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Inspection of Radiation Sources and Regulatory Enforcement

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

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FOREWORD

The achievement and maintenance of a high level of safety in the use of radiation sources depends on there being a sound legal and governmental infrastructure, including a national regulatory body with well-defined responsibilities and functions. These responsibilities and functions include establishing and implementing a system for carrying out regulatory inspections, and taking necessary enforcement actions.

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

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

This TECDOC provides practical guidance on the processes for carrying out regulatory inspections and taking enforcement actions. It includes information on the development and use of procedures and standard review plans (i.e. checklists) for inspection. Specific procedures for inspection of radiation practices and sources are provided in the Appendices.

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

EDITORIAL NOTE

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1. INTRODUCTION

1.1. BACKGROUND

This TECDOC has been developed from practical experience with regulators in various countries. It supersedes the IAEA-TECDOC-1113 on Safety Assessment Plans for Authorization and Inspection of Radiation Sources, published in September 1999 [1] and IAEA-TECDOC-1067 on Organization and Implementation of a National Regulatory Infrastructure Governing Protection against Ionizing Radiation and the Safety of Radiation Sources, published in February 1999 [2]. Specific requirements for regulatory bodies relating to inspection and enforcement are also included in the IAEA Safety Standards Series publication Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety, No. GS-R-1 [3].

The International Basic Safety Standards for Protection against Ionizing Radiation and the Safety of Radiation Sources No. 115 [4] (hereinafter termed 'Basic Safety Standards') were approved by the Board of Governors of the International Atomic Energy Agency in 1994 and published in 1996. The purpose of the Basic Safety Standards is to establish basic requirements for protection against the risks associated with exposure to ionizing radiation and for the safety of radiation sources that may deliver such exposure. The Basic Safety Standards comprise requirements to be fulfilled in all activities involving radiation exposure. They are aimed to serve as a practical guide for public authorities and services, employers and workers, specialized radiation protection bodies, enterprises and safety and health committees.

The Basic Safety Standards [4] are based on principles set out in the IAEA Safety Fundamentals on Radiation Protection and Safety of Radiation Sources, published in 1996 as IAEA Safety Series No.120 [5]. In addition to describing basic criteria for performance standards applicable to most practices and situations, the Basic Safety Standards and GS-R-1 [3] identify the need for an independent regulatory body empowered to issue authorizations to persons or organizations to deal with radiation practices and sources, and to conduct inspections of facilities and sources and carry out enforcement to ensure compliance with regulatory requirements. Guidance to regulatory bodies on regulatory functions has been further revised and consolidated in the IAEA Safety Guide on Regulatory Control of Radiation Sources, No. GS-G-1.5, published in 2004 [6].

1.2. OBJECTIVE

The objective of this publication is to provide practical approaches on the processes of inspection and enforcement during the use of radiation practices and sources to States, which may need to upgrade or perhaps establish national radiation safety regulatory programmes in order to meet the worldwide recommended requirements of GS-R-1 [3] and the Basic Safety Standards [4].

It includes information on the development and use of procedures and standard review plans (i.e. checklists) for inspection and enforcement, along with more detailed advice related to specific practices.

1.3. SCOPE

This publication provides:

- Advice on the establishment of procedures to facilitate regulatory compliance through inspections and enforcement;
- The processes to be followed and the use of standard assessment plans for inspection; and
- Examples of inspection procedures and checklists for different uses of radiation practices and sources in medicine and industry, as the following:
  - Diagnostic radiology
  - Nuclear medicine
  - Radiotherapy
  - Industrial radiography
  - Irradiators – research and industrial
  - Radioactive gauges
  - Well logging

1.4. STRUCTURE

Section 2 defines the objectives of inspection and enforcement. Section 3 outlines the organization and management of inspections. Section 4 describes the performance of the inspections. Section 5 provides details of the organization and management of enforcement activities. An example of a code of conduct for inspectors is provided in Annex I. An example of a regulatory body's enforcement policy is provided in Annex II. An example of corrective action letter is provided in Annex III. Specific procedures for inspection of radiation practices and sources are provided in the Appendices A to G of Annex IV.

