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Notification and Authorization for the Use of Radiation Sources

(Supplement to IAEA Safety Standards Series No. GS-G-1.5)

IAEA
International Atomic Energy Agency

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FOREWORD

The achievement and maintenance of a high level of safety in the use of radiation sources depend on there being a sound legal and governmental infrastructure, including a national regulatory body with well-defined responsibilities and functions. These responsibilities and functions include establishing and implementing a system for notification and authorization for control over radiation sources, including a system for review and assessment of applications for authorization.

The Safety Requirements publication entitled Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety establishes the requirements for legal and governmental infrastructure. The term 'infrastructure' refers to the underlying structure of systems and organizations. This includes requirements concerning the establishment of a regulatory body for radiation sources and the responsibilities and functions assigned to it.

The International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (the Basic Safety Standards or the BSS) establish basic requirements for protection against risks associated with exposure to ionizing radiation and for the safety of radiation sources. The application of the BSS is based on the presumption that national infrastructures are in place to enable governments to discharge their responsibilities to for radiation protection and safety.

This TECDOC provides practical guidance on the process for dealing with applications for authorization and accepting notifications to regulatory bodies. Examples of guidelines that may be used by persons required to notify or apply for authorization and of the regulatory body's review and assessment procedures are provided in the Appendices.

The TECDOC is oriented towards national regulatory infrastructures concerned with protection and safety for radiation sources used in medicine, industry, agriculture, research and education. The IAEA officers responsible for this publication were B. Djermouni and T. Boal of the Division of Radiation and Waste Safety.

EDITORIAL NOTE

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1 INTRODUCTION

1.1. BACKGROUND

The achievement and maintenance of a high level of radiation protection and safety (hereinafter, 'radiation safety') in the use of radiation sources depends on a sound legal and governmental infrastructure. An appropriately organized and staffed regulatory body, with access to appropriate resources is a key element of such infrastructure.

The IAEA Safety Requirements publication on Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety No. GS-R-1 [1] sets out the requirements for such infrastructure. And, the IAEA Safety Guide on Regulatory Control of Radiation Sources No. GS-G-1.5 [2] provides guidance to regulatory bodies on how to meet these requirements.

The International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources No. 115 [3] (hereinafter the 'Basic Safety Standards' or 'BSS') establish the basic requirements for protection against the risks associated with exposure to ionizing radiation and for the safety of radiation sources that may deliver such exposure. The Basic Safety Standards are based on the presumption that a national infrastructure for radiation safety is in place, enabling the Government to discharge its responsibilities. The Basic Safety Standards comprise requirements to be fulfilled in all activities involving radiation exposure. They are aimed to serve as a practical regulatory guidance for public authorities and services, employers and workers, specialized radiation protection bodies, enterprises and safety and health committees. The basic principles of radiation safety on which the Basic Safety Standards are based intend to prevent the occurrence of the deterministic health effects and to limit to an acceptable level the risk associated to the stochastic health effects of ionizing radiation.

This TECDOC assumes that a radiation safety law and its relevant regulations, consistent with the Safety Requirements GS-R-1 [1] and the BSS [3], apply during the use of radiation sources of different types in industry, medicine, agriculture, research and education, excluding nuclear reactors and other kinds of nuclear installations.

This TECDOC, in part, supersedes IAEA-TECDOC-1067 on Organization and Implementation of a National Regulatory Infrastructure Governing Protection against Ionizing Radiation and the Safety of Radiation Sources [4] and IAEA-TECDOC-1113 on Safety Assessment Plans for Authorization and Inspection of Radiation Sources [5].

1.2. OBJECTIVE

One of the responsibilities of the regulatory body set out in the Safety Requirements GS-R-1 [1] is to review and assess applications from operators for authorization, and to issue, amend, suspend or revoke authorizations, subject to any necessary conditions. The objective of this TECDOC is to provide practical guidance on the process for dealing with applications for authorization and accepting notifications to regulatory bodies that may need to establish or strengthen their national radiation safety legislation and/or the supporting infrastructure in order to meet the requirements of reference [1].

1.3. SCOPE

This TECDOC supplements IAEA Safety Guide No. GS-G-1.5 [2] and its scope concerns:

(a) the organization and management of a system of notification and authorization for the regulatory control over the use of radiation sources, including the provisions for granting exemptions from regulatory requirements;

(b) the notification and authorization procedures, detailing the documentation to be submitted by applicants; the basis for decisions taken by the ~~r~~regulatory body; the conduct of inspections as part of the assessment and ongoing review of authorizations; the handling of renewal applications and eventual amendments to the authorizations, and the termination of authorizations; and

(c) the identification of specific review and assessment procedures for applications concerning authorization for the use of radiation sources in diagnostic radiology, nuclear medicine, radiotherapy, industrial radiography, research and industrial irradiators, radioactive gauges, and well logging.

1.4. STRUCTURE

Section 2 defines the objectives of a control system by notification and authorization. Section 3 outlines the organization and management of the authorization process while Section 4 provides details of the performance of the authorization process. Annex IV provides examples of guidelines that may be used by persons required to notify or apply for authorization, while Annex V provides examples of regulatory body's review and assessment procedures for each of the radiation sources used in diagnostic radiology, nuclear medicine, radiotherapy, industrial radiography, research and industrial irradiators, radioactive gauges, and well logging.

2 A SYSTEM OF REGULATORY CONTROL BY NOTIFICATION AND AUTHORIZATION

2.1. OBJECTIVE

The fundamental reasons for regulating the use of ionizing radiation sources through a process of notification and authorization are provided in the Preamble to the Basic Safety Standards [3], i.e.: *"It has been recognized since early studies on X rays and radioactive minerals that exposure to high levels of radiation can cause clinical damage to the tissues of the human body. In addition, long term epidemiological studies of populations exposed to radiation, especially the survivors of the atomic bombing of Hiroshima and Nagasaki in Japan in 1945, have demonstrated that exposure to radiation also has a potential for the delayed induction of malignancies. It is therefore essential that activities involving radiation exposure, such as the production and use of radiation sources and radioactive materials, and the operation of nuclear installations, including the management of radioactive waste, be subject to certain standards of safety in order to protect those individuals exposed to radiation.***….*** The Standards are intended to place requirements on those legal persons authorized to conduct practices that cause radiation exposure or to intervene in order to reduce existing exposures; these legal persons have the primary responsibility for applying the Standards* **…** *Any legal person intending to carry out any of the actions specified under the General Obligations* **…** *shall submit a notification to the Regulatory Authority of such an intention".*

2.2. NOTIFICATION

Notification is defined in the Basic Safety Standards [3] as "*a document submitted (to the Regulatory Authority) by a legal person to notify the possession of a source or the intention to carry out a practice*".

In addition to submitting a notification, operators may also be required to submit an application for authorization. An application for authorization can also be considered as a notification to the regulatory body.

2.3. AUTHORIZATION

An "authorization" is defined in the GS-R-1 [1] as *"the granting by the regulatory or other governmental body of written permission for an operator to perform specified activities."*

An "operator" is defined in GS-R-1 [1] as "*Any organization or person applying for an authorization or authorized and/or responsible for nuclear, radiation, radioactive waste or transport safety when undertaking activities or in relation to any nuclear facilities or sources of ionizing radiation. This includes, inter alia, private individuals, governmental organizations, consignors or carriers, licensees, hospitals, self-employed persons, etc*." For the purposes of this document, it means the same as "legal person" used in the *BSS* [3]. A legal person is defined in the *BSS* as: **"***any organization, corporation, partnership, firm, association, trust, estate, public or private institution, group, political or administrative entity or other persons designated in accordance with national legislation, who or which has responsibility and authority for any action taken under these Standards."*

The Basic Safety Standards [3] states that an authorization can take the form of a *registration* or a *licence.* Registration is defined in the BSS as a form of authorization for practices of low or moderate risks whereby the legal person responsible for the particular practice, as appropriate, has prepared and submitted a safety assessment of the facilities and equipment to the regulatory body. The practice or use is authorized with conditions or limitations as appropriate. The requirements for safety assessment and the conditions or limitations applied to the practice should be less severe than those for licensing. A licence is defined in the BSS as an authorization granted by the regulatory body on the basis of a safety assessment and accompanied by specific requirements and conditions to be complied with by the operator.

It is up to the national authorities to decide on whether to make a distinction between a *registration* and *licence* when adopting the legislative wording in reference to the requirement for *authorization.*

In this respect, the Basic Safety Standards stipulates that: *"Typical practices that are amenable to 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 safety training requirements are minimal; and (d) there is a history of few problems with the safety in operation. Registration is best suited to those practices for which operations do not vary significantly"* (Ref. [3], footnote 7).

In some countries, the legislation foresees two types of *authorizations*: *personal or individual authorizations* and *institutional authorizations*. The first type — *the personal or individual authorization* — is granted to persons proving to the satisfaction of the regulatory body their knowledge, training and practical experience on the subject for which they have applied for the authorization. This type of authorization *is* not linked to any physical installation, and during their period of validity, allows the authorization holder to work at any authorized practice according to their area of expertise. The second type — *the institutional authorization* — is granted to the operator who has applied for an authorization for the performance of a given practice, after the regulatory body is convinced that such a practice can be carried out safely, and provided that the operator has in its permanent staff at least one person holding a *personal or individual authorization* for performing the same practice.

3 ORGANIZATION AND MANAGEMENT OF THE AUTHORIZATION PROCESS

3.1. REGULATORY BODY

This publication assumes that a single regulatory body is responsible for all aspects of radiation safety in a country. However, in some countries, the regulatory responsibility for different practices or different aspects of radiation safety may be divided between different authorities (e.g. transport, mining, environment, etc.). Consequently, the term "*regulatory body"* should be understood as being the relevant body that regulates particular sources or aspects of radiation safety. However, if there be a division of regulatory responsibilities, the Government must ensure appropriate and effective regulation of all non-exempt radiation sources by requiring co-operation and liaison between the different bodies as to avoid gaps and overlaps in their respective regulatory activities. The Government should also ensure that there is consistency in the application of the radiation safety standards. This could be achieved by having a single set of regulations, for example, covering occupational and public radiation protection, including the setting of limits for exposure.

The type of regulatory system adopted will depend on the size, complexity and safety implications of the regulated practices and sources, as well as on the regulatory traditions in the country. The mechanism for carrying out regulatory duties may vary, with some bodies being self-sufficient and others delegating some inspection, review and assessment, or other duties to various governmental, public or private agencies. The delegation of duties may need to be provided for in the law or regulations and, in some cases, may also require the regulatory body to accredit inspectors to ensure competence in carrying out inspections. The Safety Requirements GS-R-1 requires that: *"The use of consultants shall not relieve the regulatory body staff of any of its responsibilities. In particular, the regulatory body's responsibility for making decisions and recommendations shall not be delegated"* (Ref. [1], para. 4.4). Further, GS-R-1 requires that *"In undertaking its own review and assessment of a safety submission presented by the operator, the regulatory body shall not rely solely on any safety assessment performed for it by consultants or on that conducted by the operator. Accordingly, the regulatory body shall have a full time staff capable of either performing regulatory review and assessments, or evaluating any assessment carried out for it by consultants"* (Ref. [1], para. 4.8).

The regulatory body is required to be independent of governmental departments and agencies that are responsible for the promotion and development or responsible for the practices being regulated (Ref. [1], para. 2.2(1)). The regulatory body is required to be provided with adequate authority and power and is required to be provided also with adequate staffing and financial resources to discharge its responsibilities (Ref. [1], para 2.2(4)).

The effective separation of responsibilities between the functions of the regulatory body and those of any other party is to be made clear in the national legislation, so that the regulators retain their independence of judgment and decision making as safety authorities having the competence and resources needed to implement its functions. Further guidance on regulatory independence is provided in paragraphs 2.10-2.18 of the Safety Guide GS-G-1.5 [2].

3.2. LEGISLATIVE BASIS FOR AUTHORIZATION

In relation to authorization, the Safety Requirements GS-R-1 stipulates that: *"The legislation shall establish a regulatory body with the authority:*

(a) to require any operator to conduct a safety assessment;

(b) to require that any operator provide it with any necessary information, including information from its suppliers, even if this information is proprietary;

(c) to issue, amend, suspend or revoke authorizations and to set conditions;

(d) to require an operator to perform a systematic safety reassessment or a periodic safety review over the lifetime of facilities;

(e) to enter a site or facility at any time to carry out an inspection;

(f) to liaise and coordinate with other governmental or non-governmental bodies having competence in areas somewhat related with radiation safety; and

(g) to obtain such documents and opinions from private or public organizations or persons as may be necessary and appropriate" (Ref. [1], para. 2.4(a) and para. 2.6).

An operator is not permitted to use, transport, dispose of, etc. a radiation source until an authorization has been granted by the regulatory body (Ref. [3], para. 2.13).

Governmental agencies or institutions that possess or use radiation sources also should be bound to comply with the radiation safety legislation and with the directions of the regulatory body. Therefore, governmental agencies and institutions are required to apply to the regulatory body also for an authorization.

3.3. LEGAL ADVICE

Regarding the authorization process, the regulatory body will require legal advice for a range of matters, for**:**

(a) ensuring the validity of conditions, restrictions or limitations that might be imposed on the granted authorizations; and

(b) checking letters regarding rejection of applications for authorization.

The regulatory body may (or may be required by the governmental policy or legislation) to source its legal advice from another governmental agency. But it must be satisfied that the advice is based solely on the applicable legislation and is independent of other influences, particularly in the case that prospective legal advice will come from a governmental agency where radiation sources are in use.

The prosecution or discipline of governmental agencies or institutions for alleged breaches of the radiation safety legislation may raise special difficulties. Governmental agencies or institutions that possess or use radiation sources are required to comply with the radiation safety legislation and with the directions of the regulatory body (i.e. they should be subject to the same controls and penalties that are applicable to non-governmental users).

Legal procedures for dealing with alleged breaches (i.e. by governmental agencies or institutions) should be established by the Government, particularly if both parties (i.e. the regulatory body and the alleged offender) have access to, or are required to, use legal services provided by a single governmental department. It may be obligatory in such circumstances for either the prosecution or the defence to engage private or other governmental agency's legal support.

3.4. RESOURCING AN AUTHORIZATION PROGRAMME

The regulatory body requires a reliable register of the numbers and types of radiation sources within the country to allow it to estimate the staff resources and budget to properly implement a regulatory system for the control of radiation sources, and in particular, for an authorization programme.

For countries that are introducing a law and regulations concerning radiation safety for the first time, the regulatory body will need to disseminate details of the legislation to appropriate individuals, organizations and governmental departments, asking all operators with radiation

sources to notify the regulatory body of the number and types of radiation sources in their possession (e.g. see Section 2, Item 2.2) so that it can develop a register of sources in the country. For those radiation sources in the country that have been in use before the regulatory body was established, it would be disruptive to the operators of the radiation sources and also to the public dependent on the operators for the service provided (e.g. to patients) to require them to stop using radiation sources until the operators have submitted applications forms for authorization, and the regulatory body has reviewed and assessed the applications and issued authorization certificates for the particular practices and sources. Such operators may be given a period of time to comply with the new law and regulations, and to submit applications for authorization. The regulatory body must assess the relative risks associated with the various radiation sources and assign authorization and inspection priorities. This assessment of relative risks could be based on the IAEA's publication Categorization of Radioactive Sources [6]. The period of time given to operators to comply with the new law and regulations could be different for different types of sources, based on the relative risks of the radiation sources. Operators would be allowed to use their radiation sources until their application was approved or rejected. For those radiation sources assigned the highest priority, the regulatory body would process applications for authorization before processing applications for sources of lower priority.

For countries with mature radiation safety programmes, applications for authorization from operators may be either an initial application or it may be an application for renewal of an authorization. Renewal of authorizations is discussed further in Section 4, item 4.9.. To determine the staffing levels required for an authorization programme, the regulatory body would review past experience concerning the number of new applications for authorization for each type of radiation source practices expected each year and would analyse the number of existing authorizations that are due for renewal each year.

Figure 1 presents an example of a process to determine the number of staff required by a regulatory body to review and assess applications of authorization for different types of radiation practices and categories of radioactive sources.

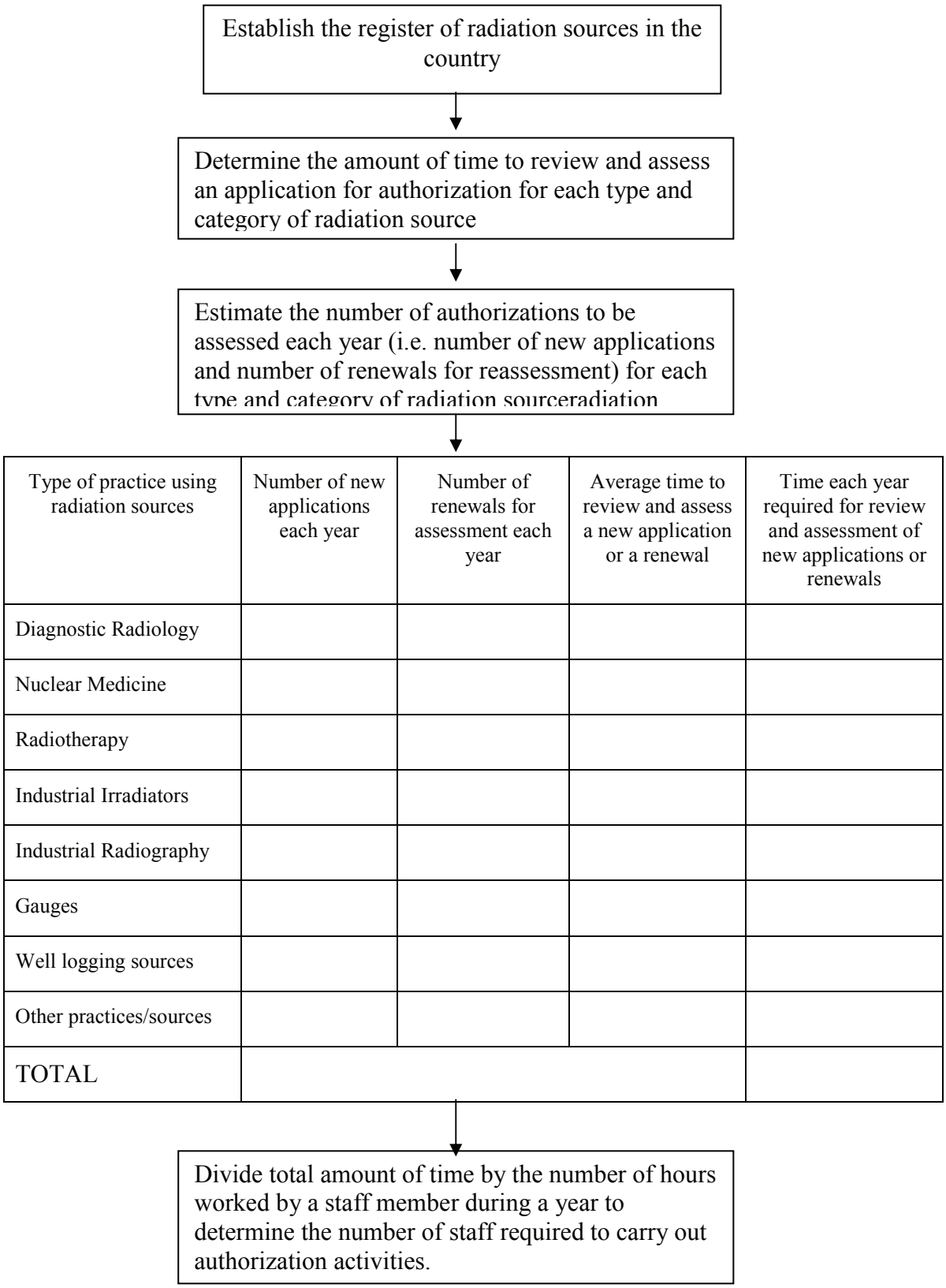

FIG. 1. Process to determine the number of staff required by a regulatory body to review and assess applications for authorization for different types of radiation practices and categories of radioactive sources.

3.5. REGULATORY PROCEDURES

The regulatory body's internal procedures should be clearly documented and available for reference by all personnel. They should be reviewed at least annually, but will also require updating whenever new procedures are created, existing procedures amended or regulations changed. The contents of such internal procedures should include**:**

(a) the structure of the regulatory body with reporting lines and primary responsibilities of office holders;

(b) the procedural guidance for review and assessment of applications for authorization including a time-frame for dealing with applications;

(c) the procedural guidance for carrying out inspections;

(d) the procedural guidance for ensuring the timely exchange of inspection and authorization data (i.e. including requests for amendments of authorizations) between review and assessment personnel and inspectors;

(e) the report and letter writing procedures including a time-frame for responding to enquiries;

(f) the memoranda of understanding with other governmental agencies;

(g) the e-mail protocols (i.e. for officers who have authority to respond on behalf of the regulatory body); the scope of those responses; keeping hard copies for authorization files;

(h) the integrity and security of records (i.e. including secure backup of electronic data); and

(i) the privacy policy for records maintained by the regulatory body under the law and the rules for releasing information.

3.6. QUALIFICATIONS AND TRAINING OF PERSONNEL FOR AUTHORIZATION

Staff of the regulatory body that have responsibility for assessing applications for authorization must have relevant qualifications and appropriate training in the fundamentals of radiation safety. Appropriate tertiary qualifications in a science related discipline or in engineering are often appropriate. However, additional training in the implementation of a regulatory programme for radiation sources is essential. Each staff member is expected to be familiar with the regulatory process, including national regulations, policies, procedures and guidance (e.g for assessment of applications for authorization). They are expected to be knowledgeable in the particularities of the practices using radiation sources being regulated. In particular, tertiary qualifications in medical physics would be beneficial for work relating to review and assessment of applications for authorization of radiation sources in the medical uses of radiation.

The IAEA has developed a training package for staff of regulatory bodies. The first part consists of a course entitled *Organization and Implementation of a National Regulatory Programme for the Control of Radiation Sources* that deals with regulatory fundamentals. The second part consists of several courses (i.e. of one week) for practical training in the regulatory control (i.e. through notification, authorization, inspection and enforcement) of specific radiation practices (e.g. industrial radiography, radiotherapy, diagnostic and interventional radiology, etc.). The third part consists of on-the-job training.

If, for a particular type of practice using radiation sources, appropriately skilled personnel are not available within the regulatory body, a review and assessment of the application for authorization could be performed for the regulatory body by consultants. Under such

circumstances, the regulatory body cannot devolve decision-making to the external consultants. The regulatory body has the responsibility under the law for granting or rejecting applications for authorization. The Safety Requirements GS-R-1 requires in this respect the following: *"In undertaking its own review and assessment of a safety submission presented by the operator, the regulatory body shall not rely solely on any safety assessment performed for it by consultants or on that conducted by the operator. Accordingly, the regulatory body shall have a full time staff capable of either performing regulatory reviews and assessments, or evaluating any assessments performed for it by consultants"* (Ref. [1], para. 4.8).

3.7. MANAGEMENT RESPONSIBILITY

The regulatory body's management must ensure that all regulatory body staff are aware that they are required to apply the law equally and impartially, respecting the privacy of applicants and users and of privileged information that they may have access to under the law. The legislation should ensure that operators have a right to appeal decisions of the regulator and all officers must recognize that they may be required to defend their actions in Court. Therefore, the management has an obligation to pursue high professional and ethical standards.

Authorization certificates will bear the signature of an appropriately authorized senior officer. (i.e. an officer of the regulatory body). Other personnel supporting the regulatory body's functions will be delegated responsibilities relevant to their expertise.

Management would review all recommendations made by staff for approval or rejection of applications for authorization, and of the conditions to be placed on authorizations, to ensure that they comply with the requirements of the legislation and, in particular, of the existing applicable regulations. In some countries, the advice of an expert advisory committee is sought for approval of applications forms for authorization (e.g. see Section 3, item 3.8). In any case, the final responsibility for approving or rejecting an application for authorization lies with the delegated manager of the regulatory body. Correspondence to applicants related to the authorization process must be reviewed by the regulatory body's management and signed only by appropriately authorized persons.

3.8. ADVISORY COMMITTEES

The Safety Requirements GS-R-1 stipulates the following: *"The Government or the regulatory body may choose to give formal structure to the processes by which expert opinion and advice are provided to the regulatory body; the need or otherwise for such formal advisory bodies is determined by many factors. When the establishment of advisory bodies is considered necessary, on a temporary or permanent basis, such bodies shall give independent advice. Any advice offered shall not relieve the regulatory body of its responsibilities for making decisions and recommendations"* (Ref. [1], para. 4.9).

In establishing advisory committees, the relationship of such committees to the regulatory body and the need for the regulatory body to maintain its independence on matters concerning radiation safety should be taken into account. Therefore, the regulatory body should prepare clearly defined terms of reference and specific criteria for the selection of the membership of the advisory committee well before it is established (Ref. [2], para. 6.18).

Many regulatory bodies wish to receive external expert advice on specific aspects of the radiation safety programme, including the review and assessment of applications for authorization. Persons nominated to be a member of an advisory committee are appointed on the basis of their qualifications and expertise and, unless specifically stated in the legislation, do not represent "interest" groups or professional associations. The legislation should require such persons to formally declare their interests in any relevant matters under discussion.

The range of specialized knowledge that might be required for persons appointed to advise a regulatory body that regulates a wide range of radiation sources may include the following practices and/or activities and areas:

(a) Radiotherapy, either in brachytherapy or teletherapy (e.g. X rays, cobalt, linear accelerators);

(b) Diagnostic Radiology;

(c) Nuclear Medicine;

(d) Medical Physics;

(e) Radiation Safety;

(f) Tertiary and Research Institutions; and

(g) Industrial Uses of Radiation Sources.

3.9. LIAISON WITH OTHER NATIONAL BODIES

The regulatory body cannot regulate radiation safety in isolation from other governmental agencies and national bodies. Most operators authorized to use radiation sources will also be required to comply with other legislation administered by different governmental agencies. This may range perhaps from simply obtaining the approval of a local governmental authority to operate a business in a particular area to, say, satisfying the requirements of other authorities responsible (e.g. for environmental protection and waste disposal).

The regulatory body must therefore be aware of and have appropriate contact with such governmental agencies to ensure that there is no conflict in terms of jurisdictional responsibilities or in the safety standards to be applied. In some cases, this may require the development of a kind of memoranda of understanding (hereinafter, MOU), which is a process that should also involve the regulatory body's legal adviser.

Two examples are provided in Attachment I. These are between the regulatory body and the customs and the health department (i.e. or agency, ministry, etc) respectively. The MOU between the regulatory body and the health department has been developed on the assumption that the regulatory body is administratively part of that health department and reliant on it for support services. Although different governmental departments or agencies may be involved, similar situations exist in a number of countries and this dependent relationship can raise questions about the regulatory body's independence, particularly where the parent body is itself subject to the national radiation safety legislation and the direction of the regulatory body. The example of MOU attempts to address these questions.

Processes should also be established to ensure that, where an authorization bears on the responsibilities of other governmental agencies or regulators, those agencies are informed when the regulatory body grants, rejects, suspends or revokes an authorization. Liaison may be required with the agencies listed in Table I.

