions also address the mandatory licensing criterion (referred to in section 4.2.5.1) and the potential for specific exemption. For each application type the following points were considered:

- Can this application be granted a specific exemption from authorization (potential doses to staff less than 1 mSv in a year)?
- Does this application come under the list of applications requiring mandatory licensing in Ref. [II–3]?
- Are operations relatively constant over time?
- Are the radioactive sources and radiation generators and other ancillary equipment designed and manufactured to national and international standards?

- Are the facilities (buildings housing the sources/radiation generators) designed and manufactured to national/international Standards?
- Do staff operating the radiation sources/radiation generators need radiation safety training?
- Do staff operating the radiation sources/radiation generators follow a set of operating procedures?
- Can the design/manufacture of the radiation sources/radiation generators alone restrict the potential radiation doses to exposed workers to less than 6 mSv in a year?
- Can the operator of the radiation sources/radiation generators give rise to exposure situations where the potential doses to exposed workers is greater than 6 mSv in a year?

Figure II–3 illustrates a summary of the decision criteria which determines the appropriate regulatory approach

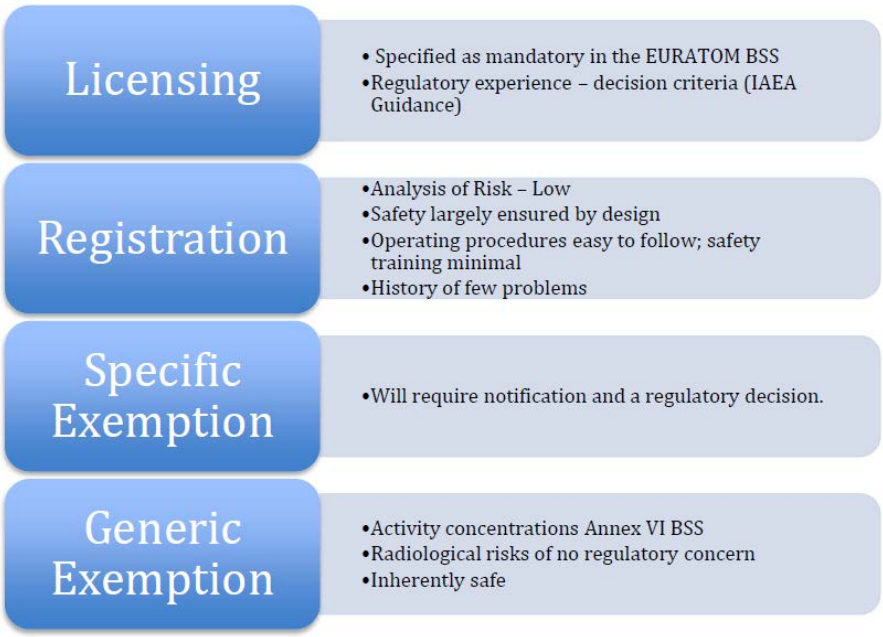

FIG.II–3. A summary of the decision criteria which determines the appropriate regulatory approach.

II–2.1.4 Applying for a licence or registration

Registration and licensing in Ireland are now administered using a web-based system. Potential users of radiation sources are required to inform EPA of their intention to undertake one or more of a pre-defined list of practices. The online tool will determine whether registration or licensing is the appropriate level of authorization, according to the practice selected. Tables II–5 and II–6 set out Ireland's list of practices that are subject to registration and licensing.

TABLE II–5. PRACTICES SUBJECT TO REGISTRATION IN IRELAND

Sector	Practice
Medical	General radiography giving rise to a medical exposure in a medical radiological installation
	Bone densitometry giving rise to a medical exposure
	Mammography giving rise to a medical exposure
	Specimen radiography for medical purposes
	Dental radiography using an intra/extra oral unit (except handheld)
	Dental cone beam CT
Dental	Dental radiography using an intra/extra oral unit (except handheld)
	Dental cone beam CT
Veterinary	General veterinary radiography carried out in a risk assessed veterinary clinic
Industry	Product inspection/industrial radiography using cabinet X-ray systems
	Use of laboratory equipment incorporating sealed sources
	Use of XRF or XRD equipment
	Installation/servicing of radiological equipment
	Security screening of baggage, cargo or parcels using X rays within shielded enclosure
	Security screening for explosive vapour detection using sealed sources
	Carriage of sources other than High Activity Sealed Sources
Security	Security screening of baggage, cargo or parcels using X ray within shielded enclosure
	Security screening for explosive vapour detection using sealed sources

