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Safety assessment plans for authorization and inspection of radiation sources

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SAFETY ASSESSMENT PLANS FOR
AUTHORIZATION AND INSPECTION OF RADIATION SOURCES

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FOREWORD

Many practices utilizing radiation sources in medicine and industry are well established and are used in most countries. The technology associated with some of these practices has become increasingly sophisticated and complex.

In parallel with the growth in the use of radiation sources and the increasing complexity of the practices, measures for radiation protection and the safety of sources have also become increasingly complex. These complexities have arisen from the elaborate and intricate nature of equipment, installations and engineering controls, increased scientific knowledge about radiation hazards, operational experience, lessons learned from accidents and incidents, and improvements in methods for assessment and control. In addition, higher technical skills are required to operate facilities safely.

One result of this evolution is that applicants for authorizations to engage in a radiation practice, and the regulatory authorities which grant authorizations and conduct inspections, must address a large number of issues and factors related to adequate protection and safety.

This TECDOC is intended to assist regulatory authorities and those involved with assessments and inspections covering protection and safety of radiation sources. Parts of the report may also be useful to applicants in the preparation of submissions for authorization. Use of this TECDOC should help to ensure that authorization and inspection procedures are comprehensive and consistent, thus contributing to the efficacy, quality and efficiency of the whole regulatory process.

The IAEA officer responsible for this publication was P. Ortiz López of the Division of Radiation and Waste Safety.

EDITORIAL NOTE

In preparing this publication for press, staff of the IAEA have made up the pages from the original manuscript(s). The views expressed do not necessarily reflect those of the IAEA, the governments of the nominating Member States or the nominating organizations.

Throughout the text names of Member States are retained as they were when the text was compiled.

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1. INTRODUCTION

1.1. BACKGROUND

The International Atomic Energy Agency has consistently assigned a high priority to ensuring adequate radiation protection and safety in its Member States. In this regard, the International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources, Safety Series No. 115, were approved by the Board of Governors in 1994 and published in their final form in 1996. The publication is jointly sponsored by the Food and Agriculture Organization of the United Nations (FAO), the International Atomic Energy Agency (IAEA), the International Labour Organisation (ILO), the Nuclear Energy Agency of the Organisation for Economic Co-operation and Development (OECD/NEA), the Pan American Health Organisation (PAHO) and the World Health Organization (WHO). The Standards, however, can only be implemented by Member States through a radiation protection and safety infrastructure which includes adequate laws and regulations, and an effective regulatory system.

The IAEA has been collecting information for many years on the status of radiation protection and safety in countries that are, or could be, recipients of technical assistance through IAEA agreements for co-operation. The information has been obtained through several channels such as Radiation Protection Advisory Team (RAPAT) missions. Although RAPAT missions and other efforts by the IAEA have led to improvements in radiation safety in some countries, the IAEA is aware that a few Member States have essentially no radiation safety infrastructure and for a substantial number, the infrastructure is inadequate for the level of radiation source usage. Accordingly, the IAEA established an Interregional Technical Co-operation Project (the Model Project), first approved in 1993, to enhance and strengthen infrastructures so that the 53 participating countries can better implement the Basic Safety Standards.

The Basic Safety Standards consist mainly of performance requirements which are applicable to most practices and intervention situations. To assist Member States, particularly those in the Model Project, to implement the performance requirements of the Standards, the IAEA has a programme for developing Safety Series Guides and other supporting documents which apply to specific types of the more common radiation source practices. The documents contain prescriptive and specific advice, which if adopted for the design, construction and operation of sources within specific practices, would meet most of the protection and safety performance requirements of the Standards.

This TECDOC is an element of the IAEA's programme to enhance the protection and safety of radiation source use. It provides advice to help achieve a systematic approach to protection and safety assessments required in the various stages of the regulatory process.

1.2. OBJECTIVE

The objective of this TECDOC is to enhance the efficacy, quality and efficiency of the whole regulatory process.

It provides advice on good practice administrative procedures for the regulatory process for preparation of applications, granting of authorizations, inspection, and enforcement. It also provides information on the development and use of standard safety assessment plans for authorization and inspection. The plans are intended to be used in conjunction with more detailed advice related to specific practices. In this sense, this TECDOC provides advice on a

systematic approach to evaluations of protection and safety while other IAEA Safety Guides assist the user to distinguish between the acceptable and the unacceptable.

1.3. SCOPE

This TECDOC covers administrative advice to facilitate the regulatory process governing authorization and inspection. It also covers the use of standard assessment and inspection plans and provides simplified plans for the more common, well established uses of radiation sources in medicine and industry, i.e. sources for irradiation facilities, industrial radiography, well logging, industrial gauging, unsealed sources in industry, X ray diagnosis, nuclear medicine, teletherapy and brachytherapy.

1.4. STRUCTURE

The main text addresses administrative advice for the authorization, inspection and enforcement functions of the regulatory authority. It also contains a brief discussion of the development, functions, benefits and limitations of standard safety assessment plans.

Annexes I–VIII contain practice specific standard safety assessment plans for the common practices identified above. There are generally two plans for each practice, one intended for use by applicants and reviewers, and one for use by inspectors. In some instances, variations in the nature of the sources and their uses within a practice resulted in multiple plans (e.g. fixed facility and mobile industrial radiography). The plans contained in Annexes I–VIII identify items to be addressed in applications and inspections, but do not contain guidance on identifying what should be acceptable within the regulatory framework. References to Safety Guides and other relevant publications are provided in the annexes. The references may be used to further develop and expand the simple “checklist” type of plan contained in the annexes and may be useful to meet the particular needs of a national regulatory authority.

Annex IX contains a standard safety assessment plan for investigation of incidents at industrial facilities. As with the other plans, there is no guidance on acceptable accident investigation or corrective actions. The plan does provide a checklist of information that is commonly useful in assessing the significance and causes of incidents. This plan would also be applicable to inspections following incidents at medical facilities that do not involve medical exposure of a patient.

Annex X lists “performance indicators” which are a set of specific factors that aid early identification of authorised users with the potential for degraded safety performance. These indicators may be useful to inspectors during commissioning and routine inspections.

2. ADMINISTRATIVE ADVICE TO FACILITATE AUTHORIZATION, INSPECTION AND ENFORCEMENT

2.1. GENERAL

Although constituting neither detailed nor complete procedures, the following advice provides actions, techniques and points of vigilance which if followed can facilitate regulatory authorization, inspection and enforcement processes. Some of the advice is distilled from

years of experience with questions and issues that commonly arise. Other advice is derived from years of learning how best to undertake certain tasks. Some of the advice is aimed at a specific task or individuals involved with the task, e.g. pre-inspection preparation by a regulatory inspector. However, by having all parties which are involved in some aspect of the regulatory process being aware of such advice, some potential problems can be avoided.

2.2. CONDUCT OF REGULATORY STAFF

2.2.1. Professionalism

The term professionalism includes a number of attributes, several of which should be particularly discernible to the regulated community in its dealings with the staff. Staff members should be knowledgeable within their sphere of responsibility and recognize the limitations of their technical knowledge. They should avoid biases and be as objective as possible in discharging their responsibilities. They should be open and receptive to receiving information and opinions from others, and their regulatory positions or decisions should have transparency and clarity. Reflecting the regulatory authority's need for independence from promotional or regulated activities, members of the staff should not engage in, or hold financial interest in, activities which may be construed as a conflict of interest with the performance of regulatory functions. The staff should be formal and friendly, but not familiar, in their transactions with the regulated community.

2.2.2. Inquisitiveness

Reviewers and inspectors should have an inquiring disposition and probe to learn more about areas where problems may exist. While many aspects of regulatory review and inspection processes might be straightforward and obvious, care must be taken to avoid becoming superficial in discharging responsibilities.

2.2.3. Helpfulness

There is a delicate balance to be struck between providing applicants and authorization holders with information sufficient to implement an adequate protection and safety programme, and becoming their consultant by advising on the details of how best to organise and operate their programmes. Whether an appropriate balance can be established depends on national situations such as the availability of qualified persons to provide advice and assistance outside the regulatory framework. If regulatory staff appear to become consultants and their recommendations are adopted, the user may perceive that the responsibility for operational safety has shifted to the regulatory staff. This should be avoided to the extent practicable.

2.2.4. Assertiveness

Staff should be sufficiently confident with their assigned responsibilities so as to discharge them in a positive manner and without ambiguity. This is particularly important for inspectors who might encounter hostile situations or circumstances where their attention may be intentionally diverted.

2.2.5. Decision making

Decisions should be timely, particularly if they involve action to correct an unsatisfactory safety situation. Procedures should be established to promptly move a needed decision to the proper level of authority within the regulatory organisation.

2.3. APPLICATIONS FOR AUTHORIZATION

2.3.1. Legal person and the representative

The legal person shall bear the responsibility for setting up and implementing the technical and organizational measures that are needed for ensuring protection and safety for the sources for which they are seeking authorization. The legal person may appoint a representative to carry out actions and tasks related to the application, but retains the responsibility for the actions and tasks themselves. In this case, the representative can make commitments on behalf of the legal person on all tasks and actions relating to the application.

The applicant (legal person or the representative) should provide the name of a person who can answer questions about the application, for example the radiation protection officer or a principal user of the sources and radiation devices. This can speed up the authorization process. The reviewer should send any clarification or deficiency letters to the applicant, with a copy to that named person.

2.3.2. Application form

The application should address all relevant items specified in the application form. The level of detail provided depends on the nature of the practice. The application must be signed by the legal person or the representative.

2.3.3. Location of the facility

The location of the site where the source is to be used should be specified. A grid reference is acceptable for a facility located far away from an urban area, but a post office box is not acceptable. If the application covers more than one location, then each location should be specified. If multiple locations cannot be identified in advance (e.g. industrial field radiography, well logging), then the location of the facility where the sources are normally stored and where operational information required by the regulations is maintained should be identified.

2.3.4. Safety assessment for sources, equipment and devices

The granting of an authorization to use a particular sealed source or device can be simplified if the applicant provides the relevant certifications of compliance with applicable international standards (e.g. the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC)) or equivalent standards which have been accepted by the regulatory authority. The basis for each certification should be appropriately documented by the manufacturer. The regulatory authority may want to accept summaries of safety assessments made by the regulatory authority in another country if they are readily available (e.g. United States Nuclear Regulatory Commission (USNRC) summaries of sealed

source and device safety assessments). The applicant should clearly identify the make and model number of sources and devices requested in the application.

The application should include arrangements for when a radioactive source needs to be exchanged. The applicant should make arrangements for the old source to be disposed of by an appropriate authorised route (e.g. returning to the manufacturer or supplier). The source exchange should be undertaken by the user only if its authorization specifically provides for it, or by another authorised organisation.

The application should include arrangements for when a radioactive source is no longer required. The applicant should arrange for an authorised organisation to dispose of the source, or for the manufacturer or supplier to take responsibility for its disposal. Alternatively, the source may be transferred to another authorised user with the approval of the regulatory authority.

The reviewer may check with an available source and device registry whether the sources and devices whose summaries of safety assessment have been presented by the applicant have been authorized (registered) for distribution in the country which conducted the safety assessment (although many sources and devices, particularly older ones, may not be on such a registry).

The reviewer should check that the applicant's arrangements for source exchange or disposal are appropriate.

The reviewer should also check that the applicant has been supplied with the appropriate documentation (e.g. special form certification, safe use and maintenance manuals). If the source, equipment, or device is second hand the applicant should also obtain copies of maintenance records from the previous owner.

2.4. REGULATORY INSPECTION

2.4.1. Advice for management of regulatory authorities

An inspection to assess the status of compliance with regulatory requirements and safety of an authorized operation should be based on direct observation of work activities, interviews with workers, independent measurements of radiation and contamination levels, and review of records. In addition, the review and inspection processes should be closely coupled, with reviewers of the application and inspectors exchanging experiences.

2.4.2. Advice for inspectors

Preparation

Good preparation before the inspection is essential. The inspector should review the documents submitted with the application, such as the safety assessment, and the history of the facility (e.g. past inspection reports, unresolved issues from the last inspection, past violations). Appropriate monitoring instruments to measure radiation and contamination levels should be obtained as necessary. The inspector should ensure that they take their own appropriate personal protective equipment and personal dosimeters, if required.

An audit plan for the inspection of the organization's safety programme should be prepared. The plan should prioritise the inspection of potential problem areas in the facility. The preparation should include a decision as to whether the applicant/licensee should be notified in advance of the inspection.

Unannounced inspections

The advantage of an unannounced inspection is that it provides the opportunity to see the facility operating under its usual conditions. The disadvantages are that the key personnel may not be available, or part of the facility may not be operating.

Knowledge of the practice should help to optimize the timing of unannounced inspections.

Entrance briefing

When first arriving at the facility the inspector should inform the most senior manager available at the facility about the purpose and scope of the inspection

Inspection

At the beginning of the first inspection, the inspector should tour the facility to become familiar with its general layout and operation. Housekeeping of the facility should be observed. Although it is not a regulatory requirement, housekeeping may be an indirect indicator of how the user's radiation safety programme is being conducted. A review of some records (e.g. dosimetry, area surveys, source inventory) can be beneficial at this stage. The facility and operating programmes should then be inspected in detail to determine whether they conform to those described in the application.

The inspector should verify that the staff present are as described in the application.

The inspector should allow sufficient time to thoroughly review all appropriate records. These should be up to date and reflect the real situation within the facility.

The inspector should interview key members of the staff, from operational through management levels, to elicit information which helps the inspector assess the status of protection and safety.

Exit briefing

The inspector should inform the senior management about observations and conclusions drawn from the inspection. The inspector should note any response to these observations and conclusions as may be expressed by senior management.

2.4.3. Frequency of inspections

The frequency of routine inspections for each facility should be planned according to the hazards and risks associated with the operation of that facility and its previous compliance history. Other factors such as the performance indicators described in Annex II may influence the frequency of inspections.

2.4.4. Inspection of field operations

The use of portable or mobile devices should be inspected at sites of use. This may require careful timing in order that the inspection coincide with operations taking place at the site.

2.5. ENFORCEMENT

Documentation of the enforcement process is very important. Documentation should include: infractions, and other conditions which compromise protection and safety, found during an inspection; enforcement actions; sanctions or other regulatory initiatives to correct unsatisfactory conditions; the authorised user's response to such initiatives, including corrective actions; and the regulatory authority's analysis of the acceptability of the response.

The regulatory authority should anticipate and consider the potential effects, in addition to the ones intended, that an enforcement action might produce. It can give rise to a situation with a greater negative impact on economic, health or safety issues than the improvement gained through the enforcement action. An example is the potential detriment to patients whose therapy is interrupted due to enforcement action which closes a therapy facility.

3. DEVELOPMENT AND USE OF STANDARD SAFETY ASSESSMENT PLANS

3.1. GENERAL

Assessments to determine the status of protection and safety for radiation source practices have many facets. They include consideration of the design, construction and operation of sources and related facilities and equipment as they pertain to normal and potential exposure. They also include consideration of management systems and procedures to safely handle sources, to operate equipment, to monitor radiation protection, to implement a quality assurance program and to handle emergencies. Standard safety assessment plans facilitate a systematic approach to performing the assessment. A standard safety assessment plan is a tool that can be applied to most users within a practice.

The items identified in standard safety assessment plans are derived from regulations as they relate to a specific practice, practice specific guidance documents, and operational and regulatory experience. The plans may consist of simple checklists of items to be covered in an assessment to more sophisticated ones which help to distinguish between the acceptable and the unacceptable. Two related standard safety assessment plans are often used for any specific practice: one for the preparation of an application for authorization to engage in a radiation source practice and for the review of an application by regulatory staff; and one for the conduct of regulatory inspections.

3.2. THE ROLE OF STANDARD SAFETY ASSESSMENT PLANS

Standard safety assessment plans contribute to the efficacy, quality and efficiency of the regulatory process.

The regulatory authority should have a quality assurance programme to ensure that the Authority's responsibilities under its legislative mandate are being adequately discharged. A standard safety assessment plan is a quality control mechanism in that it can help ensure that regulatory requirements important to protection and safety will be considered and not overlooked.

Use of standard safety assessment plans should also contribute to efficiency and reduce regulatory costs. The plans, if also shared with applicants, can better ensure that applications are complete, thus reducing the amount of time and effort the regulatory authority and

applicants might otherwise need to spend communicating about deficiencies in the application.

The plans also keep regulatory staff focused on key safety issues related to a particular practice. They are particularly helpful in situations where members of the regulatory staff may have an adequate general background in radiation protection and safety but are not familiar with the details of a particular practice which they may be required to consider. Given the staffing levels of typical regulatory organizations compared to the number of types of radiation source practices, there is often little opportunity for the staff members to become specialized in particular types of practices. Rather, they usually have a general knowledge of many types of practices.

3.3. DEVELOPMENT OF SAFETY ASSESSMENT PLANS

It is important at the outset of preparing a standard safety assessment plan to have firmly in mind the individual who will use the document. A very simple plan which only identifies topics to be addressed in the assessment might assist an applicant to prepare an application and the regulatory staff to review the submitted application equally. Such a plan usually consists of a sample check list. If a plan is expanded to include information about technical detail required for a particular aspect of the assessment and criteria to distinguish between the acceptable and the unacceptable, the plans might be specialized either for use in the preparation of applications or for the regulatory authority in the conduct of the regulatory authorization review or inspection.

The way in which requirements within a plan are expressed or the way in which questions are formulated are very critical to conveying what is needed or expected, and will vary depending on who is intended to be the primary user. For example, a plan which forms an outline for an inspection might allow for a simple yes or no, e.g. “Are the ... facilities as described in the application approved by the regulatory authority.” However, a simple yes or no would not do for eliciting information about safety systems from an applicant. A plan to be followed in the preparation of an application might have the following statement with respect to facilities: “ Describe the safety system which will be installed to prevent accidental entry to the radiation room. (Access and interlocks)”. The Review Plans in the Annexes are of the descriptive type while the Inspection Checklists are mainly in the “yes” or “no” format. In practice the regulatory authority might refer both to the more prescriptive checklist and the descriptive application during application review.

Subjects to be addressed in a standard safety assessment plan must be based upon regulatory requirements. Such requirements often require interpretation to provide specificity to the standard safety assessment plan. The IAEA's Safety Guides which cover specific practices (e.g. commercial product irradiation) or specialized topics (e.g. control of occupational exposure) can be very helpful in this regard. References which link the relevant regulation and supplemental guides to a particular subject covered in the plan can help the user distinguish between what is acceptable and what is unacceptable. Similar information about acceptability can be included in the plan itself, but it adds to the complexity of the plan and may be unnecessary for many who use the plan.

The plan should be as complete as possible, otherwise gaps in the assessment or misunderstandings as to what is required could occur. However, the scope of the plan does not necessarily need to encompass all protection and safety aspects for a particular source use if these have been evaluated elsewhere. For example, the design and construction of sealed radiation sources and associated devices are often subject to generic safety evaluations

performed by the manufacturer and approved by the regulatory authority. If so, an applicant requesting authorization to use such a source or device need only properly identify the source or device to be used, and the safety aspects of their design and construction would not need to be included in the applicant's assessment plan. Plans must be reviewed from time to time and modified as necessary to maintain them up to date with changes in technology or regulatory requirements.

Finally, the plan should be matched to the anticipated skill level of the user. The lower the skill level, the greater the need for specificity as to what needs to be addressed and the need to break major components of the plan into sub-components.

3.4. CAUTIONS AND LIMITATIONS FOR USE OF STANDARD SAFETY ASSESSMENT PLANS

Standard safety assessment plans are typically developed within the boundaries of regulatory requirements. Not all protection and safety issues can be foreseen and addressed in regulations, particularly if the regulations are very prescriptive. Also, the interpretation of regulations as applied to a specific practice might overlook a unique safety issue related to a particular use. Furthermore, compliance with all applicable regulations might only partially reflect the safety status of authorized operations. There are situations or circumstances not usually addressed directly by regulations which might make, or indicate, vulnerability to degraded safety performance or accidents. Poor housekeeping, high turn over of staff or financial instability, are examples of such situations.

The cautionary note to bear in mind is that use of standard safety assessment plans is not a substitute for inquisitiveness and professionalism in approaches to protection and safety. Plans are generally applicable but do not necessarily cover all factors at any specific facility which can bear on protection and safety. Protection and safety assessments should go beyond assessments for compliance with regulations. To do so requires professional observation and judgement.

3.5. USE OF PERFORMANCE INDICATORS

The term "performance indicator" is used to denote a specific set of circumstances that aid in the identification of radiation source users with potential for degraded safety performance. In this sense, they are negative performance indicators. Unlike "performance indicators" sometimes employed in nuclear reactor programmes which are mainly based on large amounts of information about equipment performance, the kind of information available in radiation source practices are usually early subjective warnings of degraded performance and are mainly management related, e.g. insufficient staffing or a poor record retrieval system.

A list of performance indicators for radiation source users is contained in Annex X. The list was developed on the basis of inspections, and accident and incident investigations, within a large national regulatory programme. The performance indicators are not in themselves regulatory infractions but are often found in conjunction with them.

Although subjective and outside the bounds of regulations, it is desirable to have some provision for the use of performance indicators in standard safety assessment plans covering regulatory inspections. Although the regulatory authority might not be able to take formal enforcement action on the basis of a performance indicator, it can be used as a basis to inform the authorized user of the need to improve.

ANNEXES I–X

Annex I

SAFETY ASSESSMENT PLANS FOR INDUSTRIAL IRRADIATION FACILITIES

This annex has five exhibits which include two application forms and three checklists for inspection.

(1) Example I.A: Application for authorization and review plan for a gamma irradiator facility

(2) Example I.B: Application for authorization and review plan for an electron irradiator facility

(3) Example I.C: Checklist for commissioning and regular inspection of panoramic gamma irradiation facilities

(4) Example I.D: Checklist for commissioning and regular inspection of self-contained gamma irradiation facilities

(5) example i.e: Checklist for commissioning and regular inspection of electron irradiation facilities.

References that may be useful to the regulatory authority and/or to licensees and registrants are listed in the bibliography at the end of the annex. The list is divided into references generally applicable for radiation safety and protection and those which may have particular relevance to irradiation facilities.

Example I.A

APPLICATION FOR AUTHORIZATION AND REVIEW PLAN FOR A GAMMA IRRADIATOR FACILITY

TYPE OF AUTHORIZATION

_____ New application
_____ Amendment to existing authorization number:_____
_____ Renewal of authorization number: _____

PURPOSE OF APPLICATION

_____ Construction (Complete Sections I through III)
_____ Import/Purchase (Complete Sections I and II)
_____ Use/Begin operation (Complete Sections I through IV)

You may refer to previous submissions by date and application or authorization number(s)

The legal person who will be responsible for using any sealed source or radiation generator must, unless the source is exempted, submit the following information to the regulatory authority.

I-GENERAL INFORMATION

I-1. Name and address of organization:

Main address	Mailing address (if different)	Address of use (if different)
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

I-2. Name and information about qualified experts:

Expertise: Radiation protection officer
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____
Telephone number _____

Expertise: _____
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____
_____

Expertise: _____
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____

Expertise: _____
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____
_____

I-3. The responsible representative of the legal person:

Name: _____ Telephone number _____
Title: _____ Facsimile number _____
e-mail address _____

I-4. Proposed date of installation and/or commissioning of facilities and equipment:

_____

SIGNATURE AND CERTIFICATION

_____
Signature of the authorized representative
of the legal person
Title: _____
Date: _____

Notes:

1. The regulatory authority may require additional information to fully consider this application prior to issuing an authorization.

2. In the event that all the above information is not available at the time of application, the regulatory authority may issue an authorization limiting the applicant to import, acquire, or store radiation sources, or construct facilities. Complete information will be required from the applicant prior to authorising use of the radiation sources.

II-SOURCES AND IRRADIATOR

II-1. Model/Type and identification number of irradiator

_____
_____
_____

II-2. Name and address of:

a) the manufacturer of the irradiator

_____
_____
_____

b) the supplier of the irradiator (if different from a))

_____
_____
_____

II-3. Name and address of:

a) the manufacturer of the sources

_____
_____
_____

b) the supplier of the sources (if different from a))

_____
_____
_____

Details of radioactive sources:

Radionuclides	Number of sources				Total activity (Bq)		Source details		Storage (wet/dry)
	per pencil	per module	per rack	Total	Initial	At installation	Model no(s)	Designation	
_____	_____	_____	_____	____	_____	_____	_____	_____	_____
_____	_____	_____	_____	____	_____	_____	_____	_____	_____
_____	_____	_____	_____	____	_____	_____	_____	_____	_____
_____	_____	_____	_____	____	_____	_____	_____	_____	_____
_____	_____	_____	_____	____	_____	_____	_____	_____	_____

II-4. Standards

Are the sources manufactured, prototype tested, and subject to quality control provisions of standards recognised by national or international standard setting organisations (e.g. ISO 2919)? If so, identify the standards and any applicable classification numbers.

_____
_____
_____
_____

III-FACILITIES AND EQUIPMENT

In an attachment to this application, describe the irradiator facilities, including:

III-1. Location of the facility

Provide a detailed location of the facility.

III-2. Layout of the facility

Describe factors such as the layout of the facility and its immediate surroundings, building materials, alarms, shielding, engineering controls such as interlock and warning safety devices, and remote handling tools (Safety Series No. 107). Attach a detailed sketch or drawing of the facility showing the above details. Include on the drawings any penetrations or openings in the shielding materials such as conduits or ventilation ducts. Include evaluation of the ground surface and adverse environmental conditions that may cause harm to the facility (e.g.

seismic history, strong winds, air crashes). Controlled and supervised areas should be clearly identified on the drawings.

III-3. Safety assessments

Taking account of shielding, provide calculations of maximum dose rates in all areas outside the facility (specify all assumptions, e.g. number of sources, activity). Provide estimates of the magnitude of expected doses to persons during normal operations. Identify the probability and magnitude of potential exposures arising from accidents or incidents.

III-4. Safety system

a) Describe the overall safety system which will be used to ensure the safe operation of the irradiator (e.g. design features, defence in depth, layout). Further describe, in detail, the safety systems for preventing access to the irradiation room whilst the source is exposed and for warning of unsafe conditions (e.g. interlocks, installed monitors).
b) Attach the manufacturer's specifications of that system (Safety Series No. 107).

III-5. Personal protective equipment

Describe any personal protective equipment that will be provided:

IV-RADIATION PROTECTION AND SAFETY PROGRAMME

In an attachment to this application, describe the radiation protection programme, including:

IV-1. Organisational structure

a) Describe your organisational and management control systems, including assignment of responsibilities and clear lines of authority related to radiation safety. In particular include: staffing levels, equipment selection, other assignments of the radiation protection officer, authority of the radiation protection officer to stop unsafe operations, personnel training, maintenance of records, and how problems affecting safety are identified and corrected.
b) Identify the authorised users, qualified experts, and radiation protection officer by name and include their training, education, experience and qualifications. (Note: the authorised user and/or radiation protection officer may be the same individual).
c) Confirm that training will include: explanation of radiation hazards and effects, explanation of written procedures, use of equipment (e.g. instrumentation), meaning of warning signals, and a method to confirm adequacy of training (testing or demonstrations).

IV-2. Workplace monitoring, area classification and individual monitoring

a) Describe your programme for monitoring the workplace (BSS, I.37-I.40), including: the quantities to be measured, where and when the measurements are to be made, the measurement methods and procedures, and reference levels and the actions to be taken if they are exceeded.
b) Describe your policies and procedures for classification of controlled and supervised areas. (BSS, I.21-I.25).
c) Describe personal dosimeters provided to workers and your policies for assigning dosimetry to individual workers (BSS, I.32-I.36). Describe your policy for reviewing individual doses, including reference levels and actions to be taken in exceeded.

   Name and address of dosimetry service: _____
   _____
   _____
   _____

   Denote type:
   i) Film _____
   ii) ThermoLuminescent dosimeter (TLD)_____
   iii) Direct reading dosimeter (DRD) _____
   iv) other: _____

IV-3. Local rules and supervision

a) Describe your local rules and procedures regarding: investigation or authorised levels, protective measures and safety provisions, providing adequate supervision, providing workers information regarding health risks due to occupational exposure, and emergency planning instruction (BSS, I.26-I.27).
b) Provide copies of your operating and safety procedures including: area access control, entry procedures, product entry and exit, source inventory and leak testing, etc.

c) Describe your training program to ensure that all appropriate personnel are adequately trained in the correct operating procedures and how their actions may affect safety (BSS, I.27).
d) Describe your policies regarding female workers who become pregnant (notification, adaption of working conditions to protect foetus/embryo) and the instructions you will provide to them (BSS, I.16-I.17 and I.27).
e) Describe your programme of health surveillance based on general principles of occupational health and designed to assess the initial and continuing fitness of workers for their intended tasks (BSS, I.41-I.43).

IV-4. Quality assurance

a) Describe your program for ensuring that regulatory radiation safety requirements are addressed and satisfied.
b) Describe your program to periodically review procedures, maintain procedures current and available, and your procedure modification process.
c) Describe your programme for optimising occupational and public exposures to levels as low as reasonably achievable.
d) Describe your programme of periodic maintenance and testing (safety interlocks, radiation meters, hoist cable and guide cable, etc.). Attach the manufacturers instructions.
e) Describe service arrangements with other organisations and qualified experts.

IV-5. Transportation of radioactive material

If you will be transporting or shipping new or used sources, describe your arrangements for preparation and transport of packages containing radioactive sources (IAEA Safety Standards Series No. ST-1). These procedures should address: documentation of package certification, package surveys, transfer/receipt documents, and details of shipments preparation.

IV-6. Emergency procedures

Provide your emergency procedures to address emergencies such as potential damage to the source, loss of source shielding, stuck sources or substantial accidental exposure of an individual. If other emergencies are envisaged, please provide additional appropriate emergency procedures. In all cases the magnitude of the hazard should be evaluated. Any off-site consequences should also be evaluated. Local emergency services (e.g. fire, police) may need to be provided with copies of the emergency procedures.

IV-7. Transfer or disposal of radioactive sources

Describe arrangements for transfer or disposal of spent radioactive sources.

IV-8. System of records (BSS; 2.40, I.44-I.49)**, including:**

a) Disposal of spent sources.
b) Personnel exposure
    i) current records
    ii) prior work history
c) Area surveys
    i) dose or dose rate
    ii) contamination
d) Instrument tests and calibrations
e) Tests for radioactive sealed source leakage.
f) Inventory of sources and accountability
g) Audits and reviews of radiation safety program
h) Incident and accident investigation reports
i) Maintenance and repair work
j) Facility modifications
k) Training provided
l) Evidence of health surveillance of workers
m) Transportation

Example I.B

APPLICATION FOR AUTHORIZATION AND REVIEW PLAN FOR AN ELECTRON IRRADIATOR FACILITY

TYPE OF AUTHORIZATION

_____ New application
_____ Amendment to existing authorization number: _____
_____ Renewal of authorization number: _____

PURPOSE OF APPLICATION

_____ Construction (Complete Sections I through III)
_____ Import/Purchase (Complete Sections I and II)
_____ Use/Begin operation (Complete Sections I through IV)

You may refer to previous submissions by date and application or authorization number(s)

The legal person who will be responsible for using any radiation generator must, unless the source is exempted, submit the following information to the regulatory authority.

I-GENERAL INFORMATION

I-1. Name and address of organisation:

Main address	Mailing address (if different)	Address of use (if different)
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

II-1. Name and information about qualified experts:

Expertise: Radiation protection officer
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____
Telephone number _____

Expertise: _____
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____
_____

Expertise: _____
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____
_____

Expertise: _____
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____
_____

I-3. The responsible representative of the legal person:

Name: _____
Title: _____
Telephone number _____
Facsimile number _____
e-mail address _____

I-4. Proposed date of installation and/or commissioning of facilities and equipment:

_____

SIGNATURE AND CERTIFICATION

_____
Signature of the authorised representative
of the legal person

Title: _____

Date: _____

Notes:

1. The regulatory authority may require additional information to fully consider this application prior to issuing an authorization.

2. In the event that all the above information is not available at the time of application, the regulatory authority may issue an authorization limiting the applicant to import, acquire, or store radiation sources, or construct facilities. Complete information will be required from the applicant prior to authorising use of the radiation sources.

II-ACCELERATOR

II-1. Model/Type or other identification number of accelerator

_____
_____
_____

II-2. Name and address of:

a) the manufacturer of the accelerator

_____
_____
_____

b) the supplier of the accelerator (if different from a))

_____
_____
_____

II-3. Details of the accelerator:

a) Maximum energy and type of radiation to be generated:_____
b) Voltage: _____
c) Current: _____

II-4. Standards

Is the accelerator manufactured, prototype tested, and subject to quality control provisions of standards recognised by national or international standard setting organisations (e.g. IEC 976, IEC 977)? If, so please identify the standards and any applicable classification numbers.

_____
_____
_____
_____

III-FACILITIES AND EQUIPMENT

In an attachment to this application, describe the accelerator facilities, including:

III-1. Location of the facility

Provide a detailed location of the facility.

III-2. Layout of the facility

Describe factors such as the layout of the facility and its immediate surroundings, building materials, alarms, shielding, and engineering controls such as interlock and warning safety devices (Safety Series No. 107). Attach a detailed sketch or drawing of the facility showing the above details. Include on the drawings any penetrations or openings in the shielding materials such as conduits or ventilation ducts. Controlled and supervised areas should be clearly identified on the drawings.

III-3. Safety assessments

Taking account of shielding, provide calculations of maximum dose rates in all areas outside the facility (specify all assumptions, e.g. energy, electron flux). Provide estimates of the magnitude of expected doses to persons during normal operations. Identify the probability and magnitude of potential exposures arising from accidents or incidents.

III-4. Safety system

a) Describe the overall safety system which will be used to ensure the safe operation of the irradiator (e.g. design features, defence in depth, layout). Further describe, in detail, the safety systems for preventing access to the irradiation room whilst radiation is being generated and for warning of unsafe conditions (e.g. interlocks, installed monitors).
b) Attach the manufacturer's specifications of that system (Safety Series No. 107).

III-5. Personal protective equipment

Describe any personal protective equipment that will be provided.

IV-RADIATION PROTECTION AND SAFETY PROGRAMME

In an attachment to this application, describe the irradiator facilities, including:

IV-1. Organisational structure

a) Describe your organisational and management control systems, including assignment of responsibilities and clear lines of authority related to radiation safety. In particular include: staffing levels, equipment selection, other assignments of the radiation protection officer, authority of the radiation protection officer to stop unsafe operations, personnel training, maintenance of records, and how problems affecting safety are identified and corrected.
b) Identify the authorised users, qualified experts, and radiation protection officer by name and include their training, education, experience and qualifications. (Note: the authorised user and/or radiation protection officer may be the same individual).
c) Confirm that training will include: explanation of radiation hazards and effects, explanation of written procedures, use of equipment (e.g. instrumentation), meaning of warning signals, and a method to confirm adequacy of training (testing or demonstrations).