Table I. Agencies that the regulatory body may need to liaise with on radiation safety issues

Agency	Radiation safety issues
Consumer Protection	Regulation of radioactive substances in consumer products
Customs	Control over the import and export of radiation sources
Defence Forces	Compliance with the radiation safety legislation
Education	Standards and accreditation of training courses for radiation users
Civil Defence	Radiation monitoring and assistance during radiation emergencies
Environment	Control over management of radioactive waste
Fire Services	Fires at premises where radiation sources are stored or used
Food/Agriculture	Radioactivity in foodstuffs, fertilizer production, food irradiation
Health	Public health issues (i.e. see also food, water, sewerage, fire); screening programmes (e.g. mammography, TB)
Local Governments	Alignment of building approvals; standards of facility construction
National Standards	To ensure that national standards dealing with any aspect of ionizing radiation conform to the regulatory body's requirements (e.g. the adoption of standards of the International Electrotechnical Commission, International Standards Organization, traceability of radiation measurements, etc.)
Oil, Gas Production	Use of radiation sources on oil and gas platforms
Police	Dealing with emergencies; assistance when refused access for inspection purposes, and in cases of prosecutions
Professional Registration Boards	Qualifications and competence of the professions (e.g. medicine, dentistry, etc.)
Sewerage	Disposal of low level radioactive wastes
Transport	Transport of radioactive sources
Water Supply	Drinking water standards (e.g. activity concentrations)

4 PERFORMANCE OF THE AUTHORIZATION PROCESS

4.1. SUBMISSION OF A NOTIFICATION

An operator intending to carry out any of the actions specified in the general obligations of the Basic Safety Standards [3] for practices shall submit a notification to the regulatory body of such an intention. The regulatory body may prescribe the form in which this notification is to be made.

The Safety Guide GS-G-1.5 recommends the following: *"For those sources and sources within practices for which normal exposures are expected to be very small and the likelihood and magnitudes of potential exposures are negligible, but which are not suitable for exemption for some reason (e.g. to prevent uncontrolled waste disposal), the regulatory body may require only notification"* (Ref. [2], para. 3.24). For radiation sources in a practice for which an authorization is required, an application for authorization may also serve as notification.

An example of a notification form is given in Attachment II. Depending on local requirements, the regulatory body might prefer to have separate notification forms for radioactive substances and other radiation sources.

In countries that are introducing a radiation safety law and regulations, the first requirement to be complied with by a user or holder, or prospective user of any radiation sources (i.e. except for those exposures excluded in the legislation), is to notify the regulatory body in writing of all radiation sources that they possess within an established time period. Non-compliance with this requirement should be considered a breach of the legislation. To fully implement the basic procedures of notification and authorization, the regulatory body must ensure that the purpose and impact of the legislation is widely circulated to all potential stakeholders so that they, and other parties likely to be affected by the legislation, are fully informed of their legal obligations.

The first objective of notification is for the regulatory body to know the type and how many radiation sources are in the country and where are they located. The regulatory body can then produce a reliable register of radiation sources. The regulatory body should not adopt a passive attitude, but must have an inquiring disposition for searching for potential users or holders of radiation sources among those organizations and institutions that are known to possess or use radiation sources in other countries. Subject to the degree of national compliance already achieved, the regulatory body may need**:**

(a) to contact and meet with professional associations that represent radiation users;

(b) to contact companies that import, supply, maintain, service, install or otherwise deal with radioactive sources or radiation producing devices;

(c) to ensure that there are agreed controls imposed by customs for import and export of radiation sources;

(d) to liaise with governmental agencies (e.g. health, labour, environment, waste management) whose responsibilities have a bearing on radiation safety;

(e) to check telephone directories and governmental agencies that register businesses with the aim to identify operators (i.e. including mining companies, that might use radiation sources);

(f) to obtain information on operator identification from existing personal monitoring services; and

(g) to advertise in the media.

4.2. OBJECTIVES OF THE REVIEW AND ASSESSMENT OF AN APPLICATION FOR AUTHORIZATION

At all stages of the authorization process the regulatory body must have a clear understanding of the radiation safety objectives and basic requirements that will be used to review and assess an application for authorization. Guidelines relevant to the particular radiation practice should be provided to applicants for guidance in preparing the information to be submitted to the regulatory body with their application for authorization.

Radiation safety objectives and basic requirements should specify goals or levels of performance to be achieved and may suggest or specify how such goals or levels are to be achieved. However, the regulatory body should not prescribe specific designs, safety management systems or operational procedures. The elaboration of these referred aspects is a responsibility of the applicant.

Radiation safety objectives and basic requirements will generally be developed by the regulatory body itself or adopted from requirements developed and published by regulatory authorities in other States or by international organizations. The adoption of requirements from elsewhere requires a good understanding of their development, use and effectiveness. This may require contact with regulatory bodies in other States or with relevant international organizations. Public consultation may, in some cases, also be desirable in developing radiation safety objectives and requirements for radiation uses that the public might perceive as presenting a significant risk to workers, the public and the environment.

In developing radiation safety objectives and basic requirements, for the review and assessment associated to the authorization process, the regulatory body should consider**:**

(a) its national law, regulations, codes of practices or regulatory guides;

(b) advice from persons and bodies with expertise in reviewing and assessing applications;

(c) advice from professional organizations, whose members have recognized qualifications and experience in the particular radiation use;

(d) advice from consultants and advisory bodies that may be appointed by the regulatory body; and

(e) radiation safety standards and documentation published by international organizations.

Examples of the radiation safety standards and supporting documents published by the IAEA for operators in industry, medicine, education, research and agriculture are presented in the bibliography.

4.3. DOCUMENTS SUBMITTED BY APPLICANTS FOR AUTHORIZATION

Unless the practice or radiation source is exempted, the legal person responsible for the radiation source must submit an application for authorization in a form prescribed by the regulatory body. As stated before, an application for authorization may also constitute appropriate notification of an intention to carry out a practice using radiation sources.

In this respect, the Safety Requirements GS-R-1 stipulates the following: *"Prior to the granting of an authorization, the applicant shall be required to submit a detailed demonstration of safety, which shall be reviewed and assessed by the regulatory body in accordance with clearly defined procedures"* (Ref. [1], para. 5.3). An example of an application form for authorization to use radiation sources is shown in Attachment III. It requires the applicant to submit a radiation protection programme based on items listed later in this Section 4.

For large organizations that have several departments using radiation sources (e.g. a hospital with radiotherapy, nuclear medicine and diagnostic radiology departments) the regulatory body needs to decide if it will issue a single authorization to the large organization, or if it will issue an authorization to each individual department. Whichever way the regulatory body decides, the application for authorization should be submitted by the organization as it is responsible for providing resources (i.e. staff, equipment, construction and maintenance of buildings) to the individual departments to ensure that the radiation sources are used safely.

The Safety Requirements GS-R-1 stipulates the following: *"The regulatory body shall issue guidance on the format and content of documents to be submitted by the operator in support of applications for authorization. The operator shall be required to submit or make available to the regulatory body, in accordance with agreed timescales, all information that is specified or requested"* (Ref. [1], para. 5.4). Examples of guidelines for operators to prepare an application for authorization are provided in Attachment IV, including its Appendices A to G.

The applicant is responsible for submitting the application for authorization well in advance of the intended use so that the regulatory body can review and assess the application in a timely manner:

The Safety Guide GS-G-1.5 recommends that: *"In all cases the operators should be required to submit in support of notification and for application for authorization at least the following information:*

(a) Clear identification of the applicant for authorization, i.e. the operator and/or the actual person applying;

(b) Specification of the system to be used for source accounting;

(c) Clear specification of the source(s) and associated facilities and equipment to be used in the practice;

(d) *The location(s) where the radiation source(s) will be stored and where they will be used"* (Ref. [2], para. 3.32).

The information on the inventory of radiation sources requested above would include for radioactive substances the following: type of radiation source(s), radionuclide(s), activities, physical or chemical form(s), type of use or practice; and in case of device containing radioactive substances, the manufacturer, model and serial number of the devices. For unsealed radionuclides where stocks are replenished by regular shipments (e.g. radionuclides used in medicine and research) the applicant may be asked by the regulatory body to identify the maximum activity of each radionuclide that may be on the premises at any one time. For X ray equipment, the information to be provided is the following: manufacturer, model, serial number and purpose of use.

More over the Safety Guide GS-G-1.5 also recommends that: *"In addition, an application for authorization should include the following:*

(a) Identification of the individual(s) representing the operator;

(b) Identification and details of qualifications of the Radiation Protection Officer, and where appropriate, Qualified Expert(s);

(c) Details of qualifications and training in radiation protection of workers engaged in activities that involve or could involve occupational exposure;

(d) *For practices involving medical exposure, "the qualifications in radiation protection of the medical practitioners who are to be so designated by name in the registration or licence; or a statement that only Medical Practitioners with qualifications in radiation protection specified in the relevant regulations or to be specified in the registration or licence will be permitted to prescribe medical exposure by means of the authorized source" as required in the BSS (Ref. [3], para. 2.14);*

(e) For significant risk radiation sources, unusual or complex practices, or consumer products, a justification for engaging in the regulated activity or practice;

(f) For significant risk radiation sources, copies of the operating and maintenance procedures that will be followed;

(g) A plan of the premises with an assessment of the nature, magnitude and likelihood of exposures attributable to the radiation source(s) made by the Radiation Protection Officer or a Qualified Expert;

(h) *For significant risk sources or unusual or complex practices, a safety assessment that states the probability and magnitude of potential exposures (e.g. a safety assessment should be made for Category 1 and 2 sources, as defined in Ref. [6]);*

(i) The occupational radiation protection programme, including arrangements for monitoring of workers and the workplace, and the provision and maintenance of personal protective equipment and equipment for radiation detection;

(j) For practices involving medical exposure, information relating to the radiological protection of patients, including arrangements for the calibration of sources used for medical exposure, clinical dosimetry and quality assurance programmes;

(k) Radiation protection of the public, where appropriate, with all pathways of exposure taken into account;

(l) Arrangements to ensure safety of sources;

(m) Arrangements for the management of radioactive waste, including the management of disused sources (disused sources should either be managed in the State concerned or be returned to the supplier or manufacturer), and information on the financial arrangements for such purposes;

(n) *Emergency arrangements and financial arrangements for a radiological emergency, where appropriate"* (Ref. [2], para. 3.33).

The Safety Requirements GS-R-1 stipulates that: *"For complex facilities… authorization may be carried out in several stages"* (Ref. [1], para. 5.4). Additionally, the Safety Guide GS-G-1.5 recommends that: *"For facilities such as industrial irradiators and facilities for industrial radiography, nuclear medicine and radiotherapy, the regulatory body may require a multistage process of authorization (e.g. it may require an application to construct before construction begins). The regulatory body may also prohibit the procurement of radiation sources (including their import) until a particular stage of construction has been completed and the safe and secure storage of sources can be ensured. The authorization process may also be subdivided into various steps (e.g. acceptance tests and commissioning, for which the regulatory body may require additional information before the authorization process can be completed)"* (Ref. [2], para. 3.34) and also that: *"Certain information submitted by the operator should be considered confidential, either because of its proprietary nature, for security reasons or because of the rights of the individual to privacy, in accordance with the national legislation and regulations"* (Ref. [2], para. 3.35).

4.4. CREATING RECORDS AND FILING

On receipt of an application for authorization, the regulatory body records the application details in a database (e.g. the *Regulatory Authority Information System* — RAIS[1]). Notifications are also recorded in the database, although not all will proceed to the next stage of the authorization process.

Applications for authorization are given a unique sequence number so that its subsequent progress through the authorization process can be tracked and all related data can be collated, filed and readily retrieved. The application's unique sequence number allows filing by that number.

[1] The IAEA has developed RAIS software that is available to Member States.

Once the authorization has been approved, a separate unique authorization number might also be assigned. For example, a regulatory body might identify an authorization as 345/03 where the "03" identifies the year when the authorization was first granted and "345" being the 345th authorization granted in 2003. The regulatory body should determine a system which best suit its requirements, taking into account that the above numbering system can create problems as a consequence of how to number the authorizations after their renewal. The same unique number is used to track all regulatory actions relating to the authorization, including inspections, enforcement actions, and decommissioning or disposal of radiation sources.

It should be possible to electronically retrieve information on any application or authorization (i.e. querying the database) by entering the unique sequence number, the authorization number or the legal person's name. It is also useful to be able to retrieve records by the location of the premises where radiation sources are kept, by the type of practice and the category of the radioactive source.

Bi-fold files may be useful for most filing needs. The authorization identification data can be printed on the cover, the regulatory body's copy of the authorization certificate and conditions kept inside the left hand cover with all other correspondence, inspection reports, enforcement actions, and disposal of radiation sources on the right hand side. All papers should be filed chronologically.

Only personnel who are approved by the regulatory body for this purpose should be permitted to add or remove documents from files. Numbering pages can help prevent unauthorized document removal.

The senior officer responsible for the assessment and issuance of authorizations should ensure that a viable "bring up" system is in place so that correspondence or other matters requiring follow-up within a prescribed time are indeed referred back to the responsible officer within that time. Officers initiating correspondence which require an authorized legal person to take prescribed action within a specified time frame should mark the file copy of such correspondence with the bring-up date. They should also use a diary (electronic or manual) to ensure the matter is not overlooked.

The officer responsible for administration of the filing system should ensure that no person has unauthorized access to files. A record should be kept of file movements so that their location can be readily tracked. Bar coding may be a useful means of record tracking.

4.5. REVIEW AND ASSESSMENT OF APPLICATIONS

The Safety Requirements GS-R-1 stipulates that: *"A primary basis for the review and assessment (of an application for authorization) is the information submitted by the operator. A thorough review and assessment of the operator's technical submission shall be performed by the regulatory body in order to determine whether the facility or activity complies with the safety objectives, principles and criteria. In doing this, the regulatory body shall acquire an understanding of the design of the facility or equipment, the safety concepts on which the design is based, and the operating principles proposed by the operator, to satisfy itself that:*

(1) the available information demonstrates the safety of the facility or proposed activity;

(2) the information contained in the operator's submission is accurate and sufficient to enable confirmation of compliance with regulatory requirements; and

(3) the technical solutions, and in particular any novel ones, have been proven or qualified by experience or testing or both, and are capable of achieving the required level of safety." (Ref. [1], para. 5.9). Additionally, the justification for engaging in the practice should be evaluated.

In addition, the Safety Guide GS-G-1.5 recommends that: *"The regulatory body should establish internal procedures to be followed in the review and assessment of an application for authorization, to provide assurance that all topics significant to safety will be covered and that operators for similar facilities or activities will be treated equally. The regulatory body should request any additional information that is necessary owing to deficiencies in the information provided by the applicant. The scope and depth of the review and assessment will depend on several factors such as the complexity of the practice and the associated risks"* (Ref. [2], para. 3.38).

"The regulatory body should establish which requirements, regulations, guides and industrial standards are applicable to each type of facility or activity, and should determine the requirements to be placed on operators for each type of facility or activity. Where there are no such requirements, regulations, guides or industrial standards in force, the regulatory body should consider developing them. In carrying out its review and assessment, the regulatory body should use the applicable requirements as a reference in deciding on the acceptability of an operator's submission" (Ref [2], para. 3.39).

"To facilitate the review and assessment process, the regulatory body may develop lists of approved equipment containing radiation sources, based on the submission of a certificate confirming compliance with the international industry standards (of the IEC and the ISO). An expert with the appropriate skills or an independent accreditation laboratory of the State concerned, or of another State or an international organization, would issue the certificate after reviewing a generic safety assessment. The generic safety assessment would be documented together with a summary of the conditions of use of the device and any appropriate limitations on its use" (Ref. [2], para 3.40).

"It would be inappropriate for the regulatory body to issue an authorization solely because a model of equipment was 'type approved' or carried a certificate of compliance, in accordance with IEC standards or nationally recognized equivalent standards in the State of use. The safety of each facility or activity will depend on many factors in addition to the design and manufacture of the radiation source or equipment, such as the design and construction of the building housing the radiation source, the qualification and training of the staff using the equipment, and operational aspects"(Ref. [2], par. 3.41).

Examples of review and assessment procedures for various practices using radiation sources are presented in Attachment V, including its Appendices A to G.

The regulatory body will specify timeframes for reviewing and assessing applications to ensure each is dealt with expeditiously. The time specified will depend on the complexity of the application and might range from a few weeks for the authorization of a low risk installation (e.g. dental radiography) to several months for, as an example, a nuclear medicine department.

Longer timeframes will be necessary where the authorization process necessarily requires hearings and/or inspections at various stages of construction of a facility. The regulatory body may in cases of some complex facilities require staged approvals (e.g. for the design, construction, installation and operation). This behaviour makes it easy the necessary safety controls by the regulatory body along the building and assembly process, and avoids the owner unnecessary expenses in case that a design, construction or installation modification would become indispensable.

While there will be additional points specific to particular radiation uses, a typical protocol might include the following checks:

(a) Is the application for authorization appropriate for the proposed radiation use?

(b) Does the radiation source meet exemption criteria in the legislation or, in particular, in the regulations?

(c) Is the applicant (i.e. the operator) and, where applicable, its representative clearly identified?

(d) Has a Radiation Protection Officer with suitable qualifications and experience been nominated (and, if relevant, a Radiation Protection Committee appointed)?

(e) Is the physical location of the proposed radiation use identified?

(f) Is the proposed use of the radiation sources explained?

(g) Has an inventory of radiation sources been provided? Does the inventory correctly identify each radioactive source (i.e. radionuclide, activity, date of measurement of activity, form, use, and if contained in a device: the manufacturer, model and serial number of the device) and X ray equipment (i.e. manufacturer, model, maximum kVp and mA, serial number, use, location on premises)?

(h) Has a satisfactory Radiation Protection Programme been submitted?

The contents of the Radiation Protection Programme (RPP) have been outlined in Section 4, item 4.3. The detail of the RPP depends on the type(s) of radiation sources and the perceived radiation hazard. This may range from the low risk use of dental X ray equipment to the significant hazards that can arise in radiotherapy, industrial radiography, well logging or irradiators. The RPP will need to be prepared by the radiation protection officer (RPO) or a qualified expert.

Except for field work, all applications require a scale plan of the premises showing relevant information such as the location of the sources, their purpose, beam direction (i.e. if relevant), the building and shielding materials of the construction, the purpose of surrounding rooms and areas, occupancy time factors, storage areas, etc. The construction material and shielding thickness designated in the RPP must be supported by calculations prepared by the RPO or the qualified expert.

The assessment officer may need to contact the applicant for further information and may recommend to his/her in supervisor in the regulatory body that the facilities and radiation sources be inspected before the review and assessment of the application is completed. All requests for further information and their response from the applicant should be in writing. The regulatory body's internal procedures should establish which officer signs correspondence sent to applicants. Any requirement for pre-approval inspections should be documented in the regulatory body's internal procedures along with the specific inspection procedures.

The assessment officer recommends the conditions to be placed on the authorization. These conditions may be taken from the safety requirements defined in the legislation and, in particular, the existing regulations, codes or practice or regulatory guides. In situations where a code or practice or regulatory guide does not exist, the assessment officer may have to develop appropriate conditions for authorization. An outline of the basic steps for an authorization review and approval process is given in Figure 2.

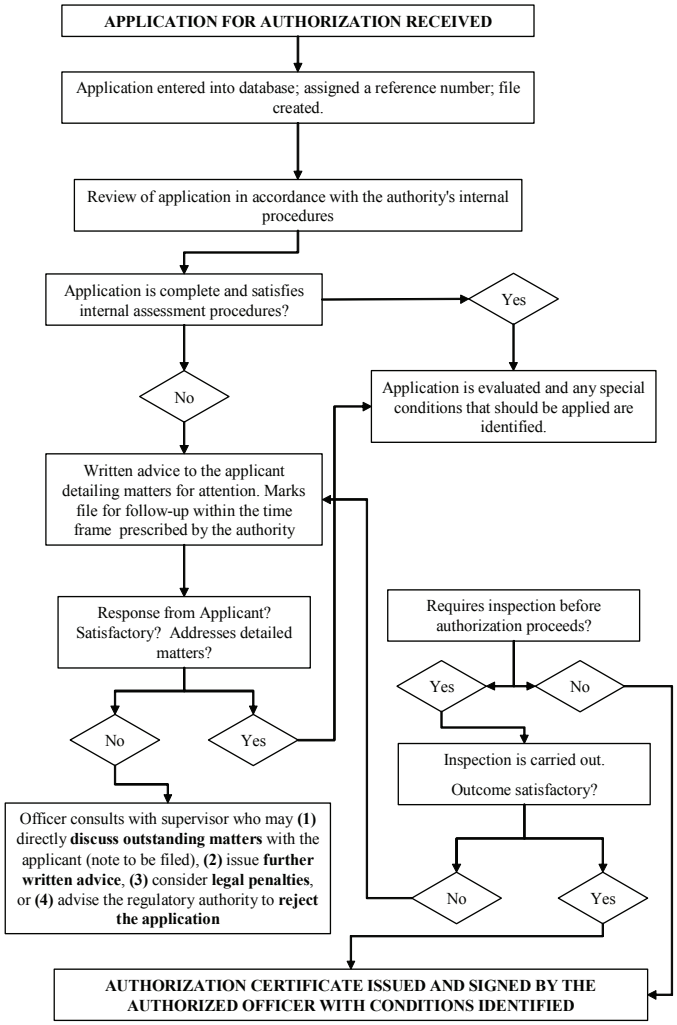

FIG. 2. Procedure for assessing applications for authorization.

4.6. INSPECTIONS BY THE REGULATORY BODY AS PART OF THE REVIEW AND ASSESSMENT PROCESS

The Safety Guide GS-G-1.5 recommends that: *"A fundamental feature of the process of review and assessment by the regulatory body of an application for authorization is its consideration of the documentation submitted by the applicant. For significant risk sources or unusual or complex practices, the regulatory body should also verify the contents of the documents submitted by means of inspection of the site where the radiation sources are to be installed or used. These inspections will also allow the regulatory body to supplement the information and data needed for review and assessment. Additionally, the regulatory body will be able to extend its practical understanding of the managerial, engineering and operational aspects of the application for authorization and to foster links with specialists of the operating organization"* (Ref. [2], para. 3.42).

An inspection as part of the review and assessment of an application for authorization process is recommended for Categories 1 and 2, and also for some cases in Category 3, of the radioactive sources listed in reference [6]. In addition, they are recommended for nuclear medicine practices, linear accelerators and some equipment used in diagnostic and interventional radiology.

For practices where the design and construction of a building housing of the radiation source(s) is particularly critical to radiation safety, one or more inspections may be necessary before the applicant takes possession of radiation source(s). Examples include facilities for the use of industrial irradiators, sources used in radiotherapy, and enclosed (permanent) industrial radiography rooms.

An inspection as part of the process involved with the review and assessment of an application for authorization might not be essential for sources dealt with by registration (e.g. X ray equipment in dental practices and some radioactive gauges). In such circumstances the regulatory body will have prepared criteria that detail generic radiation safety requirements for the particular practice and for the radiation sources. Working rules will also be established that ensure compliance with occupational and public dose limits and that radiation protection is optimised. These criteria are generally provided to operators in the form of a *code of practice* or *regulatory guide*. Provided that the RPP submitted by an applicant for the authorization of a given practice is satisfactory and an acknowledgment is included that the work practices comply with the relevant code of practice or regulatory guide, the regulatory body may be prepared to grant the authorization without a pre-operational inspection.

4.7. APPROVAL OR REJECTION OF AN APPLICATION

The Safety Requirements GS-R-1 stipulates that: *"The regulatory review and assessment will lead to a series of regulatory decisions. At a certain stage in the authorization process, the regulatory body shall take formal actions which will result in either: (1) the granting of an authorization which, if appropriate, imposes conditions or limitations on the operator's subsequent activities; or (2) the refusal of such an authorization. The regulatory body shall formally record the basis for these decisions"* (Ref. [1], para. 5.5).

The regulatory body's procedures for approving or rejecting an application for authorization must be based on the radiation safety law, regulations, codes of practice or regulatory guides that apply to the radiation sources included in the application. A supervisor should review the report of the ASSESSMENT OFFICER before any formal recommendation is made to grant or reject an application. The procedures by which authorizations are granted or rejected vary and are subject to the requirements of the law and regulations of each country.

The regulatory body should seek appropriate legal advice when rejecting applications for authorization, as a decision to reject an application may result in an appeal by the applicant with potentially lengthy and costly legal action. Notification that an application has been rejected are to be given in writing and signed by an appropriately authorized officer. Such letters should be reviewed by the regulatory body's legal adviser, and must clearly state the reasons for the decision, and include references to the relevant parts of the law and regulations. Where the applicant already possesses the radiation source(s), directions must also be given for its disposal in accordance with the law and regulations within a specified time frame. The regulatory body must verify the disposal of the radiation source.

4.8. ISSUING THE AUTHORIZATION

The Safety Requirements GS-R-1 stipulates that: *"The regulatory body shall provide for issuing, amending, suspending or revoking authorizations, subject to any necessary conditions, that are clear and unambiguous and which shall specify (unless elsewhere specified):*

(a) the facilities, activities or inventories of sources covered by the authorization;

(b) the requirements for notifying the regulatory body of any modifications to safety related aspects;

(c) the obligations of the operator in respect of its facility, equipment, radiation source(s) and personnel;

(d) any limits on operation and use (such as dose or discharge limits, action levels or limits on the duration of the authorization);

(e) conditioning criteria for radioactive waste processing for existing or foreseen waste management facilities;

(f) any additional separate authorizations that the operator is required to obtain from the regulatory body;

(g) the requirements for incident reporting;

(h) the reports that the operator is required to make to the regulatory body;

(i) the records that the operator is required to retain and the time periods for which they must be retained; and

(j) the emergency preparedness arrangements" (Ref. [1], para. 3.2(3)).

The regulatory body should issue the authorization certificate to the operator. The designated officer of the regulatory body should sign the authorization certificate. The authorization certificate would include**:** the authorization number; the date of issuance; the expiry date; the name of the legal person; the name of the person directly responsible for the use of the radiation source, if different from the operator; the location where the radiation sources are to be used, stored or otherwise dealt with; the purpose of the authorization; the name of the RPO; and any necessary additional conditions, restrictions or limitations. An example of a basic authorization certificate form is presented in the Attachment VI.

4.9. RENEWAL OF AUTHORIZATIONS

The Safety Requirements GS-R-1 requires that: *"Any subsequent amendment, renewal, suspension or revocation of the authorization shall be undertaken in accordance with a clearly defined and established procedure. The procedure shall include requirements for the timely submission of applications for renewal or amendment of authorizations"* (Ref. [1], para. 5.6).

The regulatory body should require a renewal of an authorization after a set time interval. In such instances, a review would usually be made of the findings of inspections and of other information on performance and its results would be documented as part of the revalidation process. Authorization details should be kept up to date (Ref. [2], para. 3.47). The intervals can be determined following an assessment of the potential risks associated to the relevant radioactive sources [6]. The renewal of authorizations is not a subject to be considered only from a bureaucratic view point but needs to take into account that unnecessary short authorization validity periods may increase the administrative work at the expense of more significant regulatory control work. The time intervals for authorization are not directly comparable to time intervals between inspections.