TABLE II–6. PRACTICES SUBJECT TO LICENSING

Sector	Practice
Medical	Radiotherapy using a LINAC in a medical radiological installation
	Radiotherapy using brachytherapy in a medical radiological installation
	Radiotherapy using X rays in a medical radiological installation
	Interventional radiology giving rise to a medical exposure in a medical radiological installation
	CT giving rise to a medical exposure in a medical radiological installation
	Mobile radiography or fluoroscopy giving rise to a medical exposure in a medical radiological installation
	Fluoroscopy giving rise to a medical exposure in a medical radiological installation
	Nuclear medicine giving rise to a medical exposure in a medical radiological installation
	PET/CT giving rise to a medical exposure in a medical radiological installation
	Dental radiography using handheld intra oral unit
	Product irradiation or sterilisation using high activity sealed sources
Dental	Dental radiography using a handheld intra oral unit
Veterinary	Veterinary nuclear medicine
	Veterinary fluoroscopy
	Veterinary radiography using CT
	General veterinary radiography performed in the field
Industry	Use of unsealed sources in industry and laboratories
	Use of sealed sources in industry
	Use of nuclear moisture density gauges
	Use of high activity sealed sources in geophysical exploration[1]
	Radiopharmaceutical production in a cyclotron
	Product irradiation or sterilisation using high activity sealed sources
	Product irradiation or sterilisation using electron beams
	Industrial radiography using X ray systems[1]
	Industrial radiography using high activity sealed sources
	Assembly or manufacture of devices incorporating sealed sources
	Industrial use of medical radiological equipment
	Transport of high activity sealed sources[2]
	Supply and distribution of radioactive sources[3]
Security	X ray system for cargo or container screening of vehicles
Education	Use of ionising radiation in tertiary education

Notes:

1. Practices involving the use of radioactive sources on-site are generally considered to include transport of sources to and from the site. In such circumstances the activity of sources being transported is included under the source inventory, but it is not necessary to include transport as a separate practice.
2. The practice of “transport of radioactive sources” includes temporary storage of sources while in transit.
3. The practice of “supply and distribution of radioactive sources” includes all related ancillary activities such as collection, temporary storage, importation, exportation, shipment to or from the state (for EU countries), logistics, etc. This may apply to the supply of new sources and/or the collection of disused sources.

REFERENCES TO ANNEX II

[II–1] EUROPEAN ATOMIC ENERGY COMMUNITY, FOOD AND AGRICULTURE ORGNIZATION 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, General Safety Requirements Part 3, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014).

[II–2] INTERNATIONAL ATOMIC ENERGY AGENCY, Categorization of Radioactive Sources, IAEA Safety Standards Series No. RS-G-1.9. IAEA, Vienna (2005).

[II–3] Council Directive 2013/59/Euratom of 5 December 2013, laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, Official Journal of the European Communities No. L 13, Office for Official Publications of the European Communities, Luxembourg (2014).

ANNEX III

PRACTICAL EXAMPLES OF APPLYING THE GRADED APPROACH IN THE INSPECTION PROCESS

III–1 GREECE

The elements of the inspection process in which a graded approach is applied are mainly the inspection programmes for different types of facility and activity and the inspection plans for specific types of facility and activity.

For a non-nuclear country like Greece, the facilities and activities for the inspection process are divided into the following two categories and subcategories:

Medical category:

- Radiotherapy (both teletherapy and brachytherapy) facilities;
- Diagnostic radiology facilities including interventional radiology departments as well as non-imaging departments where fluoroscopically guided practices are performed;
- Nuclear medicine (including therapy) facilities.

Non-medical category:

- Industrial radiography facilities;
- Research and education centres;
- Industrial facilities.

The activities performed in the above facilities and the sources that are used are authorized by registration or licensing. However, the inspection process is not linked with the authorization process.

For all medical facilities (apart from radiotherapy) an institutional project on national level has been performed within which the dosimetric parameters of various medical procedures were measured and the results were used to calculate the effective dose. Based on the results of this project the inspection frequencies have been determined. For the radiotherapy facilities the frequency for programmed inspections has been set to five years (taking also into account security aspects).

Moreover, analysis of the levels of occupational exposure extracted from the national dose registry were taken into account for the development of the inspection programme.

The method for developing the inspection programme is reviewed every five years. Security issues are included in the safety inspections, where applicable. The inspection programme is developed every year based on the frequencies in Tables III–1 and III–2.

TABLE III–1: INSPECTION FREQUENCIES FOR DIFFERENT PRACTICES FOR MEDICAL FACILITIES

Types of practice performed in facilities	Frequency of inspection
Mammography	5–7 years
Dental radiography	
Bone density measurements	
Simple X ray radiography	
in vitro diagnostic examinations	
Radiotherapy (including simulator)	4–5 years
Interventional radiology	
CT scans	
Nuclear medicine for diagnostic purposes	1–3 years
Nuclear medicine for therapeutic purposes	

TABLE III–2: INSPECTION FREQUENCIES FOR DIFFERENT PRACTICES FOR NON-MEDICAL FACILITIES

Types of practice performed in facilities	Frequency of inspection
Industrial radiography with sealed radioactive sources	1–2 years
Industrial radiography with X ray units	3–5 years
Industrial facilities using radioactive sources	3–5 years
Industrial facilities using X ray units	5–7 years
Transport of radioactive material	1–2 years

The above frequencies are linked with the number of resources allocated for implementing the inspection programme. The priorities for its implementation are based on risk and geographical criteria (number of facilities to be inspected per country region) as well as on historical data. Provision for conducting reactive inspections are also considered in the annual inspection programme. The number of reactive inspections is a percentage of the inspections performed in each category as set on annual basis and included in the monitoring programme of the key indicators of the inspection process.

The inspection plan is developed in a way to satisfy the objectives set by the regulatory body within its management system and is linked with the resources allocated. The set of questions, the method of conducting the inspection, the collection of data, the identification of non-compliances, and the follow up procedures are actions related to the inspection plan and are linked to the categories shown in Tables III–1 and III–2. For example, the conduct of the inspection for mammography units and for industrial facilities are different. For mammography, the inspection involves observation of the practice, operation of the equipment and interviews with personnel, while in industrial facilities the inspection also includes examinations of procedures and records, and tests of security systems.