IV-2. Workplace monitoring, area classification and individual monitoring

a) Describe your programme for monitoring the workplace (BSS, I.37-I.40), including: the quantities to be measured, where and when the measurements are to be made, the measurement methods and procedures, and reference levels and the actions to be taken if they are exceeded.
b) Describe your policies and procedures for classification of controlled and supervised areas. (BSS, I.21-I.25).
c) Describe personal dosimeters provided to workers and your policies for assigning dosimetry to individual workers (BSS, I.32-I.36). Describe your policy for reviewing individual doses, including reference levels and actions to be taken in exceeded.

   Name and address of dosimetry service: _____
   _____
   _____
   _____

   Denote type:
   i) Film _____
   ii) ThermoLuminescent dosimeter (TLD)_____
   iii) Direct reading dosimeter (DRD) _____
   iv) other: _____

IV-3. Local rules and supervision

a) Describe your local rules and procedures regarding: investigation or authorised levels, protective measures and safety provisions, providing adequate supervision, providing workers information regarding health risks due to occupational exposure, and emergency planning instruction (BSS, I.26-I.27).
b) Provide copies of your operating and safety procedures including: area access control, entry procedures, product entry and exit, etc.
c) Describe your training program to ensure all appropriate personnel are adequately trained in the operating procedures and how their actions may affect safety (BSS, I.27).
d) Describe your policies regarding female workers who become pregnant (notification, adoption of working conditions to protect foetus/embryo and the instructions you will provide to them (BSS, I.16-I.17 and I.27).
e) Describe your programme of health surveillance based on general principles of occupational health and designed to assess the initial and continuing fitness of workers for their intended tasks (BSS, I.41-I.43).

IV-4. Quality assurance

a) Describe your programme for ensuring that regulatory radiation safety requirements are addressed and satisfied.
b) Describe your program to periodically review procedures, maintain procedures current and available, and your procedure modification process.
c) Describe your programme for optimising occupational and public exposures to levels as low as reasonably achievable.
d) Describe your programme of periodic maintenance and testing (safety interlocks, radiation meters, etc.). Attach the manufacturers instructions.
e) Describe service arrangements with other organisations and qualified experts.

IV-5. Emergency procedures

Provide your emergency procedures to address emergencies such as potential damage to the safety control systems, loss of shielding, or substantial accidental exposure of an individual. If other emergencies are envisaged, please provide additional appropriate emergency procedures. In all cases the magnitude of the hazard should be evaluated. Any off-site consequences should also be evaluated. Local emergency services (e.g. fire, police) may need to be provided with copies of the emergency procedures.

IV-6. System of records (BSS; 2.40, I.44-I.49)**, including:**

a) Personnel exposure
   i) current records
   ii) prior work history
b) Area surveys (dose or dose rate)
c) Instrument tests and calibrations
d) Audits and reviews of radiation safety program
e) Incident and accident investigation reports
f) Maintenance and repair work
g) Facility modifications
h) Training provided
i) Evidence of health surveillance of workers

Example I.C

CHECKLIST FOR COMMISSIONING AND REGULAR INSPECTION OF PANORAMIC GAMMA IRRADIATION FACILITIES

Prepare a visit agenda to review the operating program with details contained in the application for authorization, the authorization certificate, prior programme review/inspection reports and their implementation, relevant correspondence, and other relevant documentation such as dosimetry reports. (References to appropriate sections and appendices of Safety Series No. 115, "International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources" (BSS), are provided at the beginning of Sections II–VI.)

Check the following for compliance with the authorization and with the regulatory authority requirements.

I-IDENTIFYING INFORMATION

I-1. Name of the institution: _____
_____

I-2. Address of facility: _____
_____

I-3. Telephone/facsimile/e-mail: Voice: _____ Fax: _____
e-mail: _____

I-4. Authorization number: _____

I-5. Name and qualification of the radiation protection officer:
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____

I-6. Name and qualifications of any qualified experts (engineers, physicists, etc.) retained:

Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____

Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____

Name: _____
Degree: _____
Certification: _____
Experience:_____
_____
_____

I-7. Name and title of the responsible representative of the legal person: _____
_____

II-VERIFICATION OF SAFETY

BSS requirements related to this section may be found in Appendix IV "Potential Exposure: Safety of Sources

II-1. Irradiator design

Compare the irradiator and sources with application descriptions and design specifications.

a) Are the irradiator and radiation sources as described in the application approved by the regulatory authority?		Yes	No
b) Irradiator model/type:			
c) Irradiator identification number:			
d) Radionuclide:			
i)	Model no(s). of the source(s):		
ii)	Initial activity of sources:		
iii)	Number of sources installed:		
iv)	Per pencil:		
v)	Per module:		
vi)	Per rack:		
e) Maximum design activity:			
f) Total activity installed:			
g) Date installed:			
Describe any irradiator differences or modifications: _____ _____ _____			

II-2. Facility design

Describe any facility differences or modifications from those approved by the regulatory authority and considered in the safety assessment (e.g. shielding design, building materials, installed fire protection and controls, etc.):

_____
_____
_____

a) Was a safety assessment by a qualified expert performed prior to any modifications?		Yes	No
b) Is protection of the sources from adverse environmental conditions (heat, moisture, etc.):	provided? working?	Yes Yes	No No
c) Is fire detection and protection in the irradiation and source storage areas:	provided? working?	Yes Yes	No No
d) Is adequate ventilation in the irradiation and source (dry) storage areas:	provided? working?	Yes Yes	No No
e) For wet storage:			
i) leakproof liner in good condition?		Yes	No
ii) good water clarity?		Yes	No
iii) pool clear of debris?		Yes	No
iv) water treatment system	provided? working?	Yes Yes	No No
v) water level controls and re-supply	provided? working?	Yes Yes	No No
vi) pool guard and cover	provided? working?	Yes Yes	No No
vii) harness anchor points		Yes	No
viii) long emergency hook		Yes	No
ix) long handling tools (must not be hollow or filled with air)		Yes	No

II-3. Safety controls system

a) Are the safety controls for irradiator operation and storage of radiation sources as described in the application approved by the regulatory authority?		Yes	No
b) If not, was a safety assessment by a qualified expert performed prior to any modifications?		Yes	No
c) Are electrical or mechanical interlocks (e.g. plug, protective barriers, material entry/exit):	provided? working?	Yes Yes	No No
d) Is automatic source return to shielded position (e.g. power failure):	provided? working?	Yes Yes	No No
e) Is manual source return to shielded position (e.g. power failure):	provided? working?	Yes Yes	No No
f) Are emergency stop buttons:	provided? working?	Yes Yes	No No
g) Is a radiation monitor inside the entrance to the irradiation room with measurements displayed outside the room and interlocked to the entrance door:	provided? working?	Yes Yes	No No
h) Is a radiation monitor at the material product exit port:	provided? working?	Yes Yes	No No
i) Is an interlock with the radiation monitor to shut down product movement	provided? working?	Yes Yes	No No
ii) Are alarms to alert operators of jams of the product conveyor system	provided? working?	Yes Yes	No No
i) Is a radiation monitor for the water circulation system:	provided? working?	Yes Yes	No No
j) Is a shroud or other barrier to protect the source rack and sources from interference by product on the conveyor system:	provided? working?	Yes Yes	No No
k) Are position indicators for source rack:	provided? working?	Yes Yes	No No
l) Is key control for electrical/mechanical connections:	provided? working?	Yes Yes	No No
m) Is interlocked access control (entry by an intruder causes the sources to return to the shielded position)	provided? working?	Yes Yes	No No
n) Is interlocked access control (safety delay timer with alarm before sources can move from the shielded position)	provided? working?	Yes Yes	No No
o) Is a means of escape or communications (e.g. bell telephone) from within the irradiation room	provided? working?	Yes Yes	No No

II-4. Warning systems

a) Are distinctive signals (e.g. visible and/or audible) and posted explanations inside and outside the radiation room for:			
i) source exposed	provided? working? local language?	Yes Yes Yes	No No No
ii) source in transit	provided? working? local language?	Yes Yes Yes	No No No
iii) source safe	provided? working? local language?	Yes Yes Yes	No No No
b) Are warning notices (e.g. illuminated signs, written signs, posters):	provided? working? local language?	Yes Yes Yes	No No No

II-5. Safety operations -management

a)	Is management knowledgeable of the certificate of authorization and its restrictions and requirements?		Yes	No
b)	Does management provide adequate staffing levels?		Yes	No
c)	Has management provided the radiation protection officer authority to stop unsafe operations?		Yes	No
d)	Does management provide adequate resources for personnel training (time and money)?		Yes	No
e)	Does management provide adequate equipment?		Yes	No
f)	Does management provide for periodic program reviews and recommendations?	scheduled? performed?	Yes Yes	No No
	i) Date of the last program review:			
	ii) Status of recommendations: _____ _____ _____			

II-6. Safety operations — technical

a)	Does the radiation protection officer (RPO) have adequate knowledge and expertise? Note: In a small organisation the manager and the RPO may be the same individual.)		Yes	No
b)	Does the RPO have qualified experts available?		Yes	No
c)	Is the RPO knowledgeable about the requirements of the regulatory authority and the provisions of the certificate of authorization?		Yes	No
d)	Is the RPO given sufficient time and resources to do the job (e.g. not kept too busy with other assignments or given insufficient technical and secretarial help)?		Yes	No
e)	Does RPO maintain knowledge of activities of workers using radiation sources?		Yes	No
f)	Does the RPO conduct initial and periodic training of workers?		Yes	No
g)	Does the RPO maintain adequate records to demonstrate worker and public protection?		Yes	No
h)	Are there provisions for inventory of sources and accountability:	procedures? performed?	Yes Yes	No No
i)	Are there provisions for audits and reviews of radiation safety program:	procedures? Performed?	Yes Yes	No No

II-7. Investigations and quality assurance

a)	Were there any incidents or accidents?		Yes	No
b)	If so, were incident and accident investigation reports prepared?		Yes	No
c)	Were safety assessments reviewed or made based on lessons learned from any accident or accidents at similar facilities?		Yes	No
d)	Is there a written quality assurance program?	procedures? performed?	Yes Yes	No No
e)	Is maintenance and repair work in accordance with manufacturer's recommendations?	scheduled? performed?	Yes Yes	No No
f)	Are repair/maintenance procedures?	developed? followed?	Yes Yes	No No

III-VERIFICATION OF WORKER PROTECTION

BSS requirements related to this section may be found in Appendix I "Occupational Exposure".

III-1. Classification of areas

a)	Are controlled areas demarcated?		Yes	No
b)	Are approved signs at access points?	provided?	Yes	No
		legible?	Yes	No
		local language?	Yes	No
c)	Is radiation source storage at a physically defined location (e.g. pool, pit, hot cell, room)?		Yes	No
	i) locked/secured location with key control?		Yes	No
	ii) radiation warning notices?	provided?	Yes	No
		legible?	Yes	No
		local language?	Yes	No
	iii) proper shielding (e.g. individual containers, enclosure)?		Yes	No
	iv) reserved only for radiation sources?		Yes	No
d)	Are supervised areas demarcated?		Yes	No
e)	Are approved signs at access points?	needed?	Yes	No
		provided?	Yes	No
		legible?	Yes	No
		local language?	Yes	No

III-2. Local rules and supervision

a)	Are rules established in writing, in a local language?		Yes	No
b)	Do rules include investigation levels and authorised levels and the procedure to be followed when a level is exceeded?		Yes	No
c)	Are workers instructed in the implementing procedures?		Yes	No
d)	Do workers have adequate supervision to ensure rules, procedures, protective measures and safety provisions are followed?		Yes	No
e)	Specifically, are operating and working procedures for:			
	i) entry into the irradiation room	provided?	Yes	No
		adequate?	Yes	No
		followed?	Yes	No
	ii) product loading	provided?	Yes	No
		adequate?	Yes	No
		followed?	Yes	No
	i)ii source loading and manipulation	provided?	Yes	No
		adequate?	Yes	No
		followed?	Yes	No
	iv) responding to alarms	provided?	Yes	No
		adequate?	Yes	No
		followed?	Yes	No
	v) performing repairs to and maintenance of safety systems	provided?	Yes	No
		adequate?	Yes	No
		followed?	Yes	No
	vi) making surveys	provided?	Yes	No
		adequate?	Yes	No
		followed?	Yes	No

III-3. Monitoring

a)	Does the authorised organisation provide personal dosimeters?	Yes	No
b)	Are the dosimeters:		
i)	Worn properly?	Yes	No
ii)	Calibrated?	Yes	No
iii)	Exchanged at required frequency?	Yes	No
c)	Are personnel exposures within limits?	Yes	No
d)	Area and portable survey instruments		
i)	Appropriate?	Yes	No
ii)	Calibrated?	Yes	No
iii)	Operational?	Yes	No
iv)	Operational check performed before use?	Yes	No
v)	Spare batteries available?	Yes	No
e)	Do the authorised organisation's surveys indicate that the radiation room shielding is adequate and the dose rates around the room meet authorised radiation levels?	Yes	No
f)	Does the authorised organisation make periodic tests for leakage of radioactive materials from sealed sources?	Yes	No
g)	Is the instrumentation:		
i)	Appropriate?	Yes	No
ii)	Calibrated?	Yes	No
iii)	Operational?	Yes	No

Record independent measurements made during the inspection:

_____
_____
_____

Type/model no. of survey meter:

Date last calibrated:

Do the inspector's independent surveys agree with the survey results of the authorised organisation?	Yes	No

Document any significant differences and any agreed upon plan to resolve the different results:

_____
_____
_____
_____

IV-VERIFICATION OF PUBLIC PROTECTION

BSS requirements related to this section may be found in Appendix III "Public Exposure".

IV-1. Control of visitors

Are visitors accompanied in controlled area?	Yes	No
Is adequate information provided to visitors entering controlled areas?	Yes	No
Are there adequate controls over entries into supervised areas and appropriate postings?	Yes	No

IV-2. Sources of exposure

Are the shielding and other protective measures optimised for restricting public exposure to external sources of radiation?	Yes	No
Are the floor plans and arrangement of equipment as described in the application and appropriate considering any public areas adjacent to the installation?	Yes	No
Have provisions been made to detect and control contamination on irradiated product in the event of a leaking source?	Yes	No

IV-3. Radioactive waste and discharges

Have provisions been made to transfer the source to an appropriate registrant or licensee or to an authorised waste disposal facility at the end of use?	Yes	No
If sources are no longer in use and being stored, does the authorised organisation have a plan for timely transfer or disposal of the sources?	Yes	No
Are there provisions for control of discharges to the environment in the event of contamination or leakage from a sealed source?	Yes	No

IV-4. Monitoring of public exposure

Are routine periodic measurements of exposure rates in public areas adjacent to controlled and supervised areas made by the staff or qualified expert?	Yes	No
Do surveys shows that the radiation room shielding is adequate and the dose rates outside the controlled and supervised areas meet authorised radiation levels?	Yes	No
Record independent measurements made during the inspection:		
_____ _____ _____		
Type/model no. of survey meter:		
_____ _____		
Date last calibrated:		
Are the inspector's independent measurements in agreement with the organisations routine measurements?	Yes	No
Document any significant differences and any agreed upon plan to resolve the different results: _____ _____ _____ _____		

V-EMERGENCY PREPAREDNESS

BSS requirements related to this section may be found in Appendix V, "Emergency Exposure Situations"

V-1. Emergency plan

a)	Is there a written plan?	Yes	No
b)	Is the plan periodically reviewed and updated?	Yes	No
c)	Does the plan take into account lessons learned from operating experience and accidents at similar facilities?	Yes	No
d)	Is appropriate emergency equipment available?	Yes	No

V-2. Training and exercises

a)	Have workers involved in implementing the plan received training?		Yes	No
b)	Have provisions been made for the plan to be rehearsed at suitable intervals in conjunction with any designated emergency response authorities?		Yes	No
c)	Date of the last rehearsal:			
d)	If appropriate, has prior information been provided to members of the public who are reasonably expected to be affected by an accident?	appropriate? provided?	Yes Yes	No No

VI-RECORDS

Note: *Records will be needed as part of the assessments and verifications outlined in the prior sections of the checklist. This list is a reminder of the type of records that may be helpful. The appearance of the list at the end of the checklist does not indicate that records review is the last item to be done. Rather, an inspection may begin with an entrance interview and facility tour followed by an initial review of some of the records listed below.*

a) Copy of authorization certificate
b) System of records management
c) Dosimetry
    i) current
    ii) prior work history
d) Area surveys
e) Instrument tests and calibrations
f) Tests for leakage of radioactive material from sources
g) Inventory of sources and accountability
h) Audits and reviews of radiation safety programme
i) Incident and accident investigation reports
j) Maintenance and repair work
k) Facility modifications
l) Training provided
    i) initial
    ii) refresher
m) Evidence of health surveillance
n) Waste disposals
o) Transportation
    i) package documentation
    ii) package surveys
    iii) transfer/receipt documents
    iv) details of shipments dispatched
p) Source exchange/replacement procedures

Example I.D

CHECKLIST FOR COMMISSIONING AND REGULAR INSPECTION OF SELF-CONTAINED GAMMA IRRADIATION FACILITIES

Prepare a visit agenda to review the operating program with details contained in the application for authorization, the authorization certificate, prior programme review/inspection reports and their implementation, relevant correspondence, and other relevant documentation such as dosimetry reports. (References to appropriate sections and appendices of Safety Series No. 115, "International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources" (BSS), are provided at the beginning of Sections II–VI.)

Check the following for compliance with the authorization and with the regulatory authority requirements.

I-IDENTIFYING INFORMATION

I-1. Name of the institution: _____
_____

I-2. Address of facility: _____
_____

I-3. Telephone/facsimile/e-mail: Voice: _____ Fax: _____
e-mail: _____

I-4. Authorization number: _____

I-5. Name and qualification of the radiation protection officer:
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____

I-6. Name and qualifications of any qualified experts (engineers, physicists, etc.) retained:

Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____

Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____

Name: _____
Degree: _____
Certification: _____
Experience:_____
_____
_____

I-7. Name and title of the responsible representative of the legal person: _____
_____

II-VERIFICATION OF SAFETY

BSS requirements related to this section may be found in Appendix IV "Potential Exposure: Safety of Sources

II-1. Irradiator design

a)	Compare the irradiator and sources with application descriptions and design specifications.		
b)	Are the irradiator and radiation sources as described in the application approved by the regulatory authority?	Yes	No
c)	Irradiator model/type:		
d)	Irradiator identification number		
e)	Radionuclide:		
f)	Model no. of the source:		
	i) Initial activity of sources:		
	ii) Number of sources installed:		
g)	Maximum design activity:		
h)	Total activity installed:		
i)	Date installed:		
j)	Describe any irradiator differences or modifications: _____ _____ _____		

II-2. Facility design

Describe any facility differences or modifications from those approved by the regulatory authority and considered in the safety assessment (e.g. shielding design, building materials, and controls, etc.):

_____
_____
_____
_____

a)	Was a safety assessment by a qualified expert performed prior to any modifications?		Yes	No
b)	Is protection of the sources from adverse environmental conditions (heat, moisture, etc.):	provided? working?	Yes Yes	No No
c)	Is fire detection and protection in the irradiation and source storage areas:	provided? working?	Yes Yes	No No
d)	Is adequate ventilation in the irradiation and source (dry) storage areas:	provided? working?	Yes Yes	No No

II-3. Safety controls system

a)	Are the safety controls for irradiator operation and storage of radiation sources as described in the application approved by the regulatory authority?		Yes	No
b)	If not, was a safety assessment by a qualified expert performed prior to any modifications?		Yes	No
c)	Are electrical or mechanical interlocks (e.g. plug, protective barriers, material entry/exit):	provided? working?	Yes Yes	No No
d)	Is automatic source return to shielded position (e.g. power failure):	provided? working?	Yes Yes	No No
e)	Is manual source return to shielded position (e.g. power failure):	provided? working?	Yes Yes	No No
f)	Are emergency stop buttons:	provided? working?	Yes Yes	No No
g)	Is a radiation monitor inside the entrance to the irradiation room with measurements displayed outside the room and interlocked to the entrance door:	provided? working?	Yes Yes	No No
h)	Is a radiation monitor at the material product exit port:	provided? working?	Yes Yes	No No
i)	Are position indicators for source rack:	provided? working?	Yes Yes	No No

j)	Is key control for electrical/mechanical connections:	provided? working?	Yes Yes	No No
k)	Are there position indicators for source, shutter, and/or sample holder	provided? working?	Yes Yes	No No

II-4.` Warning systems

a)	Are distinctive signals (e.g. visible and/or audible) and posted explanations inside and outside the radiation room for:			
	i) source exposed	provided? working? local language?	Yes Yes Yes	No No No
	ii) source in transit	provided? working? local language?	Yes Yes Yes	No No No
	iii) source safe	provided? working? local language?	Yes Yes Yes	No No No
b)	Are warning notices (e.g. illuminated signs, written signs, posters):	provided? working? local language?	Yes Yes Yes	No No No

II-5. Safety operations — management

a)	Is management knowledgeable of the certificate of authorization and its restrictions and requirements?		Yes	No
b)	Does management provide adequate staffing levels?		Yes	No
c)	Has management provided the radiation protection officer authority to stop unsafe operations?		Yes	No
d)	Does management provide adequate resources for personnel training (time and money)?		Yes	No
e)	Does management provide adequate equipment?		Yes	No
f)	Does management provide for periodic program reviews and recommendations?	scheduled? performed?	Yes Yes	No No
	i) Date of the last program review: _____ ii) Status of recommendations: _____ _____ _____			

II-6. Safety operations — technical

a)	Does the radiation protection officer (RPO) have adequate knowledge and expertise?		Yes	No
b)	Does the RPO have qualified experts available?		Yes	No
c)	Is the RPO knowledgeable about the requirements of the regulatory authority and the provisions of the certificate of authorization?		Yes	No
d)	Is the RPO given sufficient time and resources to do the job (e.g. not kept too busy with other assignments or given insufficient technical and secretarial help)?		Yes	No
e)	Does RPO maintains knowledge of activities of workers using radiation sources?		Yes	No
f)	Does the RPO conduct initial and periodic training of Workers?		Yes	No
g)	Does the RPO maintain adequate records to demonstrate worker and public protection?		Yes	No
h)	Are there provisions for inventory of sources and accountability:	procedures? performed?	Yes Yes	No No
i)	Are there provisions for audits and reviews of radiation safety program:	procedures? performed?	Yes Yes	No No

II-7. Investigations and quality assurance

a)	Were there any incidents or accidents?		Yes	No
b)	If so, were incident and accident investigation reports prepared?		Yes	No
c)	Were safety assessments reviewed or made based on lessons learned from any accident or accidents at similar facilities?		Yes	No
d)	Is there a written quality assurance program?	procedures?	Yes	No
		performed?	Yes	No
e)	Is maintenance and repair work in accordance with manufacturer's recommendations?	scheduled?	Yes	No
		performed?	Yes	No
f)	Are repair/maintenance procedures?	developed?	Yes	No
		followed?	Yes	No

III-VERIFICATION OF WORKER PROTECTION

BSS requirements related to this section may be found in Appendix I "Occupational Exposure".

III-1. Classification of areas

a)	Are controlled areas demarcated?		Yes	No
b)	Are approved signs at access points?	provided?	Yes	No
		legible?	Yes	No
		local language?	Yes	No
c)	Is radiation source storage at a physically defined location (e.g. pit, hot cell, room)?		Yes	No
	i) locked/secured location with key control?		Yes	No
	ii) radiation warning notices?	provided?	Yes	No
		legible?	Yes	No
		local language?	Yes	No
	iii) proper shielding (e.g. individual containers, enclosure)?		Yes	No
	iv) reserved only for radiation sources?		Yes	No
d)	Are supervised areas demarcated?		Yes	No
e)	Are approved signs at access points?	needed?	Yes	No
		provided?	Yes	No
		legible?	Yes	No
		local language?	Yes	No

III-2. Local rules and supervision

a)	Are rules established in writing, in a local language?		Yes	No
b)	Do rules include investigation levels and authorised levels and the procedure to be followed when a level is exceeded?		Yes	No
c)	Are workers instructed in the implementing procedures?		Yes	No
d)	Do workers have adequate supervision to ensure rules, procedures, protective measures and safety provisions are followed?		Yes	No
e)	Specifically, are operating and working procedures for:			
	i) operating the irradiator	provided?	Yes	No
		adequate?	Yes	No
		followed?	Yes	No
	ii) responding to alarms	provided?	Yes	No
		adequate?	Yes	No
		followed?	Yes	No
	iii) performing repairs to and maintenance of safety systems	provided?	Yes	No
		adequate?	Yes	No
		followed?	Yes	No
	iv) making surveys	provided?	Yes	No
		adequate?	Yes	No
		followed?	Yes	No

III-3. Monitoring

a)	Does the authorised organisation provide personal dosimeters?	Yes	No
b)	Are the dosimeters:		
i)	Worn properly?	Yes	No
ii)	Calibrated?	Yes	No
iii)	Exchanged at required frequency?	Yes	No
c)	Are personnel exposures within limits?	Yes	No
d)	Area and portable survey instruments		
i)	Appropriate?	Yes	No
ii)	Calibrated?	Yes	No
iii)	Operational?	Yes	No
iv)	Operational check performed before use?	Yes	No
v)	Spare batteries available?	Yes	No
e)	Do the authorised organisation's surveys indicate that the radiation room shielding is adequate and the dose rates around the room meet authorised radiation levels?	Yes	No
f)	Does the authorised organisation make periodic tests for leakage of radioactive materials from sealed sources?	Yes	No
g)	Is the instrumentation:		
i)	Appropriate?	Yes	No
ii)	Calibrated?	Yes	No
iii)	Operational?	Yes	No
Record independent measurements made during the inspection: _____ _____ _____ _____			
Type/model no. of survey meter:			
Date last calibrated:			
Do the inspector's independent surveys agree with the survey results of the authorised organisation?		Yes	No
Document any significant differences and any agreed upon plan to resolve the different results: _____ _____ _____ _____			

IV-VERIFICATION OF PUBLIC PROTECTION

BSS requirements related to this section may be found in Appendix III "Public Exposure".

IV-1. Control of visitors

a)	Are visitors accompanied in controlled area?	Yes	No
b)	Is adequate information provided to visitors entering controlled areas?	Yes	No
c)	Are there adequate controls over entries into supervised areas and appropriate postings?	Yes	No

IV-2. Sources of exposure

a)	Are the shielding and other protective measures optimised for restricting public exposure to external sources of radiation?	Yes	No
b)	Are the floor plans and arrangement of equipment as described in the application and appropriate considering any public areas adjacent to the installation?	Yes	No
c)	Have provisions been made to detect and control contamination in the event of a leaking source?	Yes	No

IV-3. Radioactive waste and discharges

a)	Have provisions been made to transfer the source to an appropriate registrant or licensee or to an authorised waste disposal facility at the end of use?	Yes	No
b)	If sources are no longer in use and being stored, does the authorised organisation have a plan for timely transfer or disposal of the sources?	Yes	No
c)	Are there provisions for control of discharges to the environment in the event of contamination or leakage from a sealed source?	Yes	No

IV-4. Monitoring of public exposure

a)	Are routine periodic measurements of exposure rates in public areas adjacent to controlled and supervised areas made by the staff or qualified expert?	Yes	No
b)	Do surveys shows that the radiation room shielding is adequate and the dose rates outside the controlled and supervised areas meet authorised radiation levels?	Yes	No
c)	Record independent measurements made during the inspection: _____ _____ _____ _____		
Type/model no. of survey meter:			
Date last calibrated:			
Are the inspector's independent measurements in agreement with the organisations routine measurements?		Yes	No
Document any significant differences and any agreed upon plan to resolve the different results: _____ _____ _____ _____			

V-EMERGENCY PREPAREDNESS

BSS requirements related to this section may be found in Appendix V "Emergency Exposure Situations".

V-1. Emergency plan

a)	Is there a written plan?	Yes	No
b)	Is the plan periodically reviewed and updated?	Yes	No
c)	Does the plan take into account lessons learned from operating experience and accidents at similar facilities?	Yes	No
d)	Is appropriate emergency equipment available?	Yes	No

V-2. Training and exercises

a)	Have workers involved in implementing the plan received training?	Yes	No
b)	Have provisions been made for the plan to be rehearsed at suitable intervals in conjunction with any designated emergency response authorities?	Yes	No
c)	Date of the last rehearsal:		

VI-RECORDS

Note: *Records will be needed as part of the assessments and verifications outlined in the prior sections of the checklist. This list is a reminder of the type of records that may be helpful. The appearance of the list at the end of the checklist does not indicate that records review is the last item to be done. Rather, an inspection may begin with an entrance interview and facility tour followed by an initial review of some of the records listed below.*

a) Copy of authorization certificate
b) System of records management
c) Dosimetry
    i) current
    ii) prior work history
d) Area surveys
e) Instrument tests and calibrations
f) Tests for leakage of radioactive material from sources
g) Inventory of sources and accountability
h) Audits and reviews of radiation safety programme
i) Incident and accident investigation reports
j) Maintenance and repair work
k) Facility modifications
l) Training provided
    i) initial
    ii) refresher
m) Evidence of health surveillance
n) Waste disposals/source transfers
o) Transportation
    i) package documentation
    ii) package surveys
    iii) transfer/receipt documents
    iv) details of shipments dispatched
p) Source exchange/replacement procedures

Example I.E

CHECKLIST FOR COMMISSIONING AND REGULAR INSPECTION OF ELECTRON IRRADIATION FACILITIES

Prepare a visit agenda to review the operating program with details contained in the application for authorization, the authorization certificate, prior programme review/inspection reports and their implementation, relevant correspondence, and other relevant documentation such as dosimetry reports. (References to appropriate sections and appendices of Safety Series No. 115, "International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources" (BSS), are provided at the beginning of Sections II–VI.)

Check the following for compliance with the authorization and with the regulatory authority requirements.

I-IDENTIFYING INFORMATION

I-1. Name of the institution: _____
_____

I-2. Address of facility: _____
_____

I-3. Telephone/facsimile/e-mail: Voice: _____ Fax: _____
e-mail: _____

I-4. Authorization number: _____

I-5. Name and qualification of the radiation protection officer:
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____

I-6. Name and qualifications of any qualified experts (engineers, physicists, etc.) retained:

Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____

Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____

Name: _____
Degree: _____
Certification: _____
Experience:_____
_____
_____

I-7. Name and title of the responsible representative of the legal person: _____
_____

II-VERIFICATION OF SAFETY

BSS requirements related to this section may be found in Appendix IV "Potential Exposure: Safety of Sources

II-1. Accelerator design

Is the accelerator as described in the application approved by the regulatory authority?	Yes	No
Model:		
Identification number:		
Type (electron, X ray, other):		
Energy of radiation:		
Describe any differences or modifications: _____ _____ _____		

II-2. Facility design

Describe any facility differences or modifications from those approved by the regulatory authority and considered in the safety assessment (e.g. shielding design, building materials, installed fire protection and controls, etc.):

_____
_____
_____
_____

a)	Was a safety assessment by a qualified expert performed prior to any modifications?		Yes	No
b)	Is protection of the accelerator from adverse environmental conditions (heat, moisture, etc.):	provided? working?	Yes Yes	No No
c)	Is fire detection and protection in the irradiation areas:	provided? working?	Yes Yes	No No
d)	Is adequate ventilation in the irradiation areas:	provided? working?	Yes Yes	No No

II-3. Safety controls system

a)	Are the safety controls for irradiation operations as described in the application approved by the regulatory authority?		Yes	No
b)	If not, was a safety assessment by a qualified expert performed prior to any modifications?		Yes	No
c)	Are electrical or mechanical interlocks (e.g. protective barriers, material entry/exit):	provided? working?	Yes Yes	No No
d)	Are emergency stop buttons:	provided? working?	Yes Yes	No No
e)	Is a radiation monitor inside the entrance to the irradiation room with measurements displayed outside the room and interlocked to the entrance door:	provided? working?	Yes Yes	No No
f)	Is key control for electrical/mechanical connections (note that the control should cover both the accelerating voltage and the emission source since "dark current" from cold filaments has been sufficient to cause serious personnel exposures):	provided? working?	Yes Yes	No No
g)	Is interlocked access control (entry by an intruder causes the electrical power to the accelerator to be shut off)	provided? working?	Yes Yes	No No
h)	Is interlocked access control (search and lock-up system before voltage can be supplied to the accelerator)	provided? working?	Yes Yes	No No
i)	Is a means of escape or communications (e.g. bell telephone) from within the irradiation room	provided? working?	Yes Yes	No No

II-4. Warning systems

a)	Are separate and distinctive signals (e.g. visible and/or audible) and posted explanations inside and outside the radiation room for:			
	i) accelerator ready to be energised	provided?	Yes	No
		working?	Yes	No
		local language?	Yes	No
	ii) accelerator 'ON' (radiation being produced)	provided?	Yes	No
		working?	Yes	No
		local language?	Yes	No
	iii) accelerator 'OFF'	provided?	Yes	No
		working?	Yes	No
		local language?	Yes	No
b)	Are warning notices (e.g. illuminated signs, written signs, posters):	provided?	Yes	No
		working?	Yes	No
		local language?	Yes	No

II-5. Safety operations — management

a)	Is management knowledgeable of the certificate of authorization and its restrictions and requirements?		Yes	No
b)	Does management provide adequate staffing levels?		Yes	No
c)	Has management provided the radiation protection officer authority to stop unsafe operations?		Yes	No
d)	Does management provide adequate resources for personnel training (time and money)?		Yes	No
e)	Does management provide adequate equipment?		Yes	No
f)	Does management provide for periodic program reviews and recommendations?	scheduled?	Yes	No
		performed?	Yes	No
	i) Date of the last program review: _____			
	ii) Status of recommendations:			
	_____			
	_____			
	_____			
	_____			

II-6. Safety operations — technical

a)	Does the radiation protection officer (RPO) have adequate knowledge and expertise?	Yes	No
b)	Does the RPO have qualified experts available?	Yes	No
c)	Is the RPO knowledgeable about the requirements of the regulatory authority and the provisions of the certificate of authorization?	Yes	No
d)	Is the RPO given sufficient time and resources to do the job (e.g. not kept too busy with other assignments or given insufficient technical and secretarial help)?	Yes	No
e)	Does RPO maintains knowledge of activities of workers?	Yes	No
f)	Does the RPO conduct initial and periodic training of Workers?	Yes	No
g)	Does the RPO maintain adequate records to demonstrate worker and public protection?	Yes	No

II-7. Investigations and quality assurance

a)	Were there any incidents or accidents?		Yes	No
b)	If so, were incident and accident investigation reports prepared?		Yes	No
c)	Were safety assessments reviewed or made based on lessons learned from any accident or accidents at similar facilities?		Yes	No
d)	Is there a written quality assurance program?	procedures?	Yes	No
		performed?	Yes	No
e)	Is maintenance and repair work in accordance with manufacturer's recommendations?	scheduled?	Yes	No
		performed?	Yes	No
f)	Are repair/maintenance procedures?	developed?	Yes	No
		followed?-	Yes	No

III-VERIFICATION OF WORKER PROTECTION

BSS requirements related to this section may be found in Appendix I "Occupational Exposure".