4.10. AMENDING AUTHORIZATIONS

The Safety Guide GS-G-1.5 recommends that: *"The regulatory body should require the operator to notify any significant changes to safety related aspects of the practice and to apply, where necessary, for an amendment to or a renewal of the authorization. Any modification to safety related aspects of a facility or an activity with radiation sources should be subject to an assessment by the operator, with account taken of the possible magnitude and nature of the associated risk. The regulatory body is required to review this assessment"* (Ref. [2], para. 3.48).

During the period of an authorization some operators could make changes of operational procedures or modifications in their premises that may materially affect public and occupational radiation protection. Other changes may relate to administration and supervision and may not have a direct effect on radiation safety but nevertheless may need notification to and approval of the regulatory body.

As noted earlier, the conditions placed on an authorization are required to include the requirement for notifying the regulatory body of any change or modification to radiation safety related aspects (Ref. [1], para. 3.2(3)(ii)). The types of changes or modifications for which notification might be required include:

(a) an intention to take possession of a radiation source of a nature or type not subject to the existing authorization, or the acquisition of additional radiation sources;

(b) the planned disposal (e.g. by any means) of radiation sources, whether radioactive or devices that electrically generate ionizing radiation (i.e. other than the disposal of radioactive waste in accordance with previously approved amounts and procedures);

(c) planned alterations to the premises that might adversely affect radiation safety;

(d) the planned relocation of radiation sources within the premises or their circumstantial use in other premises;

(e) the planned transfer of ownership of the business, organization, etc. which holds the authorization. The regulatory body is required to allow the authorization to be transferred only to operators who possess a valid authorization (Ref. [3], para. 2.34(b)); and

(f) a change in the RPO, QUALIFIED EXPERT, etc.

4.11. EXEMPTIONS

The Safety Requirements GS-R-1 stipulates that the legislation: *"shall establish authorization and other processes (such as notification and exemption)… and shall specify the steps of the processes"* (Ref. [1], para. 2.4(3)).

In this respect, the Safety Guide GS-G-1.5 clarifies that: *"Exemption is a regulatory mechanism that provides operators with relief from regulatory requirements, including those for notification and authorization for practices or sources within a practice. Where exemption is considered appropriate, the exemption criteria presented in Schedule I of the Basic Safety Standards [3] should be applied for such purposes. This Schedule describes those practices or sources within a practice that can be automatically exempted without further consideration from the requirements of the Basic Safety Standards and those sources for which a conditional exemption may be granted"* (Ref. [2], para. 3.15).

A request for a conditional exemption could be based on information provided on a notification form. For each request, the regulatory body should consider the conditional exemption criteria given in the *Basic Safety Standards* [3], which state that**:** *"Conditional exemptions may be granted subject to conditions specified by the Regulatory Authority, such as conditions relating to the physical or chemical form and to the use or disposal of the radioactive materials. In particular, such an exemption may be granted for an apparatus containing radioactive substances not otherwise exempted under para. I-4 (a) provided that:*

(a) it is of a type approved by the Regulatory Authority;
(b) the radioactive substances are in the form of sealed sources that effectively prevent any contact with radioactive substances or their leakage except that this should not prevent exemption of small quantities of unsealed sources such as those used for radioimmunoassay;

(c) in normal operating conditions it does not cause an ambient dose surface equivalent rate or a directional dose equivalent rate, as appropriate, exceeding 1 mSv.h^{-1} at a distance of 0.1 m from any accessible surface of the apparatus; and

(d) necessary conditions for disposal have been specified by the Regulatory Authority." (Ref. [3], para. I.5).

4.12. CANCELLATION OF AUTHORIZATION AND AUTHORIZATION OF TRANSFER OR DISPOSAL

An authorization for a practice involving the use of radiation sources may be cancelled because the radiation sources are no longer required or because the regulatory body has taken an enforcement action. The regulatory body is required to ensure that the radiation sources are transferred to an operator who possesses a valid authorization (Ref. [2], para. 2.34(b)), or are disposed of to an authorized waste management facility. Decisions to suspend or revoke an authorization are enforcement actions that are discussed also in reference [2].

Circumstances leading to the cancelling of a licence because the radiation source is no longer needed include the sale or disposal of the radiation sources, failure of the business (e.g. bankruptcy), and death of the only owner of the operating organization. The legislation is required to specify the process for removal of a facility or activity using radiation sources from regulatory control (Ref. [1], para. 2.4 (6)), and the regulatory body is required to ensure that operators follow this process.

For sales of radiation sources, the regulatory body is required to ensure that radiation sources are not transferred unless the purchaser possesses a valid authorization (Ref. [3], para. 2.34(b)). The regulatory body is to be satisfied that the premises where the radiation sources were used are not contaminated and that a final decommissioning report, including any necessary final confirmation survey, is prepared and retained with other records, as appropriate before cancelling the authorization. The report is to be prepared by a qualified expert, and a final inspection may need to be carried out by the regulatory body.

In the case of bankruptcy or death of the operator, the ownership of the radiation sources might be transferred to an insolvency administrator, bank, business partner, family member, etc. who may or may not have knowledge or experience in radiation safety. The regulatory body is required to ask the new owner to make an application for authorization, or it can require the new owners to sell or dispose of the radiation source to an operator that possesses a valid authorization. The regulatory body is required to take appropriate enforcement actions (Ref. [1], para. 5.18) and is required to ensure that such sources are kept secure (Ref. [3], para. 2.34) in these circumstances.

A difficult and potentially dangerous situation for all regulatory bodies is where radiation sources are transferred (i.e. knowingly or unknowingly) to persons who are ignorant of the legislation and of the hazards associated with radiation sources. Such sources may be on-sold or scrapped, increasing the risk that they also may be tampered with or perhaps smelted. For radioactive sources, appropriate labelling (in the local language) together with the displayed radiation-warning symbol might alert the new owners to contact the regulatory body for advice but this cannot be guaranteed. The regulatory body needs to maintain regular contact with operators through a rigorous inspection programme (particularly for high risk sources), and ensure that regulatory requirements for control and accountability of sources are enforced, to minimise the risk of sources falling out of regulatory control.

4.13. DOCUMENTATION PRODUCED BY THE REGULATORY BODY

A range of documents should be prepared by, or made available through, the regulatory body for public information. The regulatory body may maintain a web site from which notification

and application forms, and regulatory and radiation safety information can be provided to users and the public.

Available documentation should include**:**

(a) the role, responsibilities and legal powers of the regulatory body;

(b) the radiation safety law, regulations and codes of practice or regulatory guides for a range of radiation practices and sources;

(c) excluded radiation sources;

(d) exempted radiation sources and practices;

(e) notification forms;

(f) authorization application forms;

(g) regulatory body's criteria for reviewing and assessing applications;

(h) standard authorization conditions;

(i) penalties for each type of offences;

(j) design and performance standards for radiation devices (e.g. adopted or amended standards or recommendations of the International Electrotechnical Commission, the International Standards Organization, the IAEA, etc.);

(k) authorization amendment forms (i.e. an appropriate letter may suffice);

(l) shippers declaration forms (i.e. for the transport of radioactive sources);

(m) import and export regulations;

(n) fees for authorizations, if established by law;

(o) fees for inspections, if established by law;

(p) approved national or foreign providers of personal radiation monitoring;

(q) approved national or foreign performers of radiation detector-, source- and beam-calibrations;

(r) recognized training and radiation safety courses for different types of practices;

(s) minimum qualifications and training for users of the different types of radiation sources;

(t) incident or accident reporting forms; and

(u) application form for the authorization of a transfer (e.g. sale or other disposal) of radiation sources.

Annex I

EXAMPLES OF MEMORANDA OF UNDERSTANDING

MEMORANDUM OF UNDERSTANDING

between the

REGULATORY BODY

and the

DEPARTMENT OF CUSTOMS

1. Rationale

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

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

2. Purpose

The purpose of this Memorandum of Understanding (hereafter, 'MOU') is to state the roles and responsibilities of the Regulatory Body and the Department of Customs in relation to the import and export of radiation sources and to establish clear working guidelines on the actions to be taken by the respective parties.

3. Scope

For the purpose of this MOU, "radiation sources" means:

(a) all radioactive substances; and

(b) all devices that are capable of producing ionizing radiation when electrically energized[2];

other than those exempted[3] by the Regulatory Body under the Radiation Control Legislation.

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

The Harmonized Tariff Schedule for radiation sources is given in **Attachment A.**

The Regulatory Body administers the Radiation Control Legislation (***Note:** Insert proper title and date*) and the related regulations, which create an offence for a person to possess, use, manufacture, store, transport, dispose of, or otherwise deal with non-exempt radiation sources unless they do so under an authorization issued by the Regulatory Body.

The Department of Customs administers the Customs Legislation (***Note:** Insert proper title and date*) and related regulations and is responsible for controlling the country's imports and exports in accordance with this legislation.

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[2] For example, X ray equipment, linear and particle accelerators, etc.

[3] The regulations to the Radiation Control Legislation state the exempt activity of specific radioactive substances, whether as discrete sources or in bulk, and identify exempt electrical devices.

4. Governmental Agencies not Exempt from Compliance

It is noted that all government agencies are bound by the Radiation Control Legislation and subject to the prescribed penalties for non-compliance.

5. General Agreement

5.1 Customs agrees that it shall not permit the importation of any radiation source unless the person to whom the radiation source is consigned can produce an *Authority to Import*[4] certificate issued by the Regulatory Body. In the event that the authorization cannot be produced, Customs agrees that it will hold the shipment in an area approved by the Regulatory Body and immediately notify the Regulatory Body of the details of the shipment.

5.2 Customs agrees that it shall not permit the export of any radioactive substance unless the consignor can produce an *Authority to Export*[5] certificate issued by the Regulatory Body.

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

6. Informing the Regulatory Body

Notwithstanding paragraph 5, Customs agrees to promptly notify the Regulatory Body of the details of all imported radiation sources, including the name and contact details of the importer, and the date of importation. The agreed form for this purpose is given in **Attachment B**.

7. Informing Customs

The Regulatory Body agrees to promptly notify the Customs Department of any changes to the legislation, or of any other decision taken by the Regulatory Body, that has a bearing on the importation, storage or transport of radiation sources.

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

8. Training of Customs Personnel

The Regulatory Body agrees that it will provide radiation safety training to all Customs officers designated by the Customs Department and will provide additional support as may be required from time to time. However, the Department of Customs may obtain the services of an approved[6] Qualified Expert for these purposes if it so wishes.

9. Opening Packages or Containers

To ensure the health and safety of its workers, the Department of Customs agrees that its officers will not open any package or container bearing the internationally recognized radiation warning symbol, or any package or container that its officers have reason to believe may contain a radioactive source, unless an officer of the Regulatory Body (or an approved[6] Qualified Expert) is present to direct and supervise radiation safety procedures.

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[4] The purpose of this certificate is to signify the Regulatory Body's approval that importation may proceed, subject to any other requirements that may be imposed by the Department of Customs.

[5] The purpose of this certificate is to signify the Regulatory Body's approval that a radioactive substance may be exported, subject to any other requirements that may be imposed by the Department of Customs. It does **not** signify that the substance has been packaged in accordance with the Transport Regulations. That is the responsibility of the Consignor.

[6] Approved by the Regulatory Body

10. Portal radiation detection equipment

The Regulatory Body and the Department of Customs agree that they will discuss with their respective Ministers the need for the installation and operation of portal radiation detection equipment at designated[7] points of entry into the country.

11. Contact Persons

Until otherwise notified in writing, the contact person for the Regulatory Body is [***Note:*** *Insert name and title, position held, contact telephone number*] and for the Customs Department [***Note:*** *Insert name and title, position held, contact telephone number*].

This MOU takes effect from the date it is signed by both parties.

DIRECTOR	**CHIEF CUSTOMS OFFICER**
REGULATORY BODY	**DEPARTMENT OF CUSTOMS**
Date _____	**Date _____**

[7] Designated by Government

Attachment A

REFERENCE NUMBER	GOODS
28.44	**RADIOACTIVE CHEMICAL ELEMENTS AND RADIOACTIVE ISOTOPES**
	(including the fissile or fertile chemical elements and isotopes)[1] and their compounds; mixtures and residues containing these products
2844.10	Natural uranium and its compounds; alloys, dispersions (including cermets), ceramic products and mixtures containing natural uranium or natural uranium compounds
2844.20	Uranium enriched in ^{235}U and its compounds; plutonium and its compounds; alloys, dispersions (including cermets), ceramic products and mixtures containing uranium enriched in ^{235}U, plutonium or compounds of these products
2844.30	Uranium depleted in ^{235}U and its compounds; thorium and its compounds; alloys, dispersions (including cermets), ceramic products and mixtures containing uranium depleted in ^{235}U, thorium or compounds of these products
2844.40	Radioactive elements and isotopes and compounds other than those of 2844.10, 2844.20 or 2844.30; alloys, dispersions (including cermets), ceramic products and mixtures containing these elements, isotopes or compounds; radioactive residues
2844.50	Spent (irradiated) fuel elements (cartridges) of nuclear reactors
2845	Isotopes other than those of 2844; compounds, inorganic or organic, of such isotopes, whether or not chemically defined.
90.22	**APPARATUS BASED ON THE USE OF X RAYS OR OF ALPHA, BETA OR GAMMA RADIATIONS, whether or not for medical, surgical, dental or**

[1] *Heading 2844 applies only to:*

(a) Technetium (atomic number 43), promethium (atomic number 61), polonium (atomic number 84) and all elements with an atomic number greater than 84;

(b) Natural or artificial radioactive isotopes whether or not mixed together;

(c) Compounds, inorganic or organic, of these elements or isotopes, whether or not chemically defined, whether or not mixed together;

(d) Alloys, dispersions (including cermets), ceramic compounds and mixtures containing these elements or isotopes or inorganic or organic compounds thereof and having a specific radioactivity exceeding 74 Bq/g;

(e) Spend (irradiated) fuel elements (cartridges) of nuclear reactors; and

(f) Radioactive residues whether or not useable.

The term "isotopes" for the purposes of this Note and of the wording of headings 2844 and 2845, refers to:

- *Individual radionuclides, excluding, however, those existing in nature in the monoisotopic state; mixtures of isotopes of one and the same element, enriched in one or several of the said isotopes, that is, elements of which the natural isotopic composition has been artificially modified.*

REFERENCE NUMBER		GOODS
		veterinary uses, including radiography or radiotherapy apparatus, X ray tubes and other X ray generators, high tension generators, control panels and desks, screens, examination or treatment tables, chairs and the like
	9022.1	*Apparatus based on the use of X rays, whether or not for medical, surgical, dental or veterinary uses, including radiography or radiotherapy apparatus*
	9022.12	Computed tomography apparatus
	9022.13	Other, for dental uses
	9022.14	Other, for medical, surgical or veterinary uses
	9022.19	For other uses
	9022.2	*Apparatus based on the use of alpha, beta or gamma radiations, whether or not for medical, surgical, dental or veterinary uses, including radiography or radiotherapy apparatus*
	9022.21	For medical, surgical, dental or veterinary uses
	9022.29	For other uses
	9022.30	X ray tubes
	9022.90	Other, including parts and accessories
84.01		**NUCLEAR REACTORS; FUEL ELEMENTS (CARTRIDGES), NON-IRRADIATED FOR NUCLEAR REACTORS, MACHINERY AND APPARATUS FOR ISOTOPIC SEPARATION**
	8401.10	Nuclear reactors
	8401.20	Machinery and apparatus for isotopic separation, and parts thereof
	8401.30	Fuels elements (cartridges), non-irradiated
	8401.40	Parts of nuclear reactors
85.43		**ELECTRICAL MACHINES AND APPARATUS, HAVING INDIVIDUAL FUNCTIONS, NOT SPECIFIED OR INCLUDED ELSEWHERE IN THIS CHAPTER**
		- Particle accelerators
	8543.11	Ion implanters for doping semiconductor materials
	8543.19	Other

*[**Note:** The codes and goods descriptions shown above should be confirmed with your country's Customs Department or Agency]*

Attachment B

IMPORTATION OF NON-EXEMPT RADIATION SOURCES

NOTIFICATION TO THE REGULATORY BODY

To be completed by the Consignee or their authorized agent.

Original has to be retained by Customs Department. Copy to the Consignee

PORT OF ENTRY	
DATE OF ENTRY	
INDENTIFICATION NUMBER (i.e. Customs Department identification)	
IMPORT AUTHORITY CERTIFICATE NUMBER (i.e. issued by the Regulatory Body)	
IMPORTING AGENT	
ADDRESS	
TELEPHONE NUMBER	
CONSIGNEE'S NAME	
ADDRESS	
TELEPHONE NUMBER	
FAX NUMBER	
RADIATION SOURCE TYPE	**Radioactive** ☐ **Other** ☐

RADIOACTIVE SUBSTANCES	
RADIONUCLIDE(s) (e.g. ^{60}Co, ^{192}Ir, ^{235}U, etc.)	
ACTIVITY (i.e. usually Becquerels, e.g. MBq, GBq, TBq, etc.)	
PHYSICAL FORM	
INTENDED USE	

OTHER RADIATION SOURCES	
MANUFACTURER	
MODEL	
SERIAL NUMBER	
INTENDED USE	

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

For additional information, contact the Regulatory Body on (e.g. phone number: 880 222 3333).

CUSTOMS DEPARTMENT: *- Immediately fax a copy of this form to the Regulatory Body on (e.g. fax number: 880 222 3334).*

MEMORANDUM OF UNDERSTANDING

between the

REGULATORY BODY

and the

DEPARTMENT OF HEALTH

(***Note:*** *For the purpose of this example of MOU, it is been assumed that the Regulatory Body is administratively part of a Health Department. However, in some countries, the Regulatory Body may be fully independent or operate as an arm of some other governmental department. In this case, the MOU should address the question of the Regulatory Body independence*)

1 Rationale

The Regulatory Body and Department of Health necessarily have a close relationship. The Health Department has responsibility for the registration and accreditation of health professionals as well as responsibilities for the funding, staffing and administration of public hospitals and other public health facilities (e.g. screening mammography and tuberculosis control programmes). All of these facilities use ionizing radiation sources for a wide range of purposes (e.g. diagnostic radiology, nuclear medicine, radiotherapy, blood irradiation, pathology testing and research) and are required to comply with the Radiation Control Legislation and, within the provisions of that Act, the directions of the Regulatory Body.

However, the Regulatory Body is reliant on the Department of Health for its budget, staffing, administrative and legal support. Both agencies are responsible to the Minister for Health. The potential for a conflict of interest is clearly evident and it is essential that the respective roles and responsibilities of the Regulatory Body and the Department of Health are identified and accepted by all parties.

2 Purpose

The purpose of this Memorandum of Understanding (hereafter, 'MOU') is to state the roles and responsibilities of the Regulatory Body and the Department of Health in relation to the administration of the Radiation Control Legislation and the use of radiation sources by the Department of Health.

3 Scope

For the purpose of this MOU, "*radiation sources*" means:

(a) all radioactive substances; and

(b) all devices that are capable of producing ionizing radiation when electrically energized[8];

other than those exempted[9] by the Regulatory Body under the Radiation Control Legislation.

The Regulatory Body administers the Radiation Control Legislation (***Note:*** *Insert proper title and date*) and the related regulations that, in brief, create an offence for a person to possess, use, manufacture, store, transport, dispose of, or otherwise deal with non-exempt radiation sources unless they do so under an authorization issued by the Regulatory Body.

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[8] For example, X ray equipment, linear and particle accelerators, etc.

[9] The regulations to the Radiation Control Legislation state the exempt activity of specific radioactive substances, whether as discrete sources or in bulk, and identify exempt electrical devices.

The Department of Health administers a range of legislation (***Note:*** *Insert proper titles and dates*) and related regulations and is responsible, generally, for implementing the Government's public health policies.

4 Governmental Agencies and Departments not Exempt from Compliance

It is noted that all governmental agencies and departments are bound by the Radiation Control Legislation and subject to the prescribed penalties for non-compliance.

5 General

It is agreed that:

- For the purpose of administering the Radiation Control Legislation, the Regulatory Body is an independent agency responsible directly to the Minister with decision-making powers that do not require the prior approval of, or agreement with, the Department of Health.
- As both the Regulatory Body and the Department of Health are responsible to the same Minister, it is in each other's interests to co-operate and keep each other informed of matters of mutual interest.
- As the Department of Health is responsible for both the registration and accreditation of the health professionals (i.e. medical practitioners, dentists, and others) the Department will take into account the views of the Regulatory Body in relation to the qualifications and training of professionals who use (or wish to use) ionizing radiation sources for human diagnostic or therapeutic procedures as well as the radiation safety training of all professionals who prescribe (i.e. refer patients for) such procedures.
- Communications shall be between the Director of the Regulatory Body and the Director General of the Department of Health.
- Where a situation arises that is not dealt with by this Agreement, no action will be taken by either party without first consulting with the other.

6 Specific Matters

It is agreed that

6.1 If the Department of Health acts to centrally purchase radiation sources for distribution to its hospitals or agencies, it will inform the Regulatory Body in writing of its intention to do so, identifying the sources and the intended location of use.

6.2 As the Department of Health is responsible for the registration and accreditation of the health professionals, it will provide the Regulatory Body a list of all health professionals (i.e. medical practitioners, dentists, etc.) including their full name, basic and specialist qualifications and professional affiliations, and the hospitals (i.e. both public and private) to which they have accreditation.

6.3 Where the Department of Health is appraised of a matter, which has or may have relevance to the Regulatory Body's responsibilities, it will promptly refer the matter to the Regulatory Body for its advice or action. Furthermore, should the matter solely concern radiological issues, it is agreed that responsibility for the response will be transferred to the Regulatory Body and the Department of Health will inform all persons concerned accordingly.

However, if radiological concerns are not the sole issue, the Regulatory Body agrees that it will prepare advice on matters within its responsibilities for inclusion with the reply or report

being prepared by the Department of Health. The Department of Health agrees that it will not edit, amend or ignore the Regulatory Body's advice in its reply or report.

Examples of matters that may have radiological safety implications and which may require advice from or should be referred to the Regulatory Body include:

- the development of relevant public health policies;
- the drafting or amendment of legislation (such as legislation regulating the dental, medical or other professions prescribing or using ionizing radiation);
- the preparation of reports to the Minister or replies to ministerial correspondence;
- statements to the public or the media (i.e. typically on matters of current public concern);
- the Government's emergency response programme;
- enquiries concerning the implementation of the Radiation Control Legislation, the role and responsibilities of the Regulatory Body and the initiation of any prosecution or its outcome;
- advice on the potential health impact of developing land for public or private use (e.g. housing, recreation, industry, etc) that has previously been used by industry or for radioactive waste disposal, or is immediately adjacent to such land; and
- the public health impact of the use of radioactive waste materials from industry as land fill or for other purposes.

6.4 Should the Regulatory Body become aware of any radiological matter that has implications for public health in general (i.e. the potential to affect a significant proportion of the population), it will promptly notify both the Minister and the Department of Health so that an appropriate response may be coordinated.

6.5 For the Health Department's information, the Regulatory Body will provide a copy of any advice or report that it presents to the Minister.

6.6 Should the Regulatory Body conclude that a Departmental Hospital or agency has breached the legislation and that prosecution is to be pursued, the Regulatory Body may obtain legal advice and representation from sources outside the Department of Health and such actions will be fully funded.

6.7 The necessary resources for the Regulatory Body to properly fulfill its mandate (e.g. the budget, personnel, equipment, travel, legal advice, etc.) and any subsequent changes will be negotiated between the Regulatory Body, the Department of Health and the Minister.

6.8 Responsibility for compliance with the Radiation Control Legislation in hospitals and agencies operated by the Department of Health, which possess or use radiation sources, will rest with the senior management level (e.g. Director, Administrator, etc) of each hospital or agency. That person will be the "legal person[10]" as defined in the legislation.

[10] Any organization, corporation, partnership, firm, association, trust, estate, public or private institution, group, political or administrative entity or other persons designated in accordance with national legislation, who or which has responsibility and authority for any action taken under these Standards. [3]

However, as the principal employer, the Department of Health agrees that it will encourage a culture of safety[18] in all its hospitals and agencies to minimize radiation hazards to its employees, patients and the public.

7 Contact Persons

Until otherwise notified in writing, the contact person for the Regulatory Body is [***Note:*** *Insert name and title, position held, contact telephone number*] and for the Department of Health [***Note:*** *insert name and title, position held, contact telephone number*].

This MOU takes effect from the date it is signed by both parties.

DIRECTOR	**DIRECTOR GENERAL**
REGULATORY BODY	**DEPARTMENT OF HEALTH**
Date _____	**Date _____**

[18] The assembly of characteristics and attitudes in organizations and individuals, which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance. [3]. Therefore, a safety culture shall be fostered and maintained to encourage a questioning and learning attitude to protection and safety and to discourage complacency, which shall ensure that:

(a) policies and procedures shall be established that identify protection and safety as being of the highest priority;

(b) problems affecting protection and safety shall be promptly identified and corrected in a manner commensurate with their importance;

(c) the responsibilities of each individual, including those at senior management levels, for protection and safety shall be clearly identified and each individual shall be suitably trained and qualified; and

(d) clear lines of authority for decisions on protection and safety shall be defined; and organizational arrangements and lines of communications shall be effected that result in an appropriate flow of information on protection and safety at and between the various levels in the organization of the operator.

Annex II
EXAMPLE OF A NOTIFICATION FORM

RADIATION CONTROL LEGISLATION

NOTIFICATION ON THE USE [a] OF RADIATION SOURCES [b]

Complete this notification form and return to the address below of the Regulatory Body. Where space is insufficient for any item, attach additional signed sheets.

1. Name and address of the responsible officer (i.e. legal person) making the notification:

Tel: ☐ ☐

Fax: ☐ ☐

e-mail: ☐

1a. If a company, organization, etc., state the full name and position of a contact person together with their contact details:

2. Field of application and purpose(s) of the activity in which the radiation sources are or will be used:

3. Particulars of the radiation sources in use or to be used:

Note: *If space is insufficient, please, complete and attach additional sheets with the information shown below. If a radiation source is not labeled,, provide any identifying information that may be available including copies of any relevant documents.*

RADIOACTIVE SOURCES

Radionuclide (e.g. Ir-192)	**Identification Number**	**Location**	**Activity** [Becquerels]	**Activity Date**	**Form** (unsealed, sealed, solid, liquid, gas, etc.)

ELECTRICAL DEVICES PRODUCING IONIZING RADIATION (e.g. X ray equipment, accelerators, cyclotrons, etc.)