2. OBJECTIVES OF INSPECTION AND ENFORCEMENT

The Basic Safety Standards [4, Preamble] states**:** *"The Standards are intended to place requirements on those legal persons authorized to conduct practices that cause radiation exposure or intervene in order to reduce existing exposures; these legal persons have the primary responsibility for applying the Standards. Governments, however, have responsibility for their enforcement ..."*

"*Authorization*" is defined in the GS-R-1 [3] as: "*The granting by a regulatory or other governmental body of written permission for an operator to perform specified activities. Authorization could include, for example, licensing, certification, registration, etc.*" An *"operator"* is defined as "*any organization or person applying for an authorization or authorized and/or responsible for nuclear, radiation, radioactive waste or transport safety when undertaking activities or in relation to any nuclear facilities or sources of ionizing radiation. This includes, inter alia, private individuals, governmental bodies, consignors or carriers, licensees, hospitals, self-employed persons, etc*." he term "operator" therefore has the same meaning as the term *"legal person"* as used in the *Basic Safety Standards* [4].

"R*egulatory inspection*" is defined in GS-R-1 [3] as: *"An examination, observation, measurement or test undertaken by or on behalf of the regulatory body to assess structures, systems, components and materials, as well as operational activities, processes, procedures*

and personnel competence". Although this definition was perhaps developed for nuclear regulatory activities, this definition can also be applied generally to radiation safety.

"*Enforcement*" is defined in GS-R-1 [3] as: "*The action taken by the regulatory body to correct non-compliance by operators with the relevant law, regulations and conditions established in the authorizations"*.

"Regulatory inspection and enforcement activities shall cover all areas of regulatory responsibility. The regulatory body shall conduct inspections to satisfy itself that the operator is in compliance with the condition set out, for example, in the authorization or regulations" (Ref. [3], para. 5.12). Accidents or incidents that result in unacceptably high radiation doses or significant contamination are often associated with a failure to comply with the regulatory requirements that if followed might have prevented the consequences. Inspection therefore has a major role in confirming safety. "In addition, the regulatory body shall take into account, as necessary, the activities of suppliers of services and products to the operator" (Ref. [3], para. 5.12), e.g. both the operator that consigns radioactive sources for shipment, and transport companies that transport the radioactive sources, must comply with the transport regulations.

A strong, effective enforcement program should be considered by the regulatory body as a key component of the regulatory infrastructure for assuring success in meeting radiation safety objectives.

The main purposes of regulatory inspection and enforcement, set out in GS-R-1 (Ref. [3], para. 5.13) are to ensure that:

1. *"Facilities, equipment and work performance meet all necessary requirements"*.

For example, the facility design and operational aspects of the authorized radiation protection programme should not have been altered so as to compromise radiation safety. Shielded rooms or modifications to such areas should comply with the external dose rate design criteria while signs and other warning devices should be in place and functioning correctly. Air and work surface contaminations should be under specified levels. Radiation sources while not in use should be into their respective shielded boxes. Survey meters and other radiation detectors calibration should be routinely checked. All supervisors should be at work during their respective working times. Periodic re-training courses should be performed as established in the radiation protection programme. The optimization principle should be complied with.

2. *"Relevant documents and instructions are valid and are being complied with"*.

Local working rules, particularly those for controlled and supervised areas, should remain valid irrespective of any changes within the facility or to personnel. The inventory of radiation sources, unsealed radioactive sources utilization logbook, personal dose records, radiation detector calibration checking, etc., must be kept up to date.

3. *"Persons employed by the operator (including contractors) possess the necessary competence for the effective performance of their functions"*.

Radiation workers must have satisfactory qualifications and training in radiation safety relevant to the work undertaken. Training and re-training records should be maintained for each radiation worker.