III-1. Classification of areas

a)	Are controlled areas demarcated?		Yes	No
b)	Are approved signs at access points?	provided?	Yes	No
		legible?	Yes	No
		local language?	Yes	No
c)	Are supervised areas demarcated?		Yes	No
d)	Are approved signs at access points?	needed?	Yes	No
		provided?	Yes	No
		legible?	Yes	No
		local language?	Yes	No

III-2. Local rules and supervision

a)	Are rules established in writing, in a local language?			Yes	No
b)	Do rules include investigation levels and authorised levels and the procedure to be followed when a level is exceeded?			Yes	No
c)	Are workers instructed in the implementing procedures?			Yes	No
d)	Do workers have adequate supervision to ensure rules, procedures, protective measures and safety provisions are followed?			Yes	No
e)	Specifically, are operating and working procedures for:				
	i)	operating the accelerator	provided?	Yes	No
			adequate?	Yes	No
			followed?	Yes	No
	ii)	product loading	provided?	Yes	No
			adequate?	Yes	No
			followed?	Yes	No
	iii)	responding to alarms	provided?	Yes	No
			adequate?	Yes	No
			followed?	Yes	No
	iv)	performing repairs to and maintenance of safety systems	provided?	Yes	No
			adequate?	Yes	No
			followed?	Yes	No
	v)	making surveys	provided?	Yes	No
			adequate?	Yes	No
			followed?	Yes	No

III-3. Monitoring

a)	Does the authorised organisation provide personal dosimeters?	Yes	No
b)	Are the dosimeters:		
i)	Worn properly?	Yes	No
ii)	Calibrated?	Yes	No
iii)	Exchanged at required frequency?	Yes	No
c)	Are personnel exposures within limits?	Yes	No
d)	Area and portable survey instruments		
i)	Appropriate?	Yes	No
ii)	Calibrated?	Yes	No
iii)	Operational?	Yes	No
iv)	Operational check performed before use?	Yes	No
v)	Spare batteries available?	Yes	No
e)	Do the authorised organisation's surveys indicate that the radiation room shielding is adequate and the dose rates around the room meet authorised radiation levels?	Yes	No

Record independent measurements made during the inspection: _____
_____
_____
_____

Type/model no. of survey meter:

Date last calibrated:

Do the inspector's independent surveys agree with the survey results of the authorised organisation?	Yes	No

Document any significant differences and any agreed upon plan to resolve the different results:
_____
_____
_____
_____

IV-VERIFICATION OF PUBLIC PROTECTION

BSS requirements related to this section may be found in Appendix III "Public Exposure".

IV-1. Control of visitors

a)	Are visitors accompanied in controlled area?	Yes	No
b)	Is adequate information provided to visitors entering controlled areas?	Yes	No
c)	Are there adequate controls over entries into supervised areas and appropriate postings?	Yes	No

IV-2. Sources of exposure

a)	Are the shielding and other protective measures optimised for restricting public exposure to external sources of radiation?	Yes	No
b)	Are the floor plans and arrangement of equipment as described in the application and appropriate considering any public areas adjacent to the installation?	Yes	No

IV-3. Monitoring of public exposure

a)	Are routine periodic measurements of exposure rates in public areas adjacent to controlled and supervised areas made by the staff or qualified expert?	Yes	No
b)	Do surveys shows that the radiation room shielding is adequate and the dose rates outside the controlled and supervised areas meet authorised radiation levels?	Yes	No

c) Record independent measurements made during the inspection:
_____
_____
_____

Type/model no. of survey meter:		
Date last calibrated:		
Are the inspector's independent measurements in agreement with the organisations routine measurements?	Yes	No
Document any significant differences and any agreed upon plan to resolve the different results: _____ _____ _____ _____		

V-EMERGENCY PREPAREDNESS

BSS requirements related to this section may be found in Appendix V "Emergency Exposure Situations".

V-1. Emergency plan

a)	Is there a written plan?	Yes	No
b)	Is the plan periodically reviewed and updated?	Yes	No
c)	Does the plan take into account lessons learned from operating experience and accidents at similar facilities?	Yes	No

V-2. Training and exercises

a)	Have workers involved in implementing the plan received training?	Yes	No
b)	Have provisions been made for the plan to be rehearsed at suitable intervals in conjunction with any designated emergency response authorities?	Yes	No
c)	Date of the last rehearsal:		

VI-RECORDS

Note: *Records will be needed as part of the assessments and verifications outlined in the prior sections of the checklist. This list is a reminder of the type of records that may be helpful. The appearance of the list at the end of the checklist does not indicate that records review is the last item to be done. Rather, an inspection may begin with an entrance interview and facility tour followed by an initial review of some of the records listed below.*

a) Copy of authorization certificate
b) System of records management
c) Dosimetry
   i) current
   ii) prior work history
d) Area surveys
e) Instrument tests and calibrations
f) Audits and reviews of radiation safety programme
g) Incident and accident investigation reports
h) Maintenance and repair work
i) Facility modifications
j) Training provided
   i) initial
   ii) refresher
k) Evidence of health surveillance

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Annex II

SAFETY ASSESSMENT PLANS FOR INDUSTRIAL RADIOGRAPHY

This annex has three exhibits which include one application form and two checklists for inspection:

(1) Example II.A. Application for authorization and review plan for industrial radiography.

(2) Example II.B. Checklist for commissioning and regular inspection of fixed facilities for industrial radiography.

(3) Example II.C. Checklist for commissioning and regular inspection of industrial radiography with mobile devices.

References that may be useful to the regulatory authority and/or to licensees and registrants are listed in the bibliography at the end of the annex. The list is divided into references generally applicable for radiation safety and protection and those which may have particular relevance to industrial radiography.

Example II.A

APPLICATION FOR AUTHORIZATION AND REVIEW PLAN FOR INDUSTRIAL RADIOGRAPHY

TYPE OF AUTHORIZATION

_____ New application
_____ Amendment to existing authorization number: _____
_____ Renewal of authorization number: _____

PURPOSE OF APPLICATION

_____ Construction (Complete Sections I through III)
_____ Import/Purchase (Complete Sections I and II)
_____ Use/Begin operation (Complete Sections I through IV)

You may refer to previous submissions by date and application or authorization number(s)

The legal person who will be responsible for using any sealed source or radiation generator must, unless the source is exempted, submit the following information to the regulatory authority.

I-GENERAL INFORMATION

I-1. Name and address of organisation:

Main address	Mailing address (if different)	Address of use (if different)
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

I-2. Name and information about qualified experts:

Expertise: radiation protection officer
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____
Telephone number: _____

Expertise: _____
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____
_____

II-3. The responsible representative of the legal person:

Name: _____
Title: _____

Telephone number _____
Facsimile number _____
e-mail address _____

I-4. Proposed date of installation and/or commissioning of facilities and equipment:

_____

SIGNATURE AND CERTIFICATION

_____
Signature of the authorised representative
of the legal person

Title: _____

Date**:** _____

Notes:

1. The regulatory authority may require additional information to fully consider this application prior to issuing an authorization.

2. In the event that all the above information is not available at the time of application, the regulatory authority may issue an authorization limiting the applicant to import, acquire, or store radiation sources, or construct facilities. Complete information will be required from the applicant prior to authorising use of the radiation sources.

II-SOURCES AND EQUIPMENT

II-1. Sealed source radiographic devices

Manufacturer	Device model number	Source model number	Radionuclide	Source supplier	Maximum activity	Number of devices
(e.g. ABC Co.)	(e.g. model A)	(e.g. model B)	(e.g. ^{192}Ir)		(e.g. 2 TBq)	(e.g. 8)

II-2. X ray generators

Manufacturer	Model number	Serial number	Maximum voltage	Maximum current
(e.g. ABXY Co.)	(e.g. Unit 123)	(e.g. 99999)	(e.g. 150 kV)	(e.g. 40 mA)

II-3. Accelerators

Manufacturer	Model number	Serial number	Radiation type	Maximum energy	Maximum current
(e.g. ZYX Co.)	(e.g. Unit 987)	(e.g. 11111)	(e.g. X ray)	(e.g. 5 MeV)	(e.g. 2 mA)

II-4. Source standards

Are the sources manufactured, prototype tested, and subject to quality control provisions of standards recognised by national or international standard setting organisations (e.g. ISO 2919)? If, so please identify the standards and any applicable classification numbers.

_____
_____
_____
_____
_____
_____

II-5. Equipment standards

Is the radiography equipment manufactured, prototype tested, and subject to quality control provisions of standards recognised by national or international standard setting organisations (e.g. IEC) If, so please identify the standards and any applicable classification numbers.

_____
_____
_____
_____
_____

II-6. Work locations:

Will the work be carried out at any address other than given in item I–1. above? (Circle correct answer)	Do not know	Yes	No

(Note: that the regulatory authority may require notification prior to work at currently unknown addresses)

b) List all other known addresses:

_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

III-FACILITIES

Approval may be required from the regulatory authority before starting construction of any shielded enclosure.

In an attachment to this application, describe the irradiator facilities, including:

III-1. Location of the facility

Provide a detailed location of the facility.

III-2. Layout of the facility

Describe factors such as the layout of the facility and its immediate surroundings, building materials, alarms, shielding, engineering controls such as interlock and warning safety devices, and remote handling tools. Attach a detailed sketch or drawing of the facility showing the above details. Include on the drawings any penetrations or openings in the shielding materials such as conduits or ventilation ducts. Controlled and supervised areas should be clearly identified on the drawings

III-3. Safety assessments

Taking account of shielding, provide calculations of maximum dose rates in all areas outside the facility (specify all assumptions e.g. number of sources, activity). Provide estimates of the magnitude of expected doses to persons during normal operations. Identify the probability and magnitude of potential exposures arising from accidents or incidents.

III-4. Source storage

Describe the device storage site including adjacent rooms (on a plan or sketch), provide shielding calculations and security precautions.

IV-RADIATION PROTECTION AND SAFETY PROGRAMME

In an attachment to this application, describe the radiation protection programme, including:

IV-1. Organisational structure

a) Describe your organisational and management control systems, including assignment of responsibilities and clear lines of authority related to radiation safety. In particular include: staffing levels, equipment selection, other assignments of the radiation protection officer, authority of the radiation protection officer to stop

unsafe operations, personnel training, maintenance of records, and how problems affecting safety are identified and corrected.

b) Identify the authorised users, qualified experts, and radiation protection officer by name and include their training, education, experience and qualifications. (Note: the authorised user and/or radiation protection officer may be the same individual).

c) Confirm that training will include: explanation of radiation hazards and effects, explanation of written procedures, use of equipment (e.g. instrumentation), meaning of warning signals, and a method to confirm adequacy of training (testing or demonstrations).

IV-2. Workplace monitoring, area classification and individual monitoring

a) Describe your programme for monitoring the workplace (BSS, I.37-I.40), including: the quantities to be measured, where and when the measurements are to be made, the measurement methods and procedures, and reference levels and the actions to be taken if they are exceeded.

b) Describe your policies and procedures for classification of controlled and supervised areas. (BSS, I.21-I.25).

c) Describe personal dosimeters provided to workers and your policies for assigning dosimetry to individual workers (BSS, I.32-I.36). Describe your policy for reviewing individual doses, including reference levels and actions to be taken in exceeded.

Name and address of dosimetry service: _____

_____

_____

_____

Denote type:

i) Film _____

ii) ThermoLuminescent dosimeter (TLD)_____

iii) Direct reading dosimeter (DRD) _____

iv) other: _____

IV-3. Local rules and supervision

a) Describe your local rules and procedures regarding: investigation or authorised levels, protective measures and safety provisions, providing adequate supervision, providing workers information regarding health risks due to occupational exposure, and emergency planning instruction (BSS, I.26-I.27).

b) Provide copies of your operating and safety procedures including: area access control, entry procedures into shielded enclosures, source inventory and leak testing, etc.

c) Describe your training program to ensure all appropriate personnel are adequately trained in the operating procedures and how their actions may affect safety (BSS, I.27).

d) Describe your policies regarding female workers who become pregnant (notification, adoption of working conditions to protect foetus/embryo) and the instructions you will provide to them (BSS, I.16-I.17 and I.27).

e) Describe your programme of health surveillance based on general principles of occupational health and designed to assess the initial and continuing fitness of workers for their intended tasks (BSS, I.41-I.43).

IV-4. Quality assurance

a) Describe your programme for ensuring that regulatory radiation safety requirements are addressed and satisfied.

b) Describe your program to periodically review procedures, maintain procedures current and available, and your procedure modification process.

c) Describe your programme for optimising occupational and public exposures to levels as low as reasonably achievable.

d) Describe your programme of periodic maintenance and testing (safety interlocks, radiation meters, etc.). Attach the manufacturers instructions.

e) Describe service arrangements with other organisations and qualified experts.

IV-5. Transportation of radioactive material

If you will be transporting or shipping new or used sources, describe your arrangements for preparation and transport of packages containing radioactive sources (IAEA Safety Standards Series No. ST-1). These procedures should address: documentation of package certification, package surveys, transfer/receipt documents, and details of shipments preparation.

IV-6. Emergency procedures

Provide your emergency procedures to address emergencies such as potential damage to the source, loss of source shielding, stuck sources or substantial accidental exposure of an individual. If other emergencies are envisaged, please provide additional appropriate emergency procedures. In all cases the magnitude of the hazard should be evaluated. Any off-site consequences should also be evaluated. Local emergency services (e.g. fire, police) may need to be provided with copies of the emergency procedures.

IV-7. Transfer or disposal of radioactive sources

Describe arrangements for transfer or disposal of spent radioactive sources.

IV-8. System of records (BSS; 2.40, I.44-I.49)**, including:**

a) Disposal of spent sources
b) Personnel exposure
   i) current records
   ii) prior work history
c) Area surveys
   i) dose or dose rate
   ii) contamination
d) Instrument tests and calibrations
e) Tests for radioactive sealed source leakage.
f) Inventory of sources and accountability
g) Audits and reviews of radiation safety program
h) Incident and accident investigation reports
i) Maintenance and repair work
j) Facility modifications
k) Training provided
l) Evidence of health surveillance of workers
m) Transportation

Example II.B

CHECKLIST FOR COMMISSIONING AND REGULAR INSPECTION OF FIXED FACILITIES FOR INDUSTRIAL RADIOGRAPHY

Prepare a visit agenda to review the operating program with details contained in the application for authorization, the authorization certificate, prior programme review/inspection reports and their implementation, relevant correspondence, and other relevant documentation such as dosimetry reports. (References to appropriate sections and appendices of Safety Series No. 115, "International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources" (BSS), are provided at the beginning of Sections II–VI.)

Check the following for compliance with the authorization and with the regulatory authority requirements.

I-IDENTIFYING INFORMATION

I-1. Name of the institution: _____
_____

I-2. Address of facility: _____
_____
_____
_____

I-3. Telephone/facsimile/e-mail: Voice: _____ Fax: _____
e-mail: _____

I-4. Authorization number: _____

I-5. Name and qualification of the radiation protection officer:
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____

I-6 Name and qualifications of any qualified experts retained:

Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____

Name: _____
Degree: _____
Certification: _____
Experience: _____
_____

Name: _____
Degree: _____
Certification: _____
Experience: _____
_____

I-7. Name and title of the responsible representative of the legal person: _____
_____
_____

II-VERIFICATION OF SAFETY

BSS requirements related to this section may be found in Appendix IV "Potential Exposure: Safety of Sources

II-1. Sealed source radiographic devices

Manufacturer	Device model number	Source model number	Radionuclide	Source supplier	Maximum activity	Number of devices
(e.g. ABC Co.)	(e.g. Model A)	(e.g. Model B)	(e.g. ^{192}Ir)		(e.g. 2 TBq)	(e.g. 8)

Compare the radiographic devices and sources with application descriptions and design specifications. Note any differences and determine the standards to which sources and/or devices were built:

_____
_____
_____
_____

II-2. X ray generators

Manufacturer	Model number	Serial number	Maximum voltage	Maximum current
(e.g. ABXY Co.)	(e.g. Unit 123)	(e.g. 99999)	(e.g. 150 kV)	(e.g. 40 mA)

Compare the X ray generator with application descriptions and design specification. Note any differences and determine the standards to which devices were built:

_____
_____
_____
_____

II-3. Accelerators

Manufacturer	Model number	Serial number	Radiation type	Maximum energy	Maximum current
(e.g. ZYX Co.)	(e.g. Unit 987)	(e.g. 11111)	(e.g. X ray)	(e.g. 5 MeV)	(e.g. 2 mA)

Compare the accelerator with application descriptions and design specifications. Note any differences and determine the standards to which the accelerator was built

_____
_____
_____
_____

II-4. Shielded enclosure design

a)	Describe any differences or modifications from those approved by the regulatory authority and considered in the safety assessment (e.g. shielding design, building materials, installed fire protection and controls, etc.): _____ _____ _____ _____			
b)	Was a safety assessment by a qualified expert performed prior to any modifications?		Yes	No
c)	Is the thickness and type of shielding appropriate for the types and intensity of radiation produced by radiographic devices?		Yes	No
d)	Is protection of the sources and X ray generators from adverse environmental conditions (heat, moisture, etc.):	provided? working?	Yes Yes	No No
e)	Is fire detection and protection in the radiation and source storage areas:	provided? working?	Yes Yes	No No

II-5. Safety controls system

Are the safety controls for radiographic operations and storage of radiation sources as described in the application approved by the regulatory authority?			Yes	No
If not, was a safety assessment by a qualified expert performed prior to any modifications?			Yes	No
a)	Are electrical door interlocks for entry:	provided? working?	Yes Yes	No No
b)	Are emergency stop buttons:	provided? working?	Yes Yes	No No
c)	Is there an installed radiation monitor:	provided? working?	Yes Yes	No No
d)	Is a mechanical door interlock (e.g. key control system):	provided? working?	Yes Yes	No No
e)	Are portable radiation monitors for enclosure entry:	provided? required? working?	Yes Yes Yes	No No No

II-6. Warning system

a)	Are separate and distinctive warning signals (e.g. visible and/or audible) and posted explanations inside and outside the radiation room for:				
	i)	radioactive source about to be exposed/radiation about to be generated	provided? working?	Yes Yes	No No
	ii)	radioactive source exposed/radiaton 'ON'	provided? working?	Yes Yes	No No
	iii)	source safe/radiation 'OFF'	provided? working?	Yes Yes	No No
b)	Are warning notices (e.g. illuminated signs, written signs, posters):		provided? working? legible? local language?	Yes Yes Yes Yes	No No No No

II-7. Safety operations -management

a)	Is management knowledgeable of the certificate of authorization and its restrictions and requirements?	Yes	No
b)	Does management provide adequate staffing levels?	Yes	No
c)	Has management provided the radiation protection officer authority to stop unsafe operations?	Yes	No
d)	Does management provide adequate resources for personnel training (time and money)?	Yes	No

e)	Does management provide adequate equipment?		Yes	No
f)	Does management provide for periodic program reviews and recommendations?	scheduled? performed?	Yes Yes	No No
	i) Date of the last program review: _____ ii) Status of recommendations: _____ _____ _____			

II-8. Safety operations — technical

a)	Does the radiation protection officer (RPO) have adequate knowledge and expertise?		Yes	No
b)	Does the RPO have qualified experts available?		Yes	No
c)	Is the RPO knowledgeable about the requirements of the regulatory authority and the provisions of the certificate of authorization?		Yes	No
d)	Is the RPO given sufficient time and resources to do the job (e.g. not kept too busy with other assignments or given insufficient technical and secretarial help)?		Yes	No
e)	Does RPO maintains knowledge of activities of workers using radiation sources?		Yes	No
f)	Does the RPO conduct initial and periodic training of workers?		Yes	No
g)	Does the RPO maintain adequate records to demonstrate worker and public protection?		Yes	No
h)	Are there provisions for inventory of sources and accountability:	procedures? performed?	Yes Yes	No No
i)	Are there provisions for audits and reviews of radiation safety program:	procedures? Performed?	Yes Yes	No No

II-9. Safety assessment and quality assurance

a)	Were there any incidents or accidents?		Yes	No
b)	If so, were incident and accident investigation reports prepared?		Yes	No
c)	Were safety assessments reviewed or made based on lessons learned from any accident or accidents at similar facilities?		Yes	No
d)	Is there a written quality assurance program?	procedures? performed?	Yes Yes	No No
e)	Is maintenance and repair work in accordance with manufacturer's recommendations?	scheduled? Performed?	Yes Yes	No No
f)	Are repair/maintenance procedures?	Developed? Followed?-	Yes Yes	No No

III-VERIFICATION OF WORKER PROTECTION

BSS requirements related to this section may be found in Appendix I "Occupational Exposure".

III-1. Classification of areas

a)	Are controlled areas demarcated?		Yes	No
b)	Are approved signs at access points?	provided? legible? Local language?	Yes Yes Yes	No No No
c)	Is radiation source storage at a physically defined location (e.g. pit, hot cell, room)?		Yes	No
	i) locked/secured location with key control?		Yes	No
	ii) radiation warning notices?	provided? legible? Local language?	Yes Yes Yes	No No No
	iii) proper shielding (e.g. individual containers, enclosure)?		Yes	No
	iv) reserved only for radiation sources?		Yes	No
d)	Are X ray generators labelled as a source of radiation:	provided? legible? local language?	Yes Yes Yes	No No No

e)	Are gamma radiography devices labelled as a source of radiation:	provided? legible? local language?	Yes Yes Yes	No No No
f)	Are supervised areas demarcated?		Yes	No
g)	Are approved signs at access points?	needed? provided? legible? local language?	Yes Yes Yes Yes	No No No No

III-2. Local rules and supervision

a)	Are rules established in writing, in a local language?		Yes	No
b)	Do rules include investigation levels and authorised levels and the procedure to be followed when a level is exceeded?		Yes	No
c)	Are workers instructed in the implementing procedures?		Yes	No
d)	Is radiography done in accordance with prescribed operating procedures and conditions?		Yes	No
e)	Do workers have adequate supervision to ensure rules, procedures, protective measures and safety provisions are followed?		Yes	No
f)	Specifically, are operating and working procedures for:			
	i) entry into the shielded enclosure	provided? adequate? followed?	Yes Yes Yes	No No No
	ii) set-up of exposures (radiation source output beam direction, use of collimators, beam height):	provided? adequate? followed?	Yes Yes Yes	No No No
	iii) responding to alarms	provided? adequate? followed?	Yes Yes Yes	No No No
	iv) performing repairs to and maintenance of safety systems	provided? adequate? followed?	Yes Yes Yes	No No No
	v) making surveys	provided? adequate? followed?	Yes Yes Yes	No No No
	vi) safely storing sources	provided? adequate? followed?	Yes Yes Yes	No No No

III-3. Monitoring

a)	Does the authorised organisation provide personal dosimeters?	Yes	No
b)	Are the dosimeters:		
	i) Worn properly?	Yes	No
	ii) Calibrated?	Yes	No
	iii) Exchanged at required frequency?	Yes	No
c)	Are personnel exposures within limits?	Yes	No
d)	Area and portable survey instruments		
	i) Appropriate?	Yes	No
	ii) Calibrated?	Yes	No
	iii) Operational?	Yes	No
	iv) Operational check performed before use?	Yes	No
	v) Spare batteries available?	Yes	No
e)	Do the authorised organisation's surveys indicate that the radiation room shielding is adequate and the dose rates around the room meet authorised radiation levels?	Yes	No
f)	Does the authorised organisation make periodic tests for leakage of radioactive materials from sealed sources?	Yes	No
g)	Is the instrumentation:		
	i) Appropriate?	Yes	No

ii) Calibrated?	Yes	No
iii) Operational?	Yes	No
Record independent measurements made during the inspection: _____ _____ _____		
Type/model no. of survey meter:		
Date last calibrated:		
Do the inspector's independent surveys agree with the survey results of the authorised organisation?	Yes	No
Document any significant differences and any agreed upon plan to resolve the different results: _____ _____ _____ _____		

IV-VERIFICATION OF PUBLIC PROTECTION

BSS requirements related to this section may be found in Appendix III "Public Exposure".

IV-1. Control of visitors

a) Are visitors accompanied in controlled area?	Yes	No
b) Is adequate information provided to visitors entering controlled areas?	Yes	No
c) Are there adequate controls over entries into supervised areas and appropriate postings?	Yes	No

IV-2. Sources of exposure

a) Are the shielding and other protective measures optimised for restricting public exposure to external sources of radiation?	Yes	No
b) Are the floor plans and arrangement of equipment as described in the application and appropriate considering any public areas adjacent to the installation?	Yes	No
c) Have provisions been made to detect and control contamination in the event of a leaking source?	Yes	No

IV-3. Radioactive waste and discharges

a) Have provisions been made to transfer sources to an appropriate registrant or licensee or to an authorised waste disposal facility at the end of use?	Yes	No
b) If sources are no longer in use and being stored, does the authorised organisation have a plan for timely transfer or disposal of the sources?	Yes	No
c) Are there provisions for control of discharges to the environment in the event of contamination or leakage from a sealed source?	Yes	No

IV-4. Monitoring of public exposure

d) Are routine periodic measurements of exposure rates in public areas adjacent to controlled and supervised areas made by the staff or qualified expert?	Yes	No
e) Do surveys shows that the enclosure shielding is adequate and the dose rates outside the controlled and supervised areas meet authorised radiation levels?	Yes	No
f) Record independent measurements made during the inspection: _____ _____ _____		
Type/model no. of survey meter:		
_____ _____		
Date last calibrated:		

Are the inspector's independent measurements in agreement with the organisations routine measurements?	Yes	No
Document any significant differences and any agreed upon plan to resolve the different results: _____ _____ _____		

V-EMERGENCY PREPAREDNESS

BSS requirements related to this section may be found in Appendix V "Emergency Exposure Situations".

V-1. Emergency plan

a) Is there a written plan?	Yes	No
b) Is the plan periodically reviewed and updated?	Yes	No
c) Does the plan take into account lessons learned from operating experience and accidents at similar facilities?	Yes	No
d) Do the procedures include recovery of radiation sources that fail return to the shielded storage device when the source drive mechanism is operated?	Yes	No
e) Is appropriate emergency equipment available (e.g. handling tongs)?	Yes	No

V-2. Training and exercises

a) Have workers involved in implementing the plan received training?	Yes	No
b) Have provisions been made for the plan to be rehearsed at suitable intervals in conjunction with any designated emergency response authorities?	Yes	No
c) Date of the last rehearsal: _____		

VI-RECORDS

Note: *Records will be needed as part of the assessments and verifications outlined in the prior sections of the checklist. This list is a reminder of the type of records that may be helpful. The appearance of the list at the end of the checklist does not indicate that records review is the last item to be done. Rather, an inspection may begin with an entrance interview and facility tour followed by an initial review of some of the records listed below.*

a) Copy of authorization certificate
b) System of records management
c) Dosimetry
   i) current
   ii) prior work history
d) Area surveys
e) Instrument tests and calibrations
f) Tests for leakage of radioactive material from sources
g) Inventory of sources and accountability
h) Audits and reviews of radiation safety programme
i) Incident and accident investigation reports
j) Maintenance and repair work
k) Facility modifications
l) Training provided
   i) initial
   ii) refresher
m) Evidence of health surveillance
n) Waste disposals
o) Transportation
   i) package documentation
   ii) package surveys
   iii) transfer/receipt documents
   iv) details of shipments dispatched

Example II.C

CHECKLIST FOR COMMISSIONING AND REGULAR INSPECTION OF INDUSTRIAL RADIOGRAPHY WITH MOBILE DEVICES

Prepare a visit agenda to review the operating program with details contained in the application for authorization, the authorization certificate, prior programme review/inspection reports and their implementation, relevant correspondence, and other relevant documentation such as dosimetry reports. (References to appropriate sections and appendices of Safety Series No. 115, "International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources" (BSS), are provided at the beginning of Sections II–VI.)

Check the following for compliance with the authorization and with the regulatory authority requirements.

I-IDENTIFYING INFORMATION

I-1. Name of the institution: _____
_____

I-2. Address of facility: _____
_____
_____
_____

I-3. Telephone/facsimile/e-mail: Voice: _____ Fax: _____
e-mail: _____

I-4. Authorization number: _____

I-5. Name and qualification of the radiation protection officer:
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____

I-6. Name and qualifications of any qualified experts retained:

Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____

Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____

Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____

I-7. Name and title of the responsible representative of the legal person: _____
_____

II-VERIFICATION OF SAFETY

BSS requirements related to this section may be found in Appendix IV "Potential Exposure: Safety of Sources

II-1. Sealed source radiographic devices

Manufacturer	Device model number	Source model number	Radionuclide	Source supplier	Maximum activity	Number of devices
(e.g. ABC Co.)	(e.g. Model A)	(e.g. Model B)	(e.g. ^{192}Ir)		(e.g. 2 TBq)	(e.g. 8)

Compare the radiographic devices and sources with application descriptions and design specification. Note any differences and determine the standards to which sources and/or devices were built:

_____
_____
_____
_____

II-2. X ray generators

Manufacturer	Model number	Serial number	Maximum voltage	Maximum current
(e.g. ABXY Co.)	(e.g. Unit 123)	(e.g. 99999)	(e.g. 150 kV)	(e.g. 40 mA)

Compare the X ray generator with application descriptions and design specifications. Note any differences and determine the standards to which devices were built:

_____
_____
_____
_____

II-3. Storage design

Describe any differences or modifications from those approved by the regulatory authority and considered in the safety assessment (e.g. shielding design, building materials, installed fire protection and controls, etc.):

_____
_____
_____

a)	Was a safety assessment by a qualified expert performed prior to any modifications?		Yes	No
b)	Is protection of the sources and X ray generators from adverse environmental conditions (heat, moisture, etc.):	provided? working?	Yes Yes	No No
c)	Is fire detection and protection in the radiation and source storage areas:	provided? working?	Yes Yes	No No

II-4. Safety controls system

a)	Are the safety controls for radiographic operations and storage of radiation sources as described in the application approved by the regulatory authority?		Yes	No
b)	If not, was a safety assessment by a qualified expert performed prior to any modifications?		Yes	No
c)	Are gamma radiographic devices and X ray generators labelled as sources of radiation	provided? legible? local language?	Yes Yes Yes	No No No
d)	Are mechanical controls to prevent unintentional source exposure (e.g. keyed locks, source wind-out mechanisms, shutters):	provided? working?	Yes Yes	No No
e)	Are portable radiation monitors for radiographic operations:	provided? required? working?	Yes Yes Yes	No No No
f)	Are adequate controls of the production of radiation by X ray generators (e.g. timer, voltage, current):	provided? working?	Yes Yes	No No
g)	If radioactive source(s) are transported, do the container(s) satisfy the requirements for type A or type B package(s):		Yes	No

II-5. Warning systems

a)	Are separate and distinctive warning signals (e.g. visible and/or audible) provided for:			
	i) radioactive source about to be exposed/radiation about to be generated	provided? working?	Yes Yes	No No
	ii) radioactive source exposed/radiation 'ON'	provided? working?	Yes Yes	No No
	iii) radioactive source safe/radiation 'OFF'	provided? working?	Yes Yes	No No
b)	Are portable warning notices (e.g. written signs, posters):	provided? legible? local language?	Yes Yes Yes	No No No

II-6. Safety operations -management

a)	Is management knowledgeable of the certificate of authorization and its restrictions and requirements?		Yes	No
b)	Does management provide adequate staffing levels?		Yes	No
c)	Has management provided the radiation protection officer authority to stop unsafe operations?		Yes	No
d)	Does management provide adequate resources for personnel training (time and money)?		Yes	No
e)	Does management provide adequate equipment?		Yes	No
f)	Does management provide for periodic program reviews and recommendations?	scheduled? performed?	Yes Yes	No No
	i) Date of the last program review: _____ ii) Status of recommendations: _____ _____ _____			

II-7. Safety operations — technical

a)	Does the radiation protection officer (RPO) have adequate knowledge and expertise?	Yes	No
b)	Does the RPO have qualified experts available?	Yes	No
c)	Is the RPO knowledgeable about the requirements of the regulatory authority and the provisions of the certificate of authorization?	Yes	No
d)	Is the RPO given sufficient time and resources to do the job (e.g. not kept too busy with other assignments or given insufficient technical and secretarial help)?	Yes	No
e)	Does RPO maintains knowledge of activities of workers using radiation sources?	Yes	No
f)	Does the RPO audit the performance of radiographers at temporary work sites?	Yes	No

g)	Does the RPO conduct initial and periodic training of workers?		Yes	No
h)	Does the RPO maintain adequate records to demonstrate worker and public protection?		Yes	No
i)	Are there provisions for inventory of sources and accountability:	procedures? performed?	Yes Yes	No No
j)	Are locations and uses of devices recorded including site location, serial numbers of devices, date, name of supervising radiographer?		Yes	No
k)	Are there provisions for audits and reviews of radiation safety program:	procedures? Performed?	Yes Yes	No No

II-8. Safety assessment and quality assurance

a)	Were there any incidents or accidents?		Yes	No
b)	If so, were incident and accident investigation reports prepared?		Yes	No
c)	Were safety assessments reviewed or made based on lessons learned from any accident or accidents at similar facilities?		Yes	No
d)	Is there a written quality assurance program?	procedures? performed?	Yes Yes	No No
e)	Is maintenance and repair work in accordance with manufacturer's recommendations?	scheduled? performed?	Yes Yes	No No
f)	Are repair/maintenance procedures?	developed? followed?-	Yes Yes	No No

III-VERIFICATION OF WORKER PROTECTION

BSS requirements related to this section may be found in Appendix I "Occupational Exposure".