Manufacturer	**Model**	**Serial Number**	**Location**	**Maximum Power** (e.g. max radiographic kVp, mA)

NOTE:

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

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

Return the completed and signed form to the *REGULATORY BODY, BOX A5678, CAPITAL CITY 01235. (e.g. phone number 880 222 3333). No fee is required for notification.*

SIGNATURE of the person making the notification: _____

Name: (please print) _____

Date: _____

Annex III

EXAMPLE OF AN APPLICATION FORM FOR AUTHORIZATION

RADIATION CONTROL LEGISLATION

APPLICATION FOR AUTHORIZATION ON THE POSSESSION AND USE [a] OF RADIATION SOURCES[b]

Complete this application form and the supplementary form, and return both duly signed to the Regulatory Body with the fee, if required. Where space is insufficient for any item, attach additional signed sheets.

1. Name and address of the applicant (i.e. the operator / legal person):

Tel: | | |

Fax: | | |

e-mail: |

2. Location of the premises where the radiation practices and sources are to be used:

3. Field of application and purpose(s) for which the radiation practices and sources are to be used:

4. Name, qualifications, experience and contact details of the person nominated to be the Radiation Protection Officer:

5. Names, qualifications, experience and contact details of the Qualified Expert(s) retained to advise the applicant:

6. For sources used for medical exposure, the names, qualifications, experience and contact details of the medical practitioners who are to be designated by name in the registration or licence:

7. Details of the radiation sources that are used on the premises:

(Please complete the details in the attached SUPPLEMENTARY form)

NOTES:

a) "Use" means to possess, store, manufacture, sell, operate, import, export or any other meaning given in the legislation.

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

INSTRUCTIONS:

1) Guidance on completing the Application for Authorization is attached.
2) A Radiation Programme Programme (RPP) must accompany all applications for Authorization. Guidance on the content of the RPP is attached.
3) *Return the completed and signed form to the* ***REGULATORY AUTHORITY, BOX A5678, CAPITAL CITY 01235.*** *(e.g. phone number 880 222 3333).*

.

Signature of the applicant: (i.e. the operator / legal person): _____

Name: (please print) _____

Date: _____

RADIATION CONTROL LEGISLATION

APPLICATION FOR AUTHORIZATION
INVENTORY OF RADIATION SOURCES

FOR RADIOACTIVE SOURCES AND APPARATUS CONTAINING RADIOACTIVE SUBSTANCES

Radionuclide (e.g. Co-60)	**Activity** [1] [Becquerels]	**Form** [2]	**Use**	**Location**	**IF THE SOURCE IS ENCLOSED IN A DEVICE**		
					Manufacturer	**Model**	**Serial Number**

[1] For sealed sources include the date at which the activity applies.
[2] Solid, liquid, gas, sealed, unsealed

ELECTRICAL DEVICES PRODUCING IONIZING RADIATION (i.e. IONIZING RADIATION GENERATORS)

Manufacturer	**Model**	**Serial Number**	**Maximum Power** (e.g. max. radiographic kVp, mA)	**Use**	**Location**

SIGNATURE of the applicant: (i.e. the operator / legal ~~person)~~ _____

Name: (please print) _____

Date: _____

Annex IV
GUIDELINESS FOR APPLICANTS ON AUTHORIZATION

GENERAL GUIDELINES

It is an offence under the national legislation to possess, operate, manufacture or otherwise deal with prescribed (non-exempt[11]) radioactive sources, apparatus containing radioactive substances and/or ionizing radiation generators (hereinafter termed 'radiation practices and sources') unless a valid authorization certificate has been issued by the Regulatory Body.

INITIAL APPLICATIONS

These general guidelines for applicants are intended to be an information resource for persons making an initial application for authorization on the use of radiation practices and sources under the existing national legislation.

Operators who intend using different types of radiation practices and sources must complete the appropriate form for authorization in respect of each type of practice and/or category of radioactive source.

RENEWAL APPLICATIONS

These general guidelines for applicants may also be used to assist the completion of authorization renewal applications on the use of radiation practices and sources.

A completed and signed application for renewal, together with the prescribed fees, must be received by the Regulatory Body (*period of time to be determined by the regulatory body*) before the expiry date of the valid authorization certificate for the radiation practices and sources in use. Failure to do so is a breach of the national legislation.

FURTHER INFORMATION

Operators requiring further information should contact the Regulatory Body by the following address:
Note: *specify postal address, phone, facsimile and e-mail*

Additional information also can be obtained from the following regulatory body's web page:

[11] A number of radiation practices and sources are exempted from regulatory control by the legislation. The Regulatory Body may consider individual applications for exemption for other radiation practices and sources where, in its opinion and based on internationally accepted criteria, the radiation risks to individuals caused by the practice or radiation source(s) are sufficiently low as not to be of regulatory concern.

Appendix A

AUTHORIZATION GUIDANCE FOR APPLICANTS: DIAGNOSTIC RADIOLOGY & DENTAL PRACTICES

DIAGNOSTIC RADIOLOGY

Note: *The following numbers refer to the numbers on the application form (see Attachment III).*

1. Enter the legal name of the operator's business (i.e. the entity that has direct control over the possession and use of the X ray equipment). An individual may be designated as the operator only if the individual is acting in a private capacity. State the full mailing address to where correspondence (e.g. such as future renewal notices) should be sent.
2. Enter the full address of the actual location(s) where the X ray equipment will normally be used or stored.
3. In this case, the purpose for which the radiation sources are to be used is diagnostic radiology.
4. State the full name, qualifications, training, experience and contact details of the person nominated to be the operator's Radiation Protection Officer (RPO). Attach the nominee's curriculum vitae (CV) together with copies of relevant qualification and training certificates.
5. State the full name, qualifications, training, experience and contact details of the person nominated to be the operator's qualified expert (i.e.. the person who will advise the operator on radiation safety and perform regular audits of the operator's radiation protection programme). Attach the nominee's CV together with copies of supporting documentation.
6. State the full name, qualifications, training, experience and contact details of the medical practitioner (s) who will be responsible for ensuring overall patient protection and safety in the prescription of, and during the performance of, diagnostic X ray procedures. Attach the nominee's CV together with copies of supporting documentation. Include a description of the actions to be taken by the medical practitioner(s) to justify and optimise all procedures, and the actions to be taken in respect of pregnant or potentially pregnant patients.
7. Particulars of the radiation sources. State the manufacturer, model, serial number, purpose and location of the X ray equipment together with the peak tube potential (kVp) and current (mA).

Notes:

- *Purposes include radiography, fluoroscopy, computerized tomography (CT), digital subtraction angiography, dental intraoral, dental panoramic, mobile fluoroscopy, mobile radiography, etc.*
- *The location may be a room number or room description or, for mobiles, the location where the equipment is primarily used (theatre, ward).*
- *State the serial number on the X ray control panel.*

Instructions (1, 2 and 3)

The operator must also submit a Radiation Protection Programme (RPP) addressing all aspects of radiation

safety particularly the safety of the X ray equipment and work practices. At a minimum, the RPP will include the following:

- *A plan of the premises with a report from a QA verifying that the design and construction of the premises, and the siting of the X ray equipment, will ensure at least the minimum prescribed level of worker and public radiation safety. The plan and report must demonstrate compliance with the appropriate radiation dose constraints/dose limits by appropriate scientific methods.*
- *The qualifications, training and experience of medical practitioner(s), radiographers nursing staff and others, including their initial and ongoing radiation safety training, and the supervision by appropriately qualified medical practitioner(s) of those personnel who operate the X ray equipment.*
- *The occupational radiation protection programme, including arrangements for the monitoring of workers and the workplace, the classification of areas, local rules and procedures, the maintenance and provision of personal protective equipment, and equipment for radiation detection:*
  - *Identifying the service provider, the type(s) of personal monitors to be used and the proposed monitoring frequency; the maintenance of dose records and how personnel will be routinely advised of, and have access to, their dose records (irrespective of the reported dose).*
  - *Provision of protective equipment for operators of X ray equipment.*
  - *The calibration of survey meters (i.e. and routine function checks) including the name of the calibration service provider and calibration frequency.*
- *Information relating to the radiological protection of patients, including arrangements for the calibration of sources used for medical exposure, clinical dosimetry and quality assurance programmes:*
  - *Working rules for the X ray procedures to be undertaken, e.g. the use of shielding, distance and time, patient protection, pregnant patients, children, use of grids, beam collimation, type and speed of image receptor, restrictions on the use of fluoroscopy (i.e. not to be used for routine patient positioning), etc.*
  - *If research is performed that involves the exposure of patients or volunteers, explain how the operator, acting on advice from an Ethical Review Committee, will comply with the provisions of the Helsinki Declaration and the guidelines prepared by the Council for International Organizations of Medical Sciences and the World Health Organization.*
  - *The policy for pre-employment radiography or radiography for insurance or administrative purposes.*

    Note: *Any radiological examination for occupational, legal or health insurance purposes undertaken without reference to clinical indications is not justified unless it is expected to provide useful information on the health of the individual examined or unless the specific type of examination is justified by those requesting it in consultation with relevant professional bodies.*
  - *If the operator intends providing screening examinations (e.g. chest, mammography, bone density, etc.) provide the protocols to show that the specified examinations will be justified (i..e.. through the potential of the screening procedure for detecting disease as well as the likelihood of effective treatment of cases detected and, for certain diseases, the advantages to the community from the control of the disease).*

    Note*: Mass screening of population groups involving medical exposure is not justified unless the expected advantages for the individuals examined or for the population as a whole are sufficient to compensate for the economic and social costs, including the radiation detriment.*
  - *The facility's QC programme for ensuring that the X ray equipment continues to comply with the prescribed design and performance standards and that film/image processing is optimized (e.g. darkroom light tight, properly safe lit, use of appropriate film image processors)..*
  - *The operator's protocols for determining patient radiation doses and ensuring compliance, where practicable, with guidelines values established by a recognized body or professional organization.*
- *The arrangements to ensure safety of radiation sources: arrangements for regular safety audits including maintenance of the X ray equipment inventory; reviewing safe working practices, warning signs, etc.*
- *The RPO's protocols for routine audits of working practices; evidence that the RPO has authority to stop activities if they are considered unsafe or not in compliance.*
- *The legal person's plans for notifying the regulatory body of:*

- *occupational or public radiation doses which exceed prescribed limits;*
- *reportable incidents and accidents; and*
- *any significant changes to the information previously provided to the regulatory body including:*
  - *a planned change of location for the operator's principal operations; and*
  - *the receipt, transfer or other planned disposal of X ray equipment.*

The application must be signed by the operator and submitted with the applicable fee if required.

The operator may wish to give some indication of the date when it is planned to commence work with the radiation sources.

However, while the regulatory body will deal with the application expeditiously, no guarantee can be given that the licence will be granted by a particular date. Delays can be minimized by ensuring all the required and relevant information is provided in full and that the application is made well in advance.

DENTAL PRACTICES

Note: *The following numbers refer to the numbers on the application form (see Attachment III)*

1. Enter the legal name of the operator's business (i.e. the entity that has direct control over the possession and use of the X ray equipment). An individual may be designated as the operator only if the individual is acting in a private capacity. State the full mailing address to where correspondence (e.g. such as future renewal notices) should be sent.
2. Enter the full address of the actual location(s) where the X ray equipment will normally be used or stored.
3. In this case, the purpose for which the radiation sources are to be used is dental radiology.
4. State the full name, qualifications, training, experience and contact details of the person nominated to be the operator's Radiation Protection Officer (RPO). Attach the nominee's curriculum vitae (CV) together with copies of relevant qualification and training certificates. A dental practitioner may be nominated as the RPO.
5. State the full name, qualifications, training, experience and contact details of the person nominated to be the operator's qualified expert (i.e. the person who will advise the registrant on radiation safety and perform regular audits of the registrant's radiation protection programme). Attach the nominee's CV together with copies of supporting documentation.

   Note*: The regulatory body may waive this requirement for basic intraoral installations where it is satisfied that potential occupational exposures are likely to be insignificant.*

6. State the full name, qualifications, training, experience and contact details of the Dental Practitioner (or Medical Practitioner) who will be responsible for ensuring overall patient protection and safety in the prescription of, and during the performance of, the dental X ray procedures. Attach the nominee's CV together with copies of supporting documentation. Include a description of the actions to be taken by the practitioner to justify and optimise examinations.
7. Particulars of the radiation sources. State the manufacturer, model, serial number, purpose and location of the X ray equipment together with the peak tube potential (kVp) and current (mA).

Notes:

- *Purposes include intraoral, panoramic and cephalometric radiography, etc.*
- *The location may be a room number or room description.*
- *State the serial number on the X ray control panel.*

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Instructions (1, 2 and 3)

The operator must also submit a Radiation Protection Programme (RPP) addressing all aspects of radiation safety particularly the safety of the X ray equipment and work practices. At a minimum, the RPP will include the following:

- *A plan of the premises with a report from a qualified expert verifying that the design and construction of the premises, and the siting of the X ray equipment, will ensure at least the minimum prescribed level of worker and public radiation safety. The plan and report must demonstrate compliance with the appropriate radiation dose constraints dose limits by appropriate scientific methods.*

  Note: *In general, for small, basic intraoral installations, the regulatory body will be satisfied if the dentist provides a plan (to scale) showing the location of the X ray equipment, the exposure control and*

operator(s), the building materials and the use and occupancy of surrounding areas.

- *The qualifications, training and experience of Dental Practitioners, nursing staff and others, including their initial and ongoing radiation safety training, and the supervision by appropriately qualified Dental Practitioners of those personnel who operate the X ray equipment.*
- *The occupational radiation protection programme, including arrangements for the monitoring of workers and the workplace, the classification of areas, local rules and procedures, the maintenance and provision of personal protective equipment, and equipment for radiation detection: Identifying the service provider, the type(s) of personal monitors to be used and the proposed monitoring frequency; the maintenance of dose records and how personnel will be routinely advised of, and have access to, their dose records (irrespective of the reported dose).*

  ***Note:** The regulatory body may exempt individual dental practices from routine monitoring of personnel where it is satisfied that potential occupational exposures are likely to be insignificant. Information relating to the radiological protection of patients, including arrangements for the calibration of sources used for medical exposure, clinical dosimetry and quality assurance programmes:*

- *Working rules for the X ray procedures to be undertaken. (e.g. the use of shielding, distance and time, patient protection, film holders, pregnant patients, children, beam collimation, type and speed of image receptor, etc.).*
- *The facility's QC programme for ensuring that the X ray equipment continues to comply with the prescribed design and performance standards and that film/image processing is optimized; arrangements for regular safety audits including maintenance of the X ray equipment inventory; reviewing safe working practices, checking area dose rates, warning signs, etc.*
- *The registrant's protocols for determining patient radiation doses and ensuring compliance, where practicable, with guidelines values established by a recognized body or professional organization.*
- *If research is performed that involves the exposure of patients or volunteers, explain how the operator, acting on advice from an Ethical Review Committee, will comply with the provisions of the Helsinki Declaration and the guidelines prepared by the Council for International Organizations of Medical Sciences and the World Health Organization.*
- *The policy for pre-employment radiography or radiography for insurance or administrative purposes.*

  ***Note:** Any radiological examination for occupational, legal or health insurance purposes undertaken without reference to clinical indications is not justified unless it is expected to provide useful information on the health of the individual examined or unless the specific type of examination is justified by those requesting it in consultation with relevant professional bodies.*

- *if the operator intends providing screening examinations (e.g. panoramic radiography, etc.) provide the protocols to show that the specified examinations will be justified (i.e. through the potential of the screening procedure for detecting disease as well as the likelihood of effective treatment of cases detected and, for certain diseases, the advantages to the community from the control of the disease).*

  ***Note**: The mass screening of population groups involving medical exposure is not justified unless the expected advantages for the individuals examined or for the population as a whole are sufficient to compensate for the economic and social costs, including the radiation detriment.*

- *The arrangements to ensure safety of sources: arrangements for regular safety audits including maintenance of the X ray equipment inventory; reviewing safe working practices, warning signs, etc.*
- *The RPO's protocols for routine audits of working practices; evidence that the RPO has authority to stop activities if they are considered unsafe or not in compliance.*
- *The registrant's plans for notifying the regulatory body of:*
  - *occupational or public radiation doses which exceed prescribed limits;*
  - *reportable incidents and accidents;*
  - *any significant changes to the information previously provided to the regulatory body including:*
    - *a planned change of location for the registrant's operations; and*
    - *the receipt, transfer or other planned disposal of X ray equipment.*

The application must be signed by the operator and submitted with the applicable fee if required.

The operator may wish to give some indication of the date when it is planned to commence work with X ray equipment. However, while the regulatory body will deal with the application expeditiously, no guarantee can be given that the licence will be granted by a particular date. Delays can be minimized by ensuring all the required and relevant information is provided in full and that the application is made well in advance.

Appendix B

AUTHORIZATION GUIDANCE FOR APPLICANTS: NUCLEAR MEDICINE

NUCLEAR MEDICINE

Note: *The following numbers refer to the numbers on the application form (see Attachment III).*

1. Enter the legal name of the operator's business (i.e. the entity that has direct control over the possession and use of radiation sources in the practice of nuclear medicine). An individual may be designated as the operator only if the individual is acting in a private capacity. State the full mailing address to where correspondence (e.g. such as future renewal notices) should be sent.
2. Enter the full address of the actual location(s) where radiation sources will normally be stored or used.
3. In this case, the purpose for which the radiation sources are to be used is nuclear medicine. However, the operator must also indicate if the purpose is diagnostic, therapeutic, or both, for each type of radionuclides.
4. State the full name, qualifications, training, experience and contact details of the person nominated to be the operator's Radiation Protection Officer (RPO). Attach the nominee's curriculum vitae (CV) together with copies of relevant qualification and training certificates.
5. State the full name, qualifications, training, experience and contact details of the person nominated to be the operator's qualified expert (i.e. the person who will advise the operator on radiation safety and perform regular audits of the operator's radiation protection programme). Attach the nominee's CV together with copies of supporting documentation.

   Note*: This person may also be the medical physicist.*

   State the full name, qualifications, training, experience and contact details of the Medical Physicist who will be responsible for calibrating (or supervising the calibration) of the dose calibrator, imaging and counting equipment, and for supervising radiation safety during the administration of therapeutic radioactive substances. Attach the nominee's CV together with copies of supporting documentation. ***Note****: This person may also be the qualified expert.*
6. State the full name, qualifications, training, experience and contact details of the Medical Practitioner (MP) who will be responsible for ensuring overall patient protection and safety in the prescription of, and during performance of, the nuclear medicine procedures. Attach the nominee's CV together with copies of supporting documentation.
7. Particulars of the radiation sources. The operator must provide a full description of all radiation sources to be used. List all non-exempt radionuclides, including check and calibration sources, patient markers, etc. that will be used or stored (e.g. ^{99}Mo, ^{99m}Tc, ^{131}I, ^{57}Co, etc.) together with the activity or, for unsealed material, the maximum activity to be held. State all activities in SI units and, other than short half-life sealed sources, the date at which the activity was determined.

- For devices that generate ionizing radiation electrically (e.g. CT combined with SPECT), state the manufacturer, model and serial number together with the peak tube potential (kVp) and current (mA).

Instructions (1, 2 and 3)

The operator must also submit a Radiation Protection Programme (RPP) addressing all aspects of radiation safety particularly the safety of radiation sources, work practices, the transport of radioactive sources and emergency procedures. At a minimum, the RPP will include the following:

- *A plan of the premises with a report from a qualified expert verifying that the design and construction of the premises, and the siting of the radiation sources (i.e. including waiting areas for patients to whom radioactive sources have been administered) will ensure worker and public safety. The plan and report must demonstrate compliance with the appropriate radiation dose constraints/dose limits by appropriate scientific methods.*
  - *The plan also must address matters such as gas trapping procedures; ventilation (e.g. for gaseous radionuclides or aerosols); liquid waste disposal lines and dilution methods to ensure compliance with the regulations; disconnecting traps; bench, wall and other surface finishes for ready decontamination; room lighting, etc.*
- *A safety assessment that:*
  - *identifies the ways in which normal exposures and potential exposures could be incurred, account being taken of the effect of events external to the sources as well as events directly involving the sources and their associated equipment:*
  - *determines the expected magnitudes of normal exposures and, to the extent reasonable and practicable, estimates the probabilities and the magnitudes of potential exposures; and*
  - *assesses the quality and extent of the protection and safety provisions.*
- that states the probability and magnitude of potential exposures.
- *The qualifications, training and experience of medical practitioners, nucleographers nursing staff and others, including their initial and ongoing radiation safety training, and the supervision by appropriately qualified medical practitioners of personnel preparing and administering radiation to patients.*
- *The occupational radiation protection programme, including arrangements for the monitoring of workers and the workplace, the classification of areas, local rules and procedures, the maintenance and provision of personal protective equipment, and equipment for radiation detection.*
  - *Identifying the service provider, the type(s) of personal monitors to be used and the proposed monitoring frequency; the maintenance of dose records and how personnel will be routinely advised of, and have access to, their dose records (i.e. irrespective of the reported dose). The programme will also address biological monitoring where this is relevant.*
  - *The inventory of survey and contamination meters.*
  - *The calibration of meters (i.e. and routine function checks) including the name of the calibration service provider and calibration frequency.*
- *The arrangements to ensure the safety of sources.*
  - *The design and construction of storage facilities. It must show that appropriate control of sources will be in place to minimize the risk of fire, prevent theft or accidental loss of radiation sources.*
  - *The operator's procedures for monitoring incoming and outgoing packages.*
- *Information relating to the radiological protection of patients, including arrangements for the calibration of sources used for medical exposure, clinical dosimetry and quality assurance programmes.*
  - *Working rules for the nuclear medicine procedures to be undertaken. (e.g. proper identification of patients and the doses to be administered, the use of shielding, distance and time; the use of warning signs, survey meters, personal alarms and dosimeters) including pre-operational checks; procedures for identifying and dealing with contamination, etc.*
  - *The calibration and routine function checks of dose calibrators.*

- *The facility's QA[12] programme and arrangements for regular safety audits including maintenance and calibration of imaging and counting equipment, maintenance of the source inventory, source movement logbook, waste disposal, storage conditions, safe working practices, area dose rates, warning signs, etc.*
- *The operator's protocols for ensuring patient doses are minimized by ensuring that where practicable, the activity of radioactive substances administered to patients conforms to guideline values established by a recognized body or professional organization. Include a description of the actions to be taken by the practitioner to justify and optimize all procedures and in minimizing the radiation risk to pregnant or potentially pregnant patients and children.*
- *The operator's protocols for dealing with patients who are to undergo therapy with unsealed radioactive sources (i.e. administration of the radioactive source in a satisfactory environment; compliance with discharge limits; identification of treated patients; properly informing patients of the radiation safety precautions they must observe on discharge; actions to be taken in the untimely death of the patient (e.g. during autopsy, embalming, cremation) etc.).*

- *The RPO's protocols for routine audits of working practices; evidence that the RPO has authority to stop activities if they are considered unsafe or not in compliance.*
- *The arrangements for the management of radioactive waste.*
- *The arrangements to ensure compliance with the transport regulations.*
- *The arrangements for dealing with different types of emergencies including the range of safety equipment available.*
- *The arrangements for notifying the regulatory body of:*
  - *occupational or public radiation doses which exceed prescribed limits;*
  - *reportable incidents and accidents; and*
  - *any significant changes to the information previously provided to the regulatory body, including:*
    - *a planned change of location for the operator's principal operations;*
    - *a planned change in storage or disposal arrangements for radiation sources; and*
    - *the receipt, transfer or other planned disposal of radiation sources.*

The application must be signed by the operator and submitted with the applicable fee.

The operator may wish to give some indication of the date when it is planned to commence work with the radiation sources. However, while the regulatory body will deal with the application expeditiously, no guarantee can be given that the licence will be granted by a particular date. Delays can be minimized by ensuring all the required and relevant information is provided in full and that the application is made well in advance.

[12] Quality assurance programs shall provide, as appropriate

(a) adequate assurance that the specified requirements relating to protection and safety are satisfied; and

(b) quality control mechanisms and procedures for reviewing and assessing the overall effectiveness of protection and safety measures.

Appendix C

AUTHORIZATION: GUIDANCE FOR APPLICANTS - RADIOTHERAPY

RADIOTHERAPY

***Note**: The following numbers refer to the numbers on the application form (see Attachment III).*

1. Enter the legal name of the operator's business (i.e. the entity that has direct control over the possession and use of radiation sources in the practice of radiotherapy). An individual may be designated as the operator only if the individual is acting in a private capacity. State the full mailing address to where correspondence (e.g. such as future renewal notices) should be sent.
2. Enter the full address of the actual location(s) where radiation sources will normally be stored or used.
3. The purpose for which the radiation sources are to be used is radiotherapy.
4. State the full name, qualifications, training, experience and contact details of the person nominated to be the operator's Radiation Protection Officer (RPO). Attach the nominee's curriculum vitae (CV) together with copies of relevant qualification and training certificates.
5. State the full name, qualifications, training, experience and contact details of the person nominated to be the operator's qualified expert (i.e. the person who will advise the operator on radiation safety and perform regular audits of the operators radiation protection programme). Attach the nominee's CV together with copies of supporting documentation.

   ***Note**: This person may also be the Medical Physicist.*

   State the full name, qualifications, training, experience and contact details of the Medical Physicist who will be responsible for calibrating the radiation sources and supervising radiation safety during LDR, HDR and interstitial X ray radiation beams; brachytherapy, performing the patient's treatment planning, etc. Attach the nominee's CV together with copies of supporting documentation.

   ***Note**: This person may also be the Qualified Expert.*
6. State the full name, qualifications, training, experience and contact details of the medical practitioner (s) who will be responsible for ensuring overall patient protection and safety in the prescription of, and during the performance of, therapeutic procedures. Attach the nominee's CV together with copies of supporting documentation.
7. Particulars of the radiation sources. The operator must provide a full description of all radiation sources to be used.

   - List all non-exempt radionuclides, including calibration and check sources, to be used or stored together with the activity (e.g. ^{60}Co, ^{192}Ir, ^{137}Cs, etc.). State all activities in SI units and the date at which the activity was determined. For short half-life nuclides subject to regular replacement (e.g. ^{192}Ir) state the maximum activity that will be on the premises at any one time. Include the date when the radiation output (or for brachytherapy sources, the activity) of each was last determined.

- For equipment that generates ionizing radiation electrically (e.g. superficial and deep X ray therapy, linear accelerators, interstitial X ray therapy, etc.), state the manufacturer, model and serial number together with the peak tube potential (kVp) and current (mA). Include the date when each was last fully calibrated.