4. *"Deficiencies and deviations are identified and are corrected or justified without undue delay".*

Deficiencies are failures to comply with requirements, e.g. inadequate or flawed protective shielding. *Deviations* are variations from the specified requirements, e.g. the qualifications and training of radiation workers failing to meet specified standards. The regulatory body inspection should verify that any deficiency or deviation detected in a previous inspection has been corrected within the established deadline.

5. *"Any lessons learned are identified and propagated to other operators and suppliers and to the regulatory body as appropriate"*

The regulatory body must be notified of significant incidents or accidents (which may be specified in regulations or conditions) so that information on such events can be communicated to other operators where these events may be relevant to their safety.

6. *"The operator is managing safety in a proper manner".*

The facility's radiation protection programme should be updated as necessary to accommodate changing circumstances with relevant changes notified to the regulatory body. Institutional safety culture should be fostered and maintained.

"Regulatory inspections shall not diminish the operator's prime responsibility for safety or substitute for the control, supervision and verification activities that the operator must carry out" (Ref. [3], para. 5.13).

GS-R-1 (Ref. [3], para. 2.4 (14)) states that the legislation *shall define what is an offence and the corresponding penalties*". Further, GS-R-1 in para. 3.2 (items 4, 5 and 6), it is stated that "*In fulfilling its statutory obligations, the regulatory body:*

- *shall carry out regulatory inspections;*
- *shall ensure that corrective actions are taken if unsafe or potentially unsafe conditions are detected; and*
- *shall take the necessary enforcement action in the event of violations of safety requirements*."

3. ORGANIZATION AND MANAGEMENT OF INSPECTIONS

3.1. INTRODUCTION

The procedures provided in this publication are intended to illustrate to regulatory bodies on how to meet the requirements relating to inspection and enforcement set out in GS-R-1 [3]. Regulatory programs implemented by States may differ in their form and structure. The safety standards assume that a single regulatory body is responsible for all aspects of radiation protection and safety (hereinafter termed as 'radiation safety') in a country. However, in some

States, the responsibility for regulating different radiation practices and sources or different aspects of radiation safety are divided between different authorities (e.g. transport, mining, environment, etc.). Consequently, the concept *"regulatory body"* is understood to be the relevant authority that regulates particular radiation practices and sources or aspects of radiation safety in question. Regardless of any division of regulatory responsibilities, Governments must ensure that all aspects are covered.

The type of regulatory regime adopted will depend on the size, complexity and safety implications of the regulated radiation practices and sources, as well as on the regulatory traditions in the country. The mechanism for carrying out regulatory duties may vary, with some authorities being completely self-sufficient and others delegating some inspection, assessment or other duties to various governmental, public or private agencies. The delegation of duties may need to be provided for in legislation and, in some cases, may also require the regulatory body to accredit inspectors to ensure competence in carrying out inspections. However, the GS-R-1 [3] requires that: *"The use of consultants* (e.g. consultants carrying out inspections) *shall not relieve the regulatory body of any of its responsibilities. In particular, the regulatory body's responsibility for making decisions and recommendations shall not be delegated"* (Ref. [3], para. 4.4).

The principal component of monitoring is on-site inspection and is normally where a major proportion of the regulatory body's resources should be allocated. Inspections are also the principal means by which direct personal contact between operators and regulatory body's personnel is achieved.

3.2. NATIONAL LEGISLATION AND THE REGULATORY BODY

It is expected that States will have national legislation (i.e. laws and codes of practice or regulatory guides) in place that are consistent with the requirements of the GS-R-1 [3] and the *Basic Safety Standards* [4]. The regulatory body should have authority through the legislation to establish regulations through the provision of codes of practice and regulatory guides which, apart from their principal purpose, serve as a basis for establishing inspection procedures.

In relation to inspection and enforcement the national legislation must empower a regulatory body to**:**

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

(b) enforce regulatory requirements;

(c) communicate directly with governmental authorities at higher levels when such communication is considered to be necessary for exercising effectively the functions of the body;

(d) obtain such documents and opinions from private or public organizations or persons as may be necessary and appropriate;

(e) communicate independently its regulatory requirements, decisions and opinions and their basis to the public;

(f) make available, to other governmental bodies, national and international organizations, and to the public, information on incidents and abnormal occurrences, and other information, as appropriate; and

(g) liaise and coordinate with other governmental or non-governmental bodies having

competence in such areas as health and safety, environmental protection, security, and transport of dangerous goods.