III-1. Classification of areas

a)	Are controlled areas demarcated?		Yes	No
b)	Are approved signs at access points?	provided? legible? local language?	Yes Yes Yes	No No No
c)	Is radiation source storage at a physically defined location (e.g. pit, hot cell, room)?		Yes	No
	i) locked/secured location with key control?		Yes	No
	ii) radiation warning notices?	provided? legible? local language?	Yes Yes Yes	No No No
	iii) proper shielding (e.g. individual containers, enclosure)?		Yes	No
	iv) reserved only for radiation sources?		Yes	No
d)	Are X ray generators labelled as a source of radiation:	provided? legible? local language?	Yes Yes Yes	No No No
e)	Are gamma radiography devices labelled as a source of radiation:	provided? legible? local language?	Yes Yes Yes	No No No
f)	Are supervised areas demarcated?		Yes	No
g)	Are approved signs at access points?	needed? provided? legible? local language?	Yes Yes Yes Yes	No No No No

III-2. Local rules and supervision

a)	Are rules established in writing, in a local language?			Yes	No
b)	Do rules include investigation levels and authorised levels and the procedure to be followed when a level is exceeded?			Yes	No
c)	Are workers instructed in the implementing procedures?			Yes	No
d)	Is radiography done in accordance with prescribed operating procedures and conditions?			Yes	No
e)	Do workers have adequate supervision to ensure rules, procedures, protective measures and safety provisions are followed?			Yes	No
f)	Specifically, are operating and working procedures for:				
	i)	setting up controlled areas; including barriers, surveillance and posting at temporary job sites	provided? adequate? followed?	Yes Yes Yes	No No No
	ii)	set-up of exposures (radiation source output beam direction, use of collimators, beam height):	provided? adequate? followed?	Yes Yes Yes	No No No
	iii)	use of personal dosimetry and use of protective equipment such as alarming rate dosimeters:	provided? adequate? followed?	Yes Yes Yes	No No No
	iv)	performing routine maintenance of cables, connectors, etc.:	provided? adequate? followed?	Yes Yes Yes	No No No
	v)	making surveys	provided? adequate? followed?	Yes Yes Yes	No No No
	vi)	appropriate response to failure of a source to retract or other incident:	provided? adequate? followed?	Yes Yes Yes	No No No
	vii)	safely storing sources	provided? adequate? followed?	Yes Yes Yes	No No No

III-3. Monitoring

a)	Does the authorised organisation provide personal dosimeters?		Yes	No
b)	Are the dosimeters:			
	i)	Worn properly?	Yes	No
	ii)	Calibrated?	Yes	No
	iii)	Exchanged at required frequency?	Yes	No
c)	Are personnel exposures within limits?		Yes	No
d)	Area and portable survey instruments			
	i)	Appropriate?	Yes	No
	ii)	Calibrated?	Yes	No
	iii)	Operational?	Yes	No
	iv)	Operational check performed before use?	Yes	No
	v)	Spare batteries available?	Yes	No
e)	Do the authorised organisation's surveys indicate that the radiation room shielding is adequate and the dose rates around the room meet authorised radiation levels?		Yes	No
f)	Does the authorised organisation make periodic tests for leakage of radioactive materials from sealed sources?		Yes	No
g)	Is the instrumentation:			
	i)	Appropriate?	Yes	No
	ii)	Calibrated?	Yes	No
	iii)	Operational?	Yes	No

Record independent measurements made during the inspection:

_____

_____

_____

_____

Type/model no. of survey meter:		
Date last calibrated:		
Do the inspector's independent surveys agree with the survey results of the authorised organisation?	Yes	No
Document any significant differences and any agreed upon plan to resolve the different results: _____ _____ _____ _____		

IV-VERIFICATION OF PUBLIC PROTECTION

BSS requirements related to this section may be found in Appendix III "Public Exposure".

IV-1. Control of visitors

a)	Are visitors accompanied in controlled area?	Yes	No
b)	Is adequate information provided to visitors entering controlled areas?	Yes	No
c)	Are there adequate controls over entries into supervised areas and appropriate postings?	Yes	No

IV-2. Sources of exposure

a)	Are the shielding and other protective measures optimised for restricting public exposure to external sources of radiation?	Yes	No
b)	Are the floor plans and arrangement of equipment as described in the application and appropriate considering any public areas adjacent to the installation?	Yes	No
c)	Have provisions been made to detect and control contamination in the event of a leaking source?	Yes	No

IV-3. Radioactive waste and discharges

a)	Have provisions been made to transfer sources to an appropriate registrant or licensee or to an authorised waste disposal facility at the end of use?	Yes	No
b)	If sources are no longer in use and being stored, does the authorised organisation have a plan for timely transfer or disposal of the sources?	Yes	No
c)	Are there provisions for control of discharges to the environment in the event of contamination or leakage from a sealed source?	Yes	No

IV-4. Monitoring of public exposure

a)	Are routine periodic measurements of exposure rates in public areas adjacent to controlled and supervised areas made by the staff or qualified expert?	Yes	No
b)	Do surveys shows that the enclosure shielding is adequate and the dose rates outside the controlled and supervised areas meet authorised radiation levels?	Yes	No
c)	Record independent measurements made during the inspection: _____ _____ _____ _____		
Type/model no. of survey meter:			
Date last calibrated:			
Are the inspector's independent measurements in agreement with the organisations routine measurements?		Yes	No
Document any significant differences and any agreed upon plan to resolve the different results: _____ _____ _____ _____			

V-EMERGENCY PREPAREDNESS

BSS requirements related to this section may be found in Appendix V "Emergency Exposure Situations".

V-1. Emergency plan

a)	Is there a written plan?	Yes	No
b)	Is the plan periodically reviewed and updated?	Yes	No
c)	Does the plan take into account lessons learned from operating experience and accidents at similar facilities?	Yes	No
d)	Do the procedures include recovery of radiation sources that fail return to the shielded storage device when the source drive mechanism is operated?	Yes	No
e)	Is appropriate emergency equipment available (e.g. handling tongs)?	Yes	No

V-2. Training and exercises

a)	Have workers involved in implementing the plan received training?	Yes	No
b)	Have provisions been made for the plan to be rehearsed at suitable intervals in conjunction with any designated emergency response authorities?	Yes	No
c)	Date of the last rehearsal:		

VI-RECORDS

Note: *Records will be needed as part of the assessments and verifications outlined in the prior sections of the checklist. This list is a reminder of the type of records that may be helpful. The appearance of the list at the end of the checklist does not indicate that records review is the last item to be done. Rather, an inspection may begin with an entrance interview and facility tour followed by an initial review of some of the records listed below.*

a) Copy of authorization certificate
b) System of records management
c) Dosimetry
   i) current
   ii) prior work history
d) Area surveys
e) Instrument tests and calibrations
f) Tests for leakage of radioactive material from sources
g) Inventory of sources and accountability
h) Audits and reviews of radiation safety programme
i) Incident and accident investigation reports
j) Maintenance and repair work
k) Facility modifications
l) Training provided
   i) initial
   ii) refresher
m) Evidence of health surveillance
n) Waste disposals
o) Transportation
   i) package documentation
   ii) package surveys
   iii) transfer/receipt documents
   iv) details of shipments dispatched
p) Log of off site operations
   i) location
   ii) name of responsible radiographer
   iii) date

BIBLIOGRAPHY TO ANNEX II

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INTERNATIONAL ATOMIC ENERGY AGENCY, Emergency Planning and Preparedness for Accidents Involving Radioactive Materials Used in Medicine, Industry, Research and Teaching, Safety Series No. 91, IAEA, Vienna (1989).

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INTERNATIONAL ATOMIC ENERGY AGENCY, Practical Radiation Safety Manual on Gamma Radiography, IAEA, Vienna (1991).

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Annex III

SAFETY ASSESSMENT PLANS FOR WELL LOGGING, PORTABLE GAUGING, DETECTION AND ANALYTICAL DEVICES

This annex has two exhibits which include an application form and a checklist for inspection:

(1) Example III.A: Application for authorization and review plan for well logging, portable gauging, detection and analytical devices.

(2) Example III.B: Checklist for commissioning and regular inspections of well logging, portable gauging, detection and analytical devices.

References that may be useful to the regulatory authority and/or to licensees and registrants are listed in the bibliography at the end of the annex. The list is divided into references generally applicable for radiation safety and protection and that which may have particular relevance to well logging, portable gauging, detection or analytical devices.

Example III.A

APPLICATION FOR AUTHORIZATION AND REVIEW PLAN FOR WELL LOGGING, PORTABLE GAUGING, DETECTION AND ANALYTICAL DEVICES

TYPE OF AUTHORIZATION

_____ New application
_____ Amendment to existing authorization number: _____
_____ Renewal of authorization number: _____

PURPOSE OF APPLICATION

_____ Construction (Complete Sections I through III)
_____ Import/Purchase (Complete Sections I and II)
_____ Use/Begin operation (Complete Sections I through IV)

You may refer to previous submissions by date and application or authorization number(s)

The legal person who will be responsible for using any sealed source or radiation generator must, unless the source is exempted, submit the following information to the regulatory authority.

I-GENERAL INFORMATION

I-1. Name and address of organisation:

Main address	Mailing address (if different)	Address of use (if different)
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

I-2. Name and information about qualified experts:

Expertise: Radiation protection officer
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____
Telephone number: _____

Expertise: _____
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____
_____

I-3. The responsible representative of the legal person:

Name: _____ Telephone number _____
Title: _____ Facsimile number _____
e-mail address _____

I-4. Proposed date of installation and/or commissioning of facilities and equipment:

_____

SIGNATURE AND CERTIFICATION

_____
Signature of the authorised representative
of the legal person

Title: _____

Date**:** _____

Notes:

1. The regulatory authority may require additional information to fully consider this application prior to issuing an authorization.

2. In the event that all the above information is not available at the time of application, the regulatory authority may issue an authorization limiting the applicant to import, acquire, or store radiation sources, or construct facilities. Complete information will be required from the applicant prior to authorising use of the radiation sources.

II-EQUIPMENT

II-1. Equipment with sealed sources incorporated

Description:	Radionuclide	Maximum activity	Number
Manufacturer: ____________________ Radiation type (alpha, beta, gamma, neutron): __________ Model no. device: __________ Source: __________ Serial no. device: __________ Source: __________			
Manufacturer: ____________________ Radiation type (alpha, beta, gamma, neutron): __________ Model no. device: __________ Source: __________ Serial no. device: __________ Source: __________			
Manufacturer: ____________________ Radiation type (alpha, beta, gamma, neutron): __________ Model no. device: __________ Source: __________ Serial no. device: __________ Source: __________			
Manufacturer: ____________________ Radiation type (alpha, beta, gamma, neutron): __________ Model no. device: __________ Source: __________ Serial no. device: __________ Source: __________			
Manufacturer: ____________________ Radiation type (alpha, beta, gamma, neutron): __________ Model no. device: __________ Source: __________ Serial no. device: __________ Source: __________			
Manufacturer: ____________________ Radiation type (alpha, beta, gamma, neutron): __________ Model no. device: __________ Source: __________ Serial no. device: __________ Source: __________			
Manufacturer: ____________________ Radiation type (alpha, beta, gamma, neutron): __________ Model no. device: __________ Source: __________ Serial no. device: __________ Source: __________			
Manufacturer: ____________________ Radiation type (alpha, beta, gamma, neutron): __________ Model no. device: __________ Source: __________ Serial no. device: __________ Source: __________			

II-2. Neutron generators — accelerator

Manufacturer:	Model number	Serial number	Neutron energy	Target nuclide

II-3. Standards and classification

a) Are the sources manufactured, prototype tested, and subject to quality control provisions of standards recognised by national or international standard setting organisations (e.g. ISO 2919)? If, so please list and identify the standards and any applicable classification numbers.

____

____

b) Is each device that emits radiation manufactured, prototype tested, and subject to quality control provisions of standards recognised by national or international standard setting organisations (e.g. IEC)? If, so please list and identify the standards and any applicable classification numbers.

_____
_____
_____
_____
_____

II-4. Storage locations:

Will the sources be stored for long periods of time at any address other than given in item I-1. above? (Circle correct answer)	Do not know	Yes	No

(Note: that the regulatory authority may require notification prior to permitting long term storage at currently unknown addresses)

List all other known addresses:

_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

III-FACILITIES

In an attachment to this application, describe the storage facilities, including:

III-1. Location of the primary storage facility
Provide a detailed location of the facility.

III-2. Layout of the facility
Describe factors such as the layout of the facility and its immediate surroundings, building materials, alarms, shielding, engineering controls such as interlock and warning safety devices, remote handling tools and provisions for security.

III-3. Safety assessments
Taking account of shielding provide calculations of maximum dose rates (specifying all assumptions e.g. number of sources, activity):

a) in all areas outside the storage area; and
b) around the equipment during normal operating conditions.

Provide estimates of the magnitude of expected doses to persons during normal operations. Identify the probability and magnitude of potential exposures arising from accidents or incidents.

IV-RADIATION PROTECTION AND SAFETY PROGRAMME

In an attachment to this application, describe the radiation protection programme, including:

IV-1. Organisational structure

a) Describe your organisational and management control systems, including assignment of responsibilities and clear lines of authority related to radiation safety. In particular include: staffing levels, equipment selection, other assignments of the radiation protection officer, authority of the radiation protection officer to stop unsafe operations, personnel training, maintenance of records, and how problems affecting safety are identified and corrected.
b) Identify the authorised users, qualified experts, and radiation protection officer by name and include their training, education, experience and qualifications. (Note: the authorised user and/or radiation protection officer may be the same individual).

c) Confirm that training will include: explanation of radiation hazards and effects, explanation of written procedures, use of equipment (e.g. instrumentation), meaning of warning signals, and a method to confirm adequacy of training (testing or demonstrations).

IV-2. Workplace monitoring, area classification and individual monitoring

a) Describe your programme for monitoring the workplace (BSS, I.37-I.40), including: the quantities to be measured, where and when the measurements are to be made, the measurement methods and procedures, and reference levels and the actions to be taken if they are exceeded.
b) Describe your policies and procedures for classification of controlled and supervised areas. (BSS, I.21-I.25).
c) Describe personal dosimeters provided to workers and your policies for assigning dosimetry to individual workers (BSS, I.32-I.36). Describe your policy for reviewing individual doses, including reference levels and actions to be taken in exceeded.
   Name and address of dosimetry service: _____
   _____
   _____
   _____
   Denote type:
   i) Film _____
   ii) ThermoLuminescent dosimeter (TLD)_____
   iii) Direct reading dosimeter (DRD) _____
   iv) other: _____

IV-3. Local rules and supervision

a) Describe your local rules and procedures regarding: investigation or authorised levels, protective measures and safety provisions, providing adequate supervision, providing workers information regarding health risks due to occupational exposure, and emergency planning instruction (BSS, I.26-I.27).
b) Provide copies of your operating and safety procedures including: area access control, entry procedures into shielded enclosures, source inventory and leak testing, etc.
c) Describe your training program to ensure all appropriate personnel are adequately trained in the operating procedures and how their actions may affect safety (BSS, I.27).
d) Describe your policies regarding female workers who become pregnant (notification, adoption of working conditions to protect foetus/embryo) and the instructions you will provide to them (BSS, I.16-I.17 and I.27).
e) Describe your programme of health surveillance based on general principles of occupational health and designed to assess the initial and continuing fitness of workers for their intended tasks (BSS, I.41-I.43).

IV-4. Quality assurance

a) Describe your programme for ensuring that regulatory radiation safety requirements are addressed and satisfied.
b) Describe your program to periodically review procedures, maintain procedures current and available, and your procedure modification process.
c) Describe your programme for optimising occupational and public exposures to levels as low as reasonably achievable.
d) Describe your programme of periodic maintenance and testing (logging tools, radiation meters, ancillary equipment, etc.). Attach the manufacturers instructions.
e) Describe service arrangements with other organisations and qualified experts.

IV-5. Transportation of radioactive material

If you will be transporting or shipping new or used sources, describe your arrangements for preparation and transport of packages containing radioactive sources (IAEA Safety Standards Series No. ST-1). These procedures should address: documentation of package certification, package surveys, transfer/receipt documents, and details of shipments preparation.

IV-6. Emergency procedures

Provide your emergency procedures to address emergencies such as potential damage to the source, loss of source shielding, stuck sources or substantial accidental exposure of an individual. If other emergencies are envisaged, please provide additional appropriate emergency procedures. In all cases the magnitude of the hazard should be evaluated. Any off-site consequences should also be evaluated. Local emergency services (e.g. fire, police) may need to be provided with copies of the emergency procedures.

IV-7. Transfer or disposal of radioactive sources

Describe arrangements for transfer or disposal of spent radioactive sources.

IV-8. System of records (BSS; 2.40, I.44-I.49)**, including:**

a) Disposal of spent sources.
b) Personnel exposure
   i) current records
   ii) prior work history
c) Area surveys
   i) dose or dose rate
   ii) contamination
d) Instrument tests and calibrations
e) Tests for radioactive sealed source leakage.
f) Inventory of sources and accountability
g) Audits and reviews of radiation safety program
h) Incident and accident investigation reports
i) Maintenance and repair work
j) Facility modifications
k) Training provided
l) Evidence of health surveillance of workers
m) Transportation.

Example III.B

CHECKLIST FOR COMMISSIONING AND REGULAR INSPECTION OF WELL LOGGING AND PORTABLE DEVICES FOR GAUGING, DETECTING, AND ANALYSIS

Prepare a visit agenda to review the operating program with details contained in the application for authorization, the authorization certificate, prior programme review/inspection reports and their implementation, relevant correspondence, and other relevant documentation such as dosimetry reports. (References to appropriate sections and appendices of Safety Series No. 115, "International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources" (BSS), are provided at the beginning of Sections II–VI.)

Check the following for compliance with the authorization and with the regulatory authority requirements.

I-IDENTIFYING INFORMATION

I-1. Name of the institution: _____
_____

I-2. Address of facility: _____
_____
_____
_____

I-3. Telephone/facsimile/e-mail: Voice: _____ Fax: _____
e-mail: _____

I-4. Authorization number: _____

I-5. Name and qualification of the radiation protection officer:
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____

I-6. Name and qualifications of any qualified experts retained:

Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____

Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____

Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____

I-7. Name and title of the responsible representative of the legal person: _____
_____

II-VERIFICATION OF SAFETY

BSS requirements related to this section may be found in Appendix IV "Potential Exposure: Safety of Sources

II-1. Equipment with sealed sources incorporated

Description:	Radionuclide	Maximum activity	Number
Manufacturer: ____________ Radiation type (alpha, beta, gamma, neutron): ____________ Model no. device: ____________ Source: ____________ Serial no. device: ____________ Source: ____________			
Manufacturer: ____________ Radiation type (alpha, beta, gamma, neutron): ____________ Model no. device: ____________ Source: ____________ Serial no. device: ____________ Source: ____________ .			
Manufacturer: ____________ Radiation type (alpha, beta, gamma, neutron): ____________ Model no. device: ____________ Source: ____________ Serial no. device: ____________ Source: ____________			
Manufacturer: ____________ Radiation type (alpha, beta, gamma, neutron): ____________ Model no. device: ____________ Source: ____________ Serial no. device: ____________ Source: ____________			
Manufacturer: ____________ Radiation type (alpha, beta, gamma, neutron): ____________ Model no. device: ____________ Source: ____________ Serial no. device: ____________ Source: ____________			
Manufacturer: ____________ Radiation type (alpha, beta, gamma, neutron): ____________ Model no. device: ____________ Source: ____________ Serial no. device: ____________ Source: ____________			
Manufacturer: ____________ Radiation type (alpha, beta, gamma, neutron): ____________ Model no. device: ____________ Source: ____________ Serial no. device: ____________ Source: ____________			
Manufacturer: ____________ Radiation type (alpha, beta, gamma, neutron): ____________ Model no. device: ____________ Source: ____________ Serial no. device: ____________ Source: ____________			
Compare the equipment and sources with application descriptions and design specifications. Note any differences and determine the standards to which sources and/or devices were built: ____________ ____________ ____________ ____________			

II-2. Neutron generators — accelerator

Manufacturer	Model number	Serial number	Neutron energy	Target nuclide

Compare the neutron generator with application descriptions and design specifications. Note any differences and determine the standards to which devices were built:

_____
_____
_____
_____

II-3. Storage design

Describe any differences or modifications from those approved by the regulatory authority and considered in the safety assessment (e.g. shielding design, building materials, installed fire protection and controls, etc.):

_____
_____
_____

a)	Was a safety assessment by a qualified expert performed prior to any modifications?		Yes	No
b)	Is protection of the sources and generators from adverse environmental conditions (heat, moisture, etc.):	provided? working?	Yes Yes	No No
c)	Is fire detection and protection in the radiation and source storage areas:	provided? working?	Yes Yes	No No

II-4. Safety controls system

a)	Are the safety controls for radiographic operations and storage of radiation sources as described in the application approved by the regulatory authority?		Yes	No
b)	If not, was a safety assessment by a qualified expert performed prior to any modifications?		Yes	No
c)	Are gamma devices and neutron generators labelled as sources of radiation	provided? legible? local language?	Yes Yes Yes	No No No
d)	Are mechanical controls to prevent unintentional source exposure (e.g. keyed locks, shutters, etc.):	provided? working?	Yes Yes	No No
e)	Are portable radiation monitors for operations:	provided? required? working?	Yes Yes Yes	No No No
f)	Are adequate controls of the production of radiation by neutron generators (e.g. timer, voltage, current):	provided? working?	Yes Yes	No No

II-5. Warning systems

a)	If appropriate, are signals (e.g. visible and/or audible) provided for:			
	i) source exposure	provided? working?	Yes Yes	No No
	ii) neutron generator power on	provided? working?	Yes Yes	No No
b)	Are warning notices (e.g. written signs, posters):	provided? legible? local language?	Yes Yes Yes	No No No

II-6. Safety operations — management

a)	Is management knowledgeable of the certificate of authorization and its restrictions and requirements?		Yes	No
b)	Does management provide adequate staffing levels?		Yes	No
c)	Has management provided the radiation protection officer authority to stop unsafe operations?		Yes	No
d)	Does management provide adequate resources for personnel training (time and money)?		Yes	No
e)	Does management provide adequate equipment?		Yes	No
f)	Does management provide for periodic program reviews and recommendations?	scheduled? performed?	Yes Yes	No No

i) Date of the last program review: _____

ii) Status of recommendations:

_____

_____

_____

II-7. Safety operations — technical

a)	Does the radiation protection officer (RPO) have adequate knowledge and expertise?		Yes	No
b)	Does the RPO have qualified experts available?		Yes	No
c)	Is the RPO knowledgeable about the requirements of the regulatory authority and the provisions of the certificate of authorization?		Yes	No
d)	Is the RPO given sufficient time and resources to do the job (e.g. not kept too busy with other assignments or given insufficient technical and secretarial help)?		Yes	No
e)	Does RPO maintains knowledge of activities of workers using radiation sources?		Yes	No
f)	Does the RPO audit the performance of workers at temporary work sites?		Yes	No
g)	Does the RPO conduct initial and periodic training of workers?		Yes	No
h)	Does the RPO maintain adequate records to demonstrate worker and public protection?		Yes	No
i)	Are there provisions for inventory of sources and accountability:	procedures? performed?	Yes Yes	No No

II-8. Investigations and quality assurance

a)	Were there any incidents or accidents?		Yes	No
b)	If so, were incident and accident investigation reports prepared?		Yes	No
c)	Were safety assessments reviewed or made based on lessons learned from any accident or accidents at similar facilities?		Yes	No
d)	Is there a written quality assurance program?	procedures? performed?	Yes Yes	No No
e)	Is maintenance and repair work in accordance with manufacturer's recommendations?	scheduled? performed?	Yes Yes	No No
f)	Are repair/maintenance procedures?	developed? followed?-	Yes Yes	No No

III-VERIFICATION OF WORKER PROTECTION

BSS requirements related to this section may be found in Appendix I "Occupational Exposure".

III-1. Classification of areas

a)	Are controlled areas demarcated?		Yes	No
b)	Are approved signs at access points?	provided? legible? local language?	Yes Yes Yes	No No No
c)	Is radiation source storage at a physically defined location?		Yes	No
	i) locked/secured location with key control?		Yes	No

ii)	radiation warning notices?	provided? legible? local language?	Yes Yes Yes	No No No
iii)	proper shielding (e.g. individual containers, enclosure)?		Yes	No
iv)	reserved only for radiation sources?		Yes	No
d)	Are neutron generators labelled as a source of radiation:	provided? legible? local language?	Yes Yes Yes	No No No
e)	Are gamma devices labelled as a source of radiation:	provided? legible? local language?	Yes Yes Yes	No No No
f)	Are supervised areas demarcated?		Yes	No
g)	Are approved signs at access points?	needed? provided? legible? local language?	Yes Yes Yes Yes	No No No No

III-2. Local rules and supervision

a)	Are rules established in writing, in a local language?		Yes	No
b)	Do rules include investigation levels and authorised levels and the procedure to be followed when a level is exceeded?		Yes	No
c)	Are workers instructed in the implementing procedures?		Yes	No
d)	Is equipment used in accordance with prescribed operating procedures and conditions?		Yes	No
e)	Do workers have adequate supervision to ensure rules, procedures, protective measures and safety provisions are followed?		Yes	No
f)	Specifically, are operating and working procedures for:			
i)	setting up controlled areas; including barriers, surveillance and posting at temporary job sites	provided? adequate? followed?	Yes Yes Yes	No No No
ii)	set-up of exposures:	provided? adequate? followed?	Yes Yes Yes	No No No
iii)	use of personal dosimetry and use of protective equipment such as alarming rate dosimeters:	provided? adequate? followed?	Yes Yes Yes	No No No
iv)	performing routine maintenance of:	provided? adequate? followed?	Yes Yes Yes	No No No
v)	making surveys	provided? adequate? followed?	Yes Yes Yes	No No No
vi)	appropriate response to equipment damage or inability to retract a source or close a shutter:	provided? adequate? followed?	Yes Yes Yes	No No No
v)	safely storing sources	provided? adequate? followed?	Yes Yes Yes	No No No

III-3. Monitoring

a)	Does the authorised organisation provide personal dosimeters?	Yes	No
b)	Are the dosimeters:		
i)	Worn properly?	Yes	No
ii)	Calibrated?	Yes	No
iii)	Exchanged at required frequency?	Yes	No

c)	Are personnel exposures within limits?	Yes	No
d)	Area and portable survey instruments		
i)	Appropriate?	Yes	No
ii)	Calibrated?	Yes	No
iii)	Operational?	Yes	No
iv)	Operational check performed before use?	Yes	No
v)	Spare batteries available?	Yes	No
e)	Do the authorised organisation's surveys indicate that shielding is adequate and the dose rates around work areas meet authorised radiation levels?	Yes	No
f)	Does the authorised organisation make periodic tests for leakage of radioactive materials from sealed sources?	Yes	No
g)	Is the instrumentation:		
i)	Appropriate?	Yes	No
ii)	Calibrated?	Yes	No
iii)	Operational?	Yes	No

Record independent measurements made during the inspection: _____
_____
_____
_____

Type/model no. of survey meter:

Date last calibrated:

Do the inspector's independent surveys agree with the survey results of the authorised organisation?	Yes	No

Document any significant differences and any agreed upon plan to resolve the different results:
_____
_____
_____

IV-VERIFICATION OF PUBLIC PROTECTION

BSS requirements related to this section may be found in Appendix III "Public Exposure".

IV-1. Control of visitors

a)	Are visitors accompanied in controlled area?	Yes	No
b)	Is adequate information provided to visitors entering controlled areas?	Yes	No
c)	Are there adequate controls over entries into supervised areas and appropriate postings?	Yes	No

IV-2. Sources of exposure

a)	Are the shielding and other protective measures optimised for restricting public exposure to external sources of radiation?	Yes	No
b)	Is the set-up of equipment appropriate considering any public areas adjacent to work sites?	Yes	No
c)	Have provisions been made to detect and control contamination in the event of a leaking source?	Yes	No

IV-3. Radioactive waste and discharges

a)	Have provisions been made to transfer sources to an appropriate registrant or licensee or to an authorised waste disposal facility at the end of use?	Yes	No
b)	If sources are no longer in use and being stored, does the authorised organisation have a plan for timely transfer or disposal of the sources?	Yes	No
c)	Are there provisions for control of discharges to the environment in the event of contamination or leakage from a sealed source?	Yes	No
d)	Are there provisions to provide durable warnings of irretrievable sources abandoned in wells?	Yes	No
e)	Are there provisions to notify appropriate authorities about irretrievable sources abandoned in wells?	Yes	No

IV-4. Monitoring of public exposure

a) Are routine periodic measurements of exposure rates in public areas adjacent to controlled and supervised areas made by the staff or qualified expert?	Yes	No
b) Do surveys shows that the enclosure shielding is adequate and the dose rates outside the controlled and supervised areas meet authorised radiation levels?	Yes	No
c) Record independent measurements made during the inspection: _____ _____ _____ _____		
Type/model no. of survey meter:		
Date last calibrated:		
Are the inspector's independent measurements in agreement with the organisations routine measurements?	Yes	No
Document any significant differences and any agreed upon plan to resolve the different results: _____ _____ _____ _____		

V-EMERGENCY PREPAREDNESS

BSS requirements related to this section may be found in Appendix V "Emergency Exposure Situations".

V-1. Emergency plan

a) Is there a written plan?	Yes	No
b) Is the plan periodically reviewed and updated?	Yes	No
c) Does the plan take into account lessons learned from operating experience and accidents at similar facilities?	Yes	No
d) Do the procedures include recovery of radiation sources that can not be retrieved in a normal manner?	Yes	No
e) Is emergency equipment provided (e.g. handling tongs)?	Yes	No

V-2. Training and exercises

a) Have workers involved in implementing the plan received training?	Yes	No
b) Have provisions been made for the plan to be rehearsed at suitable intervals in conjunction with any designated emergency response authorities?	Yes	No
c) Date of the last rehearsal:		

VI-RECORDS

Note: *Records will be needed as part of the assessments and verifications outlined in the prior sections of the checklist. This list is a reminder of the type of records that may be helpful. The appearance of the list at the end of the checklist does not indicate that records review is the last item to be done. Rather, an inspection may begin with an entrance interview and facility tour followed by an initial review of some of the records listed below.*

a) Copy of authorization certificate
b) System of records management
c) Dosimetry
   i) current
   ii) prior work history
d) Area surveys
e) Instrument tests and calibrations
f) Tests for leakage of radioactive material from sources
g) Inventory of sources and accountability
h) Audits and reviews of radiation safety programme

i) Incident and accident investigation reports
j) Maintenance and repair work
k) Facility modifications
l) Training provided
    i) initial
    ii) refresher
m) Evidence of health surveillance
n) Waste disposals
o) Transportation
    i) package documentation
    ii) package surveys
    iii) transfer/receipt documents
    iv) details of shipments dispatched
p) Log of off site operations
    i) location
    ii) name of responsible person
    iii) date

BIBLIOGRAPHY TO ANNEX III

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Annex IV

SAFETY ASSESSMENT PLANS FOR FIXED (INSTALLED) GAUGING, DETECTION AND OTHER DEVICES

This Annex has two exhibits which include an application form and a checklist for inspection:

(1) Example IV.A: Application for authorization for fixed (installed) gauging, detection and other devices.

(2) Example IV.B: Checklist for commissioning and regular inspections of fixed (installed) gauging, detection and other devices.

References that may be useful to the regulatory authority and/or to licensees and registrants are listed in the bibliography at the end of the annex. The list is divided into references generally applicable for radiation safety and protection and that which may have particular relevance to fixed (installed) gauging, detection and other devices.

Example IV.A

APPLICATION FOR AUTHORIZATION FOR FIXED (INSTALLED) GAUGING, DETECTION AND OTHER DEVICES

TYPE OF AUTHORIZATION

_____ New application
_____ Amendment to existing authorization number: _____
_____ Renewal of authorization number: _____

PURPOSE OF APPLICATION

_____ Construction (Complete Sections I through III)
_____ Import/Purchase (Complete Sections I and II)
_____ Use/Begin operation (Complete Sections I through IV)

You may refer to previous submissions by date and application or authorization number(s)

The legal person who will be responsible for using any sealed source or radiation generator must, unless the source is exempted, submit the following information to the regulatory authority.

I-GENERAL INFORMATION

I-1. Name and address of organisation:

Main address	Mailing address (if different)	Address of use (if different)
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

I-2. Name and information about qualified experts:

Expertise: radiation protection officer
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____
Telephone number: _____

Expertise: _____
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____
_____

I-3. The responsible representative of the legal person:

Name: _____
Title: _____
Telephone number _____
Facsimile number _____
e-mail address _____

I-4. Proposed date of installation and/or commissioning of facilities and equipment:

_____

SIGNATURE AND CERTIFICATION

_____
Signature of the authorised representative
of the legal person

Title: _____

Date**:** _____

Notes:

1. The regulatory authority may require additional information to fully consider this application prior to issuing an authorization.

2. In the event that all the above information is not available at the time of application, the regulatory authority may issue an authorization limiting the applicant to import, acquire, or store radiation sources, or construct facilities. Complete information will be required from the applicant prior to authorising use of the radiation sources.

II-EQUIPMENT AND SOURCES

II-1. Equipment with sealed sources incorporated

Description:	Radionuclide	Maximum activity	Number
Manufacturer: ____________ Radiation type (alpha, beta, gamma, neutron): ____________ Model no. device: ____________ Source: ____________ Serial no. device: ____________ Source: ____________			
Manufacturer: ____________ Radiation type (alpha, beta, gamma, neutron): ____________ Model no. device: ____________ Source: ____________ Serial no. device: ____________ Source: ____________			
Manufacturer: ____________ Radiation type (alpha, beta, gamma, neutron): ____________ Model no. device: ____________ Source: ____________ Serial no. device: ____________ Source: ____________			
Manufacturer: ____________ Radiation type (alpha, beta, gamma, neutron): ____________ Model no. device: ____________ Source: ____________ Serial no. device: ____________ Source: ____________			
Manufacturer: ____________ Radiation type (alpha, beta, gamma, neutron): ____________ Model no. device: ____________ Source: ____________ Serial no. device: ____________ Source: ____________			
Manufacturer: ____________ Radiation type (alpha, beta, gamma, neutron): ____________ Model no. device: ____________ Source: ____________ Serial no. device: ____________ Source: ____________			
Manufacturer: ____________ Radiation type (alpha, beta, gamma, neutron): ____________ Model no. device: ____________ Source: ____________ Serial no. device: ____________ Source: ____________			
Manufacturer: ____________ Radiation type (alpha, beta, gamma, neutron): ____________ Model no. device: ____________ Source: ____________ Serial no. device: ____________ Source: ____________			

II-2. Neutron generators — accelerator

Manufacturer	Model number	Serial number	Neutron energy	Target nuclide

II-3. X ray generators

Manufacturer	Model number	Serial number	Maximum voltage (kV)	Maximum current (mA)

II-4. Standards and classification

a) Are the sources manufactured, prototype tested, and subject to quality control provisions of standards recognised by national or international standard setting organisations (e.g. ISO 2919)? If, so please list and identify the standards and any applicable classification numbers.

_____
_____
_____
_____
_____

b) Is each device that emits radiation manufactured, prototype tested, and subject to quality control provisions of standards recognised by national or international standard setting organisations? If, so please list and identify the standards and any applicable classification numbers.

_____
_____
_____
_____
_____

II-5. Work locations:

Will the work be carried out at any address other than given in item I–1. above? (Circle correct answer)	Do not know	Yes	No

(Note: that the regulatory authority may require notification prior to work at currently unknown addresses)

List all other known addresses:

_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

III-FACILITIES

In an attachment to this application, describe the facilities, including:

III-1. Location of the facility

Provide a detailed location of the facility.