Instructions (1, 2 and 3)

The operator must also submit a Radiation Protection Programme (RPP) addressing all aspects of radiation safety particularly the safety of radiation sources, work practices, the transport of radioactive sources and emergency procedures. At a minimum, the RPP will include the following:

- *A plan of the premises with a report from a qualified expert verifying that the design and construction of the premises, and the siting of radiation sources (i.e. including patients undergoing brachytherapy), will ensure worker and public safety. The plan and report must demonstrate compliance with the prescribed radiation dose constraints/dose limits by appropriate scientific methods.*
- *The qualifications, training and experience of medical practitioners, radiation therapists, nursing staff and others including their initial and ongoing radiation safety training and the supervision by appropriately qualified medical practitioners of other personnel.*
- *A safety assessment that:*
  - *identifies the ways in which normal exposures and potential exposures could be incurred, account being taken of the effect of events external to the sources as well as events directly involving the sources and their associated equipment:*
  - *determines the expected magnitudes of normal exposures and, to the extent reasonable and practicable, estimates the probabilities and the magnitudes of potential exposures; and*
  - *assesses the quality and extent of the protection and safety provisions.*
- *The occupational radiation protection programme, including arrangements for the monitoring of workers and the workplace, the classification of areas, local rules and procedures, the maintenance and provision of personal protective equipment, and equipment for radiation detection.*
  - *Identifying the service provider, the type(s) of personal monitors to be used and the proposed monitoring frequency; the maintenance of dose records and how personnel will be routinely advised of, and have access to, their dose records (i.e. irrespective of the reported dose).*
  - *The inventory of survey meters and dose rate meters.*
  - *The calibration of meters (i.e. and routine function checks) including the name of the calibration service provider and calibration frequency.*
- *The arrangements to ensure the safety of sources.*
  - *The design and construction of storage facilities. It must show that appropriate control of sources will be in place to minimize the risk of fire and to prevent theft or accidental loss of radiation sources.*
  - *The operator's procedures for monitoring incoming and outgoing packages.*
  - *Maintenance of the source inventory and source movement logbook.*
- *Information relating to the radiological protection of patients, including arrangements for the calibration of sources used for medical exposure, clinical dosimetry and quality assurance programmes.*
  - *Working rules for the therapy procedures to be undertaken (e.g. ensuring proper identification of patients, the use of shielding, distance and time; the use of warning signs, survey meters, personal alarms and dosimeters) including pre-operational checks: radiation beam calibrations, patient's treatment planning, etc.*
  - *If research is performed that involves the treatment of patients or volunteers, explain how the operator, acting on advice from an Ethical Review Committee, will comply with the provisions of the Helsinki Declaration and the guidelines prepared by the Council for International Organizations of Medical Sciences and the World Health Organization.*
  - *The manufacturer and model of radiation measuring instruments used to calibrate the radiation output of therapy radiation sources, the name of the organization that calibrates these instruments and the date*

of the last calibration. Calibrations must be traceable to a recognized standard.

- *The facility's QA[13] programme and arrangements for regular safety audits including maintenance of the source inventory, source movement logbook, waste disposal, source security and storage conditions, safe working practices, area dose rates, area dose rate monitors, warning signs, etc.*
- *The operator's protocols for ensuring patient treatment regimes are in conformity with guidelines established by a recognized authority (e.g. the regulatory body) or professional organization. Include a description of the actions to be taken by the practitioner to justify and optimise all procedures.*

- *The operator's protocols for training nursing staff and properly informing patients who are to undergo brachytherapy with permanent or semi-permanent implanted sources or with afterloaders.*
- *The RPO's protocols for routine audits of working practices; evidence that the RPO has authority to stop activities if they are considered unsafe or not in compliance.*
- *The arrangements for the management of radioactive waste.*
- *The arrangements to ensure compliance with the transport regulations where this is appropriate.*
- *The operator's plans for dealing with different types of emergencies including the range of safety equipment available. Emergencies will include, for example, a ^{60}Co teletherapy source jammed in the "ON" position, failure of an afterloader source retrieval mechanism, etc.*
- *The operator's plans for notifying the regulatory body of:*
  - *occupational or public radiation doses which exceed prescribed limits;*
  - *patient radiation doses which exceed prescribed treatment doses;*
  - *reportable incidents and accidents; and*
  - *any significant changes to the information previously provided to the regulatory body including:*
    - *a planned change of location for the operator's principal operations;*
    - *a planned change in storage or disposal arrangements for radiation sources; and*
    - *the receipt, transfer or other planned disposal of radiation sources.*

The application must be signed by the operator and submitted with the applicable fee.

The operator may wish to give some indication of the date when it is planned to commence work with the radiation sources. However, while the regulatory body will deal with the application expeditiously, no guarantee can be given that the licence will be granted by a particular date. Delays can be minimized by ensuring all the required and relevant information is provided in full and that the application is made well in advance.

[13] Quality assurance programs shall provide, as appropriate:

(a) adequate assurance that the specified requirements relating to protection and safety are satisfied; and

(b) quality control mechanisms and procedures for reviewing and assessing the overall effectiveness of protection and safety measures.

Appendix D

AUTHORIZATION: GUIDANCE FOR APPLICANTS — INDUSTRIAL RADIOGRAPHY

INDUSTRIAL RADIOGRAPHY

Note: *The following numbers refer to the numbers on the application form (see Attachment III.)*

1. Enter the legal name of the operator's business (i.e. the entity that has direct control over the possession and use of radiation sources in the practice of industrial radiography). An individual may be designated as the operator only if the individual is acting in a private capacity. State the full mailing address to where correspondence (e.g. such as future renewal notices) should be sent.

2. Enter the full address of the actual location(s) where radiation sources will normally be stored or used.

   - Field sites where licensed radiation sources are used for limited periods need not be included on this application (i.e. other than stating that it is the operator's intention to conduct radiography at field sites according to demand).

3. In this case, the purpose for which the radiation sources are to be used is industrial radiography. Include any other purposes as may be relevant (e.g. the use of portable mineral analyzers, radioactive gauges, etc.).

4. State the full name, qualifications, training, experience and contact details of the person nominated to be the operator's Radiation Protection Officer (RPO). Attach the nominee's curriculum vitae (CV) together with copies of relevant qualification and training certificates.

5. State the full name, qualifications, training, experience and contact details of the person nominated to be the operator's qualified expert (i.e. the person who will advise the operator on radiation safety and perform regular audits of the operator's radiation protection programme). Attach the nominee's CV together with copies of supporting documentation.

6. Not applicable.

7. Particulars of the radiation sources. The operator must provide a full description of all radiation sources to be used.

   - List all non-exempt radionuclides that will be used or stored (e.g.. ^{192}Ir, ^{60}Co, ^{175}Se, ^{137}Cs, etc.) together with the activity or, for short half-life material subject to regular replacement, the maximum activity to be held. State all activities in SI units and, except for the short half-life material, the date at which the activity was determined.
   - Identify every source container or device that contains (or will contain) radioactive material by the manufacturer, model and serial number. Crawler control sources and survey meter check sources are to be included in this inventory. If depleted uranium is used for radiation shielding in these devices state the mass (kg) in each.
   - State the manufacturer's maximum activity rating for each source container and the length of the wind-out cable and source delivery tube.
   - For X ray equipment, state the manufacturer, model and serial number together with

the peak tube potential (kVp) and current (mA). Identify which X ray tubes have beryllium windows and what permanent filtration will be used. State the length of the cables between the X ray tube housing and the X ray control panel.

Instructions (1, 2 and 3)

The operator must also submit a Radiation Protection Programme (RPP) addressing all aspects of radiation safety particularly the safety of radiation sources, work practices, the transport of radioactive sources and emergency procedures. At a minimum, the RPP will include the following:

- *The qualifications, training and experience in radiation protection of industrial radiographers. In addition to the industrial radiographers, the RPP also must address the initial and ongoing training and supervision of radiography assistants and show that the operator has, or will have, sufficient personnel to ensure that each assistant works under the immediate personal supervision of a Qualified Radiographer (QR) during all radiographic exposures.*
- *A plan of the principal premises with a report from a qualified expert verifying that the design and construction of the premises will ensure worker and public safety. The plan and report must demonstrate compliance with the prescribed radiation dose constraints / dose limits by appropriate scientific methods.*
- *A safety assessment that:*
  - *identifies the ways in which normal exposures and potential exposures could be incurred, account being taken of the effect of events external to the sources as well as events directly involving the sources and their associated equipment:*
  - *determines the expected magnitudes of normal exposures and, to the extent reasonable and practicable, estimates the probabilities and the magnitudes of potential exposures; and*
  - *assesses the quality and extent of the protection and safety provisions.*
- *The occupational radiation protection programme, including arrangements for the monitoring of workers and the workplace, the classification of areas, local rules and procedures, the maintenance and provision of personal protective equipment, and equipment for radiation detection.*
  - *Working rules for radiographic operations (e.g. the use of shielding, distance and time; the identification and marking of site boundaries; ensuring that before exposures no unauthorized persons are present; supervision and control of site boundaries; the use of warning signs; the routine use of survey meters, personal alarms and dosimeters) including pre-operational checks; the use of beam collimators, X ray beam filtration and fast image receptors to minimize dose; the use of warning klaxons on crawler equipment in pipelines; etc.*
  - *The radiation monitoring programme for occupationally exposed workers, identifying the service provider, the type(s) of personal monitors to be used and the proposed monitoring frequency; the maintenance of dose records and how personnel will be routinely advised of, and have access to, their dose records (i.e. irrespective of the reported dose).*
  - *The inventory of survey meters existing in the enterprise.*
  - *The calibration of survey meters (i.e. and routine function checks) including the name of the calibration service provider and calibration frequency. Details of the numbers of survey meters, personal alarms and dosimeters and the procedures for ensuring that each radiography team will be provided with a functioning survey meter for each radiation source; evidence that working rules will require the use of survey meters after every exposure to confirm sources are shielded.*
- *The arrangements to ensure the safety of sources.*
  - *The design and construction of storage facilities, including those of a temporary nature at semi-permanent field sites. It must show that appropriate control of sources will be in place to minimize the risk of fire, prevent theft or accidental loss of radiation sources.*
  - *The operator's procedures for ensuring that source containers and X ray equipment comply on purchase, and continue to comply, with the prescribed design and performance standards (IEC, ISO, etc).*
  - *The arrangements for safely transferring sources ("spent" for new).*
  - *The radiation monitoring procedures for incoming and outgoing packages.*
  - *The arrangements for periodic equipment service, testing and maintenance of source containers, wind-*

out cables, source delivery tubes, source-cable connectors, wipe tests of sealed sources (other than short half-life sources) and the S-bend of depleted uranium shielded containers, etc., in compliance with the manufacturers' recommendations.

- *The maintenance of the source inventory and source movement logbook.*

- *The facility's QA[14] programme and arrangements for regular safety audits including maintenance of the source inventory, source movement logbook, storage conditions, safe working practices, area dose rates, warning signs, etc.*
- *The RPO's protocols for routine and unannounced audits of working practices at field sites; evidence that the RPO has authority to stop activities if they are considered unsafe or not in compliance; working rules that give radiography workers authority to immediately cease operations when the prescribed safety requirements cannot be met or should equipment fail.*
- *The arrangements for the management of radioactive waste, including the management of spent sources, and information on the financial arrangements for such purposes.*
- *The procedures to ensure compliance with the transport regulations, including transport to and from field sites.*
- *The procedures for dealing with different types of emergencies including the range of safety equipment available (e.g. remote handling tongs, lead pots, bagged lead shot, bolt cutters, etc.).*
- *The procedures for notifying the regulatory body of:*
  - *occupational or public radiation doses which exceed prescribed limits;*
  - *reportable incidents and accidents; and*
  - *any significant changes to the information previously provided to the regulatory body including:*
    - *a planned change of location for the operator's principal operations;*
    - *the addition of, or alterations to, structures that form a fixed radiographic enclosure;*
    - *a planned change in and / or storage arrangements for radiation sources; and*
    - *the receipt, transfer or other planned disposal of radiation sources.*

The application must be signed by the operator and submitted with the applicable fee.

The operator may wish to give some indication of the date when it is planned to commence work with the radiation sources. However, while the regulatory body will deal with the application expeditiously, no guarantee can be given that the licence will be granted by a particular date. Delays can be minimized by ensuring all the required and relevant information is provided in full and that the application is made well in advance.

[14] Quality assurance programs shall provide, as appropriate:

(a) adequate assurance that the specified requirements relating to protection and safety are satisfied; and

(b) quality control mechanisms and procedures for reviewing and assessing the overall effectiveness of protection and safety measures.

Appendix E

AUTHORIZATION: GUIDANCE FOR APPLICANTS: IRRADIATORS

IRRADIATORS

***Note**: The following numbers refer to the numbers on the application form (see Attachment III)*

1. Enter the legal name of the operator's business (i.e. the entity that has direct control over the use of the radiation sources). An individual may be designated as the operator only if the individual is acting in a private capacity. State the full mailing address to where correspondence (e.g. such as future renewal notices) should be sent.
2. Enter the full address of the actual location(s) where radiation sources will normally be stored or used.
3. In this case, the primary purpose for which the radiation sources are to be used is irradiation.
4. State the full name, qualifications, training, experience and contact details of the person nominated to be the operator's Radiation Protection Officer (RPO). Attach the nominee's curriculum vitae (CV) together with copies of relevant qualification and training certificates.
5. State the full name, qualifications, training, experience and contact details of the person nominated to be the operator's qualified expert (i.e. the person who will advise the operator on radiation safety and perform regular audits of the operator's radiation protection programme). Attach the nominee's CV together with copies of supporting documentation.
6. Not applicable.
7. The operator must provide a full description of all radiation sources to be used. List all non-exempt radionuclides that will be used or stored (e.g.. ^{60}Co) together with the activity. State all activities in SI units and the date at which the activity was determined. For devices that generate ionizing radiation electrically, state the manufacturer, model and serial number together with the peak tube potential (kVp) and current (mA).

Instructions (1, 2 and 3)

The operator must also submit a Radiation Protection Programme (RPP) addressing all aspects of radiation safety particularly the safety of radiation sources, work practices, the transport of radioactive sources and emergency procedures. At a minimum, the RPP will include the following:

- The qualifications, training and experience in workers engaged in activities that involve or could involve occupational exposure, including their initial and ongoing radiation safety training.
- A plan of the premises with a report from a qualified expert verifying that the design and construction of the premises will ensure at least the minimum prescribed level of worker and public radiation safety. The plan and report must demonstrate compliance with the prescribed radiation dose constraints/dose limits by appropriate scientific methods.
- A *safety assessment that:*
  - *identifies the ways in which normal exposures and potential exposures could be incurred, account being taken of the effect of events external to the sources as well as events directly involving the sources and their associated equipment:*

- *determines the expected magnitudes of normal exposures and, to the extent reasonable and practicable, estimates the probabilities and the magnitudes of potential exposures; and*
- *assesses the quality and extent of the protection and safety provisions.*

- The occupational radiation protection programme, including arrangements for the monitoring or workers and the workplace, the classification of areas, the provision and maintenance of personal protective equipment, and equipment for radiation detection.
  - *Working rules for safe operation of the irradiator; ensuring before exposures that no persons are present in the irradiation room; supervision and control of all access points; the use of warning signs; the routine use of survey meters, personal alarms including pre-operational checks; water contamination, etc.*
  - *Identifying the service provider, the type(s) of personal monitors to be used and the proposed monitoring frequency; the maintenance of dose records and how personnel will be routinely advised of, and have access to, their dose records (i.e. irrespective of the reported dose).*
  - *The inventory of survey meters.*
  - *The calibration of survey meters (i.e. and routine function checks) including the name of the calibration service provider and calibration frequency.*
- *The arrangements to ensure safety of sources.*
  - *The design and construction of the facility, including a description of the safety system e.g. interlocks. It must show that appropriate control of sources will be in place to minimize the risk of fire and to prevent theft or accidental loss of radiation sources.*
  - *The arrangements for safely transferring sources (i.e. "spent" for new)*
  - *The radiation monitoring procedures for incoming and outgoing packages.*
  - *The calibration and function checks of other instruments required for safe operation of the irradiator (e.g. water levels, water contamination, etc.).*
  - *The arrangements for periodic service, testing and maintenance of the irradiator, particularly of the safety features and related instrumentation.*
  - *The operator's QA[15] programme and arrangements for regular safety audits including maintenance of the source inventory, source movement logbook, storage conditions, safe working practices, area dose rates, area dose rate monitors and alarms, other safety instrumentation, warning signs, etc.*
- *The RPO's protocols for routine and unannounced audits of working practices; evidence that the RPO has authority to stop activities if they are considered unsafe or not in compliance; working rules that give the irradiator's operators authority to immediately cease operations when the prescribed safety requirements cannot be met or essential equipment fails.*
- *The arrangements to ensure compliance with the transport regulations.*
- *The arrangements for dealing with radioactive waste, including the management of disused sources and information on the financial arrangements for such purposes.*
- *The procedures for dealing with different types of emergencies including the range of safety equipment available.*
- *The arrangements for notifying the regulatory body of:*
  - *occupational or public radiation doses which exceed prescribed limits;*
  - *reportable incidents and accidents; and*
  - *any significant changes to the information previously provided to the regulatory body including:*
    - *a planned change of location for the operator's operations;*

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[15] Quality assurance programs shall provide, as appropriate:

(a) adequate assurance that the specified requirements relating to protection and safety are satisfied; and

(b) quality control mechanisms and procedures for reviewing and assessing the overall effectiveness of protection and safety measures.

- *a planned change in and / or storage arrangements for radiation sources; and*
- *the receipt, transfer or other planned disposal of radiation sources.*

The application must be signed by the operator and submitted with the applicable fee.

The operator may wish to give some indication of the date when it is planned to commence work with the radiation sources. However, while the regulatory body will deal with the application expeditiously, no guarantee can be given that the licence will be granted by a particular date. Delays can be minimized by ensuring all the required and relevant information is provided in full and that the application is made well in advance.

Appendix F

AUTHORIZATION GUIDANCE FOR APPLICANTS: GAUGES (FIXED and/or PORTABLE)

GAUGES — FIXED and/or PORTABLE

Note: *The following numbers refer to the numbers on the application form (see Attachment III)*

1. Enter the legal name of the operator's business (i.e. the entity that has direct control over the use of the radiation sources in the practice with gauges, fixed and/or portable). An individual may be designated as the operator only if the individual is acting in a private capacity. State the full mailing address to where correspondence (e.g. such as future renewal notices) should be sent.
2. Enter the full address of the actual location(s) where radiation sources will normally be stored or used.
   - Field sites where authorized radiation sources are used for limited periods need not be included on this application (i.e. other than stating that it is the operator's intention to use certain gauges at field sites according to demand). However, any field site where operations may last more than 90 days must be identified. Where such sites arise after the authorization is issued, the operator must give prior written notification of the details to the regulatory body.
3. The purpose for which the radiation sources are to be used is to be stated (e.g. gauges for level detection, density measurement, in-stream analysis, road construction, etc.).
4. State the full name, qualifications, training, experience and contact details of the person nominated to be the operator's Radiation Protection Officer (RPO). Attach the nominee's curriculum vitae (CV) together with copies of relevant qualification and training certificates.
5. State the full name, qualifications, training, experience and contact details of the person nominated to be the operator's qualified expert (i.e. the person who will advise the operator on radiation safety and perform regular audits of the operator's radiation protection programme). Attach the nominee's CV together with copies of supporting documentation.
6. Not applicable.
7. The operator must provide a full description of all radiation sources to be used. An inventory also must be provided for non-radioactive sources (e.g. X ray gauges)
   - List all non-exempt radionuclides that will be used or stored (e.g. ^{60}Co, ^{137}Cs, etc.) together with the activity. State all activities in SI units together with the date at which the activity was determined.
   - Identify every gauge housing by the manufacturer, model, serial number and purpose (level, density, etc.). Survey meter check sources are to be included in this inventory unless otherwise exempted. If depleted uranium is used for radiation shielding in any device state the mass (kg) in each.
   - For X ray gauges, state the manufacturer, model and serial number together with the peak tube potential (kVp) and current (mA). Identify which X ray tubes have beryllium windows and what permanent filtration is in place.

Instructions (1, 2 and 3)

The operator must also submit a Radiation Protection Programme (RPP) addressing all aspects of radiation safety particularly the safety of radiation sources, work practices, the transport of radioactive sources and emergency procedures. At a minimum, the RPP will include the following:

- *The qualifications, training and experience of workers engaged in activities that involve or could involve occupational exposure and both their initial and ongoing radiation safety training.*
- *A plan of the premises (i.e. other than temporary field sites) with a report from a qualified expert verifying that the gauges will be installed (or used) in a manner that will ensure at least the minimum prescribed level of worker and public radiation safety. The plan and report must demonstrate compliance with the prescribed radiation dose constraints/dose limits by appropriate scientific methods.*
- *The occupational radiation protection programme, including arrangements for the monitoring of workers and the workplace, the classification of areas, local rules and procedures, the maintenance and provision of personal protective equipment, and equipment for radiation detection.*
    - *Working rules for persons who use portable gauges and for those who work near fixed gauges, who undertake work within bins or hoppers, etc. on which gauges are mounted, and for those responsible for changing windows on low energy in-stream gauges.*
    - *Identifying the service provider, the type(s) of personal monitors to be used and the proposed monitoring frequency; the maintenance of dose records and how personnel will be routinely advised of, and have access to, their dose records (i.e. irrespective of the reported dose). The use of personal monitors is not normally required for fixed gauges except during some installation and maintenance procedures.*
    - *The calibration of survey meters (i.e. and routine function checks) including the name of the calibration service provider and calibration frequency.*
- *The arrangements for safety of radiation sources.*
    - *The design and construction of storage facilities, including those of a temporary nature at semi-permanent field sites. It must show that appropriate control of sources will be in place to minimize the risk of fire and to prevent theft or accidental loss of radiation sources.*
    - *The procedures for monitoring incoming and outgoing packages containing radioactive sources.*
    - *The arrangements for periodic service, testing and maintenance of radioactive source containers and X ray gauges.*
    - *The procedures for routine leak tests of all radioactive gauges including the special requirements for low energy in-stream analysis gauges (e.g. counting the replaced window for contamination).*
    - *The facility's QA[16] programme and arrangements for regular safety audits including maintenance of the source inventory, source movement logbook, storage conditions, safe working practices, area dose rates, warning signs, etc. Controls must be addressed for gauges that are temporarily removed from their installed (fixed) locations during plant maintenance.*
    - *The RPO's protocols for ensuring he is advised of planned work on plant or equipment on which gauges are mounted and the procedures in place to instruct workers and prevent unnecessary exposure.*
    - *The procedures to ensure compliance with the transport regulations, including transport to and from field sites.*
    - *The arrangements for the management of radioactive waste, including disused sources and information on the financial arrangements for such purposes.*
    - *The procedures for dealing with emergencies.*
    - *The arrangements for notifying the regulatory body of:*

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[16] Quality assurance programs shall provide, as appropriate:

(a) adequate assurance that the specified requirements relating to protection and safety are satisfied; and

(b) quality control mechanisms and procedures for reviewing and assessing the overall effectiveness of protection and safety measures.

- *occupational or public radiation doses which exceed prescribed limits;*
- *reportable incidents and accidents; and*
- *any significant changes to the information previously provided to the regulatory body including:*
  - *a planned change of location for the operator's operations;*
  - *a planned change in and/or storage arrangements for radiation sources; and*
  - *the receipt, transfer or other planned disposal of radiation sources.*

The application must be signed by the operator and submitted with the applicable fee.

The operator may wish to give some indication of the date when it is planned to commence work with the radiation sources. However, while the regulatory body will deal with the application expeditiously, no guarantee can be given that the licence will be granted by a particular date. Delays can be minimized by ensuring all the required and relevant information is provided in full and that the application is made well in advance.

Appendix G

AUTHORIZATION: GUIDANCE FOR APPLICANTS: WELL LOGGING

WELL LOGGING

Note: *The following numbers refer to the numbers on the application form (see Attachment III)*

1. Enter the legal name of the operator's business (i.e. the entity that has direct control over the use of the radiation sources in the practice of well logging). An individual may be designated as the operator only if the individual is acting in a private capacity. State the full mailing address to where correspondence (e.g. such as future renewal notices) should be sent.
2. Enter the full address of the actual location(s) where radiation sources will normally be stored or used.
   - Field sites where authorized radiation sources are used for limited periods not need to be included on this application. However, any field site where logging operations may last more than 90 days must be identified. Where such sites arise after the licence is issued, the operator must give prior written notification of the details to the regulatory body.
3. In this case, the purpose for which the radiation sources are to be used is well logging.
4. State the full name, qualifications, training, experience and contact details of the person nominated to be the operator's Radiation Protection Officer (RPO). Attach the nominee's CV together with copies of relevant qualification and training certificates.
5. State the full name, qualifications, training, experience and contact details of the person nominated to be the operator's qualified expert (i.e. the person who will advise the operator on radiation safety and perform regular audits of the operator's radiation protection programme). Attach the nominee's curriculum vitae (CV) together with copies of supporting documentation.
6. Not applicable.
7. The operator must provide a full description of all radiation sources to be used. An inventory also must be provided for non-radioactive sources (e.g. electrically generated neutron sources, etc.).
   - List all non-exempt radionuclides to be used or stored (e.g.. ^{241}Am, ^{137}Cs, ^{131}I, etc.) together with the activity or, for short half-life material subject to regular replacement or dispersion during logging procedures, the maximum activity to be held at any one time. State all activities in SI units and, except for the short half-life material, the date at which the activity was determined.
   - Identify every source container or device that contains (or will contain) radioactive material by the manufacturer, model and serial number, including the type of logging tool in which the source is to be used. If depleted uranium is used for radiation shielding in any device state the mass (kg) in each.
   - For devices that generate ionizing radiation electrically, state the manufacturer, model and serial number together with the peak tube potential (kVp) and current (mA) and, in the case of neutron generators, the neutron flux and mean energy.