3.3. LEGAL ADVICE

In relation to inspection and enforcement, the regulatory body will require legal advice for a range of matters, including**:**

(a) the establishment of appropriate penalties for breaches of the legislation and their enforcement;

(b) instruction on evidence gathering and interview procedures for the regulatory body's inspectors; and

(c) obtaining advice on specific issues (e.g. whether there is appropriate evidence for the regulatory body to initiate a prosecution or to determine if there are grounds to withdraw, suspend or cancel an authorization, etc.).

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

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

While the regulatory body is required to have adequate authority and power to carry out inspections (Ref. [3], para. 2.2 (4)) the co-operation of the authorized legal persons is important to ensure that regulatory inspection is carried out in an effective, informed and unhindered manner. The regulatory body is required to have the authority to enter a site or facility to carry out an inspection (Ref. [3], para. 2.6 (7)). Additionally, the operator has to make arrangements to provide inspectors with access to contractors and consultants where such access is deemed necessary for the fulfillment of the regulatory body's responsibilities. Legal advice and support may be required if inspectors are prevented or frustrated by operators from carrying out their duties, but such a behaviour has to be considered serious breach of the legislation.

3.4. TYPE OF INSPECTIONS

Inspections generally comprise**:**

(a) initial or pre-operational inspections carried out prior to a practice commencing work with radiation, sometimes required as part of the process of authorization;

(b) planned inspections of existing authorizations usually at specified frequencies;

(c) inspections with the purpose of making investigations when the regulatory body so deems necessary; and

(d) inspections carried out following cessation of the radiation practice or if an authorization is otherwise cancelled, to provide an independent check for matters such as confirmation of the removal of radiation sources and radiation warning signs, decontamination of the facilities, etc.

Planned inspections will generally be the principal activity of the regulatory body. They may be either announced or unannounced. They will be a substantial part of the planned and systematic inspection programme of the regulatory body.

An *unannounced inspection* provides the regulatory body with the opportunity to see a facility operating under its usual, normal working conditions. For this reason, performance of unannounced inspections should be the one preferred by the regulatory body. Disadvantages are that key personnel may not be available or part of the facility may not be functioning at the time of the inspection. The timing of unannounced inspections generally requires a reasonable working knowledge of the practice for the inspectors being able to assume those disadvantages. Nevertheless, the whole facility and all records and documentation should be available in case of unannounced inspections.

Announced inspections provide the inspectors with the opportunity to discuss and make prior arrangements with key personnel for interviews and to ensure that relevant specific documentation, which may be needed by the regulatory body to be seen during the inspection, will be available.

3.5. ORGANIZATION OF INSPECTIONS

GS-R-1 [3] requires that: "*the regulatory body shall be structured so as to ensure that it is capable of discharging its responsibilities and fulfilling its functions effectively and efficiently. The regulatory body shall have an organizational structure and size commensurate with the extent and nature of the facilities and activities it must regulate, and it shall be provided with adequate resources and the necessary authority to discharge its responsibilities. The structure and size of the regulatory body are influenced by many factors, and it is not appropriate to require a single organizational model."* (Ref. [3], para. 4.1). "*If the regulatory body is not entirely self-sufficient in all the technical or functional areas necessary to discharge its responsibilities for review and assessment or inspection, it shall seek advice or assistance, as appropriate, from consultants"* (Ref. [3], para. 4.3). Further, *"The regulatory body shall establish a planned and systematic inspection programme. The extent to which inspection is performed in the regulatory process will depend on the potential magnitude and nature of the hazard associated with the facility or activity"* (Ref. [3], para. 5.14).