III-2. Layout of the facility

Describe factors such as:

a) the layout of the facility and its immediate surroundings (any controlled and supervised areas should be clearly identified);
b) any special environmental conditions that can affect the integrity of shielding (e.g. heat sources, corrosive atmospheres, extreme cold, moisture, etc.);
c) any fixed equipment to which the source housing or device will be physically attached;
d) building materials, alarms, shielding, engineering controls such as interlock and warning safety devices; and
e) provisions for security.

III-3. Safety assessments

Taking account of shielding, provide calculations of maximum dose rates around the equipment during normal operating conditions (specifying all assumptions, e.g. number of sources, activity).

Provide estimates of the magnitude of expected doses to persons during normal operations. Identify the probability and magnitude of potential exposures arising from accidents or incidents.

IV-RADIATION PROTECTION AND SAFETY PROGRAMME

In an attachment to this application, describe the radiation protection programme, including:

IV-1. Organisational structure

a) Describe your organisational and management control systems, including assignment of responsibilities and clear lines of authority related to radiation safety. In particular include: staffing levels, equipment selection, other assignments of the radiation protection officer, authority of the radiation protection officer to stop unsafe operations, personnel training, maintenance of records, and how problems affecting safety are identified and corrected.
b) Identify the authorised users, qualified experts, and radiation protection officer by name and include their training, education, experience and qualifications. (Note: the authorised user and/or radiation protection officer may be the same individual).
c) Confirm that training will include: explanation of radiation hazards and effects, explanation of written procedures, use of equipment (e.g. instrumentation), meaning of warning signals, and a method to confirm adequacy of training (testing or demonstrations).

IV-2. Workplace monitoring, area classification and individual monitoring

a) Describe your programme for monitoring the workplace (BSS, I.37-I.40), including: the quantities to be measured, where and when the measurements are to be made, the measurement methods and procedures, and reference levels and the actions to be taken if they are exceeded.
b) Describe your policies and procedures for classification of controlled and supervised areas. (BSS, I.21-I.25).
c) Describe personal dosimeters provided to workers and your policies for assigning dosimetry to individual workers (BSS, I.32-I.36). Describe your policy for reviewing individual doses, including reference levels and actions to be taken in exceeded.

   Name and address of dosimetry service: _____
   _____
   _____
   _____

   Denote type:
   i) Film _____
   ii) ThermoLuminescent dosimeter (TLD)_____
   iii) Direct reading dosimeter (DRD) _____
   iv) other: _____

IV-3. Local rules and supervision

a) Describe your local rules and procedures regarding: investigation or authorised levels, protective measures and safety provisions, providing adequate supervision, providing workers information regarding health risks due to occupational exposure, and emergency planning instruction (BSS, I.26-I.27).
b) Provide copies of your operating and safety procedures including: area access control, source inventory and leak testing, etc.
c) Describe your training program to ensure that all appropriate personnel are adequately trained in the current operating procedures and how their actions may affect safety (BSS, I.27).
d) Describe your policies regarding female workers who become pregnant (notification, adaption of working conditions to protect embryo/foetus) and the instructions you will provide to them (BSS, I.16-I.17 and I.27).
e) Describe your programme of health surveillance based on general principles of occupational health and designed to assess the initial and continuing fitness of workers for their intended tasks (BSS, I.41-I.43).

IV-4. Quality assurance

a) Describe your programme for ensuring that regulatory radiation safety requirements are addressed and satisfied.
b) Describe your program to periodically review procedures, maintain procedures current and available, and your procedure modification process.
c) Describe your programme for optimising occupational and public exposures to levels as low as reasonably achievable.
d) Describe your programme of periodic maintenance and testing (safety interlocks, shutter mechanisms, radiation meters, ancillary equipment, etc.). Attach the manufacturers instruction.
e) Describe service arrangements with other organisations and qualified experts.

IV-5. Transportation of radioactive material

If you will be transporting or shipping new or used sources, describe your arrangements for preparation and transport of packages containing radioactive sources (IAEA Safety Standards Series No. ST-1). These procedures should address: documentation of package certification, package surveys, transfer and receipt documents, and details of shipments preparation.

IV-6. Emergency procedures

Provide your emergency procedures to address emergencies such as potential damage to the source, loss of source shielding, stuck sources or substantial accidental exposure of an individual. If other emergencies are envisaged, please provide additional appropriate emergency procedures. In all cases the magnitude of the hazard should be evaluated. Any off-site consequences should also be evaluated. Local emergency services (e.g. fire, police) may need to be provided with copies of the emergency procedures.

IV-7. Transfer or disposal of radioactive sources

Describe arrangements for transfer or disposal of spent radioactive sources.

IV-8. System of records (BSS; 2.40, I.44-I.49)**, including:**

a) Disposal of spent sources
b) Personnel exposure
   i) current records
   ii) prior work history
c) Area surveys
   i) dose or dose rate
   ii) contamination
d) Instrument tests and calibrations
e) Tests for radioactive sealed source leakage.
f) Inventory of sources and accountability
g) Audits and reviews of radiation safety program
h) Incident and accident investigation reports
i) Maintenance and repair work
j) Facility modifications
k) Training provided
l) Evidence of health surveillance of workers
m) Transportation.

Example IV.B

CHECKLIST FOR COMMISSIONING AND REGULAR INSPECTIONS OF FIXED (INSTALLED) GAUGING, DETECTION AND OTHER DEVICES

Prepare a visit agenda to review the operating program with details contained in the application for authorization, the authorization certificate, prior programme review/inspection reports and their implementation, relevant correspondence, and other relevant documentation such as dosimetry reports. (References to appropriate sections and appendices of IAEA Safety Series No. 115, "International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources" (BSS), are provided at the beginning of Sections II–VI.)

Check the following for compliance with the authorization and with the regulatory authority requirements.

I-IDENTIFYING INFORMATION

I-1. Name of the institution: _____
_____

I-2. Address of facility: _____
_____
_____
_____

I-3. Telephone/facsimile/e-mail: Voice: _____ Fax: _____
e-mail: _____

I-4. Authorization number: _____

I-5. Name and qualification of the radiation protection officer:
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____

I-6. Name and qualifications of any qualified experts retained:

Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____

Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____

Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____

I-7. Name and title of the responsible representative of the legal person: _____
_____

II-VERIFICATION OF SAFETY

BSS requirements related to this section may be found in Appendix IV "Potential Exposure: Safety of Sources

II-1. Equipment with sealed sources incorporated

:Description:	Radionuclide	Maximum activity	Number
Manufacturer: ______ Radiation type (alpha, beta, gamma, neutron): ______ Model no. device: ______ Source: ______ Serial no. device: ______ Source: ______			
Manufacturer: ______ Radiation type (alpha, beta, gamma, neutron): ______ Model no. device: ______ Source: ______ Serial no. device: ______ Source: ______			
Manufacturer: ______ Radiation type (alpha, beta, gamma, neutron): ______ Model no. device: ______ Source: ______ Serial no. device: ______ Source: ______			
Manufacturer: ______ Radiation type (alpha, beta, gamma, neutron): ______ Model no. device: ______ Source: ______ Serial no. device: ______ Source: ______			
Manufacturer: ______ Radiation type (alpha, beta, gamma, neutron): ______ Model no. device: ______ Source: ______ Serial no. device: ______ Source: ______			
Manufacturer: ______ Radiation type (alpha, beta, gamma, neutron): ______ Model no. device: ______ Source: ______ Serial no. device: ______ Source: ______			
Manufacturer: ______ Radiation type (alpha, beta, gamma, neutron): ______ Model no. device: ______ Source: ______ Serial no. device: ______ Source: ______			
Compare the devices and sources with application descriptions and design specifications. Note any differences and determine the standards to which sources and/or devices were built: ______ ______ ______ ______			

II-2. X ray generators

Manufacturer	Model number	Serial number	Voltage	current
(e.g. ABXY Co.)	(e.g. Unit 123)	(e.g. 99999)	(e.g. 50 kV)	(e.g. 40 mA)

Compare the X ray generator with application descriptions and design specifications. Note any differences and determine the standards to which devices were built: _____ _____ _____ _____

II-3. Neutron generators — accelerator

Manufacturer	Model number	Serial number	Neutron energy	Target nuclide
Compare the neutron generator with application descriptions and design specifications. Note any differences and determine the standards to which devices were built: _____ _____ _____ _____				

II-4. Facility design and operating conditions

Describe any differences or modifications from those approved by the regulatory authority and considered in the safety assessment (e.g. environmental factors such as heat, extreme cold or moisture; shielding design, building materials, installed fire protection and controls, etc.): _____ _____ _____				
a)	Was a safety assessment by a qualified expert performed prior to any modifications?		Yes	No
b)	Is protection of the sources and generators from adverse environmental conditions (heat, moisture, etc.):	provided? working?	Yes Yes	No No
c)	Is fire detection and protection in the radiation and source storage areas:	provided? working?	Yes Yes	No No

II-5. Safety controls system

a)	Are the safety controls for operations and storage of radiation sources as described in the application approved by the regulatory authority?		Yes	No
b)	If not, was a safety assessment by a qualified expert performed prior to any modifications?		Yes	No
c)	Are gamma devices and X ray and neutron generators labelled as sources of radiation	provided? legible? local language?	Yes Yes Yes	No No No
d)	Are mechanical controls to prevent unintentional source exposure (e.g. keyed locks, shutters):	provided? working?	Yes Yes	No No
e)	Are portable radiation monitors for operations:	needed? provided? required? working?	Yes Yes Yes Yes	No No No No
f)	Are adequate controls of the production of radiation by X ray and neutron generators (e.g. timer, voltage, current):	provided? working?	Yes Yes	No No

II-6. Warning systems

a)	If appropriate, are signals (e.g. visible and/or audible) provided for:			
	i) source exposure	provided? working?	Yes Yes	No No

	ii) generator power on	provided? working?	Yes Yes	No No
b)	Are warning notices (e.g. written signs, posters):	provided? legible? local language?	Yes Yes Yes	No No No

II-7. Safety operations — management

a)	Is management knowledgeable of the certificate of authorization and its restrictions and requirements?		Yes	No
b)	Does management provide adequate staffing levels?		Yes	No
c)	Has management provided the radiation protection officer authority to stop unsafe operations?		Yes	No
d)	Does management provide adequate resources for personnel training (time and money)?		Yes	No
e)	Does management provide adequate equipment?		Yes	No
f)	Does management provide for periodic program reviews and recommendations?	scheduled? performed?	Yes Yes	No No
	i) Date of the last program review: _____ ii) Status of recommendations: _____ _____ _____			

II-8. Safety operations — technical

a)	Does the radiation protection officer (RPO) have adequate knowledge and expertise?		Yes	No
b)	Does the RPO have qualified experts available?		Yes	No
c)	Is the RPO knowledgeable about the requirements of the regulatory authority and the provisions of the certificate of authorization?		Yes	No
d)	Is the RPO given sufficient time and resources to do the job (e.g. not kept too busy with other assignments or given insufficient technical and secretarial help)?		Yes	No
e)	Does RPO maintains knowledge of activities of workers using radiation sources?		Yes	No
f)	Does the RPO conduct initial and periodic training of workers?		Yes	No
g)	Does the RPO maintain adequate records to demonstrate worker and public protection?		Yes	No
h)	Are there provisions for inventory of sources and accountability:	procedures? performed?	Yes Yes	No No
i)	Are locations and uses of devices recorded including site location, serial numbers of devices, date, name of supervising radiographer?		Yes	No

II-9. Investigation and quality assurance

a)	Were there any incidents or accidents?		Yes	No
b)	If so, were incident and accident investigation reports prepared?		Yes	No
c)	Were safety assessments reviewed or made based on lessons learned from any accident or accidents at similar facilities?		Yes	No
d)	Is there a written quality assurance program?	procedures? performed?	Yes Yes	No No
e)	Is maintenance and repair work in accordance with manufacturer's recommendations?	scheduled? performed?	Yes Yes	No No
f)	Are repair/maintenance procedures?	developed? followed?	Yes Yes	No No

III-VERIFICATION OF WORKER PROTECTION

BSS requirements related to this section may be found in Appendix I "Occupational Exposure".

III-1. Classification of areas

a)	Are controlled areas demarcated?		Yes	No
b)	Are approved signs at access points?	provided?	Yes	No
		legible?	Yes	No
		local language?	Yes	No
c)	Is radiation source storage at a physically defined location?		Yes	No
i)	locked/secured location with key control?		Yes	No
ii)	radiation warning notices?	provided?	Yes	No
		legible?	Yes	No
		local language?	Yes	No
iii)	proper shielding (e.g. individual containers, enclosure)?		Yes	No
iv)	reserved only for radiation sources?		Yes	No
d)	Are supervised areas demarcated?		Yes	No
e)	Are approved signs at access points?	needed?	Yes	No
		provided?	Yes	No
		legible?	Yes	No
		local language?	Yes	No

III-2. Local rules and supervision

a)	Are rules established in writing, in a local language?		Yes	No
b)	Do rules include investigation levels and authorised levels and the procedure to be followed when a level is exceeded?		Yes	No
c)	Are workers instructed in the implementing procedures?		Yes	No
d)	Is device operation done in accordance with prescribed operating procedures and conditions?		Yes	No
e)	Do workers have adequate supervision to ensure rules, procedures, protective measures and safety provisions are followed?		Yes	No
f)	Specifically, are operating and working procedures for:			
i)	use of personal dosimetry and use of protective equipment:	provided?	Yes	No
		adequate?	Yes	No
		followed?	Yes	No
ii)	performing routine maintenance:	provided?	Yes	No
		adequate?	Yes	No
		followed?	Yes	No
iii)	making surveys	provided?	Yes	No
		adequate?	Yes	No
		followed?	Yes	No
iv)	appropriate response to equipment damage:	provided?	Yes	No
		adequate?	Yes	No
		followed?	Yes	No

III-3. Monitoring

a)	Does the authorised organisation provide personal dosimeters?		Yes	No
b)	Are the dosimeters:			
i)	Worn properly?		Yes	No
ii)	Calibrated?		Yes	No
iii)	Exchanged at required frequency?		Yes	No
c)	Are personnel exposures within limits?		Yes	No
d)	Area and portable survey instruments			
i)	Needed?		Yes	No
ii)	Appropriate?		Yes	No
iii)	Calibrated?		Yes	No

	iv)	Operational?	Yes	No
	v)	Operational check performed before use?	Yes	No
	vi)	Spare batteries available?	Yes	No
e)	Do the authorised organisation's surveys indicate that the device shielding is adequate and the dose rates in the immediate vicinity and normally occupied areas meet authorised radiation levels?		Yes	No
f)	Does the authorised organisation make periodic tests for leakage of radioactive materials from sealed sources?		Yes	No
g)	Does the authorised organisation use an outside qualified expert to perform leak tests?		Yes	No
h)	If not, is the authorised organisation's instrumentation:			
	i)	Appropriate?	Yes	No
	ii)	Calibrated?	Yes	No
	iii)	Operational?	Yes	No
Record independent measurements made during the inspection: _____ _____ _____ _____				
Type/model no. of survey meter:				
Date last calibrated:				
Do the inspector's independent surveys agree with the survey results of the authorised organisation?			Yes	No
Document any significant differences and any agreed upon plan to resolve the different results: _____ _____ _____ _____				

IV-VERIFICATION OF PUBLIC PROTECTION

BSS requirements related to this section may be found in Appendix III "Public Exposure".

IV-1. Control of visitors

a)	Are visitors accompanied in controlled area?	Yes	No
b)	Is adequate information provided to visitors entering controlled areas?	Yes	No
c)	Are there adequate controls over entries into supervised areas and appropriate postings?	Yes	No

IV-2. Sources of exposure

a)	Are the shielding and other protective measures optimised for restricting public exposure to external sources of radiation?	Yes	No
b)	Are the floor plans and arrangement of equipment as described in the application and appropriate considering any public areas adjacent to the installation?	Yes	No
c)	Have provisions been made to detect and control contamination in the event of a leaking source?	Yes	No

IV-3. Radioactive waste and discharges

a)	Have provisions been made to transfer sources to an appropriate registrant or licensee or to an authorised waste disposal facility at the end of use?	Yes	No
b)	If sources are no longer in use and being stored, does the authorised organisation have a plan for timely transfer or disposal of the sources?	Yes	No

IV-4. Monitoring of public exposure

a) Are routine periodic measurements of exposure rates in public areas adjacent to controlled and supervised areas made by the staff or qualified expert?	Yes	No
b) Do surveys shows that the device shielding is adequate and the dose rates outside the controlled and supervised areas meet authorised radiation levels?	Yes	No
c) Record independent measurements made during the inspection: _____ _____ _____ _____		
Type/model no. of survey meter: _____ _____		
Date last calibrated:		
Are the inspector's independent measurements in agreement with the organisations routine measurements?	Yes	No
Document any significant differences and any agreed upon plan to resolve the different results: _____ _____ _____ _____		

V-EMERGENCY PREPAREDNESS

BSS requirements related to this section may be found in Appendix V "Emergency Exposure Situations".

V-1. Emergency plan

a)	Is there a written plan?	Yes	No
b)	Is the plan periodically reviewed and updated?	Yes	No
c)	Does the plan take into account lessons learned from operating experience and accidents at similar facilities?	Yes	No
d)	Do the procedures include isolation and radiation surveys of damaged radiation sources, source holders, or operating mechanisms?	Yes	No
e)	Is emergency equipment available?	Yes	No

V-2. Training and exercises

a)	Have workers involved in implementing the plan received training?	Yes	No
b)	Date of the last rehearsal:		

VI-RECORDS

Note: *Records will be needed as part of the assessments and verifications outlined in the prior sections of the checklist. This list is a reminder of the type of records that may be helpful. The appearance of the list at the end of the checklist does not indicate that records review is the last item to be done. Rather, an inspection may begin with an entrance interview and facility tour followed by an initial review of some of the records listed below.*

a) Copy of authorization certificate
b) System of records management
c) Dosimetry
   i) current
   ii) prior work history
d) Area surveys
e) Instrument tests and calibrations
f) Tests for leakage of radioactive material from sources
g) Inventory of sources and accountability

h) Audits and reviews of radiation safety programme
i) Incident and accident investigation reports
j) Maintenance and repair work
k) Facility modifications
l) Training provided
    i) initial
    ii) refresher
m) Evidence of health surveillance
n) Waste disposals
o) Transportation
    i) package documentation
    ii) package surveys
    iii) transfer/receipt documents
    iv) details of shipments dispatched

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Annex V

SAFETY ASSESSMENT PLANS FOR WORK WITH UNSEALED RADIOACTIVE SOURCES

This annex has two exhibits which include an application form and a checklist for inspection.

(1) Example V.A: Application for authorization and review plan of work with unsealed radioactive sources in industry.

(2) Example V.B: Checklist for commissioning and regular inspections of work with unsealed radioactive sources in industry.

References that may be useful to the regulatory authority and/or to licensees and registrants are listed in the bibliography at the end of the annex. The list is divided into references generally applicable for radiation safety and protection and those which may have particular relevance to work with unsealed radioactive sources.

Example V.A

APPLICATION FOR AUTHORIZATION AND REVIEW PLAN OF WORK WITH UNSEALED RADIOACTIVE SOURCES IN INDUSTRY

TYPE OF AUTHORIZATION

_____ New application
_____ Amendment to existing authorization number _____
_____ Renewal of authorization number _____

PURPOSE OF APPLICATION

_____ Construction (Complete Sections I through III)
_____ Import/Purchase (Complete Sections I and II)
_____ Use/Begin operation (Complete Sections I through IV)

You may refer to previous submissions by date and application or authorization number(s)

The legal person who will be responsible for using any unsealed source must, unless the source is exempted, submit the following information to the regulatory authority.

I-GENERAL INFORMATION

I-1. Name and address of organisation:

Main address	Mailing address (if different)	Address of use (if different)
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

I-2. Name and information about qualified experts:

Expertise: radiation protection officer
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____
Telephone number: _____

Expertise: _____
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____
_____

I-3. The responsible representative of the legal person:

Name: _____
Title: _____
Telephone number _____
Facsimile number _____
e-mail address _____

I-4. Proposed date of installation and/or commissioning of facilities and equipment:

_____

SIGNATURE AND CERTIFICATION

_____
Signature of the authorised representative
of the legal person

Title: _____

Date: _____

Notes:

1. The regulatory authority may require additional information to fully consider this application prior to issuing an authorization.

2. In the event that all the information requested is not available at the time of application, the regulatory authority may issue an authorization limiting the applicant to import, acquire, or store radiation sources, or construct facilities. Complete information will be required from the applicant prior to authorising use of the radiation sources.

II-SOURCES

II-1. Details of radionuclides involved in the work:

Radionuclide	Maximum activity	Physical/chemical form	Application
(e.g. Carbon-14)	(e.g. 20 kBq)	(e.g. solid/liquid/gas +chemical name)	(e.g. Tracer study of oil well)

II-2. Containment of the radionuclides:

Describe how the radionuclides(s) will initially be contained. Indicate whether there will be any special features such as whether the container will be pressurised or incorporate shielding.

_____
_____
_____
_____

II-3. Work pattern:

State whether this work will involve one or more consignments of radionuclides and over what period of time the work will proceed.

_____
_____
_____
_____

II-4. Work locations:

Will the work be carried out at any address other than given in item I-1. above? (Circle correct answer)	Do not know	Yes	No

(Note: that the regulatory authority may require notification prior to work at currently unknown addresses)

List all other addresses:

_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

II-5. Radioactive wastes:

Indicate whether the work covered by this application is likely to generate radioactive waste(s) and provide an assessment of the different forms:

Radionuclide	Waste form	Maximum activity	Proposed disposal route
(e.g. Carbon-14)	(e.g. Liquid)	(e.g. KBq)	(e.g. to drain)

III-FACILITIES AND EQUIPMENT

In an attachment to this application, describe the facilities and equipment, including:

III-1. Facility specifications:

Describe factors such as the layout of facilities existing or to be provided at the addresses given. In particular, mention any features which will be designed to limit the spread of surface or airborne contamination by the radioactive material. Provide details of surfaces of floor, walls, equipment and furniture that may be designed to aid the removal of any spillage. Provide copies of any drawings that may be available. Show all areas where unsealed radioactive material will be stored and used. Indicate any controlled or supervised areas on the drawings and any barrier change areas.

III-2. Equipment specification:

a) Describe proposed arrangements for restricting exposure including for example;
   i) shielding to be provided to minimise external doses; and
   ii) forms of extract ventilation to minimise the risk of internal doses.
b) Provide manufacturers specifications of any equipment that may be used.
c) State whether washing facilities will be readily accessible.
d) Describe any personal protective equipment that will be provided.

IV-RADIATION PROTECTION AND SAFETY PROGRAMME

In an attachment to this application, describe the radiation protection and safety programme including:

IV-1. Organisational structure

a) Describe your organisational and management control systems, including assignment of responsibilities and clear lines of authority related to radiation safety. In particular include: staffing levels, equipment selection, other assignments of the radiation protection officer, authority of the radiation protection officer to stop unsafe operations, personnel training, maintenance of records, and how problems affecting safety are identified and corrected.
b) Identify the authorised users, qualified experts, and radiation protection officer by name and include their training, education, experience and qualifications. (Note: the authorised user and/or radiation protection officer may be the same individual).
c) Confirm that training will include: explanation of radiation hazards and effects, explanation of written procedures, use of equipment (e.g. instrumentation), meaning of warning signals, and a method to confirm adequacy of training (testing or demonstrations).

IV-2. Workplace monitoring, area classification and individual monitoring

a) Describe your programme for monitoring the workplace (BSS, I.37-I.40), including: the quantities to be measured, where and when the measurements are to be made, the measurement methods and procedures, and reference levels and the actions to be taken if they are exceeded.
b) Describe your policies and procedures for classification of controlled and supervised areas. (BSS, I.21-I.25), specifically:
   i) how will the areas of risk of exposure to external or internal doses be defined?
   ii) how will access to these areas be restricted (e.g. use of barriers, warning notices and signals, etc.)?
c) Describe personal dosimeters provided to workers and your policies for assigning dosimetry to individual workers (BSS, I.32-I.36). Describe your policy for reviewing individual doses, including reference levels and actions to be taken in exceeded.
   Name and address of dosimetry service: _____
   _____
   _____
   _____
   Denote type:
   i) Film _____
   ii) ThermoLuminescent dosimeter (TLD)_____
   iii) Direct reading dosimeter (DRD) _____
   iv) other: _____
d) Describe what form of internal dosimetry, if any, will be provided.

IV-3. Local rules and supervision

a) Describe your local rules and procedures regarding: investigation or authorised levels, protective measures and safety provisions, providing adequate supervision, providing workers information regarding health risks due to occupational exposure, and emergency planning instruction (BSS, I.26-I.27).
b) Provide copies of your operating and safety procedures including: area access control, entry procedures into shielded enclosures, source inventory and leak testing, etc.
c) Describe your training program to ensure all appropriate personnel are adequately trained in the operating procedures and how their actions may affect safety (BSS, I.27).
d) Describe your policies regarding female workers who become pregnant (notification, adoption of working conditions to protect foetus/embryo) and the instructions you will provide to them (BSS, I.16-I.17 and I.27).
e) Describe your programme of health surveillance based on general principles of occupational health and designed to assess the initial and continuing fitness of workers for their intended tasks (BSS, I.41-I.43).

IV-4. Quality assurance

a) Describe your programme for ensuring that regulatory radiation safety requirements are addressed and satisfied.
b) Describe your program to periodically review procedures, maintain procedures current and available, and your procedure modification process.
c) Describe your programme for optimising occupational and public exposures to levels as low as reasonably achievable.
d) Describe your programme of periodic maintenance and testing (safety interlocks, radiation meters, etc.). Attach the manufacturers instructions.
e) Describe service arrangements with other organisations and qualified experts.

IV-5. Transportation of radioactive material;

If you will be transporting or shipping new or used sources, describe your arrangements for preparation and transport of packages containing radioactive sources (IAEA Safety Standards Series No. ST-1). These procedures should address: documentation of package certification, package surveys, transfer/receipt documents, and details of shipments preparation.

IV-6. Emergency procedures

Provide your emergency procedures to address emergencies such as potential damage to the source, loss of source shielding, stuck sources or substantial accidental exposure of an individual. If other emergencies are envisaged, please provide additional appropriate emergency procedures. In all cases the magnitude of the hazard should be evaluated. Any off-site consequences should also be evaluated. Local emergency services (e.g. fire, police) may need to be provided with copies of the emergency procedures.

IV-7. Transfer or disposal of radioactive sources

Describe arrangements for transfer or disposal of spent radioactive sources.

IV-8. System of records (BSS; 2.40, I.44-I.49)**, including:**

a) Disposal of waste
b) Personnel exposure
    i) current records
    ii) prior work history
c) Area surveys
    i) dose or dose rate
    ii) contamination
d) Instrument tests and calibrations
e) Inventory and material accountability
f) Audits and reviews of radiation safety program
g) Incident and accident investigation reports
h) Training provided
i) Evidence of health surveillance of workers
j) Transportation

Example V.B

CHECKLIST FOR COMMISSIONING AND REGULAR INSPECTIONS OF WORK WITH UNSEALED RADIOACTIVE SOURCES IN INDUSTRY

Prepare a visit agenda to review the operating program with details contained in the application for authorization, the authorization certificate, prior programme review/inspection reports and their implementation, relevant correspondence, and other relevant documentation such as dosimetry reports. (References to appropriate sections and appendices of IAEA Safety Series No. 115, "International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources" (BSS), are provided at the beginning of Sections II–VI.)

Check the following for compliance with the authorization and with the regulatory authority requirements.

I-IDENTIFYING INFORMATION

I-1. Name of the institution: _____
_____

I-2. Address of facility: _____
_____

I-3. Telephone/facsimile/e-mail: Voice: _____ Fax: _____
e-mail: _____

I-4. Authorization number: _____

I-5. Name and qualification of the radiation protection officer:
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____

I-6. Name and qualifications of any qualified experts retained:

Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____

Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____

I-7. Name and title of the responsible representative of the legal person: _____
_____

II-VERIFICATION OF SAFETY

BSS requirements related to this section may be found in Appendix IV "Potential Exposure: Safety of Sources

II-1. Radioactive materials available

Radionuclides	Activity suthorised (MBq)	Activity present (MBq)	Maximum individual source activity (MBq)	Chemical/ physical forms

Are the stocks of radioactive materials within authorised limits?

_____

_____

II-2. Measuring and handling equipment

Type of equipment	Manufacturer:	Model no:	Number	Comments:
Liquid scintillation counter				
Well counter				
Lead blocks				
L-Block				
Tongs				
Fume hood				

II-3. Facility design

a)	Describe any differences or modifications from those approved by the regulatory authority and/or considered in the safety assessment (e.g. ventilation, plumbing system, shielding design, building materials and floor plan.): _____ _____ _____		
b)	Was a safety assessment by a qualified expert performed prior to any modifications?	Yes	No
c)	Is the thickness and type of shielding appropriate for the types and intensity of radiation produced by radioisotopes in use?	Yes	No

II-4. Safety control and equipment design

a)	Are adequate number of lead containers, lead blocks, and portable or fixed shields available for shielding in storage and handling rooms?	Provided? Used?	Yes Yes	No No
b)	Is remote handling equipment such as (tongs, automatic pipettes, etc.) available?	Provided? Used?	Yes Yes	No No
c)	Are ventilated fume hoods for handling large quantities of volatile radioactive material available?	Provided? Used?	Yes Yes	No No

d)	Are the drainage ducts of the laboratory (sinks, wash basins, toilets, etc.) connected directly to the sanitary sewage system	Yes	No
e)	Are adequate provision made for storage of wastes before disposal?	Yes	No

II-5. Warning systems:

Written notices	provided?	Yes	No
	legible?	Yes	No
	in local language?	Yes	No

II-6. Safety operations — management

a)	Is management knowledgeable of the certificate of authorization and its restrictions and requirements?	Yes	No
b)	Does management provide adequate staffing levels?	Yes	No
c)	Has management provided the radiation protection officer authority to stop unsafe operations?	Yes	No
d)	Does management provide adequate resources for personnel training (time and money)?	Yes	No
e)	Does management provide adequate equipment?	Yes	No
f)	Does management provide for periodic program reviews and recommendations?	Yes	No

Date of the last program review: _____

Status of recommendations:

_____

_____

II-7. Safety operations — technical

a)	Does the radiation protection officer (RPO) have adequate knowledge and expertise?		Yes	No
b)	Does the RPO have qualified experts available?		Yes	No
c)	Is the RPO knowledgeable about the requirements of the regulatory authority and the provisions of the certificate of authorization?		Yes	No
d)	Is the RPO given sufficient time and resources to do the job (e.g. not kept too busy with other assignments or given insufficient technical and secretarial help)?		Yes	No
e)	Does RPO maintains knowledge of activities of workers using radiation sources?		Yes	No
f)	Does the RPO conduct initial and periodic training of workers?		Yes	No
g)	Does the RPO maintain adequate records to demonstrate worker and public protection?		Yes	No
h)	Are there provisions for inventory of sources and accountability:	Procedure?	Yes	No
		Performed?	Yes	No
i)	Are there provisions for audits and reviews of radiation safety program:	Procedure?	Yes	No
		Performed?	Yes	No

II-8. Investigation and quality assurance

a)	Were there any incidents or accidents?		Yes	No
b)	If so, were incident and accident investigation reports prepared?		Yes	No
c)	Were safety assessments reviewed or made based on lessons learned from any accident or accidents at similar facilities?		Yes	No
d)	Is there a written quality assurance program?	Procedure?	Yes	No
		Performed?	Yes	No
e)	Is maintenance and repair work (measuring equipment, ventilation systems, etc.) in accordance with manufacturer's recommendations?	Scheduled?	Yes	No
		Performed?	Yes	No
f)	Are repair/maintenance procedures?	Developed?	Yes	No
		Followed?	Yes	No

III-VERIFICATION OF WORKER PROTECTION

BSS requirements related to this section may be found in Appendix I "Occupational Exposure".

III-1. Classification of areas

a)	Are controlled areas demarcated?		Yes	No
b)	Are approved signs at access points?	provided?	Yes	No
		legible?	Yes	No
		local language?	Yes	No
c)	Are supervised areas demarcated?		Yes	No
d)	Are approved signs at access points?	needed?	Yes	No
		provided?	Yes	No
		legible?	Yes	No
		local language?	Yes	No

III-2. Local rules and supervision

a)	Are rules established in writing, in a local language?	Yes	No
b)	Do rules include investigation levels and authorised levels and the procedure to be followed when a level is exceeded?	Yes	No
c)	Are workers instructed in the implementing procedures?	Yes	No
d)	Are work activities done in accordance with prescribed operating procedures and conditions including the use of remote handling tools and shielding?	Yes	No
e)	Do workers have adequate supervision to ensure rules, procedures, protective measures and safety provisions are followed?	Yes	No

III-3. Monitoring — external

a)	Does the authorised organisation provide personal dosimeters?	Yes	No
b)	Are the dosimeters:		
i)	Worn properly?	Yes	No
ii)	Calibrated?	Yes	No
iii)	Exchanged at required frequency?	Yes	No
c)	Are personnel exposures within limits?	Yes	No
d)	Area and portable survey instruments		
i)	Appropriate?	Yes	No
ii)	Calibrated?	Yes	No
iii)	Operational?	Yes	No
iv)	Operational check performed before use?	Yes	No
v)	Spare batteries available?	Yes	No
e)	Do the authorised organisation's surveys indicate that the radiation room shielding is adequate and the dose rates around the room meet authorised radiation levels?	Yes	No

Record independent measurements made during the inspection:

_____
_____
_____

Type/model no. of survey meter:

Date last calibrated:

Do the inspector's independent surveys agree with the survey results of the authorised organisation?	Yes	No

Document any significant differences and any agreed upon plan to resolve the different results:

_____
_____
_____
_____

III-4. Monitoring — internal

a)	Adequate containment measures against leakage?		Yes	No
b)	Are surfaces designed for easy decontamination?		Yes	No
c)	Are surfaces covered to aid decontamination?		Yes	No
d)	User surveys show contamination less than authorised limits?		Yes	No
e)	Protective clothing available to cover the body (e.g. overall, coat)?		Yes	No
f)	Protective clothing available to cover hair (e.g. hood)?		Yes	No
g)	Protective clothing available to cover hands (e.g. gloves?		Yes	No
h)	Protective clothing available to cover feet (e.g. change of shoes overshoes)?		Yes	No
i)	Respiratory protective equipment	Provided?	Yes	No
		Adequate?	Yes	No
		Tested?	Yes	No
j)	Hygiene precautions (e.g. restrictions on eating, etc.)		Yes	No
k)	Washing and changing facilities	Provided?	Yes	No
		Adequate?	Yes	No
l)	Personal air sampling	Provided?	Yes	No
		Adequate?	Yes	No
		Working?	Yes	No
m)	Bioassay	Provided?	Yes	No
		Adequate?	Yes	No
n)	Surface contamination meters	Provided?	Yes	No
		Adequate?	Yes	No
		Working?	Yes	No
o)	Area airborne monitoring	Provided?	Yes	No
		Adequate?	Yes	No
		Working?	Yes	No

Record independent measurements made during the inspection: _____
_____
_____
_____
_____

Type/model no. of measuring instrument:

Date last calibrated:

Do the inspector's independent surveys agree with the survey results of the authorised organisation?	Yes	No

Document any significant differences and any agreed upon plan to resolve the different results:
_____
_____
_____
_____

IV-VERIFICATION OF PUBLIC PROTECTION

BSS requirements related to this section may be found in Appendix III "Public Exposure".