Instructions (1, 2 and 3)

The operator must also submit a Radiation Protection Programme (RPP) addressing all aspects of radiation safety particularly the safety of radiation sources, work practices, the transport of radioactive sources and emergency procedures. At a minimum, the RPP will include the following:

- *The qualifications, training and experience of in radiation protection of workers engaged in activities that involve or could involve occupational exposure. In addition to the well logger, the RPP also must address the initial and ongoing radiation safety training and supervision of logging assistants and show that the operator has, or will have, sufficient personnel to ensure that each assistant works under the immediate personal supervision of a qualified logger during all logging procedures.*
- *A plan of the principal premises (i.e. where sources may be stored, maintained, calibrated, etc.) with a report from a qualified expert verifying that the design and construction of the premises will ensure at least the minimum prescribed level of worker and public radiation safety. The plan and report must demonstrate compliance with the prescribed radiation dose constraints/dose limits by appropriate scientific methods.*
- *The occupational radiation protection programme, including arrangements for the monitoring of workers and the workplace, the classification of areas, local rules and procedures, the maintenance and provision of personal protective equipment, and equipment for radiation detection.*
  - *Working rules for logging operations (e.g. the use of shielding, distance and time; the identification and marking of site boundaries; ensuring that before exposures no unauthorized persons are within controlled areas; supervision and control of site boundaries; the use of warning signs; the routine use of survey meter and personal alarms, including pre-operational checks; procedures for handling unsealed radiation sources).*
  - *Procedures for attempting recovery of radiation sources jammed in wells, including contamination-checking precautions in case a source is ruptured during the process, and the subsequent actions to be taken should this occur.*
  - *If a radiation source jammed in a well is not recoverable, procedures for:*
    - *securing the radiation source in the well (i.e. including the use of dyed concrete or other warning devices);*
    - *capping the well and, where practicable, providing appropriate permanent identification at the well cap to minimize the risk of subsequent drilling through the source;*
    - *reporting to the company drilling and/or holding the exploration or mining lease of the location of the jammed source (e.g. depth and geographical co-ordinates) to prevent further drilling that might intersect the location of the source; and*
    - *informing the regulatory body (and other relevant government bodies such as the Department of Mining and Petroleum Resources) of the jammed source, its location and the actions taken.*
  - *Identifying the service provider, the type(s) of personal monitors to be used and the proposed monitoring frequency; the maintenance of dose records and how personnel will be routinely advised of, and have access to, their dose records (i.e. irrespective of the reported dose). The programme will also address biological monitoring for the use of unsealed radiation sources.*
  - *The calibration and function checks of survey and contamination meters, including identifying the calibration service provider and calibration frequency. Details of the numbers of survey meters, personal alarms and detectors and the protocols for ensuring that each well logging team will be provided with appropriate and functioning survey meters for each radiation source they are using; evidence that working rules will require the use of survey meters after the use of a well logging tool to confirm sources are retrieved and returned to their shielded containers.*
- *The arrangements to ensure the safety of sources.*
  - *The design and construction of storage facilities, including those of a temporary nature at semi-permanent field sites. It must show that appropriate controls will be in place to prevent theft or accidental loss of radiation sources.*
  - *The operator's procedures for safely transferring sources from storage containers to logging tools and vice versa, "spent" sources for new and the radiation monitoring procedures for incoming and outgoing packages.*

- *The arrangements for periodic equipment service, testing and maintenance of source containers, logging tools, etc. and for leak (wipe) tests of sealed sources in compliance with the manufacturers' recommendations.*
- *The facility's QA[17] programme and arrangements for regular safety audits including maintenance of the source inventory, source movement logbook, storage conditions, safe working practices, area dose rates, warning signs, etc.*

- *The RPO's protocols for routine and unannounced audits of working practices at field sites; evidence that the RPO has authority to stop activities if they are considered unsafe or not in compliance; working rules that give logging personnel authority to immediately cease operations when the prescribed safety requirements cannot be met or radiation safety related equipment fails.*
- *The arrangements for the management of radioactive waste, including the management of disused sources.*
- *The procedures to ensure compliance with the transport regulations, including transport to and from field sites.*
- *The procedures for dealing with different types of emergencies (i.e. for both sealed and unsealed radiation sources) including the range of safety equipment available.*
- *The operator's plans for notifying the regulatory body of:*
  - *occupational or public radiation doses which exceed prescribed limits;*
  - *reportable incidents and accidents, including jammed sources; and*
  - *any significant changes to the information previously provided to the regulatory body including:*
    - *a planned change of location for the operator's principal operations;*
    - *a planned change in and / or storage arrangements for radiation sources; and*
    - *the receipt, transfer or other planned disposal of radiation sources.*

The application must be signed by the operator and submitted with the applicable fee.

The operator may wish to give some indication of the date when it is planned to commence work with the radiation sources. However, while the regulatory body will deal with the application expeditiously, no guarantee can be given that the licence will be granted by a particular date. Delays can be minimized by ensuring all the required and relevant information is provided in full and that the application is made well in advance.

[17] Quality assurance programs shall provide, as appropriate:

(a) adequate assurance that the specified requirements relating to protection and safety are satisfied; and

(b) quality control mechanisms and procedures for reviewing and assessing the overall effectiveness of protection and safety measures.

Annex V

GUIDELINESS FOR REVIEW AND ASSESSMENT OF APPLICATIONS FOR AUTHORIZATION

Appendix A

PROCEDURES FOR AUTHORIZATION REVIEW AND ASSESSMENT OF APPLICATIONS FOR DIAGNOSTIC RADIOLOGY & DENTAL PRACTICES

Application No

REVIEW AND ASSESSMENT OF APPLICATION FOR AUTHORIZATION DIAGNOSTIC RADIOLOGY

FIRST APPLICATION ☐ **RENEWAL** ☐ **DATE RECEIVED** _____ / _____ / _____

NAME OF OPERATOR _____

PROCESSING OFFICER

ITEM	YES	NO	NOTES and ACTIONS
DATABASE ENTRY, PRELIMINARY DATA CHECK, FILE CREATION			
Database entry completed?	☐	☐	New applications - enter information into the database and record the application sequence number (and/or future authorization number) on the application. Renewals - update the database as required.
Required details provided?	☐	☐	Has required information been provided including postal and physical address, RPO, X ray equipment inventory, RPP, etc? If not, or if unclear, discuss with the Assessment Officer and, return the application for the additional information as directed. Mark record with bring-up date.
Operator identified?	☐	☐	Name and position held has been stated? If not, discuss with the Assessment Officer.
Application signed by the operator?	☐	☐	Application to be returned if unsigned. However, first discuss with the Assessment Officer, as other matters may need to be raised with the operator. Return the application for signature as directed. Mark record with bring-up date.
Correct fees paid?	☐	☐	Check that the correct fee has been paid. If not, first discuss with the Assessment Officer, as other matters may need to be raised with the operator. Send letter advising fee details. Mark record with bring-up date.
File and related papers prepared for assessment?	☐	☐	Create the authorization file (retrieve previous file for renewal) and transfer with the application, related papers and the relevant review and assessment forms to the Assessment Officer
If all matters have been satisfactorily completed, the application is to be forwarded to the officer assigned to review this class of application. Applications held for further information must be followed up within 10 working days.			
COMMENTS (Record the details if the application is returned to the operator for further information)			
		Signature	**Date**

ASSESSMENT OFFICER *(Tick relevant box or enter "n/a" if not applicable)*

ITEM	YES	NO	NOTES and ACTIONS
PERSONNEL RESOURCES AND TRAINING			
Nominated Radiation Protection Officer satisfactory?	☐	☐	Confirm that the nominated Radiation Protection Officer has appropriate qualifications and experience for the position and has appropriate authority to undertake the required duties and responsibilities.
Nominated Qualified Expert satisfactory?	☐	☐	Confirm that the nominated Qualified Expert has appropriate qualifications and experience
Responsible Medical Practitioner satisfactory?	☐	☐	Confirm that the nominated Medical Practitioner has appropriate qualifications and experience.
Radiographers appropriately qualified?	☐	☐	Confirm that the radiographers employed (or contracted by) the operator have appropriate qualifications and will be supervised by an appropriately qualified Medical Practitioner.
Other personnel appropriately trained and supervised?	☐	☐	Confirm that other personnel have appropriate training and will be adequately supervised.
SOURCES AND FACILITIES			
X ray equipment complies?	☐	☐	Are all details regarding equipment (manufacturer, model,, serial no. etc.) provided? Does the X ray equipment comply with relevant design and performance standards (e.g. IEC)? Will the equipment be used for X ray examinations appropriate to its designed purpose?
Premises satisfactory?	☐	☐	Confirm that the design and construction of the premises, the siting of the X ray equipment and the provision of operator protective barriers, etc. will ensure at least the minimum prescribed level of worker and public radiation safety.
Qualified Expert report provided?	☐	☐	A report is required to demonstrate that the premises are constructed to ensure compliance with the dose constraints/dose limits prescribed by the regulations/regulatory body. The report will also address all safety related matters including working rules for the operation of the X ray equipment, warning signs and lights, disposal of unwanted equipment, etc.
Qualified Expert report satisfactory?	☐	☐	The report may need to be reviewed by an external expert if the regulatory body does not have internal expertise.
X ray equipment subject to regular maintenance?	☐	☐	Is the X ray equipment subject to maintenance at intervals prescribed by the manufacturer? Is service of x ray equipment undertaken by authorized personnel?
Access to X ray equipment?	☐	☐	Are appropriate measures in place to control access to and prevent use of the X ray equipment by unauthorized persons ***Note:*** *e.g. restricting the use of fluoroscopic equipment to appropriately trained Medical Practitioners*?
Darkroom, film / image processing equipment satisfactory?	☐	☐	Is the darkroom light proof and are safelights appropriate? Will the operator be using appropriate and satisfactory film/image equipment and processing equipment

ITEM	YES	NO	NOTES and ACTIONS
Disposal of unwanted X ray equipment?	☐	☐	Does the operator have procedures in place to ensure that unwanted X ray equipment is transferred only to an appropriate authorized user unless otherwise approved by the regulatory body?
OCCUPATIONAL RADIATION PROTECTION			
Occupational protection programme complies?	☐	☐	Are local rules satisfactory? Is classification of areas appropriate? Does the operator apply appropriate limits to workers exposed as part of their work and to workers whose exposure is not directly related to their work?
Protective aprons, gloves and other protective devices satisfactory?	☐	☐	Is sufficient personal protective equipment (e.g. lead protective aprons) provided and does it comply with the relevant standard (e.g. IEC)?
Arrangements for Personal Radiation Monitoring comply?	☐	☐	Has the operator provided satisfactory information on the numbers and types of personal monitoring devices that will be used (film badges, TLD, etc)? Has the operator made suitable arrangement for keeping personnel regularly and routinely informed of their recorded occupational radiation dose? Is the stated monitoring period (frequency) satisfactory?
Is Personal Monitoring Service Provider approved?	☐	☐	Is the personal monitoring service provider approved by the regulatory body
RADIOLOGICAL PROTECTION OF PATIENTS			
Are there appropriate protocols for ensuring overall patient protection and safety in the prescription of, and during the performance of diagnostic procedures	☐	☐	These matters are the responsibility of the designated Medical Practitioner. Protocols should describe the procedures required to perform the examination as well as working rules to properly identify patients and to ensure safety for the patient, staff and public. Protocols should also explain procedures for pregnant or potentially pregnant patients and for examinations of children. Does the operator possess patient protective devices and enforce their use where these will not interfere with the examination?
Is QA programme satisfactory?	☐	☐	Is the operator's QA programme (including image receptors, film/image processors, repeat analysis, etc.) satisfactory?
Has the operator to determine typical patient doses for comparison to guidance levels?	☐	☐	The operator's Qualified Expert will determine typical patient doses for comparison to guidance levels published by an appropriate professional organization or prescribed by the regulatory body.
Research procedures and protocols satisfactory?	☐	☐	If research is performed that involves the exposure of patients or volunteers, the operator must show that they act on advice from an acceptable Ethical Review Committee and will comply with the provisions of the Helsinki Declaration and the guidelines prepared by the Council for International Organizations of Medical Sciences and the World Health Organization.

ITEM	YES	NO	NOTES and ACTIONS
Screening protocols satisfactory?	☐	☐	***Note:*** *Mass screening of population groups involving medical exposure is not justified unless the expected advantages for the individuals examined or for the population as a whole are sufficient to compensate for the economic and social costs, including the radiation detriment.* If the operator intends providing screening examinations (e.g. chest, mammography, bone density, etc.) is there evidence that account has been taken to justify the potential of the screening procedure for detecting disease, the likelihood of effective treatment of cases detected and, for certain diseases, the advantages to the community from the control of the disease?
Pre-employment, legal or administrative radiography policy satisfactory?	☐	☐	***Note:*** *Any radiological examination for occupational, legal or health insurance purposes undertaken without reference to clinical indications is not justified unless it is expected to provide useful information on the health of the individual examined or unless the specific type of examination is justified by those requesting it in consultation with relevant professional bodies.*
ACCIDENT/INCIDENT PROCEDURES			
Accident/incident plans satisfactory?	☐	☐	Are the operator's procedures for dealing with accidents and incidents appropriate? Are workers appropriately trained with regard to the requirements for notifying accidents/incidents?
RECORDS, AUDITS			
Records satisfactory?	☐	☐	Has the operator made suitable arrangements for maintaining records (e.g. inventory, occupational dose records, audits, etc.)?
Routine audit programme satisfactory?	☐	☐	Does the operator propose to audit the RPP at suitable intervals? Does the operator/RPO regularly (and without notice) audits radiation safety practices of its personnel?
If a renewal, are there any outstanding items of non-compliance and/or is a legal action being considered by the regulatory body?	☐	☐	If yes, the application should be discussed with the assessor's Supervisor to determine an appropriate course of action
If all matters have been satisfactorily completed, the application is to be forwarded to the assessor's Supervisor and then to the officer authorised to sign the application			

COMMENTS		
	Signature	**Date**

SUPERVISOR

ITEM	YES	NO	NOTES and ACTIONS
Review and assessment procedures are satisfactory?	☐	☐	Check that the Assessment Officer has completed all relevant sections, that the fee, authorization period, operator's name, licensed location(s) and purpose(s) are correct.
Authorization can be approved?	☐	☐	Confirm that any attached conditions, restrictions or limitations imposed on the authorization are appropriate before the authorization is signed.
Inspection personnel is informed?	☐	☐	Inspection personnel advised of the application for inclusion in the routine inspection programme

COMMENTS		
	Signature	**Date**

Application No

REVIEW AND ASSESSMENT OF APPLICATION FOR AUTHORIZATION DENTAL PRACTICES

FIRST APPLICATION ☐ **RENEWAL** ☐ **DATE RECEIVED** _____ / _____ / _____

NAME OF OPERATOR _____

PROCESSING OFFICER

ITEM	YES	NO	NOTES and ACTIONS
DATABASE ENTRY, PRELIMINARY DATA CHECK, FILE CREATION			
Database entry completed?	☐	☐	New applications - enter information into the database and record the application sequence number (and/or future registration number) on the application. Renewals - update the database as required.
Required details provided?	☐	☐	Has required information been provided including postal and physical address, RPO, X ray equipment inventory, RPP, etc? If not, or if unclear, discuss with the Assessment Officer and, return the application for the additional information as directed. Mark record with bring-up date.
Operator identified?	☐	☐	Name and position held has been stated? If not, discuss with the Assessment Officer.
Application signed by the operator?	☐	☐	Application to be returned if unsigned. However, first discuss with the Assessment Officer, as other matters may need to be raised with the operator. Return the application for signature as directed. Mark record with bring-up date.
Correct fees paid?	☐	☐	Check that the correct fee has been paid. If not, first discuss with the Assessment Officer, as other matters may need to be raised with the operator. Send letter advising fee details. Mark record with bring-up date.
File and related papers prepared for assessment?	☐	☐	Create the registration file (retrieve previous file for renewal) and transfer with the application, related papers and the relevant review and assessment forms to the Assessment Officer
If all matters have been satisfactorily completed, the application is to be forwarded to the officer assigned to review this class of application. Applications held for further information must be followed up within 10 working days.			

COMMENTS (Record the details if the application is returned to the operator for further information)	
Signature	**Date**

ASSESSMENT OFFICER *(Tick relevant box or enter "n/a" if not applicable)*

ITEM	YES	NO	NOTES and ACTIONS
PERSONNEL RESOURCES AND TRAINING			
Nominated Radiation Protection Officer satisfactory?	☐	☐	Confirm that the nominee has appropriate qualifications and experience for the position and has appropriate authority to undertake the required duties and responsibilities.
Nominated Qualified Expert satisfactory?	☐	☐	**Note***: The regulatory body may waive this requirement for basic intraoral installations where it is satisfied that potential occupational and public exposures are likely to be insignificant and patient doses will be within normal bounds.*
Responsible Dental (or Medical) Practitioner satisfactory?	☐	☐	Confirm that the nominated Dental (or Medical) Practitioner has appropriate qualifications and experience.
Equipment operators appropriately qualified and trained?	☐	☐	Confirm that the persons operating the X ray equipment have appropriate qualifications and training and will be supervised by an appropriately qualified Dental (or Medical) Practitioner.
Other personnel appropriately trained and supervised?	☐	☐	Confirm that other personnel have appropriate radiation safety training and will be adequately supervised.
RADIATION APPARATUS AND PREMISES			
X ray equipment complies?	☐	☐	Are all details regarding equipment (e.g. manufacturer, model no., serial no. etc.) provided? Does the X ray component comply with relevant design and performance standards? Will the equipment only be used for examinations appropriate to its designed purpose?
Premises satisfactory?	☐	☐	Confirm that the design and construction of the premises, the siting of the X ray equipment, the location of the operator (and the provision of operator protective barriers should this be necessary) will ensure at least the minimum prescribed level of worker and public radiation safety.
Qualified Expert report provided?	☐	☐	***Note:*** *For small, basic intraoral installations, the regulatory body, in general, should be satisfied if the dentist provides a scale plan showing the location of the X ray equipment, the exposure control(s), the position of the operator(s), the building materials and describes the use and occupancy of surrounding areas.*
Qualified Expert report satisfactory?	☐	☐	The report (if required) may need to be reviewed by an external expert if the regulatory body does not have internal expertise.
Equipment subject to regular maintenance?	☐	☐	Is the X ray equipment subject to maintenance at intervals prescribed by the manufacturer?
Access to X ray equipment?	☐	☐	Are appropriate measures in place to control access to and prevent use of the X ray equipment by unauthorized persons? ***Note:*** *Exposure controls should not be in waiting rooms or other public areas.*

ITEM	YES	NO	NOTES and ACTIONS
Image receptors and film/image processing facilities satisfactory?	☐	☐	Will the operator be using the fastest practicable image receptor (>= 'D' speed)? Will the operator develop the mage using chemicals and procedures specified by the manufacturer, or if an electronic image, using techniques that ensure the patient dose is not greater than that required for 'F' speed film?
Protective devices (e.g. patient lead aprons, intraoral film holders) satisfactory?	☐	☐	**Note***: Patient lead aprons are not of great significance during intraoral or panoramic radiography provided the X ray equipment complies with standards and proper working rules are observed*
Disposal of unwanted X ray equipment?	☐	☐	Does the operator have procedures to ensure that unwanted X ray equipment is transferred only to an appropriate operator unless otherwise approved by the regulatory body?
OCCUPATIONAL RADIATION PROTECTION			
Occupational and public protection programme complies?	☐	☐	Do operator's protocols ensure that occupational and public radiation protection is optimized, work areas are appropriately classified, and doses will comply with the prescribed limits?
Arrangements for Personal Radiation Monitoring comply?	☐	☐	***Note:*** *The regulatory body may exempt individual dental practices from routine monitoring of personnel where it is satisfied that potential occupational exposures are likely to be insignificant*. If not exempt, has the operator: • Provided satisfactory information on the numbers and types of personal monitoring devices that will be used (film badges, TLD)? • Made suitable arrangement for keeping personnel regularly and routinely informed of their recorded occupational radiation dose? • Is the stated monitoring period (frequency) satisfactory?
Personal Monitoring Service Provider is approved?	☐	☐	Is the personal monitoring service provider approved by the regulatory body
RADIOLOGICAL PROTECTION OF PATIENT			
Are there appropriate protocols for ensuring overall patient protection and safety in the prescription of, and during the performance of diagnostic procedures	☐	☐	These matters are the responsibility of the designated Dental (or Medical) Practitioner. Guidelines on entrance surface doses during dental radiography should be available from the relevant professional body.
QA satisfactory?	☐	☐	Is the operator's QA programme (including image receptors, film/image processors, repeat analysis, etc.) satisfactory?
Has the operator taken action to determine typical patient doses for comparison to guideline values?	☐	☐	***Note:*** *Measurements made by a Qualified Expert should only be required in exceptional circumstances. The regulatory body can estimate patient entrance surface doses from the exposure times used and knowledge of typical radiation outputs. Note that improper film development is probably the most significant cause of unnecessarily increased patient doses in dental radiography.*

ITEM	YES	NO	NOTES and ACTIONS
Research procedures and protocols satisfactory?	☐	☐	If research is performed that involves the exposure of patients or volunteers, the operator must show that they act on advice from an acceptable Ethical Review Committee and will comply with the provisions of the Helsinki Declaration and the guidelines prepared by the Council for International Organizations of Medical Sciences and the World Health Organization.
Screening protocols satisfactory?	☐	☐	Mass screening of population groups involving medical exposure is not justified unless the expected advantages for the individuals examined or for the population as a whole are sufficient to compensate for the economic and social costs, including the radiation detriment. If the operator intends providing screening examinations (e.g. panoramic radiography) is there evidence that account has been taken to justify the potential of the screening procedure for detecting disease, the likelihood of effective treatment of cases detected and, for certain diseases, the advantages to the community from the control of the disease?
Pre-employment, legal or administrative radiography policy satisfactory?	☐	☐	Any radiological examination for occupational, legal or health insurance purposes undertaken without reference to clinical indications is not justified unless it is expected to provide useful information on the health of the individual examined or unless the specific type of examination is justified by those requesting it in consultation with relevant professional bodies.
ACCIDENT/INCIDENT PROCEDURES			
Accident/incident plans satisfactory?	☐	☐	Are the operator's procedures for dealing with accidents and incidents appropriate? Personnel are appropriately trained with regard to the requirements for notifying accidents/incidents?
RECORDS, AUDITS			
Records satisfactory?	☐	☐	Has the operator made suitable arrangements for maintaining records (e.g. inventory, occupational dose records, audits, etc.)?
Routine audit programme satisfactory?	☐	☐	The registrant audits the RPP at suitable intervals?
If a renewal, are there any outstanding items of non-compliance and/or is a legal action being considered by the regulatory body?	☐	☐	If yes, the application should be discussed with the assessor's Supervisor to determine an appropriate course of action
If all matters have been satisfactorily completed, the application is to be forwarded to the assessor's Supervisor and then to the officer authorised to sign the application			

COMMENTS		
	Signature	**Date**

SUPERVISOR

ITEM	YES	NO	NOTES and ACTIONS
Review and assessment procedures satisfactory?	☐	☐	Check that the Assessment Officer has completed all relevant sections, that the fee, authorization period, operator's name, registered location(s) and purpose(s) are correct.
Authorization can be approved?	☐	☐	Confirm that any attached conditions, restrictions or limitations imposed on the authorization are appropriate before the authorization is signed.
Inspection personnel informed?	☐	☐	Inspection personnel advised of the application for inclusion in the routine inspection programme.

COMMENTS		
	Signature	**Date**

Appendix B

PROCEDURES FOR AUTHORIZATION: REVIEW AND ASSESSMENT OF APPLICATIONS FOR NUCLEAR MEDICINE

Application No

REVIEW AND ASSESSMENT OF AUTHORIZATION APPLICATION

NUCLEAR MEDICINE

Diagnostic ☐ **Therapy** ☐

FIRST APPLICATION ☐ **RENEWAL** ☐ **DATE RECEIVED** _____ / _____ / _____

NAME OF OPERATOR _____

PROCESSING OFFICER

ITEM	YES	NO	NOTES and ACTIONS
DATABASE ENTRY, PRELIMINARY DATA CHECK, FILE CREATION			
Database entry completed?	☐	☐	New applications - enter information into the database and record the application sequence number (and/ or future authorization number) on the application. Renewals - update the database as required.
Required details provided?	☐	☐	Has required information been provided including postal and physical address, RPO, source inventory, RPP, etc.? If not, or if unclear, discuss with the Assessment Officer and, return the application for the additional information as directed. Mark record with bring-up date.
Operator identified?	☐	☐	Name and position held has been stated? If not, discuss with the Assessment Officer.
Application signed by the operator?	☐	☐	Application to be returned if unsigned. However, first discuss with the Assessment Officer as other matters may need to be raised with the operator. Return the application for signature as directed. Mark record with bring-up date.
Correct fees paid?	☐	☐	Check that the correct fee has been paid. If not, first discuss with the Assessment Officer as other matters may need to be raised with the operator. Send letter advising fee details. Mark record with bring-up date.
File and related papers prepared for assessment?	☐	☐	Create the authorization file (retrieve previous file for renewal) and transfer with the application, related papers and the relevant review and assessment forms to the Assessment Officer
If all matters have been satisfactorily completed, the application is to be forwarded to the officer assigned to review this class of application. Applications held for further information must be followed up within 10 working days.			