III–2 CANADA

In Canada, facilities and activities are regulated by the Canadian Nuclear Safety Commission (CNSC), and specifically the Directorate of Nuclear Substance Regulation. The Canadian example of risk-analysis does not include considerations of X ray machines or of medical exposure of patients or, as these are outside of the CNSC's mandate, and regulated by other federal or provincial organizations.

Different types of activity are licensed by 'use-type', meaning that they are distinguished by the purpose for which the licence has been issued. Examples of use-types include diagnostic nuclear medicine, industrial radiography, portable gauges, and fixed gauges.

Risk ranking of licensed activities in the Directorate of Nuclear Substance Regulation is an important exercise in determining the regulatory effort that need to be spent on any given use type. In general, the higher the risk of the licensed activity, the more effort that need to be expended to ensure the licensee is operating safely. This applies to both licensing (programme expectations and review) and compliance activities (types and frequency of inspections).

In the context of authorization, it may be used to determine the effort and technical expertise needed to ensure that regulatory expectations are satisfied by the licensee or the applicant. Hence, a graded approach is applied whereby expectations for licence applications are generally greater for higher risk activities.

III–2.1 Safety and Control Areas

In order to examine this risk for all the different use types, a set of criteria had to be developed under this main risk heading. It was decided that the most logical criteria to use when defining the risk of a particular activity need to be based on Safety and Control Areas (SCAs), which would allow for the risk to health and safety to be divided into manageable categories.

SCAs form a framework used by the CNSC to assess, review, verify and report on regulatory requirements and performance across all regulated activities and facilities. This framework is used throughout the CNSC's regulatory processes. The SCAs are:

1. Management system;
2. Human performance management;
3. Operating performance;
4. Safety analysis;
5. Physical design;
6. Fitness for service;
7. Radiation protection;
8. Conventional health and safety;
9. Environmental protection;
10. Emergency management and fire protection;
11. Waste management;
12. Security;
13. Safeguards and non-proliferation;
14. Packaging and transport.

For each use type, each SCA was assessed taking into account the impact of non-compliance on health and safety and the probability of non-compliance and a total score was determined. Scores for magnitude and probability were derived based on expert judgement and group

consensus. Each of the divisions within the directorate was represented by a senior staff member with extensive experience in licensing and/or compliance. In addition, less senior staff were part of the working group to bring a different perspective to the discussions. The final scores were agreed to by consensus within the working group.

The impact of non-compliance on health and safety in a particular SCA was assigned a ranking of significant, moderate or minor as defined below:

- *Significant Impact* - High impact on health and safety of the public, workers and the environment (e.g. whole body dose in excess of the regulatory limit defined in the Radiation Protection Regulations).
- *Moderate Impact* - Moderate impact on health and safety of the public, workers and the environment (e.g. action level as defined in a radiation safety programme is exceeded).
- *Minor Impact* - Low impact on health and safety of the public, workers and the environment (e.g. administrative deficiency)

The probability of non-compliance in a particular SCA was assigned a ranking of high, moderate or low and was based on the past performance of a given use type in this area. This ranking was determined through discussions amongst subject matter experts where anecdotal evidence about performance and events were discussed.

For each SCA, the impact and probability were each assigned a corresponding number (3, 2, or 1). The product of the two determined the overall risk rank for that given SCA within that use type. The risk rankings for each of the SCAs were totalled to give an overall ranking. The assumption was made that higher risk rankings involve higher regulatory effort. Table III–3 illustrates the resultant regulatory effort needed on a risk-informed basis.

TABLE III–3: REGULATORY EFFORT MATRIX

Impact on H&S	Regulatory Effort Needed		
Significant Impact 3	**3**	**6**	**9**
Moderate Impact 2	**2**	**4**	**6**
Minor Impact 1	**1**	**2**	**3**
Probability of Non-Compliance	Low 1	Moderate 2	High 3

It is expected that the high regulatory efforts (score of 6 or higher; indicated in red in the matrix in Table III–3) across all 12 SCAs would yield a final score of 72 or higher, therefore all use types with a score of 72 or higher would be considered highest priority and deserving of the highest regulatory effort. Similarly, low regulatory effort (indicated in blue in the matrix) in each of the 12 SCAs would result in a final score of 24 or less, therefore all use types with a final score of 24 or less will receive the least amount of regulatory effort.

III–2.2 Other considerations

Outside of the probability and impact of non-compliances within each SCA, the team also looked at three additional factors that could potentially affect the risk ranking of a use type as a whole. The three areas considered were event frequency, security of sources and complexity of the licence.

- *Event Frequency* - The team examined five years of data regarding numbers of events reported per use type normalized to the number of licensees in each of the use types. Data trending showed that those use types ranked higher risk tended to report more events, and therefore incorporating events into the analysis would not change the risk ranking.
- *Security of Sources* - Although it is out of scope of this TECDOC, security of sources was also considered.
- *Licence Complexity* - The final factor examined as part of this review was the effect of complexity on the risk of a use type. Many issues that might arise due to the complexity of a licence are inherently built into the regulations and guides – the more complex a programme is, the more extensive the regulatory requirements are. Complexity is something that is licensee-specific as opposed to use type-specific and could act as a driver for more program-specific inspections.