IV-1. Control of visitors

a)	Are visitors permitted in controlled areas?		Yes	No
b)	Is adequate information provided to visitors entering controlled areas?		Yes	No
c)	Are there adequate controls over entries into controlled and supervised areas and appropriate postings?	provided?	Yes	No
		legible?	Yes	No
		local language?	Yes	No

IV-2. Sources of exposure

a)	Are the shielding and other protective measures optimised for restricting public exposure to external sources of radiation?	Yes	No
b)	Are the floor plans and arrangement of equipment appropriate considering public areas adjacent to the installation?	Yes	No

IV-3. Monitoring of public exposure — external

a)	Are routine periodic measurements of exposure rates in areas adjacent to treatment and storage made by the staff or qualified expert?	Yes	No
Record independent measurements made during the inspection: _____ _____ _____ _____ _____ Type/model no. of survey meter: Date last calibrated:			
Are the inspector's independent measurements in agreement with the organisations routine measurements?		Yes	No
Do surveys shows that the shielding is adequate and the dose rates outside the controlled and supervised areas meet authorised radiation levels?		Yes	No

IV-4. Monitoring of public exposure — internal

a)	Waste forms and locations as anticipated?			Yes	No
b)	Quantities within authorised limits?			Yes	No
c)	Airborne waste pathway				
	i)	Local ventilation (e.g. fume hood, glove box, room, flow rates)	provided? working? adequate?	Yes Yes Yes	No No No
	ii)	Discharge point of ventilation (e.g. location, height, flow rates, proximity to occupied areas)	adequate? monitored?	Yes Yes Yes	No No No
	iii) iv)	Release to off site public locations? If yes, explain:_____ _____ _____ _____		Yes	No
d)	Liquid waste pathway				
	i)	Drainage systems (e.g. dedicated sink, closed collection system, enclosed drainage and sewer, dilution factors)	Provided? Adequate?	Yes Yes	No No
	ii) iii)	Precautions for mixed hazardous wastes? If yes, explain: _____ _____ _____ _____		Yes	No
e)	Solid waste pathway				
	i)	Storage container (e.g. bags, drums)	strong/tight? labelled? secured?	Yes Yes Yes	No No No
	ii)	Disposal method	decay-in-storage? secure? burial? Incinerate?	Yes Yes Yes Yes	No No No No

iii) iv)	Precautions for mixed hazardous wastes? If needed, explain: _____ _____ _____ _____	Yes	No
v) vi)	Release to off site public locations? If yes, explain: _____ _____ _____ _____	Yes	No

V-EMERGENCY PREPAREDNESS

BSS requirements related to this section may be found in Appendix V "Emergency Exposure Situations".

V-1. Emergency plan

a)	Is there a written plan?	Yes	No
b)	Written procedures for handling emergencies (e.g. spillage, skin contamination, etc.)	Yes	No
c)	Is the plan periodically reviewed and updated?	Yes	No
d)	Does the plan take into account lessons learned from operating experience and accidents at similar facilities?	Yes	No
e)	Have workers involved in implementing the plan received training?	Yes	No
f)	Have provisions been made for the plan to be rehearsed at suitable intervals (particularly what to do if equipment malfunctions or personal contamination is detected)?	Yes	No
g)	Date of the last rehearsal:		

VI-RECORDS

Note: *Records will be needed as part of the assessments and verifications outlined in the prior sections of the checklist. This list is a reminder of the type of records that may be helpful. The appearance of the list at the end of the checklist does not indicate that records review is the last item to be done. Rather, an inspection may begin with an entrance interview and facility tour followed by an initial review of some of the records listed below.*

a) Copy of authorization certificate
b) System of records management
c) Dosimetry
   i) current
   ii) prior work history
d) Area surveys
e) Instrument tests and calibrations
f) Inventory of sources and accountability
g) Audits and reviews of radiation safety programme
h) Incident and accident investigation reports
i) Maintenance and repair work
j) Facility modifications
k) Training provided
   i) initial
   ii) refresher
l) Evidence of health surveillance
m) Waste disposals
n) Transportation
   i) package documentation
   ii) package surveys
   iii) transfer/receipt documents
   iv) details of shipments dispatched

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Annex VI

SAFETY ASSESSMENT PLANS FOR DIAGNOSTIC X RAY EQUIPMENT

This annex has two exhibits which include an application form and a checklist for inspection.

(1) Example VI.A: Application for authorization and review plan for diagnostic X ray equipment.

(2) Example VI.B: Checklist for commissioning and regular inspection of diagnostic X ray installations.

References that may be useful to the regulatory authority and/or to licensees and registrants are listed in the bibliography at the end of the annex. The list is divided into references generally applicable for radiation safety and protection and those which may have particular relevance to work with diagnostic x ray equipment.

Example VI.A

APPLICATION FOR AUTHORIZATION AND REVIEW PLAN FOR DIAGNOSTIC X RAY EQUIPMENT

TYPE OF AUTHORIZATION

_____ New application
_____ Amendment to existing authorization number _____
_____ Renewal of authorization number _____

PURPOSE OF APPLICATION

_____ Construction (Complete Sections I through III)
_____ Import/Purchase (Complete Sections I and II)
_____ Use/Begin operation (Complete Sections I through V)

You may refer to previous submissions by date and application or authorization number(s)

The legal person who will be responsible for using any radiation generator must, unless the source is exempted, submit the following information to the regulatory authority.

I-GENERAL INFORMATION

I-1. Name and address of organisation:

Main address	Mailing address (if different)	Address of use (if different)
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

I-2. Name and information about qualified experts:

Expertise: Radiation protection officer
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____
Telephone number: _____

Expertise: Physician — Diagnostic Radiology
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____
_____

Expertise: Radiodiagnostic Physics
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____
_____

Expertise: _____
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____
_____

I-3. The responsible representative of the legal person:

Name: _____ Telephone number _____

Title: _____ Facsimile number _____

e-mail address _____

I-4. Proposed date of installation and/or commissioning of facilities and equipment:

_____

SIGNATURE AND CERTIFICATION

_____

Signature of the authorised representative
of the legal person

Title: _____

Date**:** _____

Notes:

1. The regulatory authority may require additional information to fully consider this application prior to issuing an authorization.

2. In the event that all the above information is not available at the time of application, the regulatory authority may issue an authorization limiting the applicant to import, acquire, or store radiation sources, or construct facilities. Complete information will be required from the applicant prior to authorising use of the radiation sources.

3. Medical exposure may be under the jurisdiction of a regulatory authority other than the regulatory authority responsible for occupational and public exposure. However, the authorised user should address the items in Section V for referral to any appropriate authority.

II-EQUIPMENT

II-1. X ray generators

Manufacturer/Address/Workload	Number of tubes	Model number	Serial number	Maximum voltage (kV)	Maximum current (mA)
Name: _____ Address:_____ _____ _____ Max output: _____ Exposure time per week: _____ Weekly workload:					
Name: _____ Address:_____ _____ _____ Max output: _____ Exposure time per week: _____ Weekly workload:					
Name: _____ Address:_____ _____ _____ Max output: _____ Exposure time per week: _____ Weekly workload:					
Name: _____ Address:_____ _____ _____ Max output: _____ Exposure time per week: _____ Weekly workload:					

Is each device that emits radiation manufactured, prototype tested, and subject to quality control provisions of standards recognised by national or international standard setting organisations (e.g. IEC)? If, so please list and identify the standards and any applicable classification numbers.

_____
_____
_____
_____
_____
_____
_____
_____

II-2. Work locations:

Will the work be carried out at any address other than given in item I–1. above? (Circle correct answer)	Do not know	Yes	No

(Note: that the regulatory authority may require notification prior to work at currently unknown addresses)

List all other known addresses:

_____ _____ _____ _____ _____	_____ _____ _____ _____ _____	_____ _____ _____ _____ _____

II-3. Service and maintenance

Identify who will be authorised to perform service and maintenance on the X ray equipment.

_____
_____
_____
_____
_____

III-FACILITIES

In an attachment to this application, describe the facilities, including:

III-1. Layout of X ray rooms

Attach a layout plan of the X ray rooms indicating the locations of the control panel, mobile protective barrier, cassette pass box, doors, windows/ventilators, passages, dark room, patient waiting area, the occupancies around the installation, the material and thickness of the wall materials, and the location and size of any windows.

III-2. Safety assessments

Taking into account existing shielding, provide calculations of the maximum dose rates expected in all areas outside the X ray room(s) which could be occupied. For these calculations, assume the radiation beam is oriented in the position that would result in the highest directional exposures. Provide estimates of expected doses to workers during normal operations. Identify the probability and magnitude of potential exposures (to workers) arising from accidents or incidents. Include a statement of all assumptions used in the calculations.

IV-RADIATION PROTECTION AND SAFETY PROGRAMME

In an attachment to this application, describe the radiation protection programme, including:

IV-1. Organisational structure

a) Describe your organisational and management control systems including assignment of responsibilities and clear lines of authority related to radiation safety. In particular include: staffing levels, equipment selection, other assignments of the radiation protection officer, a requirement for the RPO to notify the Radiation Safety Committee or Licensee of unsafe operations, personnel training, maintenance of records and how problems affecting safety are identified and corrected.
b) Identify the authorised physician users, by name and include their training, qualifications, and experience in diagnostic radiology.
c) Identify ancillary personnel who will be involved in authorised activities and describe the training that will be provided to these individuals for working with X ray equipment (BSS I.27; II.1).
d) Confirm that training will include: explanation of radiation hazards and effects, explanation of written procedures, use of equipment (radiation source and instrumentation), meanings of warning signals, and a method to confirm adequacy of training (testing or demonstrations).

IV-2. Individual monitoring and classification and monitoring of areas

a) Describe your programme for monitoring the work areas (BSS, I.37-I.40), including: the quantities to be measured, where and when the measurements are to be made, the measurement methods and procedures, and reference levels and the actions to be taken if they are exceeded.
b) Describe your policies and procedures for classification of controlled and supervised areas. (BSS, I.21-I.25).
c) Describe personal dosimeters provided to workers and your policies for assigning dosimetry to individual workers (BSS, I.32-I.36). Describe your policy for reviewing individual doses, including reference levels and actions to be taken in exceeded.

   Name and address of dosimetry service: _____
   _____
   _____
   _____

   Denote type:
   i) Film _____
   ii) ThermoLuminescent dosimeter (TLD)_____
   iii) Direct reading dosimeter (DRD) _____
   iv) other: _____

IV-3. Local rules and supervision

a) Describe your local rules and procedures regarding: investigation or authorised levels, protective measures and safety provisions, providing adequate supervision, providing workers information regarding health risks due to occupational exposure, and emergency planning instruction (BSS, I.26-I.27).
b) Provide copies of your operating and safety procedures including: area access control.
c) Describe your training program to ensure that all appropriate personnel are adequately trained in the correct operating procedures and how their actions may affect safety.
d) Describe your policies regarding female workers who become pregnant (notification, adoption of working conditions to protect foetus/embryo) and the instructions you will provide to them (BSS, I.16-I.17 and I.27).
e) Describe your programme of health surveillance based on general principles of occupational health and designed to assess the initial and continuing fitness of workers for their intended tasks (BSS, I.41-I.43).

IV-4. Quality assurance

a) Describe your programme for ensuring regulatory radiation safety requirements are addressed and satisfied.
b) Describe your program to periodically review procedures, maintain procedures current and available, and your procedure modification process.
c) Describe your programme for optimising occupational and public exposures to levels as low as reasonably achievable.
d) Describe your programme of periodic maintenance and testing (safety interlocks, shutter mechanisms, radiation meters, ancillary equipment, etc.). Attach the manufacturers instructions.
e) Describe service arrangements with other organisations and qualified experts.

IV-5. System of records (BSS; 2.40, I.44-I.49, II.31-I.32)**, including:**

a) Personnel exposure
   i) current records
   ii) prior work history
b) Area surveys
   i) dose or dose rate
c) Instrument tests and calibrations
d) Audits and reviews of radiation safety program
e) Incident and accident investigation reports
f) Maintenance and repair work
g) Facility modifications
h) Training provided
i) Evidence of health surveillance of workers
j) Clinical dosimetry records

V-MEDICAL EXPOSURE

If appropriate for the purposes of the regulatory authority, in an attachment to this application, describe the programme to control medical exposure, including:

(BSS requirements related to this section may be found in Appendix II "Medical Exposure").

V-1. Responsibilities

a) Describe your arrangements to ensure that no patient is diagnostically exposed unless the exposure is prescribed by a medical practitioner.
b) Describe your arrangements to ensure that there are an adequate number of trained medical and paramedical personnel to discharge assigned tasks.
c) Confirm diagnostic imaging and quality assurance requirements are fulfilled with the advice of a qualified expert in nuclear medicine physics.

V-2. Justification

a) Describe your arrangements to ensure that medical exposures are justified by weighing the benefits they produce against the radiation detriment they might cause, taking into account the benefits and risks of alternate techniques that do not involve ionising radiation.
b) Describe your arrangements to ensure that exposure of humans for medical research is in accordance with the Helsinki Declaration and follows the guidelines for its application prepared by the Council for International Organizations of Medical Sciences and the World Health Organization.

c) Describe your arrangements to ensure that exposure of humans for medical research is subject to the advice of an Ethical Review Committee or other similar institutional body.
d) If you intend to use radiological examinations for screening of large populations or for occupational, legal or health insurance purposes; include a description of the standards you will use for justification.

V-3. Optimisation of protection

a) Describe your arrangements for medical practitioners to ensure that the exposure of patients is the minimum necessary to achieve the diagnostic objective and to take into account relevant information from previous examinations to avoid unnecessary additional examinations.
b) Describe your arrangements to ensure that newly purchased equipment:
   i) whether imported into or manufactured in the country, the equipment conforms to applicable standards of the International Electrotechnical Commission (IEC) and the ISO or to equivalent national standards;
   ii) performance specifications and operating and maintenance instructions, including protection and safety instructions, be provided in a major world language understandable to the users and in compliance with the relevant IEC or ISO standards with regard to "accompanying documents", and that this information be translated into local languages when appropriate;
   iii) where applicable, the operating terminology (or its abbreviations) and operating values be displayed on operating consoles in a major world language acceptable to the user;
c) Describe your arrangements regarding medical exposure of women who are, or may be, pregnant.

V-4. Calibration, clinical dosimetry and quality assurance

a) Describe your program for calibration of the X ray radiation beams traceable to a Standards dosimetry laboratory. (BSS II.19).
b) Describe your program for clinical dosimetry including representative values for typical sized adult patients of entrance surface doses, dose-area products, dose rates and exposure times or organ doses,
c) Describe your program for preventive maintenance and quality assurance for medical exposures established taking into account the principles established by the WHO, and the PAHO.
d) The quality assurance programme for medical exposures shall include:
   i) measurements of the physical parameters of the radiation generators, imaging devices and irradiation installations at the time of commissioning and periodically thereafter;
   ii) verification of the appropriate physical and clinical factors used in patient diagnosis or treatment;
   iii) written records of relevant procedures and results;
   iv) verification of the appropriate calibration and conditions of operation of dosimetry and monitoring equipment; and
   v) as far as possible, regular and independent quality audit reviews of the quality assurance programme for diagnostic procedures.

V-5. Dose constraints

Describe your policies to ensure any dose to individuals incurred knowingly while voluntarily helping (other than in their occupation) in the care support and comfort of patients undergoing medical diagnosis will be constrained to a level not exceeding that specified by national authorities.

V-6. Investigations of accidental medical exposures

a) Confirm that you will investigate any or all instances where:
   i) A diagnostic dose was substantially greater than intended or resulted in doses repeatedly and substantially exceeding the established guidance levels.
   ii) An equipment failure, accident, error, mishap or other unusual occurrence with the potential for causing a patient exposure significantly different from that intended.
b) With respect to any incidents investigated, confirm you will:
   i) Calculate or estimate the doses received and their distribution within the patient.
   ii) Indicate the corrective measures required to prevent recurrence of such an incident.
   iii) Implement all corrective measures that were under their control.
   iv) Submit to the regulatory authority, as soon as possible after the investigation or as otherwise specified by the regulatory authority, a written report which stated the cause of the accident and included the information specified in “i” to “iii”, as relevant.
   v) Inform the patient and his or her doctor about the incident.

EXAMPLE VI.B

CHECKLIST FOR COMMISSIONING AND REGULAR INSPECTION OF DIAGNOSTIC X RAY INSTALLATIONS

Prepare a visit agenda to review the operating program with details contained in the application for authorization, the authorization certificate, prior programme review/inspection reports and their implementation, relevant correspondence, and other relevant documentation such as dosimetry reports. (References to appropriate sections and appendices of IAEA Safety Series No. 115, "International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources" (BSS), are provided at the beginning of Sections II–VII.)

Check the following for compliance with the authorization and with the regulatory authority requirements.

I-IDENTIFYING INFORMATION

I-1. Name of the institution: _____
_____

I-2. Address of facility: _____
_____
_____

I-3. Telephone/facsimile/e-mail: Voice: _____ Fax: _____
e-mail: _____

I-4. Authorization number: _____

I-5. Name and qualification of the radiation protection officer:
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____

I-6. Name and qualifications of any qualified experts retained:

Diagnostic Radiology Physics:
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____

Physician–Diagnostic Radiologist:
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____

Expertise:_____
Name: _____
Degree: _____
Certification: _____
Experience:_____
_____
_____

I-7. Name and title of the responsible representative of the legal person: _____
_____

II-VERIFICATION OF SAFETY

BSS requirements related to this section may be found in Appendix IV "Potential Exposure: Safety of Sources

II-1. Radiation generating equipment

Type of X ray equipment	Manufacturer:	Model no:	Number of X ray tubes	Maximum voltage	Maximum current	Exposure time per week	Weekly work-load

Describe any differences between equipment in use and that approved by the regulatory authority and any features outside the parameters considered in the original safety assessment (i.e. higher energy or output.)

_____
_____
_____
_____

II-2. Shielding design

Describe any differences or modifications from those approved by the regulatory authority and/or considered in the safety assessment (e.g. shielding design, building materials and controls, etc.):

_____
_____
_____
_____

a)	Was a safety assessment by a qualified expert performed prior to any modifications?	Yes	No
b)	Is the thickness and type of shielding appropriate for the types and intensity of radiation produced by X ray devices?	Yes	No
c)	Are the areas of installation adequate?	Yes	No
d)	Is operator protection adequate?	Yes	No
e)	Are appropriate accessories available? (Mobile protective barrier/Lead rubber apron/lead rubber gloves/Lead rubber flaps/Red goggles/Fluoroscopic chair/Gondola shield)	Yes	No

II-3. Safety control and equipment design

a)	Radiology			
	i)	Light beam diaphragm available:	Yes	No
	ii)	Diaphragm opening symmetrical:	Yes	No
	iii)	Grid movement satisfactory:	Yes	No
	iv)	Chest stand lead backing satisfactory?	Yes	No
v)	Diaphragm/Cone available:		Yes	No
b)	Fluoroscopy			
	i)	Fluoroscopic screen brightness satisfactory?	Yes	No
	ii)	Tube to screen alignment satisfactory?	Yes	No
	iii)	Beam confinement to screen at maximum fields size and table to screen distance satisfactory?	Yes	No

iv)	Shutter movements satisfactory?		Yes	No
v)	Foot switch	Provided? Used?	Yes Yes	No No
vi)	Diaphragm control knobs shielded?		Yes	No
vii)	Red light provided inside the room?		Yes	No
viii)	Room darkening adequate?		Yes	No

II-4. Warning systems:

a)	Exposure signals and posted explanation (e.g. illuminated signs written signs, posters)	provided? working?	Yes Yes	No No
b)	Warning notices (In local language?)	provided? working? legible? local language?	Yes Yes Yes Yes	No No No No

II-5. Safety operations — management

a)	Is management knowledgeable of the certificate of authorization and its restrictions and requirements?	Yes	No
b)	Does management provide adequate staffing levels?	Yes	No
c)	Has management provided the radiation protection officer authority to stop unsafe operations?	Yes	No
d)	Does management provide adequate resources for personnel training (time and money)?	Yes	No
e)	Does management provide adequate equipment?	Yes	No
f)	Does management provide for periodic program reviews and recommendations?	Yes	No
	i) Date of the last program review: _____ ii) Status of recommendations:_____ _____ _____ _____		

II-6. Safety operations — technical

a)	Does the radiation protection officer (RPO) have adequate knowledge and expertise?	Yes	No
b)	Does the RPO have qualified experts available?	Yes	No
c)	Is the RPO knowledgeable about the requirements of the regulatory authority and the provisions of the certificate of authorization?	Yes	No
d)	Is the RPO given sufficient time and resources to do the job (e.g. not kept too busy with other assignments or given insufficient technical and secretarial help)?	Yes	No
e)	Does RPO maintains knowledge of activities of workers using radiation sources?	Yes	No
f)	Does the RPO conduct initial and periodic training of workers?	Yes	No
g)	Does the RPO maintain adequate records to demonstrate worker and public protection?	Yes	No

II-7. Investigations and quality assurance

a)	Were there any incidents or accidents?		Yes	No
b)	If so, were incident and accident investigation reports prepared?		Yes	No
c)	Were safety assessments reviewed or made based on lessons learned from any accident or accidents at similar facilities?		Yes	No
d)	Is there a written quality assurance program?	Procedure? Performed?	Yes Yes/	No No
e)	Is maintenance and repair work in accordance with manufacturer's recommendations?	Scheduled? Performed?	Yes Yes/	No No
f)	Are repair/maintenance procedures?	Developed? Followed?	Yes Yes/	No No

III-VERIFICATION OF WORKER PROTECTION

BSS requirements related to this section may be found in Appendix I "Occupational Exposure".

III-1. Classification of areas

a)	Are controlled areas demarcated?		Yes	No
b)	Are approved signs at access points?	provided?	Yes	No
		legible?	Yes	No
		local language?	Yes	No
c)	Are supervised areas demarcated?		Yes	No
d)	Are approved signs at access points?	needed?	Yes	No
		provided?	Yes	No
		legible?	Yes	o
		local language?	Yes	No

III-2. Local rules and supervision

a)	Are rules established in writing?	Yes	No
b)	Do rules include investigation levels and authorised levels and the procedure to be followed when a level is exceeded?	Yes	No
c)	Are workers (including nurses attending patients) instructed in the implementing procedures?	Yes	No
d)	Do workers have adequate supervision to ensure rules, procedures, protective measures and safety provisions are followed?	Yes	No

III-3. Monitoring

a)	Does the authorised organisation provide personal dosimeters?	Yes	No
b)	Are the dosimeters:		
	i) Worn properly?	Yes	No
	ii) Calibrated?	Yes	No
	iii) Exchanged at required frequency?	Yes	No
c)	Are personnel exposures within limits?	Yes	No
d)	Area and portable survey instruments		
	i) Appropriate?	Yes	No
	ii) Calibrated?	Yes	No
	iii) Operational?	Yes	No
	iv) Operational check performed before use?	Yes	No
e)	Do the authorised organisation's surveys indicate that the radiation room shielding is adequate and the dose rates around the room meet authorised radiation levels?	Yes	No

Record independent measurements made during the inspection:

_____
_____
_____
_____
_____

Type/model no. of survey meter:

Date last calibrated:

Do the inspector's independent surveys agree with the survey results of the authorised organisation?	Yes	No

Document any significant differences and any agreed upon plan to resolve the different results:

_____
_____
_____

IV-VERIFICATION OF PUBLIC PROTECTION

BSS requirements related to this section may be found in Appendix III "Public Exposure".

IV-1. Control of visitors

a)	Are visitors permitted in controlled areas?		Yes	No
b)	Is adequate information provided to visitors entering controlled areas?		Yes	No
c)	Are there adequate controls over entries into controlled and supervised areas and appropriate postings?	provided? legible? local language?	Yes Yes Yes	No No No

IV-2. Sources of exposure

a)	Are the shielding and other protective measures optimised for restricting public exposure to external sources of radiation?	Yes	No
b)	Are the floor plans and arrangement of equipment appropriate considering public areas adjacent to the installation?	Yes	No

IV-3. Monitoring of public exposure

a)	Are routine periodic measurements of exposure rates in areas adjacent to treatment and storage made by the staff or qualified expert?	Yes	No
b)	Record independent measurements made during the inspection:		
	_____ _____ _____		
	Type/model no. of survey meter:		
	Date last calibrated:		
	Are the inspector's independent measurements in agreement with the organisations routine measurements?	Yes	No
	Do surveys shows that the shielding is adequate and the dose rates outside the controlled and supervised areas meet authorised radiation levels?	Yes	No

V-EMERGENCY PREPAREDNESS

BSS requirements related to this section may be found in Appendix V "Emergency Exposure Situations".

V-1. Emergency plan

a)	Is there a written plan?	Yes	No
b)	Is the plan periodically reviewed and updated?	Yes	No
c)	Does the plan take into account lessons learned from operating experience and accidents at similar facilities?	Yes	No
d)	Have workers involved in implementing the plan received training?	Yes	No

VI-MEDICAL EXPOSURE

BSS requirements related to this section may be found in Appendix II "Medical Exposure".

VI-1. Responsibilities

a)	No patient treated unless the exposure is prescribed by a medical practitioner?	procedures? followed?	Yes Yes	No No
b)	Are there an adequate number of trained medical and paramedical personnel to discharge assigned tasks?		Yes	No
c)	Are diagnostic imaging and quality assurance requirements fulfilled with the advice of a qualified expert in radiodiagnostic physics?		Yes	No

VI-2. Justification

a)	Are diagnostic medical exposures justified by taking into account the benefits and risks of alternate techniques that do not involve medical exposure?	Yes	No
b)	Are there procedures to ensure that exposure of humans for medical research is in accordance with the Helsinki Declaration and follows the guidelines for its application prepared by the Council for International Organizations of Medical Sciences and the World Health Organization?	Yes	No
c)	Is each exposure of humans for medical research subject to the advice of an Ethical Review Committee or other similar institutional body?	Yes	No
d)	Are standards available and followed for radiological examinations for screening of large populations or for occupational, legal, or health insurance purposes.	Yes	No

VI-3. Optimisation

a)	Does newly acquired equipment conform to applicable standards of the International Electrotechnical Commission (IEC) and the ISO or to equivalent national standards?	Yes	No
b)	Are performance specifications and operating and maintenance instructions provided in a major world language understandable to the users and in compliance with the relevant IEC or ISO standards with regard to "accompanying documents"?	Yes	No
c)	The operating terminology (or its abbreviations) and operating values be displayed on operating consoles in a major world language acceptable to the user; where practicable?	Yes	No

VI-4. Operational considerations

a)	Do medical practitioners ensure that appropriate equipment is used, that the exposure of patients is the minimum necessary to achieve the diagnostic objective, and take into account relevant information from previous examinations to avoid unnecessary additional exposure?	Yes	No
b)	Do the medical practitioner, the technologists or other imaging staff select the parameters such that their combination produces the minimum patient exposure consistent with acceptable image quality and the clinical purpose of the examination?	Yes	No
c)	Are radiological examinations causing exposure of the abdomen or pelvis of women who are pregnant avoided unless there are strong clinical reasons for such examinations?	Yes	No
d)	Are diagnostic examinations causing exposure of the abdomen or pelvis of women of reproductive capacity planned to deliver the minimum dose to any embryo or foetus?	Yes	No

VI-5. Calibration

a)	Is the calibration of X ray equipment used for medical exposure traceable to a Standards dosimetry laboratory?	Yes	No
b)	Are calibrations carried out at commissioning of a unit, after maintenance that could affect dosimetry and at periodic intervals?	Yes	No

VI-6 Clinical dosimetry

Are representative values for typical sized adult patients of entrance surface doses, dose-area products, dose rates and exposure times, or organ doses determined and documented?		Yes	No

VI-7. Quality assurance

a)	Does the medical quality assurance program include:			
	i) measurements and verification of physical parameters at the time of commissioning and periodically thereafter?	procedures? followed?	Yes Yes	No No
	ii) written records of relevant procedures and results?		Yes	No
	iii) verification of the appropriate calibration and conditions of operation of dosimetry and monitoring equipment?	procedures? followed?	Yes Yes	No No
	iv) verification of patient identity?	procedures? followed?	Yes Yes	No No
	v) regular and independent quality audit reviews?	procedures? followed?	Yes Yes	No No

b)	Darkroom procedures:			
	i)	Dark room light-proof	Yes	No
	ii)	Film storage satisfactory?	Yes	No
	iii)	Cassette pass box available?	Yes	No
	iv)	Timer available?	Yes	No
	v)	Temperature control in the dark room adequate?	Yes	No
c)	Processing of films:			
	i)	Type of film used:		
	ii)	Films developed/week:		
	iii)	Type of developer:		
	iv)	Developing time:		
	v)	Frequency of change of processing solutions:		

VI-8. Dose constraints

a)	Does an Ethical Review Committee or other institutional body specify dose constraints to be applied on a case by case basis in the optimisation of protection for persons exposed for medical research purposes if such medical exposure does not produce direct benefit to the exposed individual?	Yes	No
b)	Have dose constraints been established for individuals knowingly exposed while voluntarily helping in the care or comfort of patients under going medical treatment?	Yes	No
c)	Have dose constraints been established for individuals knowingly exposed while voluntarily visiting patients under going medical treatment?	Yes	No

VI-9. Investigations of accidental medical exposures

a)	Did the registrant or licensee promptly investigate any or all instances where:			
	i)	A diagnostic exposure was substantially greater than intended or resulting in doses repeatedly and substantially exceeding guidance levels?	Yes	No
	ii)	An equipment failure, accident, error, mishap or other unusual occurrence with the potential for causing a patient exposure significantly different from that intended?	Yes	No
b)	With respect to any incidents investigated, did the registrant or licensee:			
	i)	Calculate or estimate the doses received and their distribution within the patient?	Yes	No
	ii)	Indicate the corrective measures required to prevent recurrence of such an incident?	Yes	No
	iii)	Implement all corrective measures that were under their control?	Yes	No
	iv)	Submit to the regulatory authority, as soon as possible after the investigation or as otherwise specified by the regulatory authority, a written report which stated the cause of the accident and included the information specified in “i” to “iii”, as relevant?	Yes	No
v)	Inform the patient and his or her doctor about the incident?		Yes	No

VII-RECORDS

Note: Records will be needed as part of the assessments and verifications outlined in the prior sections of the checklist. This list is a reminder of the type of records that may be helpful. The appearance of the list at the end of the checklist does not indicate that records review is the last item to be done. Rather, an inspection may begin with an entrance interview and facility tour followed by an initial review of some of the records listed below.

a) Copy of authorization certificate
b) System of records management
c) Dosimetry
   i) current
   ii) prior work history
d) Area surveys
e) Instrument tests and calibrations
f) Audits and reviews of radiation safety programme
g) Incident and accident investigation reports

h) Maintenance and repair work
i) Facility modifications
j) Training provided
    i) initial
    ii) refresher
k) Evidence of health surveillance
l) Clinical dosimetry records

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Annex VII

SAFETY ASSESSMENT PLANS FOR UNSEALED RADIOACTIVE SOURCES IN MEDICINE

This annex has two exhibits which include an application form and a checklist for inspection:

(1) Example VII.A: Application for authorization and review plan for use of unsealed radioactive sources in medicine.

(2) Example VII.B: Checklist for commissioning and regular inspection of nuclear medicine installations.

References that may be useful to the regulatory authority and/or to licensees and registrants are listed in the bibliography at the end of the annex. The list is divided into references generally applicable for radiation safety and protection and those which may have particular relevance to work with unsealed radioactive sources in medicine.

Example VII.A

APPLICATION FOR AUTHORIZATION AND REVIEW PLAN FOR USE OF UNSEALED RADIOACTIVE SOURCES IN MEDICINE

TYPE OF AUTHORIZATION

_____ New application
_____ Amendment to existing authorization number: _____
_____ Renewal of authorization number: _____

PURPOSE OF APPLICATION

_____ Construction (Complete Sections I through III)
_____ Import/Purchase (Complete Sections I and II)
_____ Use/Begin operation (Complete Sections I through V)

You may refer to previous submissions by date and application or authorization number(s)

The legal person who will be responsible for using any unsealed source must, unless the source is exempted, submit the following information to the regulatory authority.

I-GENERAL INFORMATION

I-1. Name and address of organisation:

Main address	Mailing address (if different)	Address of use (if different)
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

I-2. Name and information about qualified experts:

Expertise: Radiation protection officer
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____
Telephone number: _____

Expertise: Physician
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____
_____

Expertise: Nuclear Medicine Physics
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____
_____

Expertise: _____
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____
_____

I-3. The responsible representative of the legal person:

Name: _____
Title: _____
Telephone number _____
Facsimile number _____
e-mail address _____

I-4. Proposed date of installation and/or commissioning of facilities and equipment:
_____

SIGNATURE AND CERTIFICATION

_____
Signature of the authorised representative
of the legal person

Title: _____

Date**:** _____

Notes:

1. The regulatory authority may require additional information to fully consider this application prior to issuing an authorization.

2. In the event that all the above information is not available at the time of application, the regulatory authority may issue an authorization limiting the applicant to import, acquire, or store radiation sources, or construct facilities. Complete information will be required from the applicant prior to authorising use of the radiation sources.

3. Medical exposure may be under the jurisdiction of a regulatory authority other than the regulatory authority responsible for occupational and public exposure. However, the authorised user should address the items in Section V for referral to any appropriate authority.

II-SOURCES

II-1. Details of Radionuclides involved in the work:

Radionuclide/ pharmaceutical	Maximum activity at one time (Bq)	Physical/ chemical form	Use application
(e.g. Tc-99m generator)	(e.g. 37 GBq)	(e.g. Sodium pertechnetate)	(e.g. Diagnostic imaging)

II-2. Containment of the radionuclides:

Describe how the radionuclides(s) will initially be contained. Indicate whether there will be any special features such as whether the container will be pressurised or incorporate shielding.

_____
_____
_____
_____

II-3. Work Pattern:

State the frequency of consignments of radionuclides and over what period of time the work will proceed.