The management of inspection activities is an important function, perhaps the most outstanding duty for the regulatory body from a radiation safety point of view, and should be under the responsibility of one organizational unit. The responsibilities of the officer who leads the unit include**:**

- assuring his/her own adequate knowledge and on-the-job-training on inspection duties;
- selecting appropriate persons to be taught and trained for becoming inspectors;
- programming of inspection activities by establishing the appropriate priorities;
- developing guidelines for inspectors;
- determining whether an inspection should be announced or unannounced;
- assessing the resource requirements for the inspection programme (e.g. purchase and

calibration checking of radiation detectors, expenses associated with inspectors' travel, accommodation and incidentals, etc.) and assigning resources to the programmes in the annual budget;
- coordinating inspections with those responsible for assessing authorization applications and renewals;
- maintaining records of inspections (i.e. by correlative inspection number, and including full name of the facility inspected, date, starting and exit time of inspection, surname and name of inspectors);
- ensuring that requirements arising from inspections are followed up in a timely manner;
- keeping all inspectors informed of each inspection outcomes;
- updating the training of inspectors; and
- liaising with legal services on guidance for enforcement actions.

If the regulatory process is in the early stages of being established, the regulatory body's resources initially should be directed to inspecting those radiation practices and sources that present the most significant risk to both users and the public.

3.6. INSPECTION PRIORITIES AND FREQUENCES

A key component of a successful inspection programme is establishing inspection priorities and frequencies. Guidance on the categorization of radiation sources is given in Ref. [7]. This is primarily based on the hazard or potential consequences of an accident but also on the type and frequency of non-compliance issues found during inspections. Maintaining a relevant inspection programme requires ongoing analysis of inspection data for the different types of radiation practices and sources. Inspection priority should be resolved first as frequency is subject to the regulatory body's available resources.

In countries where the radiation source register and its control system are not established, the regulatory body will first focus its relevant activities on the following operators:

- Hospitals and clinics (i.e. using radiotherapy and nuclear medicine sources);
- Pipeline and big metallic structure construction companies, and oil exploitation companies (i.e. for industrial radiography sources);
- Oil exploration companies (i.e. for well logging sources); and
- Industrial irradiation facilities.

In some countries the frequency of inspection is directly linked to the frequency of authorization renewal. However, this practice is not supported from a technical point of view. In fact, the frequency of inspections should be directly related to the relative risk associated to each type of radiation practice or sources within a practice. And, the frequency of authorization renewal should be depend on the relative steadiness over time of the radiation safety conditions in each type of radiation practice and of the workload of the available regulatory body's assessing and inspection staff. The inspection programme operates independently of the authorization renewal process and renewal frequency. Table 1 suggests a range of minimum inspection frequencies for the radiation practices and sources within the scope of this publication.

TABLE 1. SUGGESTED INSPECTION FREQUENCES

Use	Inspection Frequency (years)
Dental radiography	5
Nuclear medicine	1-2
Radiotherapy	1
Diagnostic radiology – centres with complex equipment (e.g. computed tomography, interventional radiology, fluoroscopy, mammography)	2-3
Diagnostic radiology – centres with conventional X ray equipment only	3-5
Industrial radiography	1
Irradiators (i.e. industrial)	1
Irradiators (i.e. research)	3-5
Radiation gauges	3-5
Well logging	1-3

Some States specify inspection frequencies in regulations or in authorization conditions but such arrangements have implications for resource availability that may vary from year to year. Indeed, such arrangements give the regulatory body no flexibility to concentrate resources on inspection of radiation practices and sources that have the greatest priority. Therefore such a commitment is not recommended.

3.7. QUALIFICATION AND TRAINING OF INSPECTION PERSONNEL

"The regulatory body shall employ a sufficient number of personnel with the necessary qualifications, experience and expertise to undertake its functions and responsibilities" (Ref. [5], para. 4.6). Guidance on the organization and staffing of a regulatory body is provided in Ref. [6]. Inspection personnel must be capable of performing the tasks required by the inspection programme. The level and depth of training will also vary according to the duties performed and the potential hazards associated with the regulated radiation practices and sources in the respective country.