In all three areas, it was deemed that the analysis did not warrant a change in use type risk ranking, that the information was captured in an existing SCA or that the area was not something to be considered at the use type level.

III–2.3 Conclusion

The overall risk ranking can be found in Table III–4. The risk ranking provides a relative order of suggested regulatory effort and subsequently informs the regulatory effort expended.

The risk assessment of the various use types will affect the decision making process with regards to regulatory oversight for licensees. The methodology used to risk rank the use types was a combination of approaches. Revised risk ranking of all use types were developed based on the impact of non-compliance on health and safety and on the probability of non-compliance within each of the selected SCAs.

The relative risk ranking presented in this document will be used as a component in determining the regulatory oversight of all Directorate of Nuclear Substance Regulation licensees. Regulatory oversight plans include other components such as compliance history, licence complexity, event frequency, quality of submissions and regulatory body resources.

TABLE III–4. EXAMPLES OF THE RESULTS OF RISK RANKING OF USE TYPES

USE TYPE Description	**RISK CATEGORIES**															Overall Risk Score
	Safety Analysis	Conventional Health and Safety	Environmental Protection	Radiation Protection	Waste Management	Packaging and Transport	Human Performance Management	Management Systems	Operating Performance	Emergency Management	Safeguards and non-proliferation	Security	Physical Design	Fitness for Service	Other Matters of Regulatory Interest	
Industrial Radiography	n.a.	n.a.	0	9	0	6	9	9	9	9	6	9	6	9	n.a.	81
Logging Sealed Source	n.a.	n.a.	0	9	0	9	6	6	9	9	6	9	6	4	n.a.	73
Operate Isotope Production Accelerator	n.a.	n.a.	4	6	6	6	6	6	6	3	0	4	6	9	n.a.	62
Portable Gauges	n.a.	n.a.	0	6	0	3	3	9	9	6	0	4	2	4	n.a.	46
Nuclear Medicine Diagnostic	n.a.	n.a.	1	6	2	3	2	9	6	6	0	3	4	1	n.a.	43
Therapeutic Nuclear Medicine	n.a.	n.a.	2	6	2	1	2	9	6	6	0	3	4	0	n.a.	41
Manual Brachytherapy	n.a.	n.a.	1	3	3	3	6	6	6	3	0	3	0	0	n.a.	34
Operate Mobile Accelerator	n.a.	n.a.	0	6	0	0	6	6	6	1	0	1	0	3	n.a.	29
Static Elimination	n.a.	n.a.	0	1	0	1	1	1	2	3	0	2	0	1	n.a.	12
Radioactive Check Sources	n.a.	n.a.	0	1	0	1	1	1	2	3	0	2	0	0	n.a.	11

Legend:

- Risk Ranking Low (White) - Overall Risk Score < 24
- Risk Ranking Moderate (Green) - Overall Risk Score 25 - 71
- Risk Ranking High (Red) - Overall Risk Score > 72

ANNEX IV

PRACTICAL EXAMPLES OF APPLYING THE GRADED APPROACH IN ENFORCEMENT

IV–1 CANADA

The Canadian Nuclear Safety Commission (CNSC) uses a graduated enforcement strategy in responding to non-compliance with regulatory requirements. This strategy is part of a wider graded approach to regulation, as shown in Fig. IV–1. This strategy is applied using a handbook that inspectors can bring with them into the field. This handbook describes the graduated approach that the CNSC uses when responding to non-compliance. General considerations for the selection and use of each response are provided, along with the level(s) of authority needed for their use and any special considerations that might apply.

When non-compliance has been identified, the CNSC's graduated enforcement strategy provides staff with the flexibility and discretion to select from a broad spectrum of options to restore compliance.

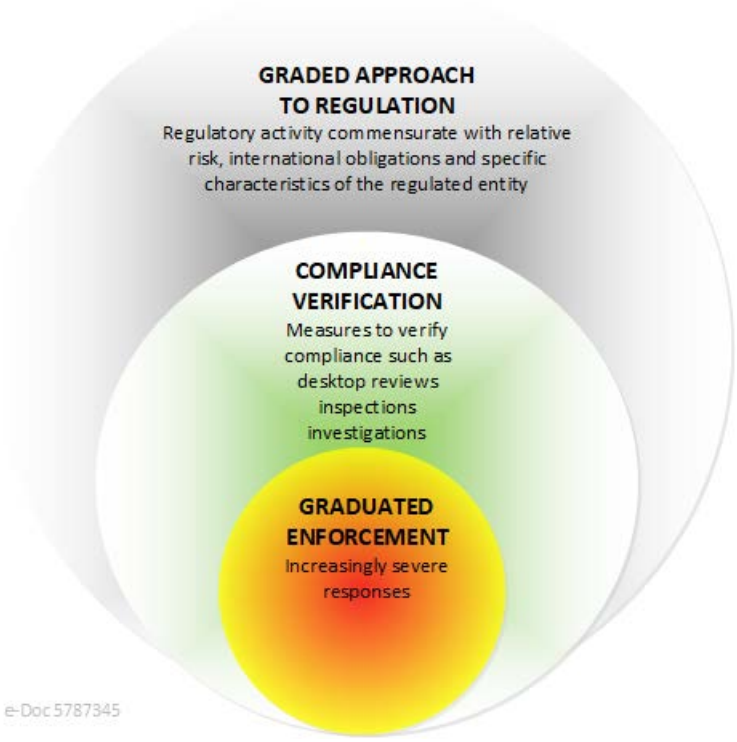

FIG. IV–1. Graduated enforcement within the graded approach to regulation (courtesy of CNSN)

The CNSC has established an integrated set of tools for influencing compliance awareness and responding to non-compliance. With this agile approach, CNSC staff are able to choose the appropriate instrument or combination of instruments to address the issues raised in any specific situation. Figures IV–2 and IV–3illustrate how the tools in the CNSC's graduated enforcement strategy fit together.