_____
_____
_____
_____

II-4. Work locations:

Will the work be carried out at any address other than given in item I-1. above? (Circle correct answer)	Do not know	Yes	No

(Note: that the regulatory authority may require notification prior to work at currently unknown addresses)

List all other known addresses:

_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

II-5. Radioactive wastes:

Indicate whether the work covered by this application is likely to generate radioactive waste(s) and provide an assessment of the different forms:

Radionuclide	Waste form	Maximum activity	Proposed disposal route
Examples: Iodine-125 Technetium 99^{m}	Liquid Used syringes	10 KBq 2 MBq	To drain Decay in storage

III-FACILITIES AND EQUIPMENT

Approval must be obtained from the regulatory authority before starting construction of the radiopharmacy facilities.

In an attachment to this application, describe the facilities and equipment, including:

III-1. Facility specifications:

a) Provide a detailed location of the facility.
b) Prepare a layout of the laboratory clearly indicating the areas for storage of radioisotopes, Tc-99 generator and radiopharmacy, dose administration, counting and imaging rooms and wards for cancer of thyroid patients. Indicate the occupancy around and the wall and ceiling material and thickness. The drainage ducts such as sinks, wash, basins, toilets, etc. should be connected directly to the sanitary sewage system. Provide copies of drawings of the facilities or provide a detailed sketch.
c) Describe any features which will be designed to limit the spread of surface or airborne contamination by the radioactive material. Provide details of surfaces of floors, walls, equipment and furniture that may be designed to aid the removal of any spillage.
d) Indicate the proposed category of the facility (Safety Series 102).

III-2. Equipment specifications:

a) Provide manufacturers specifications for any imaging equipment to be used.
b) Provide manufacturers specifications and type approval certificate for radiopharmaceutical dose measuring or calibrating equipment.
c) Describe proposed arrangements for restricting exposure including for example:
   i) Shielding to be provided to minimise external doses including vial and syringe shields.
   ii) Forms of extract ventilation to minimise the risk of internal doses to staff.
   iii) State whether decontamination facilities will be readily accessible.
   iv) Describe any personal protective equipment that will be provided.
   v) Describe any remote handling equipment.

IV-RADIATION PROTECTION AND SAFETY PROGRAMME

In an attachment to this application, describe the radiation protection programme, including:

IV-1. Organisational structure

a) Describe your organisational and management control systems, including assignment of responsibilities and clear lines of authority related to radiation safety. In particular include: staffing levels, equipment selection, other assignments of the radiation protection officer, a requirement for the RPO to report unsafe operations to the Radiation Safety Committee or Licensee, personnel training, maintenance of records, and how problems affecting safety are identified and corrected.
b) Identify the authorised users, qualified experts, and radiation protection officer by name and include their training, education, experience and qualifications. (Note: the authorised user and/or radiation protection officer may be the same individual).
c) Confirm that training will include: explanation of radiation hazards and effects, explanation of written procedures, use of equipment (e.g. instrumentation), meaning of warning signals, and a method to confirm adequacy of training (testing or demonstrations).

IV-2. Workplace monitoring, area classification and individual monitoring

a) Describe your programme for monitoring the workplace (BSS, I.37-I.40), including: the quantities to be measured, where and when the measurements are to be made, the measurement methods and procedures, and reference levels and the actions to be taken if they are exceeded.
b) Describe your policies and procedures for classification of controlled and supervised areas. (BSS, I.21-I.25).
c) Describe personal dosimeters provided to workers and your policies for assigning dosimetry to individual workers (BSS, I.32-I.36). Describe your policy for reviewing individual doses, including reference levels and actions to be taken in exceeded.
   Name and address of dosimetry service: _____
   _____
   _____
   _____

Denote type:

i) Film _____
ii) ThermoLuminescent dosimeter (TLD)_____
iii) Direct reading dosimeter (DRD) _____
iv) other: _____

d) Describe what form of internal dosimetry, if any, will be provided.

IV-3. Local rules and supervision

a) Describe your local rules and procedures regarding: investigation or authorised levels, protective measures and safety provisions, providing adequate supervision, providing workers information regarding health risks due to occupational exposure, and emergency planning instruction (BSS, I.26-I.27).
b) Provide copies of your operating and safety procedures including: area access control, entry procedures into shielded enclosures, source inventory and leak testing, etc.
c) Describe your training program to ensure all appropriate personnel are adequately trained in the operating procedures and how their actions may affect safety (BSS, I.27).
d) Describe your policies regarding female workers who become pregnant (notification, adoption of working conditions to protect foetus/embryo) and the instructions you will provide to them (BSS, I.16-I.17 and I.27).
e) Describe your programme of health surveillance based on general principles of occupational health and designed to assess the initial and continuing fitness of workers for their intended tasks (BSS, I.41-I.43).

IV-4. Quality assurance

a) Describe your programme for ensuring that regulatory radiation safety requirements are addressed and satisfied.
b) Describe your program to periodically review procedures, maintain procedures current and available, and your procedure modification process.
c) Describe your programme for optimising occupational and public exposures to levels as low as reasonably achievable.
d) Describe service arrangements with other organisations and qualified experts.

IV-5. Transportation of radioactive material

If you will be transporting or shipping radiopharmaceuticals or radioactive waste, describe your arrangements for preparation and transport of packages containing radioactive sources (IAEA Safety Standards Series No. ST-1). These procedures should address: documentation of package certification, package surveys, transfer/receipt documents, and details of shipments preparation.

IV-6. Emergency procedures

Provide your emergency procedures to address potential emergencies such as loss of material, spillage of radioactive material, exposures of patients substantially greater than intended and substantial accidental exposure of a worker. If other emergencies are envisaged, please provide additional appropriate emergency procedures.

IV-7. Transfer or disposal of radioactive sources

Describe arrangements for transfer radioactive waste described in Section II-5.

IV-8. System of records (BSS; 2.40, I.44-I.49, II.31-I.32)**, including:**

a) Disposal of material.
b) Personnel exposure
   i) current records
   ii) prior work history
c) Area surveys
   i) dose or dose rate
   ii) contamination
d) Instrument tests and calibrations
e) Inventory and material accountability
f) Audits and reviews of radiation safety program
g) Incident and accident investigation reports
h) Training provided
i) Evidence of health surveillance of workers
j) Transportation

V-MEDICAL EXPOSURE

If appropriate for the purposes of the regulatory authority, in an attachment to this application, describe the programme to control medical exposure, including:

(BSS requirements related to this section may be found in Appendix II "Medical Exposure").

V-1. Responsibilities

a) Describe your arrangements to ensure that no patient is diagnostically exposed unless the exposure is prescribed by a medical practitioner.
b) Describe your arrangements to ensure that there are an adequate number of trained medical and paramedical personnel to discharge assigned tasks.
c) Confirm diagnostic imaging and quality assurance requirements are fulfilled with the advice of a qualified expert in nuclear medicine physics.

V-2. Justification

a) Describe your arrangements to ensure that medical exposures are justified by weighing the benefits they produce against the radiation detriment they might cause, taking into account the benefits and risks of alternate techniques that do not involve ionising radiation.
b) Describe your arrangements to ensure that exposure of humans for medical research is in accordance with the Helsinki Declaration and follows the guidelines for its application prepared by the Council for International Organizations of Medical Sciences and the World Health Organization.
c) Describe your arrangements to ensure that exposure of humans for medical research is subject to the advice of an Ethical Review Committee or other similar institutional body.

V-3. Optimisation of protection

Operational considerations

a) Describe your arrangements for medical practitioners to ensure that the exposure of patients is the minimum necessary to achieve the diagnostic objective and to take into account relevant information from previous examinations to avoid unnecessary additional examinations.
b) Describe your policies to ensure that the practitioner, the technologists or other imaging staff will endeavour to achieve the minimum patient exposure consistent with acceptable image quality by:
    i) appropriate selection of the radiopharmaceutical and its activity, noting special requirements for children and for patients with impaired organ function.
    ii) use of methods for blocking the uptake in organs not under study and for accelerated excretion when applicable.
    iii) appropriate image acquisition and processing.
c) Confirm procedures causing exposure of women who are pregnant or likely to be pregnant are avoided except when there are strong clinical indications.
d) Describe your policies to ensure that for mothers in lactation, discontinuation of nursing will be recommended until the radiopharmaceutical is no longer secreted in an amount estimated to give an unacceptable dose to the nursing child.
e) Describe your policies to ensure that administration of radionuclides to children for diagnostic procedures will be carried out only if there is a strong clinical indication, and the amount of radioactivity will be reduced according to body weight, body surface area or other appropriate criteria.

V-4. Calibration

a) Describe your policies to ensure that the calibration of sources used for medical exposure is traceable to a Standards dosimetry laboratory.
b) Describe your policies to ensure that unsealed sources will be calibrated in terms of the activity of the radiopharmaceutical to be administered, with the activity being determined and recorded at the time of administration.

V-5. Clinical dosimetry

Describe your procedures to ensure that in diagnosis and treatment with unsealed sources representative absorbed doses to patients will be determined and documented

V-6. Quality assurance

a) Confirm that the medical quality assurance program includes:
b) Measurements and verification of physical parameters at the time of commissioning and periodically thereafter.

c) Written records of relevant procedures and results.
d) Verification of the appropriate calibration and conditions of operation of dosimetry and monitoring equipment.
e) Verification of patient identity.

V-7. Dose constraints

Describe your policies to ensure any dose to individuals incurred knowingly while voluntarily helping (other than in their occupation) in the care support and comfort of patients undergoing medical diagnosis will be constrained to a level not exceeding that specified by national authorities (normally less than 5 mSv).

V-8. Investigations of accidental medical exposures

a) Confirm that you will investigate any or all instances where:
   i) A diagnostic dose was substantially greater than intended or resulted in doses repeatedly and substantially exceeding the established guidance levels.
   ii) An equipment failure, accident, error, mishap or other unusual occurrence with the potential for causing a patient exposure significantly different from that intended.
b) With respect to any incidents investigated, confirm you will:
   i) Calculate or estimate the doses received and their distribution within the patient.
   ii) Indicate the corrective measures required to prevent recurrence of such an incident.
   iii) Implement all corrective measures that were under their control.
   iv) Submit to the regulatory authority, as soon as possible after the investigation or as otherwise specified by the regulatory authority, a written report which stated the cause of the accident and included the information specified in “i” to “iii”, as relevant.
   v) Inform the patient and his or her doctor about the incident.

Example VII.B

CHECKLIST FOR COMMISSIONING AND REGULAR INSPECTION OF NUCLEAR MEDICINE INSTALLATIONS

Prepare a visit agenda to review the operating program with details contained in the application for authorization, the authorization certificate, prior programme review/inspection reports and their implementation, relevant correspondence, and other relevant documentation such as dosimetry reports. (References to appropriate sections and appendices of Safety Series No. 115, "International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources" (BSS), are provided at the beginning of Sections II–VII.)

Check the following for compliance with the authorization and with the regulatory authority requirements.

I-IDENTIFYING INFORMATION

I-1. Name of the institution: _____
_____

I-2. Address of facility: _____
_____
_____

I-3. Telephone/facsimile/e-mail: Voice: _____ Fax: _____
e-mail: _____

I-4. Authorization number: _____

I-5. Name and qualification of the radiation protection officer:
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____

I-6. Name and qualifications of any qualified experts retained:

Nuclear Medicine Physics:
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____

Physician:
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____

Expertise: _____
Name: _____
Degree: _____
Certification: _____
Experience:_____
_____
_____

I-7. Name and title of the responsible representative of the legal person: _____
_____

II-VERIFICATION OF SAFETY

BSS requirements related to this section may be found in Appendix IV "Potential Exposure: Safety of Sources

II-1. Description of radioactive materials in use

Radionuclide/ pharmaceutical	Maximum activity at one time (Bq)	Physical/ chemical form	Use application
Example: Tc-99m generator	Example: 37 GBq	Example: Sodium pertechnetate	Example: Diagnostic imaging

II-2. Description of measuring and handling equipment

Type of equipment	Manufacturer:	Model no:	Number	Comments:
Dose calibrator				
Imaging equipment				
Syringe shield				
L-Block				
Tongs				
Forceps				
Lead blocks				
Well counter				
^{99}Mo generator				
Fume hood				
Xenon trap				

II-3. Facility design

Describe any differences or modifications from those approved by the regulatory authority and/or considered in the safety assessment (e.g. shielding design, building materials and floor plan.):		
_____ _____ _____		
a) Was a safety assessment by a qualified expert performed prior to any modifications?	Yes	No
b) Is the thickness and type of shielding appropriate for the types and intensity of radiation produced by radioisotopes in use?	Yes	No

II-4. Safety control and equipment design

a) Are adequate number of lead containers, lead blocks, and portable or fixed shields available for shielding in storage and handling rooms?	Provided? Used?	Yes Yes	No No
b) Is remote handling equipment such as (tongs, forceps, etc.) available?	Provided? Used?	Yes Yes	No No
c) Are ventilated fume hoods for handling large doses of ^{131}I and for carrying out extraction of ^{99m}Tc available?	Provided? Used?	Yes Yes	No No
d) Are the drainage ducts of the laboratory (sinks, wash basins, toilets, etc.) connected directly to the sanitary sewage system		Yes	No
e) Are adequate provision made for storage of wastes before disposal?		Yes	No

II-5. Warning systems:

Warning notices	provided?	Yes	No
	working?	Yes	No
	legible?	Yes	No
	in local language?	Yes	No

II-6. Safety operations -management

a)	Is management knowledgeable of the certificate of authorization and its restrictions and requirements?		Yes	No
b)	Does management provide adequate staffing levels?		Yes	No
c)	Has management provided the radiation protection officer authority to stop unsafe operations?		Yes	No
d)	Does management provide adequate resources for personnel training (time and money)?		Yes	No
e)	Does management provide adequate equipment?		Yes	No
f)	Does management provide for periodic program reviews and recommendations?	scheduled?	Yes	No
		performed?	Yes	No
	i) Date of the last program review:			
	ii) Status of recommendations: _____ _____ _____			

II-7. Safety operations — technical

a)	Does the radiation protection officer (RPO) have adequate knowledge and expertise?		Yes	No
b)	Does the RPO have qualified experts available?		Yes	No
c)	Is the RPO knowledgeable about the requirements of the regulatory authority and the provisions of the certificate of authorization?		Yes	No
d)	Is the RPO given sufficient time and resources to do the job (e.g. not kept too busy with other assignments or given insufficient technical and secretarial help)?		Yes	No
e)	Does RPO maintains knowledge of activities of workers using radiation sources?		Yes	No
f)	Does the RPO conduct initial and periodic training of workers?		Yes	No
g)	Does the RPO maintain adequate records to demonstrate worker and public protection?		Yes	No
h)	Are there provisions for inventory of sources and accountability:	procedures?	Yes	No
		performed?	Yes	No
i)	Are there provisions for audits and reviews of radiation safety program:	procedures?	Yes	No
		Performed?	Yes	No

II-8. Investigation and quality assurance

a)	Were there any incidents or accidents?		Yes	No
b)	If so, were incident and accident investigation reports prepared?		Yes	No
c)	Were safety assessments reviewed or made based on lessons learned from any accident or accidents at similar facilities?		Yes	No
d)	Is there a written quality assurance program?	procedures?	Yes	No
		performed?	Yes	No
e)	Is maintenance and repair work (measuring equipment, imaging devices, ventilation systems, etc.) in accordance with manufacturer's recommendations?	scheduled?	Yes	No
		performed?	Yes	No
f)	Are repair/maintenance procedures?	developed?	Yes	No
		followed?	Yes	No

III-VERIFICATION OF WORKER PROTECTION

BSS requirements related to this section may be found in Appendix I "Occupational Exposure".

III-1. Classification of areas

a)	Are controlled areas demarcated?		Yes	No
b)	Are approved signs at access points?	provided?	Yes	No
		legible?	Yes	No
		local language?	Yes	No
c)	Is radioactive material storage (including waste) at physically defined locations?		Yes	No
i)	locked/secured location with key control?		Yes	No
ii)	radiation warning notices?	provided?	Yes	No
		legible?	Yes	No
		local language?	Yes	No
iii)	proper shielding (e.g. individual containers, enclosures)?		Yes	No
iv)	reserved only for radioactive material?		Yes	No
d)	Are supervised areas demarcated?		Yes	No
e)	Are approved signs at access points?	needed?	Yes	No
		provided?	Yes	No
		legible?	Yes	No
		local language?	Yes	No

III-2. Local rules and supervision

a)	Are rules established in writing, in a local language?		Yes	No
b)	Do rules include investigation levels and authorised levels and the procedure to be followed when a level is exceeded?		Yes	No
c)	Are workers instructed in the implementing procedures?		Yes	No
d)	Do workers have adequate supervision to ensure rules, procedures, protective measures and safety provisions are followed?		Yes	No
e)	Specifically, are operating and working procedures for:			
i)	nurses attending patients	provided?	Yes	No
		adequate?	Yes	No
		followed?	Yes	No
ii)	diagnostic examinations	provided?	Yes	No
		adequate?	Yes	No
		followed?	Yes	No
iii)	therapy administrations	provided?	Yes	No
		adequate?	Yes	No
		followed?	Yes	No
iv)	performing repairs to and maintenance of safety systems	provided?	Yes	No
		adequate?	Yes	No
		followed?	Yes	No
v)	making surveys	provided?	Yes	No
		adequate?	Yes	No
		followed?	Yes	No

III-3. Monitoring

a)	Does the authorised organisation provide personal dosimeters?		Yes	No
b)	Are the dosimeters:			
i)	Worn properly?		Yes	No
ii)	Calibrated?		Yes	No
iii)	Exchanged at required frequency?		Yes	No
c)	Are personnel exposures within limits?		Yes	No
d)	Area and portable survey instruments			
i)	Appropriate?		Yes	No
ii)	Calibrated?		Yes	No

	iii) Operational?	Yes	No
	iv) Operational check performed before use?	Yes	No
	v) Spare batteries available?	Yes	No
e)	Do the authorised organisation's surveys indicate that the shielding is adequate and the dose rates around storage and patient treatment rooms meet authorised radiation levels?	Yes	No
f)	Does the authorised organisation make periodic tests for leakage of radioactive materials from any sealed sources (e.g. calibration sources)?	Yes	No
g)	Is the instrumentation:		
	i) Appropriate?	Yes	No
	ii) Calibrated?	Yes	No
	iii) Operational?	Yes	No
Record independent measurements made during the inspection:			
_____ _____ _____			
Type/model no. of survey meter:			
Date last calibrated:			
Do the inspector's independent surveys agree with the survey results of the authorised organisation?		Yes	No
Document any significant differences and any agreed upon plan to resolve the different results: _____ _____ _____ _____			

IV-VERIFICATION OF PUBLIC PROTECTION

BSS requirements related to this section may be found in Appendix III "Public Exposure".

IV-1. Control of visitors

a)	Are visitors accompanied in controlled area?	Yes	No
b)	Is adequate information provided to visitors entering controlled areas?	Yes	No
c)	Are there adequate controls over entries into supervised areas and appropriate postings, if needed?	Yes	No

IV-2. Sources of exposure

a)	Are the shielding and other protective measures optimised for restricting public exposure to external sources of radiation?	Yes	No
b)	Are the floor plans and arrangement of equipment as described in the application and appropriate considering any public areas adjacent to the installation?	Yes	No

IV-3. Radioactive waste and discharges

a)	Have provisions been made to transfer waste to an authorised waste disposal facility at the end of use?	Yes	No
b)	If any sealed sources are no longer in use and being stored, does the authorised organisation have a plan for timely transfer or disposal of the sources?	Yes	No
c)	Are there provisions for control of discharges to the environment in the event of contamination?	Yes	No

IV-4. Monitoring of public exposure

a)	Are routine periodic measurements of exposure rates in public areas adjacent to areas used for diagnostic examinations, therapy treatments or radioactive materials made by the staff or qualified expert?	Yes	No
b)	Do surveys shows that the room shielding is adequate and the dose rates outside the areas meet authorised radiation levels?	Yes	No

c) Record independent measurements made during the inspection: _____ _____ _____ _____		
Type/model no. of survey meter:		
Date last calibrated:		
Are the inspector's independent measurements in agreement with the organisations routine measurements?	Yes	No
Document any significant differences and any agreed upon plan to resolve the different results: _____ _____ _____ _____ _____		

V-EMERGENCY PREPAREDNESS

BSS requirements related to this section may be found in Appendix V "Emergency Exposure Situations".

V-1. Emergency plan

a)	Is there a written plan?	Yes	No
b)	Is the plan periodically reviewed and updated?	Yes	No
c)	Does the plan take into account lessons learned from operating experience and accidents at similar facilities?	Yes	No

Training and exercises

a)	Have workers involved in implementing the plan received training?	Yes	No
b)	Have provisions been made for the plan to be rehearsed at suitable intervals in conjunction with any designated emergency response authorities?	Yes	No
c)	Date of the last rehearsal:		

VI-MEDICAL EXPOSURE

BSS requirements related to this section may be found in Appendix II "Medical Exposure".

VI-1. Responsibilities

a)	No patient treated unless the exposure is prescribed by a medical practitioner?	procedures? followed?	Yes Yes	No No
b)	Are there an adequate number of trained medical and paramedical personnel to discharge assigned tasks?		Yes	No
c)	Are diagnostic imaging and quality assurance requirements fulfilled with the advice of a qualified expert in nuclear medicine physics?		Yes	No

VI-2. Justification

a)	Are diagnostic medical exposures justified by taking into account the benefits and risks of alternate techniques that do not involve medical exposure?	Yes	No
b)	Are there procedures to ensure that exposure of humans for medical research is in accordance with the Helsinki Declaration and follows the guidelines for its application prepared by the Council for International Organizations of Medical Sciences and the World Health Organization?	Yes	No
c)	Is each exposure of humans for medical research subject to the advice of an Ethical Review Committee or other similar institutional body?	Yes	No
d)	Are standards available and followed for radiological examinations for screening of large populations or for occupational, legal, or health insurance purposes.	Yes	No

VI-3. Optimisation

a)	Do medical practitioners ensure that appropriate equipment is used, that the exposure of patients is the minimum necessary to achieve the diagnostic objective, and take into account relevant information from previous examinations to avoid unnecessary additional examinations?	Yes	No
b)	Do the medical practitioner, the technologists or other imaging staff endeavour to achieve the minimum patient exposure consistent with acceptable image quality by:	Yes	No
	i) appropriate selection of the radiopharmaceutical and its activity, noting special requirements for children and for patients with impaired organ function?	Yes	No
	ii) use of methods for blocking the uptake in organs not under study and for accelerated excretion when applicable?	Yes	No
	iii) appropriate image acquisition and processing?	Yes	No
c)	Are radiological examinations causing exposure of women who are pregnant or likely to be pregnant avoided unless there are strong clinical reasons for such examinations?	Yes	No
d)	For mothers in lactation, is discontinuation of nursing recommended until the radiopharmaceutical is no longer secreted in an amount estimated to give an unacceptable dose to the nursing child?	Yes	No
e)	Are administration of radionuclides to children for diagnostic procedures carried out only if there is a strong clinical indication, and the amount of radioactivity is reduced according to body weight, body surface area or other appropriate criteria?	Yes	No

VI-4. Calibration

a)	Is the calibration of sources used for medical exposure traceable to a Standards dosimetry laboratory?	Yes	No
b)	Are unsealed sources calibrated in term of the activity of the radiopharmaceutical to be administered, with the activity being determined and recorded at the time of administration?	Yes	No

VI-5. Clinical dosimetry

Are representative absorbed doses determined and documented?		Yes	No

VI-6. Quality assurance

Does the medical quality assurance program include:

a)	Measurements and verification of physical parameters at the time of commissioning and periodically thereafter?	procedures? followed?	Yes Yes	No No
b)	Written records of relevant procedures and results?	procedures? followed?	Yes Yes	No No
c)	Verification of the appropriate calibration and conditions of operation of dosimetry and monitoring equipment?	procedures? followed?	Yes Yes	No No
d)	Verification of patient identity?	procedures? followed?	Yes Yes	No No
e)	Regular and independent quality audit reviews?	procedures? followed?	Yes Yes	No No

VI-7. Dose constraints

a)	Does an Ethical Review Committee or other institutional body specify dose constraints to be applied on a case by case basis in the optimisation of protection for persons exposed for medical research purposes if such medical exposure does not produce direct benefit to the exposed individual?	Yes	No
b)	Have dose constraints been established for individuals knowingly exposed while voluntarily helping in the care or comfort of patients under going medical diagnosis?	Yes	No

VI-8. Investigations of accidental medical exposures

a)	Did the registrant or licensee promptly investigate any or all instances where:			
	i)	A diagnostic dose was substantially greater than intended or resulting in doses repeatedly and substantially exceeding guidance levels?	Yes	No
	ii)	An equipment failure, accident, error, mishap or other unusual occurrence with the potential for causing a patient exposure significantly different from that intended?	Yes	No
b)	With respect to any incidents investigated, did the registrant or licensee:			
	i)	Calculate or estimate the doses received and their distribution within the patient?	Yes	No
	ii)	Indicate the corrective measures required to prevent recurrence of such an incident?	Yes	No
	iii)	Implement all corrective measures that were under their control?	Yes	No
	iv)	Submit to the regulatory authority, as soon as possible after the investigation or as otherwise specified by the regulatory authority, a written report which stated the cause of the accident and included the information specified in "i" to "iii", as relevant?	Yes	No
	v)	Inform the patient and his or her doctor about the incident?	Yes	No

VII-RECORDS

Note: *Records will be needed as part of the assessments and verifications outlined in the prior sections of the checklist. This list is a reminder of the type of records that may be helpful. The appearance of the list at the end of the checklist does not indicate that records review is the last item to be done. Rather, an inspection may begin with an entrance interview and facility tour followed by an initial review of some of the records listed below.*

a) Copy of authorization certificate
b) System of records management
c) Dosimetry
   i) current
   ii) prior work history
d) Area surveys
e) Instrument tests and calibrations
f) Tests for leakage of radioactive material from sources
g) Inventory of sources and accountability
h) Audits and reviews of radiation safety programme
i) Incident and accident investigation reports
j) Maintenance and repair work
k) Facility modifications
l) Training provided
   i) initial
   ii) refresher
m) Evidence of health surveillance
n) Waste disposals
o) Transportation
   i) package documentation
   ii) package surveys
   iii) transfer/receipt documents
   iv) details of shipments dispatched
p) Patient discharge surveys
q) Clinical dosimetry records

BIBLIOGRAPHY TO ANNEX VII

GENERALLY APPLICABLE

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HUDSON, A.P., SHAW, J., Categorization and Designation of Working Areas in which Unsealed Radioactive Materials are Used, NRPB-M443, National Radiological Protection Board (1993).

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Annex VIII

SAFETY ASSESSMENT PLANS FOR RADIOTHERAPY

This annex has two exhibits which include an application form and a checklist for inspection:

(1) Example VIII.A: Application for authorization and review plan for radiotherapy.

(2) Example VIII.B: Checklist for commissioning and regular inspection of radiotherapy.

References that may be useful to the regulatory authority and/or to licensees and registrants are listed in the bibliography at the end of the annex. The list is divided into references generally applicable for radiation safety and protection and those which may have particular relevance to work with radiotherapy.

Example VIII.A

APPLICATION FOR AUTHORIZATION AND REVIEW PLAN FOR RADIOTHERAPY

TYPE OF AUTHORIZATION

_____ New application
_____ Amendment to existing authorization number: _____
_____ Renewal of authorization number: _____

PURPOSE OF APPLICATION

_____ Construction (Complete Sections I through III)
_____ Import/Purchase (Complete Sections I and II)
_____ Use/Begin operation (Complete Sections I through V)

You may refer to previous submissions by date and application or authorization number(s)

The legal person who will be responsible for using any sealed source or radiation generator must, unless the source is exempted, submit the following information to the regulatory authority.

I-GENERAL INFORMATION

I-1. Name and address of organisation:

Main address	Mailing address (if different)	Address of use (if different)
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

I-2. Name and information about qualified experts:

Expertise: Radiation protection officer
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____
Telephone number: _____

Expertise: Radiation Oncology
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____
_____

Expertise: Radiotherapy Physics
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____
_____

Expertise: _____
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____
_____

I-3. The responsible representative of the legal person:

Name: _____
Title: _____
Telephone number _____
Facsimile number _____
e-mail address _____

I-4. Proposed date of installation and/or commissioning of facilities and equipment:
_____

SIGNATURE AND CERTIFICATION

_____
Signature of the authorised representative
of the legal person

Title: _____

Date**:** _____

Notes:

1. The regulatory authority may require additional information to fully consider this application prior to issuing an authorization.

2. In the event that all the above information is not available at the time of application, the regulatory authority may issue an authorization limiting the applicant to import, acquire, or store radiation sources, or construct facilities. Complete information will be required from the applicant prior to authorising use of the radiation sources.

3. Medical exposure may be under the jurisdiction of a regulatory authority other than the regulatory authority responsible for occupational and public exposure. However, the authorised user should address the items in Section V for referral to any appropriate authority.

II-SOURCES AND EQUIPMENT

II-1. For external beam therapy specify the following:

Type: (accelerator or gamma)
Name of manufacturer:_____
Address: _____
_____
_____

Model no. and name: _____
_____

Country of manufacture: _____

Year of manufacture: _____

Type of gantry: (stationary or rotary)
output Gy/min at isocenter: _____

Describe the movement of the treatment table:
_____
_____
_____

a) For Gamma units:
   i) Radionuclide:
   ii) Model no. of the source:
   iii) Initial activity of sources:
   iv) Number of sources installed:
   v) Maximum design activity:
   vi) Total activity installed:
   vii) Types of source carrier or shutter (exposure mechanism):
   viii) Supplier of the source(s):
b) For accelerator:
   i) Maximum energy:
   ii) Maximum current (mA):
   iii) Type of radiation:

II-2. For External beam therapy, describe the features that will be available, including:

a) External Beam Therapy Electrical Indicators/Interlocks (treatment room door, head lock, off shield, hand control, treatment mode–Fixed/Arc/Skip/Rotation, treatment angle, source drawer or shutter, emergency stop buttons to interrupt the irradiation, head collision switch, fixed area radiation monitor).
b) External Beam Source Head Displays (Beam "OFF" indicator, beam "ON" indicator, head lock indicator, collimator rotation indicator, off shield indicator, light field displays).
   i) performance specifications and operating and maintenance instructions, including protection and safety instructions, be provided in a major world language understandable to the users and in compliance with the relevant IEC or ISO standards with regard to "accompanying documents", and that this information be translated into local languages when appropriate;
   ii) where practicable, the operating terminology (or its abbreviations) and operating values be displayed on operating consoles in a major world language acceptable to the user;
c) Teletherapy Control Console Displays (beam "OFF" indicator, beam "ON" indicator, head lock indicator, off shield indicator, arm position indicator, door position indicator).
d) Teletherapy Control Console Functions
   i) power switch,
   ii) reset switch,
   iii) beam "ON" switch,
   iv) beam "OFF" switch,
   v) timer switch (with treatment & elapsed time displays),
   vi) treatment mode selection switch–Fixed/Arc/Skip/, and
   vii) Rotation selection switch for clockwise & anti-clockwise rotation).

II-3. For brachytherapy, specify:

Devices:

Manufacturer:	Model no:	Radionuclide:	Type of loading: Manual (M) Remote (R)	Dose Rate: High (H) Low (L)	Number of channels: (Remote)	Maximum activity
			M R	H L		
			M R	H L		
			M R	H L		
			M R	H L		

Sources:

Manufacturer:	Model no:	Radionuclide	Physical type: Ribbon (R) Wire (W) Individual (I)	Physical dimensions and shape	Total activity (per cm for wires and ribbons)	Number of sources: (total activity for wire)
			R W I			
			R W I			
			R W I			
			R W I			
			R W I			
			R W I			
			R W I			

II-4. Standards

Indicate to which IEC and ISO standards does the equipment and sources used for medical exposure conform:

_____
_____
_____
_____

II-5. For remotely loaded brachytherapy sources, describe the equipment features including:

a) Door to treatment room electrically interlocked with source movement mechanism, and
b) Fixed area radiation monitor.

II-6. For manual brachytherapy, describe source handling devices that will be available including:

a) Source storage and transport container,
b) Source handling devices and accessories (such as tongs, lead containers, etc.), and
c) Radiation protection barrier during manual source loading in patient.

II-7. Servicing of equipment

Identify who will be authorised to perform service and maintenance on the equipment and their authorization number:

_____
_____
_____

III-FACILITIES

Approval should be obtained from the regulatory authority before starting construction of the treatment rooms.

In an attachment to this application, describe the facilities, including:

III-1. Location of the facility.

Provide a detailed description of the location of the radiotherapy facilities including surrounding structures or rooms and activities.

III-2. Layout of facilities

a) Describe factors such as the layout of the facility and its safety systems, including:
b) building materials,
c) alarms,
d) shielding,
e) engineering controls(mechanical interlocks, warning safety devices, emergency stop buttons inside/outside enclosure, prevention of unauthorised personnel entering area, and means of escape or communication from within enclosure.)

III-3. Sketch or drawing

Attach a detailed sketch or drawing of the facility showing the above details. Include on the drawings any penetrations or openings in the shielding materials such as conduits or ventilation ducts.

III-4. Safety assessments

Taking into account existing shielding, provide calculations of the maximum dose rates expected in all areas outside the treatment room(s) which could be occupied. For these calculations, assume any radiation beam is oriented in the position that would result in the highest directional exposures. Provide estimates of the magnitude of expected doses to workers during normal operations. Identify the probability and magnitude of potential exposure (to workers) arising from accidents or incidents. Include a statement of all assumptions used in the calculations.

IV-RADIATION PROTECTION AND SAFETY PROGRAMME

In an attachment to this application, describe the radiation protection programme, including:

IV-1. Organisational structure

a) Describe your organisational and management control systems including assignment of responsibilities related to radiation safety. In particular include: staffing levels, equipment selection, other assignments of the radiation protection officer, a requirement for the RPO to report unsafe operations to the Radiation Safety Committee or Licensee, personnel training, and maintenance of records and how problems affecting safety are identified and corrected.
b) Identify the authorised users, radiation physicist, and radiation protection officer by name and include their training, qualifications, and experience. (Note: the authorised user, radiation physicist, and/or radiation protection officer may be the same individual).
c) Confirm that training will include: explanation of radiation hazards and effects, explanation of written procedures, use of equipment (radiation source and instrumentation), meanings of warning signals, and a method to confirm adequacy of training (testing or demonstrations).

IV-2. Workplace monitoring, area classification and individual monitoring

a) Describe your programme for monitoring the workplace (BSS, I.37-I.40), including: the quantities to be measured, where and when the measurements are to be made, the measurement methods and procedures, and reference levels and the actions to be taken if they are exceeded.
b) Describe your policies and procedures for classification of controlled and supervised areas. (BSS, I.21-I.25).
c) Describe personal dosimeters provided to workers and your policies for assigning dosimetry to individual workers (BSS, I.32-I.36). Describe your policy for reviewing individual doses, including reference levels and actions to be taken in exceeded.