COMMENTS (Record the details if the application is returned to the operator for further information)		
	Signature	**Date**

ASSESSMENT OFFICER *(Tick relevant box or enter "n/a" if not applicable)*

ITEM	**YES**	**NO**	**NOTES and ACTIONS**
PERSONNEL RESOURCES AND TRAINING			
Nominated Radiation Protection Officer satisfactory?	☐	☐	Confirm that the nominee has appropriate qualifications and experience for the position and has appropriate authority to undertake the required duties and responsibilities.
Nominated Qualified Expert satisfactory?	☐	☐	Confirm that the nominated Qualified Expert has appropriate qualifications and experience. ***Note**: This person may also be the Medical Physicist.*
Responsible Medical Practitioner satisfactory?	☐	☐	Confirm that the nominated Medical Practitioner has appropriate qualifications and experience
Nominated Medical Physicist satisfactory?	☐	☐	The Medical Physicist is to be accredited in nuclear medicine by the appropriate professional body. Duties include performing or supervising the calibration of dose calibrators, imaging and counting equipment, supervising radiation safety during therapy administrations, etc. ***Note**: This person may also be the Qualified Expert.*
Nucleographers appropriately qualified?	☐	☐	Confirm that the nucleographers employed (or contracted by) the operator have appropriate qualifications and will be supervised by an appropriately qualified Medical Practitioner. (If the operator has combined CPECT/CT equipment, additional radiographic qualifications and/or training may be required.)
Other personnel appropriately trained and supervised?	☐	☐	Confirm that other personnel have appropriate radiation safety training and will be adequately supervised.
Nursing staff appropriately trained for in-vivo therapy procedures?	☐	☐	Where patients undergo therapy (and are in-patents) are nursing staff appropriately trained in radiation safety and emergency procedures?
RADIATION SOURCES, EQUIPMENT, SAFETY OF SOURCES			
Radioactive sources comply?	☐	☐	Are the radioactive sources and activities listed in the inventory approved by the regulatory body for use in nuclear medicine (e.g. ^{99m}Tc, ^{99}Mo, ^{131}I, etc.)?
X ray equipment complies?	☐	☐	If the operator has X ray equipment (e.g. a combined SPECT/CT scanner) does the X ray equipment comply with relevant design and performance standards?
Control of radioactive sources satisfactory?	☐	☐	Is access to radioactive sources, whether in storage or in use, adequately controlled?
Premises satisfactory?	☐	☐	Confirm that the design and construction of the premises,

ITEM	YES	NO	NOTES and ACTIONS
			and the siting of the radiation sources (i.e. including patients to whom radioactive sources have been administered) and the use of operator protective barriers (where necessary) will ensure at least the minimum prescribed level of worker and public radiation safety.
Therapy facilities satisfactory?	☐	☐	Confirm that the design, construction, ventilation, etc. of hospital rooms used for nursing therapy patients will ensure at least the minimum prescribed level of worker and public radiation safety. For iodine therapy, in particular, ensure that the facility has waste storage tanks, etc. to ensure that appropriate delay and decay takes place and that the effluent subsequently complies with the regulations.
Safety assessment provided?	☐	☐	A safety assessment is required that: (a) identifies the ways in which normal exposures and potential exposures could be incurred, account being taken of the effect of events external to the sources as well as events directly involving the sources and their associated equipment: (b) determines the expected magnitudes of normal exposures and, to the extent reasonable and practicable, estimates the probabilities and the magnitudes of potential exposures; and (c) assesses the quality and extent of the protection and safety provisions. The safety assessment may need to be reviewed by an external expert if the regulatory body does not have internal expertise
Leak Testing	☐	☐	Procedures for leak testing of sealed radioactive sources (other than short half-life sources) satisfactory?
Storage facility complies?	☐	☐	Is the store for radioactive sources suitably constructed in compliance with the regulations, including minimizing fire risks, control, ventilation, external dose rate limits and potential public exposure? Is it suitably labelled, including stating the means of contacting the operator and / or RPO in case of emergency?
OCCUPATIONAL RADIATION PROTECTION			
Occupational protection programme complies?	☐	☐	Do operator's protocols ensure that occupational radiation protection is optimized, work areas are appropriately classified, and doses will comply with the prescribed limits?
Survey meters, contaminations meters and personal alarms, dosimeters, etc. comply?	☐	☐	Are the survey meters identified by the operator suitable for the intended purposes? Do they have a current satisfactory calibration for the radiation energies to be used, including test for fold back when subject to high radiation exposure rates? Are there sufficient contamination meters, personal alarms and dosimeters and are they subject to regular function checks?
Arrangements for Personal Radiation Monitoring comply?	☐	☐	Has the operator provided satisfactory information on the numbers and types of personal monitoring devices that will be used (i.e. film badges, TLD, personal alarms, etc? Biological monitoring performed when necessary? Has the operator made suitable arrangement for keeping personnel regularly and routinely informed of their recorded occupational radiation dose? Is the stated monitoring period (frequency) satisfactory?
Personal Monitoring Service provider is approved?	☐	☐	Is the personal monitoring service provider approved by the regulatory body

ITEM	YES	NO	NOTES and ACTIONS
RADIOLOGICAL PROTECTION OF PATIENTS			
Are there appropriate protocols for ensuring overall patient protection and safety in the prescription of, and during the performance of diagnostic and therapeutic procedures	☐	☐	These matters are the responsibility of the designated Medical Practitioner. Guidelines on applicable activities to be administered should be available from the relevant professional body. Protocols should describe the procedures required to perform the examination (or therapy) as well as working rules to properly identify patients and the radionuclide to be administered, and to ensure safety for the patient, staff and public. Protocols should also explain procedures for investigations on pregnant or potentially pregnant patients, lactating mothers and children
QA satisfactory?	☐	☐	Is the operator's QA programme satisfactory for the procedures to be undertaken by the operator?
Operator has suitable, functioning dose calibrator?	☐	☐	Is the dose calibrator suitable for the radionuclides used? Routinely used to measure all radionuclides to be administered? Calibrated at satisfactory intervals?
Working rules for therapy administration satisfactory?	☐	☐	Does a medical physicist attend therapy administrations to ensure all safety procedures are satisfactory and that contamination risks are minimized? Do protocols ensure compliance with the activity limits for the discharge of treated patients? Are therapy out-patients given appropriate instructions on travel and other safety related matters? Are procedures in place to deal with therapy patients who might die shortly after administration of the therapy (e.g. for autopsy, embalming, cremation)?
Imaging devices are subject to regular maintenance?	☐	☐	Is the imaging equipment subject to maintenance and calibration at intervals prescribed by the manufacturer?
Research procedures and protocols satisfactory?	☐	☐	If research is performed that involves the exposure of patients or volunteers, the operator must show that they act on advice from an acceptable Ethical Review Committee and will comply with the provisions of the Helsinki Declaration and the guidelines prepared by the Council for International Organizations of Medical Sciences and the World Health Organization.
TRANSPORT OF RADIOACTIVE MATERIAL			
Transport of radioactive sources complies (where relevant)?	☐	☐	Has the operator made complying arrangements (where responsible) for the transport of radioactive sources? Source containers secured, vehicles labelled, etc. in compliance with IAEA Transport Regulations? Procedures for monitoring incoming and outgoing packages satisfactory?
RADIOACTIVE WASTE MANAGEMENT			
Waste disposal arrangements comply?	☐	☐	Has the operator made suitable arrangements for the disposal of radioactive waste (e.g. gaseous, aerosols, liquids, solids) clearly identifying how this will be achieved?

EMERGENCY PROCEDURES			
Emergency, accident and incident plans satisfactory?	☐	☐	The operator's emergency procedures are appropriate? Does the operator have appropriate equipment to deal with emergencies (e.g. spills)? Are the operator's procedures for dealing with accidents and incidents appropriate? Personnel appropriately trained with regard to dealing with emergencies and with the requirements for notifying accidents / incidents?
RECORDS, AUDITS			
Records satisfactory?	☐	☐	Has the operator made suitable arrangements for maintaining records (e.g. inventory, source movement logbook, occupational dose records, audits, etc.)?
Routine audit programme satisfactory?	☐	☐	The operator audits the RPP at suitable intervals? The operator/RPO regularly (and without notice) audits radiation safety practices of its personnel?
If a renewal, are there any outstanding items of non-compliance and / or is a legal action being considered by the regulatory body?	☐	☐	If yes, the application should be discussed with the assessor's Supervisor to determine an appropriate course of action
If all matters have been satisfactorily completed, the application is to be forwarded to the assessor's Supervisor and then to the officer authorised to sign the application			

COMMENTS		
	Signature	**Date**

SUPERVISOR

ITEM	YES	NO	NOTES and ACTIONS
Review and assessment procedures satisfactory?	☐	☐	Check that the Assessment Officer has completed all relevant sections, that the fee, authorization period, operator's name, licensed location(s) and purpose(s) are correct.
Authorization can be approved?	☐	☐	Confirm that any attached conditions, restrictions or limitations imposed on the authorization are appropriate before the authorization is signed.
Inspection personnel informed?	☐	☐	Inspection personnel advised of the application for inclusion in the routine inspection programme.

COMMENTS		
	Signature	**Date**

Appendix C

PROCEDURES FOR AUTHORIZATION: REVIEW AND ASSESSMENT OF APPLICATIONS FOR RADIOTHERAPY

Application No

REVIEW AND ASSESSMENT OF AUTHORIZATION APPLICATION
RADIOTHERAPY

FIRST APPLICATION ☐ **RENEWAL** ☐ **DATE RECEIVED** _____ / _____ / _____

NAME OF OPERATOR _____

PROCESSING OFFICER

ITEM	YES	NO	NOTES and ACTIONS
DATABASE ENTRY, PRELIMINARY DATA CHECK, FILE CREATION			
Database entry completed?	☐	☐	New applications - enter information into the database and record the application sequence number (and / or future authorization number) on the application. Renewals - update the database as required.
Required details provided?	☐	☐	Has required information been provided including postal and physical address, RPO, source inventory, RPP, etc.? If not, or if unclear, discuss with the Assessment Officer and, return the application for the additional information as directed. Mark record with bring-up date.
Operator identified?	☐	☐	Name and position held has been stated? If not, discuss with the Assessment Officer.
Application signed by the operator?	☐	☐	Application to be returned if unsigned. However, first discuss with the Assessment Officer as other matters may need to be raised with the operator. Return the application for signature as directed. Mark record with bring-up date.
Correct fees paid?	☐	☐	Check that the correct fee has been paid. If not, first discuss with the Assessment Officer as other matters may need to be raised with the operator. Send letter advising fee details. Mark record with bring-up date.
File and related papers prepared for assessment?	☐	☐	Create the authorization file (retrieve previous file for renewal) and transfer with the application, related papers and the relevant review and assessment forms to the Assessment Officer
If all matters have been satisfactorily completed, the application is to be forwarded to the officer assigned to review this class of application. Applications held for further information must be followed up within 10 working days.			

COMMENTS (Record the details if the application is returned to the operator for further information)		
	Signature	**Date**

ASSESSMENT OFFICER *(Tick relevant box or enter "n/a" if not applicable)*

ITEM	**YES**	**NO**	**NOTES and ACTIONS**
PERSONNEL RESOURCES AND TRAINING			
Nominated Radiation Protection Officer satisfactory?	☐	☐	Confirm that the nominee has appropriate qualifications and experience for the position and has appropriate authority to undertake the required duties and responsibilities.
Nominated Qualified Expert satisfactory?	☐	☐	Confirm that the nominated Qualified Expert has appropriate qualifications and experience. ***Note**: This person may also be the Medical Physicist.*
Responsible Medical Practitioner satisfactory?	☐	☐	Confirm that the nominated Medical Practitioner has appropriate qualifications and experience
Nominated Medical Physicist satisfactory?	☐	☐	The physicist is to be accredited in radiotherapy physics by the appropriate professional body. ***Note**: This person may also be the Qualified Expert.*
Radiation Therapist(s) appropriately qualified?	☐	☐	Confirm that the Radiation Therapist(s) employed (or contracted by) the operator have appropriate qualifications and will be supervised by an appropriately qualified Medical Practitioner.
Other personnel appropriately trained and supervised?	☐	☐	Confirm that other personnel have appropriate radiation safety training and will be adequately supervised.
Nursing staff appropriately trained for brachytherapy and after-loading techniques?	☐	☐	Where patients undergo brachytherapy with implanted sources (i.e. and are in-patents) or are treated by after-loader techniques, are nursing staff appropriately trained in radiation safety and emergency procedures?
RADIATION SOURCES, EQUIPMENT, SAFETY OF SOURCES			
Radioactive sources comply?	☐	☐	Are the radioactive sources and activities listed in the inventory approved by the regulatory body for use in radiotherapy (e.g. ^{192}Ir, ^{60}Co, ^{137}Cs)?
Therapy devices and X ray equipment comply?	☐	☐	Do the radiation devices (i.e. X ray equipment, linear accelerators, teletherapy and brachytherapy equipment) comply with specified design and performance standards? (e.g. ISO, IEC)
Premises satisfactory?	☐	☐	Confirm that the design and construction of the premises, and the siting of the radiation sources (including those within patients), will ensure at least the minimum prescribed level of worker and public radiation safety.

Safety assessment provided?	☐	☐	A safety assessment is required that: (a) identifies the ways in which normal exposures and potential exposures could be incurred, account being taken of the effect of events external to the sources as well as events directly involving the sources and their associated equipment: (b) determines the expected magnitudes of normal exposures and, to the extent reasonable and practicable, estimates the probabilities and the magnitudes of potential exposures; and (c) assesses the quality and extent of the protection and safety provisions. The safety assessment may need to be reviewed by an external expert if the regulatory body does not have internal expertise
Control of radioactive sources satisfactory?	☐	☐	Is access to radioactive sources whether in use, storage or installed in radiation devices adequately controlled? Are the devices physically controlled to prevent operation (e.g. key required to operate), tampering, interference, removal or maintenance by unauthorized persons?
Leak testing	☐	☐	Procedures for leak testing of sealed radioactive sources (i.e. other than short half-life sources) satisfactory?
Radioactive source replacement equipment?	☐	☐	Does the operator have appropriate equipment to safely exchange new and spent sources? Are the source transfer procedures satisfactory?
Radiation devices are subject to regular maintenance?	☐	☐	Are the radiation devices subject to maintenance at intervals prescribed by the manufacturer? Do authorized personnel undertake maintenance?
Storage facility complies?	☐	☐	Is the store for radioactive sources suitably constructed in compliance with the regulations, including minimizing fire risks, control, external dose rate limits and potential public exposure? Is it suitably labelled, including stating the means of contacting the operator and/or RPO in case of emergency?
OCCUPATIONAL RADIATION PROTECTION			
Occupational and public protection programme complies?	☐	☐	Do operator's protocols ensure that occupational and public radiation protection is optimized, work areas are appropriately classified, and doses will comply with the prescribed limits?
Arrangements for Personal Radiation Monitoring comply?	☐	☐	Has the operator provided satisfactory information on the numbers and types of personal monitoring devices that will be used (e.g. film badges, TLD, OSL, personal alarms, etc.)? Has the operator made suitable arrangement for keeping personnel regularly and routinely informed of their recorded occupational radiation dose? Is the stated monitoring period (i.e. frequency) satisfactory?
Personal Monitoring Service provider is approved?	☐	☐	Is the personal monitoring service provider approved by the regulatory body
Survey meters and personal alarms, dosimeters, etc. comply?	☐	☐	Are the survey meters identified by the operator suitable for the intended purposes? Do they have a current satisfactory calibration for the radiation energies to be used, including test for fold back when subject to high radiation exposure rates? Are there sufficient personal alarms and dosimeters and are they subject to regular function checks?

RADIOLOGICAL PROTECTION OF PATIENTS			
Are there appropriate protocols for ensuring patient protection and safety in the prescription of, and during the performance of, therapeutic procedures?	☐	☐	These matters are the responsibility of the designated Medical Practitioner. Guidelines on applicable treatment regimes should be available from the relevant professional body. Protocols should describe the procedures required to achieve the desired clinical outcome as well as working rules to properly identify patients and to ensure safety for the patient, staff and public.
Research procedures and protocols satisfactory?	☐	☐	If research is performed that involves the exposure of patients or volunteers, the operator must show that they act on advice from an acceptable Ethical Review Committee and will comply with the provisions of the Helsinki Declaration and the guidelines prepared by the Council for International Organizations of Medical Sciences and the World Health Organization.
Does the operator possess a suitable radiation-measuring instrument for calibrating the radiation output of the radiation sources?	☐	☐	The manufacturer and model should be described, together with details of its calibration schedule, identification of the calibrating organization and confirmation that the calibration is traceable to a recognized standard.
Have all radiation devices been calibrated in compliance with the regulatory body's requirements?	☐	☐	The operator should provide details of the last full calibration for each device. For brachytherapy sources, the date when the activity (i.e. or dose rate) was last re-calculated should be stated.
Are protocols for daily, weekly, monthly performance and safety checks of radiation devices satisfactory?	☐	☐	Routine output reproducibility and related safety checks will usually be performed by the medical physicist and / or Radiation Therapist(s) under the supervision of the Medical Physicist. These checks do not replace full calibration procedures.
QA and working rules satisfactory?	☐	☐	Are the operator's QA programmes and working rules satisfactory for each type of therapy to be undertaken by the operator?
Brachytherapy (LDR, HDR, permanent implants, interstitial X ray therapy) procedures satisfactory?	☐	☐	Permanent implants - does the Medical Physicist attend treatments to ensure all sealed sources are accounted for and that safe working procedures are observed? Afterloaders (LDR) – does the Medical Physicist supervise the device's initial set-up, the commencement of treatment and confirm source retrieval at the end of the treatment? HDR and interstitial X ray therapy – is the Medical Physicist present throughout the procedure to supervise radiation safety procedures?
TRANSPORT OF RADIOACTIVE MATERIAL			
Transport of radioactive sources complies (i.e. where relevant)?	☐	☐	Has the operator (i.e. when responsible) made complying arrangements for the transport of radioactive sources? Source containers secured, vehicles labelled, etc. in compliance with IAEA Transport Regulations? Procedures for monitoring incoming and outgoing packages satisfactory?
RADIOACTIVE WASTE MANAGEMENT			
Radiation source disposal arrangements satisfactory?	☐	☐	Has the operator made suitable arrangements for the disposal of spent radioactive sources and unwanted X ray equipment, clearly identifying how this will be achieved?

EMERGENCY PROCEDURES			
Emergency plans satisfactory?	☐	☐	The operator's emergency procedures are appropriate? Does the operator have appropriate emergency equipment? Personnel appropriately trained in these procedures?
RECORDS, AUDITS			
Records satisfactory?	☐	☐	Has the operator made suitable arrangements for maintaining records (e.g. for inventory, source movement logbook, occupational dose records, audits, etc.)?
Routine audit programme satisfactory?	☐	☐	The operator audits the RPP at suitable intervals? The operator/RPO regularly (i.e. and without notice) audits radiation safety practices of its personnel?
If a renewal, are there any outstanding items of non-compliance and/or is a legal action being considered by the regulatory body?	☐	☐	If yes, the application should be discussed with the assessor's Supervisor to determine an appropriate course of action
If all matters have been satisfactorily completed, the application is to be forwarded to the assessor's Supervisor and then to the officer authorised to sign the application			

COMMENTS		
	Signature	**Date**

SUPERVISOR

ITEM	YES	NO	NOTES and ACTIONS
Review and assessment procedures satisfactory?	☐	☐	Check that the Assessment Officer has completed all relevant sections, that the fee, authorization period, operator's name, licensed location(s) and purpose(s) are correct.
Authorization can be approved?	☐	☐	Confirm that any attached conditions, restrictions or limitations imposed on the authorization are appropriate before the authorization is signed.
Inspection personnel informed?	☐	☐	Inspection personnel advised of the application for inclusion in the routine inspection programme.

COMMENTS		
	Signature	**Date**

Appendix D

PROCEDURES FOR AUTHORIZATION: REVIEW AND ASSESSMENT OF APPLICATIONS FOR INDUSTRIAL RADIOGRAPHY

Application No

REVIEW AND ASSESSMENT OF AUTHORIZATION APPLICATION INDUSTRIAL RADIOGRAPHY

FIRST APPLICATION ☐ **RENEWAL** ☐ **DATE RECEIVED** _____ / _____ / _____

NAME OF OPERATOR _____

PROCESSING OFFICER

ITEM	YES	NO	NOTES and ACTIONS
DATABASE ENTRY, PRELIMINARY DATA CHECK, FILE CREATION			
Database entry completed?	☐	☐	New applications - enter information into the database and record the application sequence number (and / or future authorization number) on the application. Renewals - update the database as required.
Required details provided?	☐	☐	Has required information been provided including postal and physical address, RPO, source inventory, including details of radionuclides or x ray apparatus, activity, manufacturer, model no., serial no., RPP, etc.? If not, or if unclear, discuss with the Assessment Officer and, return the application for the additional information as directed. Mark record with bring-up date.
Operator identified?	☐	☐	Name and position held has been stated? If not, discuss with the Assessment Officer.
Application signed by the operator?	☐	☐	Application to be returned if unsigned. However, first discuss with the Assessment Officer, as other matters may need to be raised with the operator. Return the application for signature as directed. Mark record with bring-up date.
Correct fees paid?	☐	☐	Check that the correct fee has been paid. If not, first discuss with the Assessment Officer, as other matters may need to be raised with the operator. Send letter advising fee details. Mark record with bring-up date.
File and related papers prepared for assessment?	☐	☐	Create the authorization file (i.e. or retrieve previous file for renewal) and transfer with the application, related papers and the relevant review and assessment forms to the Assessment Officer
If all matters have been satisfactorily completed, the application is to be forwarded to the officer assigned to review this class of application. Applications held for further information must be followed up within 10 working days.			

COMMENTS (Record the details if the application is returned to the operator for further information)		
	Signature	**Date**

ASSESSMENT OFFICER *(Tick relevant box or enter "n/a" if not applicable)*

ITEM	**YES**	**NO**	**NOTES and ACTIONS**
PERSONNEL RESOURCES AND TRAINING			
Nominated Radiation Protection Officer satisfactory?	☐	☐	Confirm that the nominee has appropriate qualifications and experience for the position and has appropriate authority to undertake the required duties and responsibilities.
Nominated Qualified Expert satisfactory?	☐	☐	Confirm that the nominated Qualified Expert has appropriate qualifications and experience
Industrial Radiographer(s) appropriately trained?	☐	☐	Confirm that the Industrial Radiographer(s) employed (or contracted by) the operator have appropriate training and experience
Assistants appropriately trained and supervised?	☐	☐	Confirm that persons assisting the Industrial Radiographer(s) have appropriate training and experience and will be adequately supervised
Sufficient personnel to perform work safely?	☐	☐	Does the operator have sufficient resources to ensure two person radiography teams for each radiation source that may be in use?
RADIATION SOURCES, EQUIPMENT, AND SAFTY OF SOURCES			
Radioactive sources comply?	☐	☐	Are the radioactive sources and activities listed in the inventory approved by the regulatory body for use in industrial radiography (e.g. ^{192}Ir, ^{60}Co, ^{175}Se, ^{137}Cs control sources) and does the encapsulation comply with standards (e.g. ISO)?
X ray equipment and source containers comply?	☐	☐	Are the source containers and X ray equipment of a type approved by the regulatory body for industrial radiography? Do they comply with specified design and performance standards (e.g. IEC)?
Permanent exposure facility complies?	☐	☐	Does the operator plan to perform radiography in a permanent exposure facility? Does the facility satisfy the requirements of the regulations? Does the construction of an enclosed radiography facility complies with dose constraints and dose limits prescribed by the regulations (i.e. under the worst practicable conditions).

ITEM	YES	NO	NOTES and ACTIONS
Safety assessment provided?	☐	☐	A safety assessment is required that: (a) identifies the ways in which normal exposures and potential exposures could be incurred, account being taken of the effect of events external to the sources as well as events directly involving the sources and their associated equipment: (b) determines the expected magnitudes of normal exposures and, to the extent reasonable and practicable, estimates the probabilities and the magnitudes of potential exposures; and (c) assesses the quality and extent of the protection and safety provisions. The safety assessment may need to be reviewed by an external expert if the regulatory body does not have internal expertise
Qualified Expert report satisfactory?	☐	☐	The report may need to be reviewed by an external expert if the regulatory body does not have internal expertise.
Leak testing	☐	☐	Procedures for leak testing of longer lived sealed sources and S-tubes of depleted uranium source containers satisfactory?
Radioactive source replacement equipment?	☐	☐	Arrangements to safely exchange new and spent sources are satisfactory?
Operator has protocols in place to ensure regular maintenance of all radiation sources?	☐	☐	Radioactive source pigtails and wind-out cables are subject to wear and disconnect testing at intervals prescribed by the manufacturer? Source containers are inspected daily (i.e or immediately prior to use) for safe operation? The labelling of radioactive source containers is updated when sources are exchanged?
Storage facilities comply?	☐	☐	Is the store for radioactive sources suitably constructed in compliance with the regulations, including meeting external dose rate limits and potential public exposure? Is it suitably labelled, including stating the means of contacting the operator and / or RPO in case of emergency? Are all locations where sources are stored secure? (i.e. in a permanent store, during transport and in field use).
Operator has appropriate safety equipment for routine radiography operations?	☐	☐	Does the operator have sufficient warning signs, ropes (i.e. for barriers), beam collimators, etc.
OCCUPATIONAL AND PUBLIC EXPOSURE			
Occupational and public protection programme complies?	☐	☐	Do operator's protocols ensure that occupational and public radiation protection is optimized, work areas are appropriately classified, and doses will comply with the prescribed limits? Do protocols ensure dose rates at boundaries around radiography operations comply with prescribed limits?
Working rules satisfactory?	☐	☐	Are the operator's working rules satisfactory? Do the rules require work to cease if the user's survey meter fails or in the event of any safety related failure of a radiation source or a breach of a site boundary? Do the rules require users to verify with a survey meter that radioactive sources have been safely returned to the source container after each and every exposure?

ITEM	YES	NO	NOTES and ACTIONS
Arrangements for Personal Radiation Monitoring comply?	☐	☐	Has the operator provided satisfactory information on the numbers and types of personal monitoring devices that will be used (e.g. film badges, TLD, personal alarms, etc.)? Has the operator made suitable arrangement for keeping personnel regularly and routinely informed of their recorded occupational radiation dose? Is the stated monitoring period (i.e. frequency) satisfactory?
Personal Monitoring Service provider is approved?	☐	☐	Is the personal monitoring service provider approved by the regulatory body
Survey meters and personal alarms, dosimeters, etc. comply?	☐	☐	Are the survey meters identified by the operator suitable for the intended purpose? Do they have a current satisfactory calibration for the radiation energies to be used, including test for fold back when subject to high radiation exposure rates? Are there sufficient complying survey meters for the number of potential radiographic operations? Are there sufficient personal alarms and dosimeters and are they subject to regular function checks?
TRANSPORT OF RADIOACTIVE MATERIAL			
Transport of radioactive sources complies?	☐	☐	Has the operator made complying arrangements for the transport of radioactive sources? Source containers secured, vehicles labelled, etc. in compliance with IAEA Transport Regulations? Procedures for monitoring incoming and outgoing packages satisfactory?
MANAGEMENT OF RADIOACTIVE WASTE			
Waste disposal arrangements comply?	☐	☐	Has the operator made suitable arrangements for the disposal of spent sources and clearly identified how this will be achieved?
EMERGENCY PROCEDURES			
Emergency plans satisfactory?	☐	☐	The operator's emergency procedures are appropriate? Does the operator have appropriate emergency equipment (e.g. remote handling tools, bolt cutters, lead pots, bagged lead shot, etc.) Personnel appropriately trained in these procedures?
RECORDS, AUDITS			
Records satisfactory?	☐	☐	Has the operator made suitable arrangements for maintaining records (e.g. inventory, source movement logbook, occupational dose records, audits, etc.)?
QA programme?			Has the operator a suitable QA programme?
Routine audit programme satisfactory?	☐	☐	The operator audits the RPP at suitable intervals? The operator/RPO regularly (i.e. and without notice) audits radiation safety practices of its personnel both at the principal premises and at field sites?
If a renewal, are there any outstanding items of non-compliance and / or is a legal action being considered by the regulatory body?	☐	☐	If yes, the application should be discussed with the assessor's Supervisor to determine an appropriate course of action
If all matters have been satisfactorily completed, the application is to be forwarded to the assessor's Supervisor and then to the officer authorised to sign the application			

COMMENTS		
	Signature	**Date**

SUPERVISOR

ITEM	YES	NO	NOTES and ACTIONS
Review and assessment procedures satisfactory?	☐	☐	Check that the Assessment Officer has completed all relevant sections, that the fee, authorization period, operator's name, licensed location(s) and purpose(s) are correct.
Authorization can be approved?	☐	☐	Confirm that any attached conditions; restrictions or limitations imposed on the authorization are appropriate before the authorization is signed.
Inspection personnel informed?	☐	☐	Inspection personnel advised of the application for inclusion in the routine inspection programme.

COMMENTS		
	Signature	**Date**

Appendix E

PROCEDURES FOR AUTHORIZATION: REVIEW AND ASSESSMENT OF APPLICATIONS FOR IRRADIATORS

Application No

REVIEW AND ASSESSMENT OF AUTHORIZATION APPLICATION IRRADIATOR

FIRST APPLICATION ☐ **RENEWAL** ☐ **DATE RECEIVED** _____ / _____ / _____

NAME OF OPERATOR _____

PROCESSING OFFICER

ITEM	YES	NO	NOTES and ACTIONS
DATABASE ENTRY, PRELIMINARY DATA CHECK, FILE CREATION			
Database entry completed?	☐	☐	New applications - enter information into the database and record the application sequence number (and / or future authorization number) on the application. Renewals - update the database as required.
Required details provided?	☐	☐	Has required information been provided including postal and physical address, RPO, source inventory, RPP, etc.? If not, or if unclear, discuss with the Assessment Officer and, return the application for the additional information as directed. Mark record with bring-up date.
Operator identified?	☐	☐	Name and position held has been stated? If not, discuss with the Assessment Officer.
Application signed by the operator?	☐	☐	Application to be returned if unsigned. However, first discuss with the Assessment Officer as other matters may need to be raised with the operator. Return the application for signature as directed. Mark record with bring-up date.
Correct fees paid?	☐	☐	Check that the correct fee has been paid. If not, first discuss with the Assessment Officer as other matters may need to be raised with the operator. Send letter advising fee details. Mark record with bring-up date.
File and related papers prepared for assessment?	☐	☐	Create the authorization file (i.e. or retrieve previous file for renewal) and transfer with the application, related papers and the relevant review and assessment forms to the assessment officer
If all matters have been satisfactorily completed, the application is to be forwarded to the officer assigned to review this class of application. Applications held for further information must be followed up within 10 working days.			