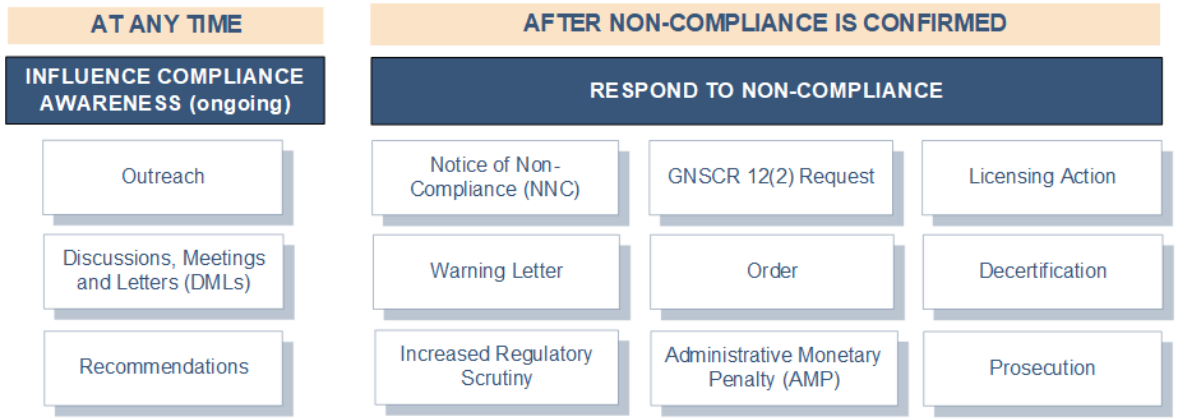

FIG. IV–2. Tools for applying the graduated enforcement strategy (courtesy of CNSN)

A Notice of Non-Compliance is a written notice from the CNSC requesting that the licensee take the necessary action(s) to correct non-compliance.

Warning Letters notify a licensee's senior management of unresolved non-compliance and informs them that CNSC management is aware of the situation.

Increased Regulatory Scrutiny means increasing regulatory oversight of a particular facility or activity beyond baseline compliance verification activities.

Request under subsection 12(2) of the *General Nuclear Safety and Control Regulations* (GNSCR 12(2)), often referred to as a "12(2) request," is a legal instrument to which the licensee has to respond. A licensee who receives a 12(2) request is legally required to provide the requested information within the time specified.

An Order is a powerful legal instrument used to compel a person or licensee to take any measure considered necessary to protect the health and safety of persons and the environment, and to maintain national security and compliance with Canada's international obligations.

An Administrative Monetary Penalty (AMP) is a monetary penalty imposed by the CNSC in response to a violation of a regulatory requirement.

A Licensing Action is considered an enforcement response only when it is taken by the Commission on its own motion to review, suspend in whole or in part, amend, revoke, or replace a licence.

Decertification is the revocation of certification of persons carrying out prescribed duties, prescribed equipment, or the packaging and transport of nuclear material. The legal basis for decertification is provided in the national legislation.

Prosecution is the laying of charges against a person for an offence under an act.

When determining which response is most appropriate, staff may consider any service line-specific strategies, as applicable. The goal is to determine the response(s) that would be most likely to result in restoring compliance as quickly and effectively as possible, taking the following considerations into account:

- The regulatory significance of the non-compliance;
- The circumstances that led to the non-compliance;

- The entire compliance history of the regulated party;
- Any operational and legal constraints;
- Any industry-specific factors.