   Name and address of dosimetry service: _____
   _____
   _____
   _____

   Denote type:
   i) Film _____
   ii) ThermoLuminescent dosimeter (TLD)_____
   iii) Direct reading dosimeter (DRD) _____
   iv) other: _____

IV-3. Local rules and supervision

a) Describe your local rules and procedures regarding: investigation or authorised levels, protective measures and safety provisions, providing adequate supervision, providing workers information regarding health risks due to occupational exposure, and emergency planning instruction (BSS, I.26-I.27).

b) Provide copies of your operating and safety procedures including: area access control, entry procedures, source inventory and leak testing, etc.
c) Describe your training program to ensure that all appropriate personnel are adequately trained in the correct operating procedures and how their actions may affect safety (BSS, I.27).
d) Describe your policies regarding female workers who become pregnant (notification adoption of working conditions to protect feotus/embryo) and the instructions you will provide to them (BSS, I.16-I.17 and I.27).
e) Describe your programme of health surveillance based on general principles of occupational health and designed to assess the initial and continuing fitness of workers for their intended tasks (BSS, I.41-I.43).

IV-4. Quality assurance

a) Describe your programme for ensuring that regulatory radiation safety requirements are addressed and satisfied.
b) Describe your program to periodically review procedures, maintain procedures current and available, and your procedure modification process.
c) Describe your programme for optimising occupational and public exposures to levels as low as reasonably achievable.
d) Describe service arrangements with other organisations and qualified experts.

IV-5. Transportation of radioactive material

If you will be transporting or shipping new or used sources, describe your arrangements for preparation and transport of packages containing radioactive sources (IAEA Safety Standards Series No. ST-1). These procedures should address: documentation of package certification, package surveys, transfer/receipt documents, and details of shipments preparation.

IV-6. Emergency procedures

Provide your emergency procedures to address potential emergencies such as potential damage to the source, loss of source shielding, or stuck sources, and misadministration to patients. If other emergencies are envisaged, please provide additional appropriate emergency procedures. In all cases the magnitude of the hazard should be evaluated. Any off-site consequences should also be evaluated. Local emergency services (e.g. fire, police) may need to be provided with copies of the emergency procedures.

IV-7. Transfer or disposal of radioactive sources

Describe arrangements for transfer or disposal of spent radioactive sources.

IV-8. System of records (BSS; 2.40, I.44-I.49, II.31-II.32)**, including:**

a) Disposal of spent sources.
b) Personnel exposure
    i) current records
    ii) prior work history
c) Area surveys
    i) dose or dose rate
    ii) contamination
d) Instrument tests and calibrations
e) Tests for radioactive sealed source leakage.
f) Inventory of sources and accountability
g) Audits and reviews of radiation safety program
h) Incident and accident investigation reports
i) Maintenance and repair work
j) Facility modifications
k) Training provided
l) Evidence of health surveillance of workers
m) Transportation
n) Patient discharge surveys
o) Clinical dosimetry records

V-MEDICAL EXPOSURE

If appropriate for the purposes of the regulatory authority, in an attachment to this application, describe the programme to control medical exposure, including:

(BSS requirements related to this section may be found in Appendix II "Medical Exposure").

V-1. Responsibilities

a) Describe your arrangements to assure that patient treatment will only be prescribed by medical practitioners.
b) Describe your arrangements to assure that calibration, dosimetry and quality assurance requirements for therapy are conducted by or under the supervision of a qualified expert in radiotherapy physics.
c) Describe criteria and arrangements to ensure an adequate number of trained medical and paramedical personnel to discharge assigned tasks.

V-2. Justification

a) Describe your arrangements to ensure that the therapeutic benefits will be weighted against the radiation detriment they might cause, taking into account the benefits and risks of available alternative techniques that do not involve ionising radiation.
b) Describe your arrangements to ensure that exposure of humans for medical research will always be in accordance with the Helsinki Declaration and will follow the guidelines for its application prepared by the Council for International Organizations of Medical Sciences and the World Health Organisation.
c) Describe your arrangements to ensure that each exposure of humans for medical research is subject to the advice of an Ethical Review Committee or other similar institutional body.

V-3. Optimisation of protection

a) Describe your arrangements to ensure that:
   i) exposure of normal tissue during radiotherapy be kept as low as reasonably achievable consistent with delivering the required dose to the planning target volume, and organ shielding be used when feasible and appropriate;
   ii) radiotherapeutic procedures causing exposure of the abdomen or pelvis of women who are pregnant or likely to be pregnant be avoded unless there are strong clinical indications;
   iii) any therapeutic procedure for pregnant women be planned to deliver the minimum dose to any embryo or foetus; and
   (i) the patient be informed of possible risks.
b) Describe your arrangements to ensure that with regard to equipment consisting of radiation generators or containing sealed sources for medical exposures:
c) the equipment conforms to applicable standards of the International Electrotechnical Commission (IEC) and the ISO or to equivalent national standards (whether imported into or manufactured in the country where it is used);
d) performance specifications and operating and maintenance instructions, including protection and safety instructions, will be provided in a major world language understandable to the users and in compliance with the relevant IEC or ISO standards with regard to "accompanying documents", and that this information be translated into local languages when appropriate;
e) where practicable, the operating terminology (or its abbreviations) and operating values will be displayed on operating consoles, in a major world language acceptable to the user.

V-4. Calibration

a) Describe your systems to ensure the calibration of sources used for medical is exposure traceable to a Standards dosimetry laboratory.
b) Describe radiotherapy equipment calibration in terms of radiation quality or energy and either absorbed dose or absorbed dose rate at a predefined distance under specified conditions. (IAEA Technical Report Series No. 277.)
c) Describe procedures for calibration of sealed sources as of a reference date, for activity or at a specific distance in terms of reference air kerma in air or absorbed dose rate in a specific medium.
d) Describe your programme of calibration to be carried out at commissioning of a unit, after maintenance that could affect dosimetry and at periodic intervals.

V-5. Clinical dosimetry

Describe your arrangements to ensure determination and documentation of:

a) for each patient treated with external beam radiotherapy equipment, the maximum and minimum absorbed doses to the planning target volume together with the absorbed dose to a relevant point such as the centre of

the planning target volume, plus the dose to other relevant points selected by the medical practitioner prescribing the treatment;
b) in brachytherapeutic treatments performed with sealed sources, the absorbed doses at selected relevant points in each patient;
c) in diagnosis or treatment with unsealed sources, representative absorbed doses to patients; and
d) in all radiotherapeutic treatments, the absorbed doses to relevant organs.

V-6. Quality assurance for medical exposure

Describe your quality assurance program (BSS II.22) which should include:
a) Verification of the appropriate physical and clinical factors used in treatment including measurements of physical parameters at the time of commissioning and periodically thereafter.
b) Written records of relevant procedures and results.
c) Verification of the appropriate calibration and conditions of operation of dosimetry and monitoring equipment.
d) Verification of patient identity.
e) Regular and independent quality audit reviews.

V-7. Investigation of accidental medical exposure

Describe the procedures to promptly investigate any of the following incidents:
a) any therapeutic treatment delivered to either the wrong patient or the wrong tissue, or using the wrong pharmaceutical, or with a dose fractionation differing substantially from the values prescribed by the medical practitioner or which may lead to undue acute secondary effects;
b) any equipment failure, accident, error, mishap or other unusual occurrence with the potential for causing a patient exposure significantly different from that intended.

V-8. With respect to any investigation

Confirm that you will:
a) calculate or estimate the doses received and their distribution within the patient;
b) indicate the corrective measures required to prevent recurrence of such an incident;
c) implement all the corrective measures that are under your responsibility;
d) submit to the regulatory authority, as soon as possible after the investigation or as otherwise specified by the regulatory authority, a written report which states the cause of the incident and includes the information specified in (a) to (c), as relevant, and any other information required by the regulatory authority; and
e) inform the patient and his or her doctor about the incident.

V-9. Dose constraints to comforters and visitors to patients

Describe your procedures to ensure that the dose of any comforter or visitor of patients will be constrained to a level not exceeding that specified by national authorities (normally less than 5 mSv during the patient's treatment).

Example VIII.B

CHECKLIST FOR COMMISSIONING AND REGULAR INSPECTION OF RADIOTHERAPY

Prepare a visit agenda to review the operating program with details contained in the application for authorization, the authorization certificate, prior programme reviews, inspection reports and their implementation, relevant correspondence, and other relevant documentation such as dosimetry reports. (References to appropriate sections and appendices of Safety Series No. 115, "International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources" (BSS), are provided at the beginning of Sections II–VII.)

Check the following for compliance with the authorization and with the regulatory authority requirements.

I-IDENTIFYING INFORMATION

I-1. Name of the institution: _____
_____

I-2. Address of facility: _____
_____

I-3. Telephone/facsimile/e-mail: Voice: _____ Fax: _____
e-mail: _____

I-4. Authorization number: _____

I-5. Name and qualification of the radiation protection officer:
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____
_____

I-6. Name and qualifications of any qualified experts retained:

Radiotherapy Physics:
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____

Physician–Radiation oncology:
Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____

Expertise:
Name:_____
Degree:_____
Certification:_____
Experience:_____
_____
_____

I-7. Name and title of the responsible representative of the legal person: _____
_____

II-VERIFICATION OF SAFETY

BSS requirements related to this section may be found in Appendix IV "Potential Exposure: Safety of Sources

II-1. For brachytherapy devices:

Manufacturer:	Model no:	Radionuclide:	Type of loading: Manual (M) Remote (R)	Dose Rate: High (H) Low (L)	Number of Channels:	Maximum activity (design/ loaded)
			M R	H L		_____/
			M R	H L		_____/
			M R	H L		_____/
			M R	H L		_____/

Sealed sources

Manufacturer:	Model no:	Radionuclide	Physical type: Ribbon (R) Wire (W) Individual (I)	Physical dimensions and shape	Total activity (per cm for wires and ribbons)	Number of sources: (total activity for wire)
			R W I			
			R W I			
			R W I			
			R W I			
			R W I			
			R W I			
			R W I			

Do the devices and sources listed above conform to the standards in the application? If not, note the standards to which the devices and sources were manufactured.

_____
_____
_____
_____
_____

II-2. External beam therapy unit design

Compare the External Beam Therapy unit with application descriptions and design specifications.

a)	Is the unit as described in the application approved by the regulatory authority?		Yes	No
b)	Type:	Accelerator? Gamma?	Yes Yes	No No
c)	Name of manufacturer:_____			
d)	Model no. and Name _____ _____			
e)	Country of manufacture: _____			
f)	Year of manufacture: _____			
g)	Type of gantry:	Stationary? Rotary?	Yes Yes	No No
h)	Output Gy/min at isocenter:			

i)	Describe the movement of the treatment table: _____ _____ _____
j)	For gamma units: i) Radionuclide: _____ ii) Model no. of the source: _____ iii) Initial activity of sources: _____ iv) Number of sources installed: _____ v) Maximum design activity: _____ vi) Total activity installed: _____
k)	For accelerators: i) Maximum energy: _____ ii) Maximum current (mA): _____
l)	Describe any accelerator differences or modifications: _____ _____ _____

II-3. Facility design

a)	Was a safety assessment by a qualified expert performed prior to any modifications?		Yes	No
b)	Is protection of the devices and sources from adverse environmental conditions (heat, moisture, etc.):	provided? working?	Yes Yes	No No
c)	Is fire detection and protection in the radiation and source storage areas:	provided? working?	Yes Yes	No No
d)	Is adequate ventilation in the radiation and source storage areas:	provided? working?	Yes Yes	No No
e)	Fixed area radiation monitor(s)	provided? working?	Yes Yes	No No
f)	Mechanical door interlocks	provided? working?	Yes Yes	No No
g)	Prevention of unauthorised personnel entering treatment areas:	provided? working?	Yes Yes	No No
h)	Means of escape or communication from within treatment enclosure:	provided? working?	Yes Yes	No No
Describe any facility differences or modifications from those approved by the regulatory authority and considered in the safety assessment (e.g. shielding design, building materials, installed fire protection and controls, etc.): _____ _____ _____				

II-4. Safety control systems

a)	External beam therapy electrical indicators/interlocks				
	i)	Treatment room door	provided? working?	Yes Yes	No No
	ii)	Head lock	provided? working?	Yes Yes	No No
	iii)	Off shield	provided? working?	Yes Yes	No No
	iv)	Hand control	provided? working?	Yes Yes	No No
	v)	Treatment mode — fixed/arc/skip/rotation	provided? working?	Yes Yes	No No

vi)	Treatment angle	provided? working?	Yes Yes	No No
vii)	Source drawer or shutter	provided? working?	Yes Yes	No No
viii)	Emergency stop buttons to interrupt the irradiation	provided? working?	Yes Yes	No No
ix)	Head collision switch	provided? working?	Yes Yes	No No
b)	External beam therapy source head displays			
i)	Beam “OFF” indicator	provided? working?	Yes Yes	No No
ii)	Beam “ON” indicator	provided? working?	Yes Yes	No No
iii)	Head lock indicator	provided? working?	Yes Yes	No No
iv)	Collimator rotation indicator	provided? working?	Yes Yes	No No
v)	Light field displays	provided? working?	Yes Yes	No No
vi)	Off shield indicator	provided? working?	Yes Yes	No No
c)	External beam therapy control console displays			
i)	Beam “OFF” indicator	provided? working?	Yes Yes	No No
ii)	Beam “ON” indicator	provided? working?	Yes Yes	No No
iii)	Head lock indicator	provided? working?	Yes Yes	No No
iv)	Off shield indicator	provided? working?	Yes Yes	No No
v)	Arm position indicator	provided? working?	Yes Yes	No No
vi)	Door position indicator	provided? working?	Yes Yes	No No
d)	External beam therapy control console functions			
i)	Power switch	provided? working?	Yes Yes	No No
ii)	Reset switch	provided? working?	Yes Yes	No No
iii)	Beam “ON” switch	provided? working?	Yes Yes	No No
iv)	Beam “OFF” switch	provided? working?	Yes Yes	No No
v)	Emergency switch	provided? working?	Yes Yes	No No
vi)	Timer switch with treatment & elapsed time displays	provided? working?	Yes Yes	No No
vii)	Treatment mode selection switch — fixed/arc/skip/rotation	provided? working?	Yes Yes	No No
viii)	Selection switch for clockwise & anti-clockwise rotation	provided? working?	Yes Yes	No No

II-5. Warning systems:

a)	Exposure signals and posted explanation (e.g. audible or visible alarms, illuminated signs)	provided? working? local language?	Yes Yes Yes	No No No

b)	Warning notices	provided? local language?	Yes Yes	No No

II-6. Safety operations -management

a)	Is management knowledgeable of the certificate of authorization and its restrictions and requirements?		Yes	No
b)	Does management provide adequate staffing levels?		Yes	No
c)	Has management provided the radiation protection officer authority to stop unsafe operations?		Yes	No
d)	Does management provide adequate resources for personnel training (time and money)?		Yes	No
e)	Does management provide adequate equipment?		Yes	No
f)	Does management provide for periodic program reviews and recommendations?	Scheduled? Performed?	Yes Yes	No No
	i) Date of the last program review:			
	ii) Status of recommendations: _____ _____ _____ _____			

II-7. Safety operations — technical

a)	Does the radiation protection officer (RPO) have adequate knowledge and expertise?		Yes	No
b)	Does the RPO have qualified experts available?		Yes	No
c)	Is the RPO knowledgeable about the requirements of the regulatory authority and the provisions of the certificate of authorization?		Yes	No
d)	Is the RPO given sufficient time and resources to do the job (e.g. not kept too busy with other assignments or given insufficient technical and secretarial help)?		Yes	No
e)	Does RPO maintains knowledge of activities of workers using radiation sources?		Yes	No
f)	Does the RPO conduct initial and periodic training of Workers?		Yes	No
g)	Does the RPO maintain adequate records to demonstrate worker and public protection?		Yes	No
h)	Are there provisions for inventory of sources and accountability:	Procedures? Performed?	Yes Yes	No No

II-8. Investigation and quality assurance

a)	Were there any incidents or accidents?		Yes	No
b)	If so, were incident and accident investigation reports prepared?		Yes	No
c)	Were safety assessments reviewed or made based on lessons learned from any accident or accidents at similar facilities?		Yes	No
d)	Is there a written quality assurance program?	Procedures? Performed?	Yes Yes	No No
e)	Is maintenance and repair work in accordance with manufacturer's recommendations?	Scheduled? Performed?	Yes Yes	No No
f)	Are repair/maintenance procedures?	Developed? Followed?	Yes Yes	No No

III-VERIFICATION OF WORKER PROTECTION

BSS requirements related to this section may be found in Appendix I "Occupational Exposure

III-1. Classification of areas

a)	Are controlled areas demarcated?		Yes	No
b)	Are approved signs at access points?	provided? legible? Local language?	Yes Yes Yes	No No No

c)	Is radiation source storage at a physically defined location (e.g. cabinet, safe, room)?		Yes	No
	i) locked/secured location with key control?		Yes	No
	ii) proper shielding (e.g. individual containers, room)?		Yes	No
	iii) reserved only for radiation sources?		Yes	No
d)	Are supervised areas demarcated?		Yes	No
e)	Are approved signs at access points?	needed?	Yes	No
		provided?	Yes	No
		legible?	Yes	No
		Local language?	Yes	No

III-2. Local rules and supervision

a)	Are rules established in writing, in a local language?	Yes	No
b)	Do rules include investigation levels and authorised levels and the procedure to be followed when a level is exceeded?	Yes	No
c)	Are workers (including nurses attending brachytherapy patients) instructed in the implementing procedures?	Yes	No
d)	Are work activities involved with treatment done in accordance with prescribed operating procedures and conditions?	Yes	No
e)	Do workers have adequate supervision to ensure rules, procedures, protective measures and safety provisions are followed?	Yes	No

III-3. Monitoring

a)	Does the authorised organisation provide personal dosimeters?		Yes	No
	i) Worn properly?		Yes	No
	ii) Calibrated?		Yes	No
	iii) Exchanged at required frequency?		Yes	No
b)	Are personnel exposures within limits?		Yes	No
c)	Are area and portable survey instruments:			
	i) Appropriate?		Yes	No
	ii) Calibrated?		Yes	No
	iii) Operational?		Yes	No
	iv) Operational check performed before use?		Yes	No
d)	Do the authorised organisation's surveys indicate that the radiation room shielding is adequate and the dose rates around the room meet authorised radiation levels?		Yes	No
e)	Does the authorised organisation make periodic tests for leakage of radioactive materials from sealed sources?		Yes	No
f)	Is the instrumentation:	Appropriate?	Yes	No
		Calibrated?	Yes	No
		Operational?	Yes	No

Record independent measurements made during the inspection:

_____
_____
_____

Type/model no. of survey meter:

Date last calibrated:

Do the inspector's independent surveys agree with the survey results of the authorised organisation?	Yes	No

Document any significant differences and any agreed upon plan to resolve the different results:

_____
_____
_____

IV-VERIFICATION OF PUBLIC PROTECTION

BSS requirements related to this section may be found in Appendix III "Public Exposure".

IV-1. Control of visitors

a)	Are visitors accompanied in controlled area?	Yes	No
b)	Is adequate information provided to visitors entering controlled areas?	Yes	No
c)	Are there adequate controls over entries into supervised areas and appropriate postings?	Yes	No

IV-2. Sources of exposure

a)	Are the shielding (including rooms of patients implanted with brachytherapy sources) and other protective measures optimised for restricting public exposure to external sources of radiation?	Yes	No
b)	Are the floor plans and arrangement of equipment appropriate considering public areas adjacent to the installation?	Yes	No
c)	Have provisions been made to control contamination in the event of a leaking source?	Yes	No

IV-3. Radioactive waste and discharges

a)	Have provisions been made to transfer sources to an appropriate registrant or licensee or to an authorised waste disposal facility at the end of use?	Yes	No
b)	If sources are no longer in use and being stored, does the authorised organisation have a plan for timely transfer or disposal of the sources?	Yes	No

IV-4. Monitoring of public exposure

Are routine periodic measurements of exposure rates in areas adjacent to treatment and storage made by the staff or qualified expert?	Yes	No
Record independent measurements made during the inspection: _____ _____ _____		
Type/model no. of survey meter:		
Date last calibrated:		
Are the inspector's independent measurements in agreement with the organisations routine measurements?	Yes	No
Do surveys shows that the shielding is adequate and the dose rates outside the controlled and supervised areas meet authorised radiation levels?	Yes	No

V-EMERGENCY PREPAREDNESS

BSS requirements related to this section may be found in Appendix V "Emergency Exposure Situations".

V-1. Emergency plan

a)	Is there a written plan?	Yes	No
b)	Is the plan periodically reviewed and updated?	Yes	No
c)	Are there procedures for staff to safely handle gamma teletherapy and brachytherapy patients if the radiation source fails to return to the shielded position?	Yes	No
d)	Does the plan take into account lessons learned from operating experience and accidents at similar facilities?	Yes	No

V-2. Training and exercises

a)	Have workers involved in implementing the plan received training?	Yes	No
b)	Have provisions been made for the plan to be rehearsed at suitable intervals?	Yes	No

VI-MEDICAL EXPOSURE

BSS requirements related to this section may be found in Appendix II "Medical Exposure".

VI-1. Responsibilities

a)	Are there procedures or arrangements to ensure that no patient treated unless the exposure is prescribed by a medical practitioner?	provided? followed?	Yes Yes	No No
b)	Are there an adequate number of trained medical and paramedical personnel to discharge assigned tasks?		Yes	No
c)	Are calibration, dosimetry, and quality assurance requirements conducted by or under the supervision of a qualified expert in radiotherapy physics?		Yes	No

VI-2. Justification

a)	Are new therapy procedures justified by taking into account the benefits and risks of alternate techniques that do not involve medical exposure?	Yes	No
b)	Are there procedures to ensure that exposure of humans for medical research is in accordance with the Helsinki Declaration and follows the guidelines for its application prepared by the Council for International Organizations of Medical Sciences and the World Health Organisation?	Yes	No
c)	Is each exposure of humans for medical research subject to the advice of an Ethical Review Committee or other similar institutional body?	Yes	No

VI-3. Optimisation

Design considerations				
a)	Is there documentary evidence that equipment and sources comply with IEC and ISO standards?		Yes	No
b)	Whether imported into or manufactured in the country, does the equipment conform to applicable standards of IEC and ISO or to equivalent national standards;		Yes	No
c)	Are performance specifications and operating and maintenance instructions provided in a major world language understandable to the users and in compliance with the relevant IEC or ISO standards with regard to "accompanying documents"?		Yes	No
d)	Where practicable, are the operating terminology (or its abbreviations) and operating values displayed on operating consoles in a major world language acceptable to the user?		Yes	No
e)	Is the of design newly acquired equipment evaluated to ensure that failures of components are promptly detectable and the incidence of human error is minimised?		Yes	No
f)	Is a backup system for terminating irradiation:	provided? working?	Yes Yes	No No
g)	Do radioactive sources conform to the definition of a sealed source?		Yes	No
h)	Are there appropriate contingency plans for responding to events that may occur, while the patient is being treated?	provided? practised?	Yes Yes	No No
i)	Are these plans for patient protection displayed prominently and practised periodically?		Yes	No
j)	Are there provisions for selection, reliable indication and confirmation (when appropriate and to the extent feasible) of operational parameters such as type of radiation, indication of energy, beam modifiers, treatment distance, field size, beam orientation and either treatment time or preset dose?	provided? working?	Yes Yes	No No
k)	Will radioactive sources be automatically shielded in the event of an interruption of power and remain shielded until reactivated at the control panel?	provided? working?	Yes Yes	No No
l)	Are monitors provided to give warning of an unusual situation such as high radiation levels when position indicators show the source has been returned to a shielded position?	provided? working?	Yes Yes	No No

VI-4. Operational considerations

a)	Do treatment plans include exposure of normal tissue is kept as low as is reasonably achievable consistent with delivering the planned dose to the target volume?	provided? followed?	Yes Yes	No No
b)	Are radiotherapeutic procedures causing exposure of the abdomen or pelvis of women who are pregnant avoided except when there are strong clinical indications?	provided? followed?	Yes Yes	No No
c)	Are any therapeutic procedures for pregnant women planned to deliver the minimum dose to any embryo or foetus?	provided? followed?	Yes Yes	No No
d)	Are patients informed of possible risks?		Yes	No

VI-5. Calibration

a)	Is the calibration of sources used for medical exposure traceable to a Standards dosimetry laboratory?	Yes	No
b)	Is radiotherapy equipment calibrated in terms of radiation quality or energy and either absorbed dose or absorbed dose rate at a predefined distance under specified conditions? (IAEA Technical Report Series No. 277.)	Yes	No
c)	Are sealed sources calibrated for a specified reference date for activity or at a specific distance in terms of reference air kerma in air or absorbed dose rate in a specific medium?	Yes	No
d)	Are calibrations carried out at commissioning of a unit, after maintenance that could affect dosimetry and at periodic intervals?	Yes	No

VI-6. Clinical dosimetry

a)	Are the maximum and minimum absorbed doses from external beam teletherapy determined and documented for the planning target volume together with the absorbed dose at selected relevant points?	Yes	No
b)	For brachytherapy, is the absorbed dose determined and documented for selected relevant points in each patient?	Yes	No
c)	For all radiotherapy, is the absorbed dose to relevant organs determined and documented?	Yes	No

VI-7. Quality assurance

Does the medical quality assurance program include:				
a)	Verification of the appropriate physical and clinical factors used in treatment including measurements of physical parameters at the time of commissioning and periodically thereafter?	provided? followed?	Yes Yes	No No
b)	Written records of relevant procedures and results?	provided? followed?	Yes Yes	No No
c)	Verification of the appropriate calibration and conditions of operation of dosimetry and monitoring equipment?	provided? followed?	Yes Yes	No No
d)	Verification of patient identity?	provided? followed?	Yes Yes	No No
e)	Regular and independent quality audit reviews?	provided? followed?	Yes Yes	No No

VI-8. Dose constraints

a)	Does an Ethical Review Committee or other institutional body specify dose constraints to be applied on a case by case basis in the optimisation of protection for persons exposed for medical research purposes if such medical exposure does not produce direct benefit to the exposed individual?	Yes	No
b)	Have dose constraints been established for individuals knowingly exposed while voluntarily helping in the care or comfort of patients under going medical treatment?	Yes	No
c)	Have dose constraints been established for individuals knowingly exposed while voluntarily visiting patients under going medical treatment?	Yes	No

VI-9. Discharge of patients

Are patients monitored prior to discharge to determine that all temporary implants of radioactive sources have been removed and that the activity is below the level specified in Schedule III, Table III-VI of the BSS?	procedure followed?	Yes Yes	No No

VI-10. Investigations of accidental medical exposures

Did the registrant or licensee promptly investigate any or all instances where:				
a)	A therapeutic treatment was delivered to the wrong patient, the wrong treatment site, or with a dose or dose fractionation differing substantially from the values prescribed by the medical practitioner?		Yes	No
b)	An equipment failure, accident, error, mishap or other unusual occurrence with the potential for causing a patient exposure significantly different from that intended?		Yes	No
c)	With respect to any incidents investigated, did the registrant or licensee:			
	i)	Calculate or estimate the doses received and their distribution within the patient?	Yes	No
	ii)	Indicate the corrective measures required to prevent recurrence of such an incident?	Yes	No
	iii)	Implement all corrective measures that were under their control?	Yes	No
	iv)	Submit to the regulatory authority, as soon as possible after the investigation or as otherwise specified by the regulatory authority, a written report which stated the cause of the accident and included the information specified in “i” to “iii”, as relevant?	Yes	No
	v)	Inform the patient and his or her doctor about the incident?	Yes	No

VII-RECORDS

Note: Records will be needed as part of the assessments and verifications outlined in the prior sections of the checklist. This list is a reminder of the type of records that may be helpful. The appearance of the list at the end of the checklist does not indicate that records review is the last item to be done. Rather, an inspection may begin with an entrance interview and facility tour followed by an initial review of some of the records listed below.

a) Copy of authorization certificate
b) System of records management
c) Dosimetry
   i) current
   ii) prior work history
d) Area surveys
e) Instrument tests and calibrations
f) Tests for leakage of radioactive material from sources
g) Inventory of sources and accountability
h) Audits and reviews of radiation safety programme
i) Incident and accident investigation reports
j) Maintenance and repair work
k) Facility modifications
l) Training provided
   i) initial
   ii) refresher
m) Evidence of health surveillance
n) Waste disposals
o) Transportation
   i) package documentation
   ii) package surveys
   iii) transfer/receipt documents
   iv) details of shipments dispatched
p) Patient discharge surveys
q) Clinical dosimetry records

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Annex IX

INVESTIGATION OF INCIDENTS AT INDUSTRIAL FACILITIES

This checklist should be used for investigating incidents at industrial facilities to reconstruct the events leading to the incident, and identify any contributing factors.

In general it is good practice to interview any individual directly or indirectly connected with the incident. Each person should be interviewed separately and without their supervisor. Note times, places, names, equipment, procedures followed, surveys performed, and other information even if it does not seem relevant at the time. Consider the need to have the incident re-enacted with a non radioactive source if doses received by individuals need to be estimated.

If time permits, prepare a visit agenda to review the programme with details contained in the application for authorization, the authorization certificate, and any information available on the incident.

I-SITE DETAILS

Review the following details at the site:

I-1. Comparison with authorization

Note any changes from the general information available in the application for authorization and authorization certificate:

a) Radioactive materials
   i) lost Yes/No
   ii) stolen Yes/No
b) if yes, explain and give details of radiation source

_____
_____
_____

a) Responsible individuals
   i) changed Yes/No
   ii) available Yes/No
b) Authorised use
   i) changed Yes/No
c) Authorised address
   i) changed Yes/No

I-2. Facility design and equipment

a) Housekeeping
   i) Is everything in its proper place? Yes/No
   ii) Is equipment, floors, work surfaces clean and orderly Yes/No
b) Shielding
   i) integrity lost Yes/No
      if yes, explain_____
      _____
      _____
   ii) source stored properly Yes/No
      if no, explain_____
      _____
      _____

I-3. Radiation Protection equipment

a) portable survey meters
   i) available Yes/No
   ii) working Yes/No
   iii) current radiation levels_____

b) dosimetry
   i) available Yes/No
   ii) emergency reading Yes/No
   iii) bioassay needed Yes/No
c) radiation area monitors
   i) available Yes/No
   ii) working Yes/No
   iii) current radiation levels_____

I-4. Warning signs and access control

a) signs properly posted Yes/No
b) signs visible Yes/No
c) signs legible Yes/No
d) adequate control Yes/No
   i) if no, explain _____
_____
_____
   ii) interlocks defeated Yes/No
   iii) if yes, explain_____
_____
_____

I-5. Procedures

a) Written procedures followed Yes/No
   if no, explain_____
   _____
   _____
b) Emergency procedures followed Yes/No
   if no, explain_____
   _____
   _____
c) Were activities properly supervised? Yes/No
   if no, explain_____
   _____
   _____

II-DOCUMENTATION

II-1. General

Obtain and review all documentation related to the incident (e.g. licensee's incident report, dosimetry. Incident report must contain information about:

a) simulation of individual doses
b) reconstruction of the accident situation
c) checking the individual monitoring results

II-2. Additional information needed based on type of event

a) Potential Radiation Overexposure
   i) number of people receiving overexposures
   ii) dose received from overexposures
   iii) number of members of the public overexposed
   iv) number of members of the public exposed
   v) number of radiation workers overexposed
   vi) worker exposures
   vii) source of radiation
   viii) manufacturer
   ix) serial number of device
   x) model number of source
   xi) radionuclide
   xii) activity or energy level of source
   xiii) source assay date

b) Lost/stolen/abandoned/leaking/damaged/malfunctioning device or source
   i) source of radiation
   ii) manufacturer
   iii) serial number of device
   iv) model number of source
   v) radionuclide
   vi) activity or energy level of source
   vii) source assay date
   viii) leak test result or last leak test result_____
   ix) note contaminated areas
   x) current status of source(s)

c) Release of Radioactive material (complete item 7a above). Describe the radioactive materials and forms dispersed, determine the volume and concentration of contamination, and where it has been dispersed (e.g. air, groundwater, sewer, surfaces).

Annex X

PERFORMANCE INDICATORS

This annex contains two lists of performance indicators. Table X-1 contains 5 performance indicators that are most commonly found during inspections. Table X-2 contains additional performance indicators that also may be of value in identifying situations with the potential for degraded safety performance in the use of radiation sources.

TABLE X-1. COMMON PERFORMANCE INDICATORS

Number	Description
1	Lack of senior management commitment to or involvement with the radiation safety programme
2	Minimal radiation protection officer oversight and/or too busy with other assignments
3	Too few staff trained to conduct an effective radiation protection programme and/or too heavy workload
4	Issues relating to radiation protection programme are not discussed by the appropriate responsible individuals within the organisation
5	Quality assurance fails to detect radiation safety problems

TABLE X-2. ADDITIONAL PERFORMANCE INDICATORS

Number	Description
1	Failure to follow approved procedures
2	Users not familiar with safety procedures or authorization conditions
3	Allowing production activities to take precedence over radiation protection programme
4	Failure to implement lasting corrective action
5	Frequent repeated minor problems, perhaps arising from failure to correct a fundamental problem
6	Poor record keeping
7	Evidence of financial instability of authorised organisation
8	Frequent resignations of staff
9	Inability to perform on time all tasks required by the radiation protection programme
10	Lack of training documentation
11	Failure to assess the effectiveness of training provided
12	Concerns about radiation safety from the workforce
13	Poor accounting for, or security of, radiation sources
14	Major change of organisation or structure
15	Excessive accumulation of radioactive waste
16	Lack of refresher training
17	Lack of emergency preparedness
18	Inadequate radiation and contamination monitoring

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McCready-Shea, S.	Health & Safety Executive, United Kingdom
Murthy, M.S.S.	Bhabha Atomic Research Centre, India
Oresegun, M.	International Atomic Energy Agency
Ortiz López, P.	International Atomic Energy Agency
Prouza, Z.	State Office of Nuclear Safety, Czech Republic
Rojkind, R.H.	Ente Nacional Regulador Nuclear, Argentina
Santiago, P.	US Nuclear Regulatory Commission, United States of America
Spitzberg, D.B.	US Nuclear Regulatory Commission, United States of America
Velasques, S.	Comissao Nacional de Energia Nuclear, Brazil
Wheatley, J.	International Atomic Energy Agency
Wheelton, R.	National Radiological Protection Board, United Kingdom

Consultants Meetings

Vienna, Austria: 3–6 June 1996, 4–6 December 1996,
10 February – 21 March 1997, 9–11 July 1997

Technical Committee Meeting

Vienna, Austria: 4–8 November 1996