COMMENTS (Record the details if the application is returned to the operator for further information)

Signature	**Date**

ASSESSMENT OFFICER *(Tick relevant box or enter "n/a" if not applicable)*

ITEM	YES	NO	NOTES and ACTIONS
PERSONNEL RESOURCES AND TRAINING			
Nominated Radiation Protection Officer satisfactory?	☐	☐	Confirm that the nominee has appropriate qualifications and experience for the position and has appropriate authority to undertake the required duties and responsibilities.
Nominated Qualified Expert satisfactory?	☐	☐	Confirm that the nominated Qualified Expert has appropriate qualifications and experience.
Personnel appropriately trained?	☐	☐	Confirm that personnel employed to operate and maintain the irradiator and its associated equipment have training and experience appropriate to the potential radiation hazard.
Other workers appropriately trained and supervised?	☐	☐	Confirm that other persons working at the facility have appropriate training and will be adequately supervised.
Sufficient personnel to perform work safely?	☐	☐	Does the operator have sufficient resources to operate the irradiator safely?
RADIATION SOURCES, EQUIPMENT, AND SAFETY OF SOURCES			
Radiation sources comply?	☐	☐	Are the radioactive sources and activities listed in the inventory approved by the regulatory body for use in irradiators (e.g. ^{60}Co)? Do any devices that generates ionizing radiation electrically (e.g. linear accelerator) complies with the regulatory body's requirements.
Premises satisfactory?	☐	☐	Confirm that the irradiator facility has been designed and constructed to ensure at least the minimum prescribed level of worker and public radiation safety.
Safety Assessment provided?	☐	☐	A safety assessment is required that: (a) identifies the ways in which normal exposures and potential exposures could be incurred, account being taken of the effect of events external to the sources as well as events directly involving the sources and their associated equipment: (b) determines the expected magnitudes of normal exposures and, to the extent reasonable and practicable, estimates the probabilities and the magnitudes of potential exposures; and (c) assesses the quality and extent of the protection and safety provisions. The safety assessment may need to be reviewed by an external expert if the regulatory body does not have internal expertise
Control of radioactive sources satisfactory?	☐	☐	Is there an appropriate level of control for radioactive sources in use and in storage?

ITEM	YES	NO	NOTES and ACTIONS
Leak testing	☐	☐	Procedures for leak testing radioactive sources satisfactory?
Radioactive source replacement?	☐	☐	Are the arrangements for the exchange of new and spent sources satisfactory?
Storage facility complies?	☐	☐	Is the store for radioactive sources suitably constructed in compliance with the regulations, including fire minimization, control, external dose rate limits and potential public exposure? Is it suitably labelled, including stating the means of contacting the operator and/or RPO in case of emergency?
OCCUPATIONAL AND PUBLIC EXPOSURE			
Occupational and public protection programme complies?	☐	☐	Do operator's protocols ensure that occupational and public radiation protection is optimized, work areas are appropriately classified, and doses will comply with the prescribed limits?
QA and working rules satisfactory?	☐	☐	Are the operator's QA programme and working rules satisfactory? The rules require work to cease in the event of any safety related failure. Do the rules require users to verify that radioactive sources have been safely returned to their shielded condition before entering the irradiation room?
Survey meters and personal alarms, etc. comply?	☐	☐	Are the survey meters identified by the operator suitable for the intended purpose? Do they have a current satisfactory calibration for the radiation energies to be used, including test for fold back when subject to high radiation exposure rates? Are sufficient complying survey meters available? Are there sufficient personal alarms and are they subject to regular function checks?
Arrangements for Personal Radiation Monitoring comply?	☐	☐	Has the operator provided satisfactory information on the numbers and types of personal monitoring devices that will be used (e.g. film badges, TLD, OSL, personal alarms, etc.)? Has the operator made suitable arrangement for keeping personnel regularly and routinely informed of their recorded occupational radiation dose? Is the stated monitoring period (i.e. frequency) satisfactory?
Personal Monitoring Service provider is approved?	☐	☐	Is the personal monitoring service provider approved by the regulatory body?
TRANSPORT OF RADIOACTIVE MATERIAL			
Transport of radioactive sources complies?	☐	☐	Has the operator made (i.e. where responsible) complying arrangements for the transport of radioactive sources? Source containers secured, vehicles labelled, etc. in compliance with IAEA Transport Regulations? Procedures for monitoring incoming and outgoing packages satisfactory?
MANAGEMENT OF RADIOACTIVE WASTE			
Waste disposal arrangements comply?	☐	☐	Has the operator made suitable arrangements for the disposal of spent sources and clearly identified how this will be achieved?

EMERGENCY PROCEDURES			
Emergency plans and equipment satisfactory?	☐	☐	Are the operator's emergency procedures appropriate? Personnel are appropriately trained in these procedures?
RECORDS, AUDITS			
Records satisfactory?	☐	☐	Has the operator made suitable arrangements for maintaining records (e.g. inventory, source movement logbook, occupational dose records, audits, etc.)?
Routine audit programme satisfactory?	☐	☐	The operator audits the RPP at suitable intervals? The operator/RPO regularly (i.e. and without notice) audits radiation safety practices of its personnel?
If a renewal, are there any outstanding items of non-compliance and / or is a legal action being considered by the regulatory body?	☐	☐	If yes, the application should be discussed with the assessor's Supervisor to determine an appropriate course of action.
If all matters have been satisfactorily completed, the application is to be forwarded to the assessor's Supervisor and then to the officer authorised to sign the application			

COMMENTS		
	Signature	**Date**

SUPERVISOR

ITEM	YES	NO	NOTES and ACTIONS
Review and assessment procedures satisfactory?	☐	☐	Check that the Assessment Officer has completed all relevant sections, that the fee, authorization period, operator's name, licensed location(s) and purpose(s) are correct.
Authorization can be approved?	☐	☐	Confirm that any attached conditions; restrictions or limitations imposed on the authorization are appropriate before the authorization is signed.
Inspection personnel informed?	☐	☐	Inspection personnel advised of the application for inclusion in the routine inspection programme.

COMMENTS		
	Signature	**Date**

Appendix F

PROCEDURES FOR AUTHORIZATION: REVIEW AND ASSESSMENT OF APPLICATIONS FOR GAUGES

Application No

REVIEW AND ASSESSMENT OF AUTHORIZATION APPLICATION
GAUGES – FIXED and/or PORTABLE

FIRST APPLICATION ☐ **RENEWAL** ☐ **DATE RECEIVED** _____ / _____ / _____

NAME OF OPERATOR _____

PROCESSING OFFICER

ITEM	YES	NO	NOTES and ACTIONS
DATABASE ENTRY, PRELIMINARY DATA CHECK, FILE CREATION			
Database entry completed?	☐	☐	New applications - enter information into the database and record the application sequence number (and/or future authorization number) on the application. Renewals - update the database as required.
Required details provided?	☐	☐	Has required information been provided including postal and physical address, RPO, source inventory, including details of radionuclides or x ray apparatus, activity, manufacturer, model no., serial no., RPP, etc.? If not, or if unclear, discuss with the Assessment Officer and, return the application for the additional information as directed. Mark record with bring-up date.
Operator identified?	☐	☐	Name and position held has been stated? If not, discuss with the Assessment Officer.
Application signed by the operator?	☐	☐	Application to be returned if unsigned. However, first discuss with the Assessment Officer as other matters may need to be raised with the operator. Return the application for signature as directed. Mark record with bring-up date.
Correct fees paid?	☐	☐	Check that the correct fee has been paid. If not, first discuss with the Assessment Officer as other matters may need to be raised with the operator. Send letter advising fee details. Mark record with bring-up date.
File and related papers prepared for assessment?	☐	☐	Create the authorization file (retrieve previous file for renewal) and transfer with the application, related papers and the relevant review and assessment forms to the Assessment Officer.
If all matters have been satisfactorily completed, the application is to be forwarded to the officer assigned to review this class of application. Applications held for further information must be followed up within 10 working days.			

COMMENTS (Record the details if the application is returned to the operator for further information)		
	Signature	**Date**

ASSESSMENT OFFICER *(Tick relevant box or enter "n/a" if not applicable)*

ITEM	**YES**	**NO**	**NOTES and ACTIONS**
PERSONNEL RESOURCES AND TRAINING			
Nominated Radiation Protection Officer satisfactory?	☐	☐	Confirm that the nominee has appropriate qualifications and experience for the position and has appropriate authority to undertake the required duties and responsibilities.
Nominated Qualified Expert satisfactory?	☐	☐	Confirm that the nominated Qualified Expert has appropriate qualifications and experience.
Personnel appropriately trained?	☐	☐	Confirm that personnel who may use portable gauges or who work in controlled areas in the vicinity of fixed gauges have appropriate training and experience for the range of radiation sources to be used. Confirm that persons who install, service or maintain gauges have appropriate training to carry out these procedures. ***Note**: The operator must provide appropriate instruction to all employees who may work near fixed gauges to minimize tampering, interference or unauthorized maintenance, to ensure workers do not inadvertently put themselves at risk, and to allay health fears that might otherwise lead to avoidable industrial action.*
Portable gauge assistants appropriately trained and supervised?	☐	☐	Confirm that persons assisting portable gauge users have appropriate training and experience and will be adequately supervised.
FACILITIES, SOURCES AND EQUIPMENT, TRANSPORT			
Radioactive sources comply?	☐	☐	Are the radioactive sources, activities and form listed in the inventory approved by the regulatory body for use in gauges (e.g. ^{241}Am, ^{137}Cs, ^{131}I, ^{192}Ir, etc.)?
X ray equipment and source containers comply?	☐	☐	Are the radioactive source containers and X ray gauges of a type approved by the regulatory body for this purpose? Do they comply with specified design and performance standards (e.g. ISO, IEC)?
Principal premises satisfactory?	☐	☐	Confirm that the plan of the premises (i.e. excluding temporary field sites) shows the location of fixed gauges and that a report from a Qualified Expert verifies that they will be installed (or used) in a manner that will ensure at least the minimum prescribed level of worker and public radiation safety. ***Note:** For portable gauges, the principal premises will only be used for storage and / or maintenance.*

Qualified Expert report provided?	☐	☐	A report is required to demonstrate that fixed gauges storage and maintenance areas comply with dose and dose rate limits prescribed by the regulations. The report also might deal with the disposal of sources, safe working practices, transport, etc.
Qualified Expert report satisfactory?	☐	☐	The report may need to be reviewed by an external expert if the regulatory body does not have internal expertise.
Leak testing	☐	☐	Procedures for leak testing sealed sources satisfactory? Are the windows of low energy in-stream analysis gauges counted for contamination when replaced?
Storage facility (ies) comply?	☐	☐	Is the store for radioactive sources suitably constructed in compliance with the regulations, including meeting external dose rate limits and potential public exposure? Is it suitably labelled, including stating the means of contacting the operator and / or RPO in case of emergency? Are all locations where sources are stored secure (i.e. in permanent stores, on vehicles transporting portable gauges, during field use, etc.)?
Survey meters comply?	☐	☐	Are the survey meters identified by the operator suitable for the intended purpose? Do they have a current satisfactory calibration for the radiation energies to be used, including test for fold back when subject to high radiation exposure rates? For portable gauges, are there sufficient complying survey meters for the number of potential operations? ***Note**: Neutron survey meters are not essential provided manufacturer's data is available to indicate the intensity relationship between the measurable gamma dose rate and the neutron dose rate.*
Transport of radioactive sources complies?	☐	☐	Has the operator made complying arrangements for the transport of radioactive sources? Source containers secured, vehicles labelled, etc. in compliance with IAEA Transport Regulations? Procedures for monitoring incoming and outgoing packages satisfactory?
Disposal arrangements satisfactory?	☐	☐	Has the operator made suitable arrangements for the disposal of unwanted sources and clearly identified how this will be achieved?
OCCUPATIONAL AND PUBLIC EXPOSURE			
Occupational and public protection programme complies?	☐	☐	Do operator's protocols ensure that occupational and public radiation protection is optimized, work areas are appropriately classified, and doses will comply with the prescribed limits? Do protocols ensure dose rates at boundaries around logging operations comply with prescribed limits?
Arrangements for Personal Radiation Monitoring comply?	☐	☐	Has the operator provided satisfactory information on the numbers and types of personal monitoring devices that will be used (e.g. film badges, TLD, OSL, personal alarms, etc.)? Has the operator made suitable arrangement for keeping personnel regularly and routinely informed of their recorded occupational radiation dose? Is the stated monitoring period (frequency) satisfactory? ***Note**: The use of personal monitors is not normally required for fixed gauges other than during some installation and maintenance procedures. Users of portable neutron moisture*

			/ density gauges and persons maintaining those gauges require personal dosimeters capable of measuring both gamma and neutron radiations
Personal Monitoring Service provider is approved?	☐	☐	Is the personal monitoring service provider approved by the regulatory body.
WORKING RULES, RECORDS, EMERGENCY PROCEDURES, AUDITS,			
QA and working rules satisfactory?	☐	☐	Are the operator's QA programme and working rules satisfactory ensuring: – by regular inspection that gauges function correctly and that all labels and warning signs remain legible? – that radioactive gauges are locked OFF prior to movement? – that gauges temporarily removed from their installed (i.e. fixed) locations during plant maintenance are securely stored pending re-installation? For portable gauges, do the rules require: – work to cease if the user's survey meter fails or in the event of any other safety related failure? – users to verify with a survey meter that radioactive sources have been safely returned to the shielded container after each use?
Emergency plans and equipment satisfactory?	☐	☐	Are the operator's emergency procedures appropriate? Does the operator have appropriate emergency equipment.(e.g. remote handling tools, lead pots, etc.). Personnel are appropriately trained in these procedures?
Routine audit programme satisfactory?	☐	☐	The operator audits the RPP at suitable intervals? The operator/RPO regularly (and without notice) audits radiation safety practices of its personnel, including the use of portable gauges at field sites?
Records satisfactory?	☐	☐	Has the operator made suitable arrangements for maintaining records (e.g. inventory, source movement logbook including disposal, occupational dose records, audits, etc.)?
If a renewal, are there any outstanding items of non-compliance and / or is a legal action being considered by the regulatory body?	☐	☐	If yes, the application should be discussed with the assessor's Supervisor to determine an appropriate course of action
If all matters have been satisfactorily completed, the application is to be forwarded to the assessor's Supervisor and then to the officer authorised to sign the application			

COMMENTS		
	Signature	**Date**

SUPERVISOR

ITEM	YES	NO	NOTES and ACTIONS
Review and assessment procedures satisfactory?	☐	☐	Check that the Assessment Officer has completed all relevant sections, that the fee, authorization period, operator's name, licensed location(s) and purpose(s) are correct.
Authorization can be approved?	☐	☐	Confirm that any attached conditions, restrictions or limitations imposed on the authorization are appropriate before the authorization is signed.
Inspection personnel informed?	☐	☐	Inspection personnel advised of the application for inclusion in the routine inspection programme.

COMMENTS		
	Signature	**Date**

Appendix G

PROCEDURES FOR AUTHORIZATION: REVIEW AND ASSESSMENT OF APPLICATIONS FOR WELL LOGGING

Application No

REVIEW AND ASSESSMENT OF AUTHORIZATION APPLICATION
WELL LOGGING

FIRST APPLICATION ☐ **RENEWAL** ☐ **DATE RECEIVED** _____ / _____ / _____

NAME OF OPERATOR _____

PROCESSING OFFICER

ITEM	YES	NO	NOTES and ACTIONS
DATABASE ENTRY, PRELIMINARY DATA CHECK, FILE CREATION			
Database entry completed?	☐	☐	New applications - enter information into the database and record the application sequence number (and/or future authorization number) on the application. Renewals - update the database as required.
Required details provided?	☐	☐	Has required information been provided including postal and physical address, RPO, source inventory, including details of radionuclides or x ray apparatus, activity, manufacturer, model no., serial no., RPP, etc.? If not, or if unclear, discuss with the Assessment Officer and, return the application for the additional information as directed. Mark record with bring-up date.
Operator identified?	☐	☐	Name and position held has been stated? If not, discuss with the Assessment Officer.
Application signed by the operator?	☐	☐	Application to be returned if unsigned. However, first discuss with the Assessment Officer as other matters may need to be raised with the operator. Return the application for signature as directed. Mark record with bring-up date.
Correct fees paid?	☐	☐	Check that the correct fee has been paid. If not, first discuss with the Assessment Officer as other matters may need to be raised with the operator. Send letter advising fee details. Mark record with bring-up date.
File and related papers prepared for assessment?	☐	☐	Create the authorization file (i.e. or retrieve previous file for renewal) and transfer with the application, related papers and the relevant review and assessment forms to the Assessment Officer
If all matters have been satisfactorily completed, the application is to be forwarded to the officer assigned to review this class of application. Applications held for further information must be followed up within 10 working days.			

COMMENTS (Record the details if the application is returned to the operator for further information)		
	Signature	**Date**

ASSESSMENT OFFICER *(Tick relevant box or enter "n/a" if not applicable)*

ITEM	YES	NO	NOTES and ACTIONS
PERSONNEL RESOURCES AND TRAINING			
Nominated Radiation Protection Officer satisfactory?	☐	☐	Confirm that the nominee has appropriate qualifications and experience for the position and has appropriate authority to undertake the required duties and responsibilities.
Nominated Qualified Expert satisfactory?	☐	☐	Confirm that the nominated Qualified Expert has appropriate qualifications and experience.
Logging personnel appropriately trained?	☐	☐	Confirm that logging personnel employed (or contracted by) the operator have appropriate training and experience for the range of radiation sources to be used.
Assistants appropriately trained and supervised?	☐	☐	Confirm that persons assisting logging personnel have appropriate training and experience and will be adequately supervised.
Sufficient personnel to perform work safely?	☐	☐	Does the operator have sufficient resources to ensure two person well logging teams?
RADIATION SOURCES, EQUIPMENT AND SAFETY OF SOURCES			
Radioactive sources comply?	☐	☐	Are the radioactive sources, activities and form listed in the inventory approved by the regulatory body for use in well logging (e.g. ^{241}Am, ^{137}Cs, ^{131}I, ^{192}Ir, etc.)?
Other radiation sources satisfactory?	☐	☐	Other devices that generate ionizing radiation electrically (e.g. X ray or neutron generators) are satisfactory?
Principal premises satisfactory?	☐	☐	Do the premises where the operator maintains and services well logging equipment (i.e. with radiation sources) satisfy the requirements of the regulations?
Qualified Expert report provided?	☐	☐	A report is required to demonstrate that the premises where radiation sources are used complies with dose and dose rate limits prescribed by the regulations. The report also might deal with the disposal of sources, safe working practices, storage, transport, etc.
Qualified Expert report satisfactory?	☐	☐	The report may need to be reviewed by an external expert if the regulatory body does not have internal expertise.
Leak testing	☐	☐	Procedures for leak testing sealed sources satisfactory?
Radioactive source replacement?	☐	☐	Does the operator have appropriate equipment to safely exchange new and spent sources? Are procedures for transferring sources satisfactory?
Storage facility(ies) comply?	☐	☐	Is the store for radioactive sources suitably constructed in compliance with the regulations, including minimizing fire risks, control, meeting external dose rate limits and potential public exposure?

ITEM	YES	NO	NOTES and ACTIONS
			Is it suitably labelled, including stating the means of contacting the operator and/or RPO in case of emergency? Are all locations where sources are stored secure (i.e. permanent stores, on logging vehicles during field use, during transport, etc.)?
Operator has appropriate safety equipment for routine well logging operations?	☐	☐	Does the operator have sufficient warning signs, ropes (e.g. for barriers), remote handling equipment, etc.
Procedures for dealing with sources jammed or to be abandoned in boreholes satisfactory?	☐	☐	Are procedures for attempting the retrieval of sources jammed in bore holes satisfactory, including contamination checks for ruptured sources? If jammed sources are not retrievable and will be abandoned, do the protocols include: – securing the source in the borehole (including the use of dyed concrete, etc.)? – capping the well and, where practicable, providing appropriate permanent identification at the well cap to prevent drilling through the source? – reporting to the company drilling and / or holding the mining or exploration lease of the location of the jammed source (i.e. depth and geographical co-ordinates) to prevent further drilling that might intersect the location of the source? – informing the regulatory body (i.e. and other relevant government bodies such as the Department of Mining and Petroleum Resources) of the jammed source, its location and the actions taken?
Procedures for using unsealed radiation sources satisfactory?	☐	☐	Has the operator provided suitable handling and source delivery equipment, equipment for area and contamination monitoring, protective clothing, suitable respirators, decontamination equipment? Have satisfactory procedures for the disposal of contaminated waste been developed?
OCCUPATIONAL AND PUBLIC EXPOSURE			
Occupational and public protection programme complies?	☐	☐	Do operator's protocols ensure that occupational and public radiation protection is optimized, work areas are appropriately classified, and doses will comply with the prescribed limits? Do protocols ensure dose rates at boundaries around logging operations comply with prescribed limits?
QA and working rules satisfactory?	☐	☐	Are the operator's QA programme and working rules satisfactory? Do the rules require work to cease if the user's survey meter fails or in the event of any safety related failure of a radiation source or a breach of a site boundary? Do the rules require users to verify with a survey meter that radioactive sources have been safely returned to the shielded container after use?
Survey meters and personal alarms, dosimeters, etc. comply?	☐	☐	Are the survey meters identified by the operator suitable for the intended purpose? Do they have a current satisfactory calibration for the radiation energies to be used, including test for fold back when subject to high radiation exposure rates? Are there sufficient complying survey meters for the number of potential well logging operations?

ITEM	YES	NO	NOTES and ACTIONS
			Are there sufficient personal alarms and dosimeters and are they subject to regular function checks? For the use of unsealed sources, does the operator have suitable, calibrated contamination survey meters?
Arrangements for Personal Radiation Monitoring comply?	☐	☐	Has the operator provided satisfactory information on the numbers and types of personal monitoring devices that will be used (e.g. film badges, TLD, OSL, personal alarms, etc.)? If unsealed sources are used, will appropriate biological monitoring be used? Has the operator made suitable arrangement for keeping personnel regularly and routinely informed of their recorded occupational radiation dose? Is the stated monitoring period (i.e. frequency) satisfactory?
Personal Monitoring Service provider is approved?	☐	☐	Is the personal monitoring service provider approved by the regulatory body.
TRANSPORT OF RADIOACTIVE MATERIAL			
Transport of radioactive sources complies?	☐	☐	Has the operator made complying arrangements for the transport of radioactive sources? Source containers secured, vehicles labelled, etc. in compliance with IAEA Transport Regulations? Procedures for monitoring incoming and outgoing packages satisfactory?
MANAGEMENT OF RADIOACTIVE WASTE			
Waste disposal arrangements comply?	☐	☐	Has the operator made suitable arrangements for the disposal of unwanted sources and clearly identified how this will be achieved? Are there satisfactory procedures for detecting, measuring and dealing with contamination when using unsealed sources or when attempting to retrieve sources jammed in a borehole?
EMERGENCY PROCEDURES			
Emergency plans and equipment satisfactory?	☐	☐	Are the operator's emergency procedures appropriate? Does the operator have appropriate emergency equipment (e.g. remote handling tools, lead pots, bagged lead shot, etc.)? Personnel are appropriately trained in these procedures?
RECORDS, AUDITS			
Routine audit programme satisfactory?	☐	☐	The operator audits the RPP at suitable intervals? The operator/RPO regularly (i.e. and without notice) audits radiation safety practices of its personnel both at the principal premises and at field sites?
Records satisfactory?	☐	☐	Has the operator made suitable arrangements for maintaining records (e.g. inventory, source movement logbook including waste disposal, occupational dose records, audits, etc)?
If a renewal, are there any outstanding items of non-compliance and / or is a legal action being considered by the regulatory body?	☐	☐	If yes, the application should be discussed with the assessor's supervisor to determine an appropriate course of action
If all matters have been satisfactorily completed, the application is to be forwarded to the assessor's supervisor and then to the officer authorised to sign the application			

ITEM	YES	NO	NOTES and ACTIONS
COMMENTS			
		Signature	**Date**

SUPERVISOR

ITEM	YES	NO	NOTES and ACTIONS
Review and assessment procedures satisfactory?	☐	☐	Check that the Assessment Officer has completed all relevant sections, that the fee, authorization period, operator's name, licensed location(s) and purpose(s) are correct.
Authorization can be approved?	☐	☐	Confirm that any attached conditions, restrictions or limitations imposed on the authorization are appropriate before the authorization is signed.
Inspection personnel informed?	☐	☐	Inspection personnel advised of the application for inclusion in the routine inspection programme.

COMMENTS		
	Signature	**Date**

Annex VI

EXAMPLE OF A CERTIFICATE FORM FOR AUTHORIZATION

RADIATION CONTROL LEGISLATION

Government of *(Specify the country)*

AUTHORIZATION
FOR PRACTICES AND SOURCES WITHIN PRACTICES

AUTHORIZED PERSON FOR THE PRACTICE AND THE USE OF SOURCES WITHIN THE PRACTICE:
Note: In this part the address, telephone, fax and e-mail of the authorized person to conduct the practice and the use of sources within the practice (i.e. the licensee or legal person) should be provided

RADIATION PROTECTION OFFICER:

QUALIFIED EXPERT:

PURPOSE OF AUTHORIZATION:

LOCATION OF THE PREMISES:
Note: *In this part the address of the premises where the practices and sources within the practices are located should be provided*

RADIOACTIVE SOURCES AND APPARATUS CONTAINING RADIOACTIVE SUBSTANCES (i.e. approved for use)

Manufacturer	Model	Serial Number	Radionuclide	Activity [Becquerels]	Activity Date	Use	Location

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ELECTRICAL DEVICES PRODUCING IONIZING RADIATION (i.e. ionizing radiation generators)

Manufacturer	Model	Serial Number	Maximum Power (e.g. max radiographic kVp, mA)	Use	Location

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LICENCE CONDITIONS

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

- *comply with regulations (specifying the number of paragraphs)*
- *ensure that any person who subsequently may be engaged to operate, install, maintain or otherwise kept activities with the practices and sources within the practices on the premises have approved training in accordance with the criteria stated in the Radaition Protection Programme;*
- provide prior written notification to the Regulatory Body of any intension to sell, relocate, install, or dispose of radiation sources (i.e. by any means); or plans to modify the structure of the premises in any way that may significantly impact on radiation safety; nominate a replacement of the Qualified Expert(s) or Radiation Protection Officer (RPO);
- ensure that the installation, service or maintenance of the practices and the use of sources within practices on the premises is performed only by personnel authorized by the Regulatory Body; and
- ensure any other specific conditions that the Regulatory Body will require, as necessary.

The authorized person is approved: _____
Note: *Not valid unless signed by an authorized officer of the Regulatory Body*

Date: _____

Regulatory Body: _____
Note*: In this part the address, telephone, fax and e-mail of the Regulatory Body should be provided*

LICENCE NUMBER:	**EXPIRY DATE:**

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

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