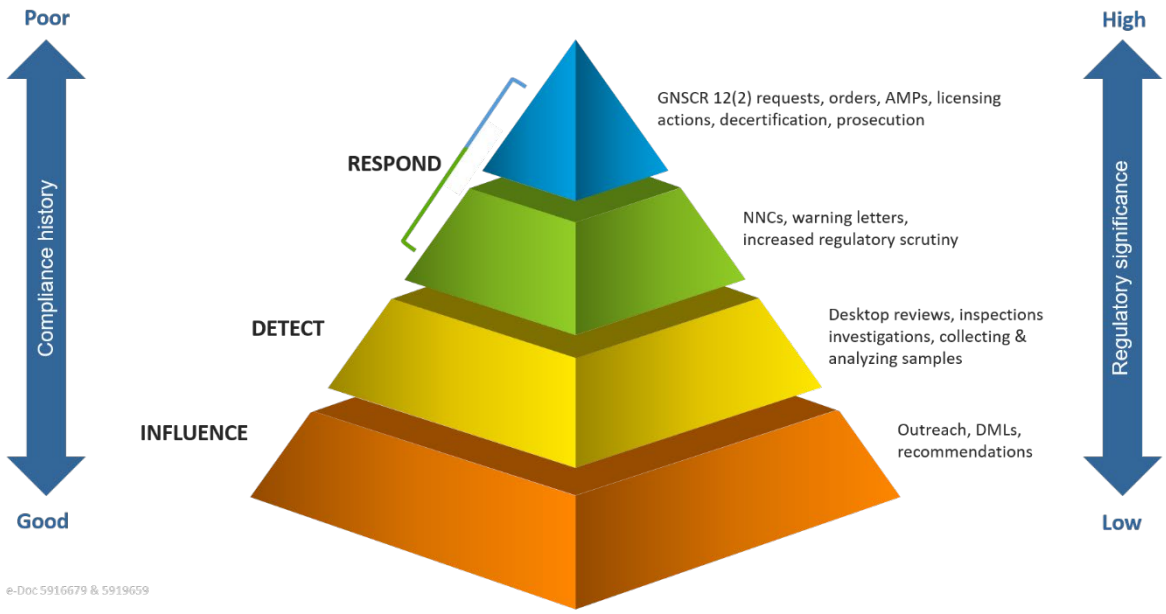

FIG. IV–3. Toolbox continuum (courtesy of CNSN)

For each tool, the handbook includes a description of the tool, when it may be selected, how it needs to be applied and by whom, as well as any special considerations. For example, an inspector considering the issuance of an order would find the following information in the handbook:

(1) A description of what an order is and guidance on when to select it as enforcement action.
For example, "With respect to responding to non-compliance, orders are typically selected in response to issues identified during inspection or during events or emergencies. They may also be considered when previous CNSC responses have been ineffective in restoring compliance and concerns of regulatory significance have arisen as a result. An order may be issues in conjunction with another enforcement action."
(2) Who can issue an order, including references to the relevant legislation.
(3) How the order needs to be applied. For example, "The terms of an order should be commensurate with the regulatory significance associated with the non-compliance, and might include restricting the use of certain equipment, restricting certain parts of a licensee's operation, conducting specific tests or retraining employees."
(4) Special considerations regarding orders, including:
   – Guidance on when to consult legal services;
   – Reference to a document to help with the drafting of orders.

IV–2.1 Enforcement principles

In deciding an enforcement action in a given set of circumstances, unless otherwise mentioned by legislation, the guiding principles set out in Fig. IV–4 are taken into consideration.

FIG. IV–4. Enforcement principles

Risk-based - Enforcement work is risk-based, focusing resources and regulatory action on activities that pose a risk to human health and/or the environment.

Proportionality - Enforcement action taken is proportionate with the risk posed to human health and/or the environment, the damage already caused, and the costs of remedial works. Enforcement action is also considered where there are persistent regulatory breaches.

Consistency - The Environmental Protection Agency (EPA) has systems which provide consistency in the approach to the use of enforcement powers and in deciding the appropriate enforcement response. This means the public, the regulated community and other stakeholders know what to expect from the regulatory body. The EPA promotes consistency nationally through effective liaison with those regulated and other regulatory authorities.

Transparency - Compliance within the regulated community is promoted by the regulatory body being clear and open about what is expected of them in terms of regulatory requirements and compliance and what they may expect from the regulatory body in terms of regulatory oversight. The EPA publish inspection activities and enforcement report annually.

Polluter pays - The EPA works to ensure that polluters are held financially accountable for their actions, that they do not profit from illegal activity and that they do not gain a competitive advantage over law-abiding operating organizations.

IV–2.2 Compliance actions and enforcement powers

The EPA has a wide range of enforcement powers, including statutory enforcement powers. These powers are utilised in enforcing regulatory requirements, promoting compliance and achieving good environmental outcomes. These powers include:

(a) *Support, advice and guidance:* Clear guidance is published outlining what is expected from the regulated community. The EPA supports other enforcement bodies through networks and compliance promotion events such as conferences.
(b) *Inspections*: Authorized parties are inspected using a risk-based approach to focus on poorly performing or high-risk activities. EPA Inspectors have the power to enter and to seize objects/substances.
(c) *Warning letters*: Warning letters can be issued where non-compliances are discovered.
(d) *Statutory notices, directions and penalties*: Statutory notices, enforcement notices, fixed penalty notices or mandatory penalties and directions can be issued to achieve compliance.
(e) *Prosecution:* A prosecution can be initiated summarily in the District Court or, in more serious cases, through the Director of Public Prosecutions with a view to prosecution on indictment. Where an offence is committed by a body corporate, the company and its officers can be prosecuted.
(f) *Civil actions:* The EPA can apply for court orders or injunctions to have works undertaken or an activity ceased; the EPA can intervene directly to carry out works on a site and recover the costs.
(g) *Revocation or suspension of licences*: The EPA has the power to revoke or suspend a licence in full or in part, and the power to suspend a process at a licensed facility.

IV–2.3 Criteria considered in determining enforcement action

The EPA's enforcement principles are considered when deciding which enforcement action to take. The EPA decides which enforcement action can deliver the best outcome for the environment and human health by considering the urgency of the situation and the public interest in environmental protection.

In deciding which enforcement action to take, the following criteria is considered:

(1) The impact or potential impact of the breach on human health or the environment, which includes:
   – Seriousness of the non-compliance – the harm or potential harm to human health or the environment;
   – The duration of the non-compliance.
(2) The behaviour of the individual or organization responsible for the breach, including:
   – Evidence of intention (if any) behind the regulatory non-compliance;
   – History of compliance or non-compliance;
   – Financial gain made as a result of non-compliance with regulations; or
   – Conduct after the non-compliance is discovered.

Having considered the principles, criteria and enforcement powers available, it is decided on a case-by-case basis which enforcement action to take. Where necessary the enforcement response is escalated if previous sanctions have failed to achieve the desired outcome.

A prosecution or higher sanction will normally be considered in the following circumstances:

– Incidents or breaches that have significant consequences for human health and/or the environment, or have the potential for such consequences;
– Carrying out activities without a relevant authorization from the EPA;
– Excessive or persistent breaches of regulatory requirements;

- The use of unauthorized waste disposal facilities or waste recovery facilities;
- Failure to comply with statutory notices;
- Failure to supply information without reasonable excuse, or knowingly or recklessly supplying false or misleading information;
- Obstruction of EPA inspectors or other authorized persons carrying out their legitimate functions or using threatening behaviour or assault.

IV–2.3 Communication of compliance and enforcement activities

The policy of the EPA is to make our compliance and enforcement activities available and accessible to the public. We communicate and engage with the public, stakeholders and the regulated community to ensure that they can be involved in decision making that affects their health and their environment, and to highlight key environmental issues and priorities.

In communicating our inspection and enforcement activities, the EPA publish annual inspection activities and enforcement reports in addition to guidance to promote compliance.

ANNEX V

PRACTICAL EXAMPLES OF APPLYING THE GRADED APPROACH IN COMMUNICATION AND CONSULTATION

V–1 CANADA

In 2008 and 2009, CNSC staff observed a high-level of non-compliance amongst licensees with portable gauges (see Figure V–1). CNSC staff formed a working group in 2010 to develop a unified strategy for outreach to licensees with portable gauges to promote a positive safety culture, to improve communication between the CNSC and the licensees, to improve licensee's compliance with regulatory requirements, and to encourage the safe use of portable gauges in the field.

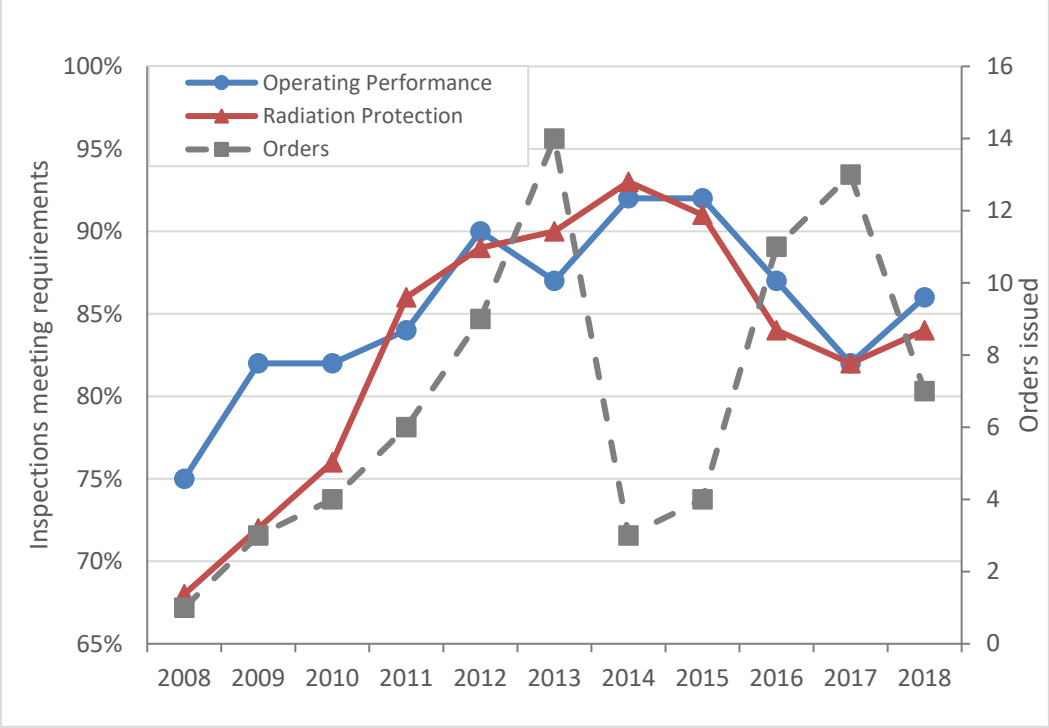

FIG. V–1. Performance of licensee with portable gauge, 2008–2018[3]

The portable gauge working group developed the following methods of communication and consultation in an attempt to increase compliance:

V–1.1 Outreach program

In the summer of 2014, CNSC staff launched a workshop with licensees with portable gauges in Mississauga with the focus on providing Radiation Safety Officers (RSOs) with information on licensing and compliance expectations. Based on the feedback received at this initial session, CNSC staff developed a suite of six presentations:

- Portable Gauge Logistics and Introduction;
- Radiation Protection and Assessment of Doses;

[3] An Order is a powerful legal instrument used to compel a person or licensee to take any measure considered necessary to protect the health and safety of persons and the environment, and to maintain national security and compliance with Canada's international obligations.

- Compliance Programme;
- Training Requirements;
- Transport of Radioactive Materials – Overview of Regulatory Requirements;
- Event Reporting and Emergency Response.

These presentations were delivered in 28 workshops across Canada between 2014 and 2018.

V–1.2 Webpage on the CNSC website

A section of the CNSC website was developed specifically for licensees with portable gauge (see Fig. V–2). This page lists a number of tools/resources available to these licensees including safety posters, relevant legislation and links to service providers.

FIG. V–2. Webpage on portable gauges on the CNSC website

V–1.3 Safety video

A short safety video entitled “Stay safe working with portable nuclear gauges” was developed and posted on the CNSC website. This video[4] shows a worker operating a portable gauge and covers aspects such as dosimetry, operation, transport, security and event reporting.

V–1.4 Portable gauge quick reference guide

A one-page reference sheet (see Fig. V–3) containing important information was developed and posted on the CNSC website in HTML and PDF formats. This was intended to be a summary

[4] https://www.youtube.com/watch?v=LW_UXZK-vHg&feature=youtu.be

that could be brought in the field that would help to mitigate risks associated with portable gauge use. This sheet as also distributed to workers in the field during routine compliance verification activities.

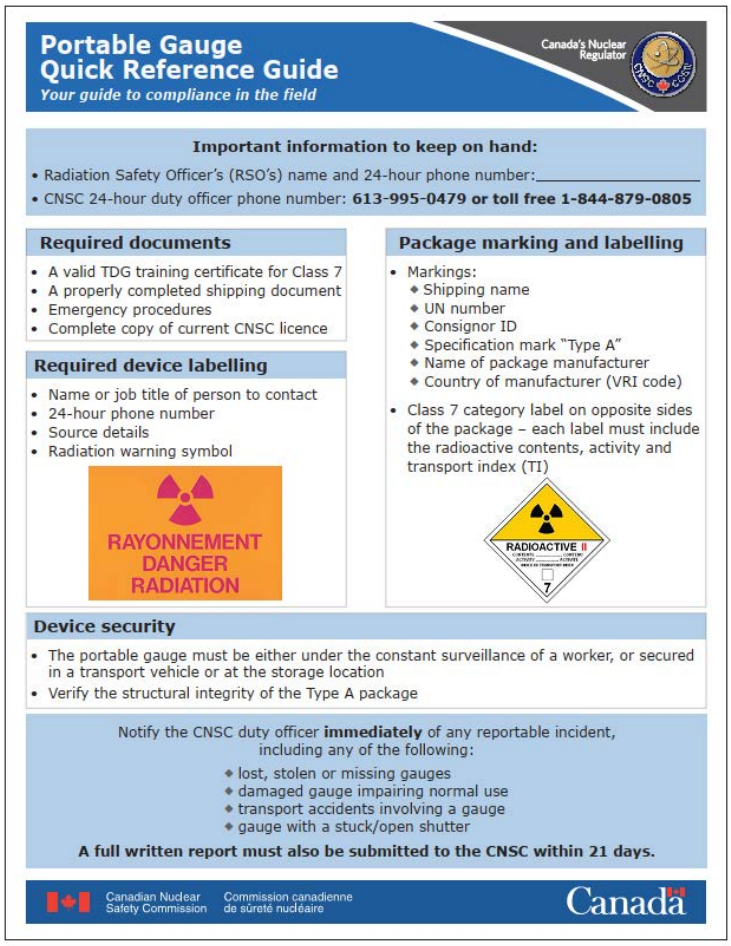

FIG. V–3. Reference sheet on the CNSC website

CNSC staff have continued to monitor the performance of this subsector. In 2018, CNSC staff noted an increase in licensees' performance in the operating performance and radiation protection Safety and Control Areas. Furthermore, in 2017 and 2018, the percentage of workers using portable gauges receiving doses between 1 and 5 mSv dropped compared to previous years. Taken together, these observations could be an indication that the interventions and outreach put in place by CNSC staff are having the desired effect – workers in the portable gauge sector performing their duties in a safe manner.

V–2 FINLAND

V–2.1 Consultation

For consultation with interested parties in the process of drafting regulations, an on-line system is used. This system is provided by the Ministry of Justice. Consultation refers to a stage of the regulation drafting process where the key stakeholders' views, knowledge and experiences of the matter under preparation are obtained. Authorities, experts, operating organizations, companies and citizens are stakeholders. According to a graded approach the number of stakeholders to be consulted depends on the safety significance of the regulations to be consulted on.

V–2.2 Communication in social media

The regulatory body (STUK) uses social media such as Twitter and Facebook for communication. The benefit is that it is a fast way of communicating and it is possible to share also relevant information from other organizations. Social media is well suited for campaigns. One example is an awareness campaign of the Heads of the European Radiological Protection Competent Authorities (HERCA). The information from HERCA was further communicated among others by the IAEA RPOP (Radiation Protection of Patients) and STUK prepared communication materials such as a tweet in Finnish language.

CONTRIBUTORS TO DRAFTING AND REVIEW

Bly, R.	Radiation and Nuclear Safety Authority (STUK), Finland
Bosnjak, J.	International Atomic Energy Agency
Cunningham, N.	Environmental Protection Agency, Ireland
Da Silva Silveira, C.	National Nuclear Energy Commission (CNEN), Brazil
Kamenopoulou, V.	International Atomic Energy Agency
Karinou, E.	Greek Atomic Energy Commission (EEAE), Greece
Pacheco, R.	International Atomic Energy Agency
Pozihun, L.	Canadian Nuclear Safety Commission, Canada
Rajappa, U.	Consultant, Australia

Consultants Meetings

Vienna, Austria: 27-31 May 2019

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