Inspectors are to be provided with training that ensures they have a sound understanding of:

- safety principles and concepts (i.e. including hazards other than from ionising radiation that may be encountered during inspections);
- radiation monitoring instrumentation and operating techniques;
- interaction of ionizing radiation with matter and radiation dosimetry;
- quick assessment of external and internal doses;
- basic principles of radiobiology and ionizing radiation effects;
- comparison of different kinds of risks;
- procedures for calculating shielding;
- national legislation, codes of practice or regulatory guides and the existing international safety standards in the field;

- notification and authorization procedures;
- applications of ionizing radiation through different practices performed in the country (e.g. in medicine, industry and research) with a clear and full understanding of how and why ionizing radiation is used;
- inspection procedures and survey techniques for such different practices;
- interviewing and evidence gathering requirements;
- breaches of the law and enforcement procedures;
- ongoing technological developments; and
- emergency procedures.

Relevant practical exercises, on-the-job training and closely supervised inspections should supplement formal training. Inspectors are to be aware of all technical aspects of each radiation practice and source that they are required to inspect.

A suggested code of conduct for inspectors is included in Attachment I.

In some countries, a single inspector carries out inspections. In other countries, however, a single inspector only carries out inspections of a simpler nature (e.g. dental radiology facilities, radioactive gauges, etc.) with two inspectors undertaking inspections of more complex facilities. It is recommendable, at least in the developmental stage of the inspection programme and for training of new inspection personnel for inspectors to work in pairs. For a country with a limited numbers of authorizations and range of sources, two persons might be appropriate for all inspections.

Staff should rotate between inspection duties at different kinds of radiation facilities and authorization duties to broaden their experience and improving staff utilization, particularly where there may be staff with specialized knowledge in particular categories of radiation use (e.g. industrial radiography, the use of unsealed radionuclides in medicine or research, medical diagnosis, brachytherapy, etc.).

The regulatory body should keep up to date records of the qualifications and training completed by its staff. Training programmes for regulatory staff have also been developed by the IAEA.

3.8. RESOURCING THE INSPECTION PROGRAMME

Estimating staff resources and a budget to implement an effective inspection programme first requires a reliable register of radiation sources in the country.

Where a regulatory body is implementing radiation safety legislation for the first time or is significantly upgrading existing legislation, some radiation sources may need to be inspected prior to authorization. However, in such circumstances, the regulatory body will first need to direct its resources to the most safety critical areas and prioritize inspections (and the required resources) accordingly.

A suggested process for determining the number of staff required for carrying out inspections is provided in Figure 1.

The regulatory body also requires appropriate equipment and devices to carry out inspection activities. This will comprise a suitable range of radiation survey instruments and low level counting equipment for contamination monitoring, for example. Low level counting

equipment may also be required to support the regulatory body's role in advising the Government on radiation emergencies. The inspectors need to ensure that its equipment is maintained and calibrated at required intervals.

In some countries, the regulatory body provides calibration laboratories for radiation measuring instruments, dosimetry services for the measurement of occupational radiation doses and other technical support services. *"When such functions are undertaken, care shall be taken by the regulatory body to ensure that any conflict with its main regulatory functions is avoided and that the prime responsibility of the operator for safety is not diminished"* (Ref. [3], para. 3.5). The range of scientific and technical services required in a country will depend on the types of radiation sources within the country. *"The managements of the regulatory functions and of the technical support services should be in separate organizational entities"* (Ref. [6], para. 8.4).

3.9. LIAISON WITH OTHER NATIONAL BODIES

The legislation is required to empower the regulatory body: *"to communicate directly with governmental authorities at higher-levels when such communication is considered to be necessary for exercising effectively the functions of the body"* (Ref. [3], para 2.6 (9)). The regulatory body is also required: *"to liaise and co-ordinate with other governmental or non-governmental bodies having competence in such areas as health and safety, environmental protection, security, and transport of dangerous goods*" (Ref. [3], para 2.6 (13)) so that agreements or arrangements can be made to facilitate inspection duties at all times.

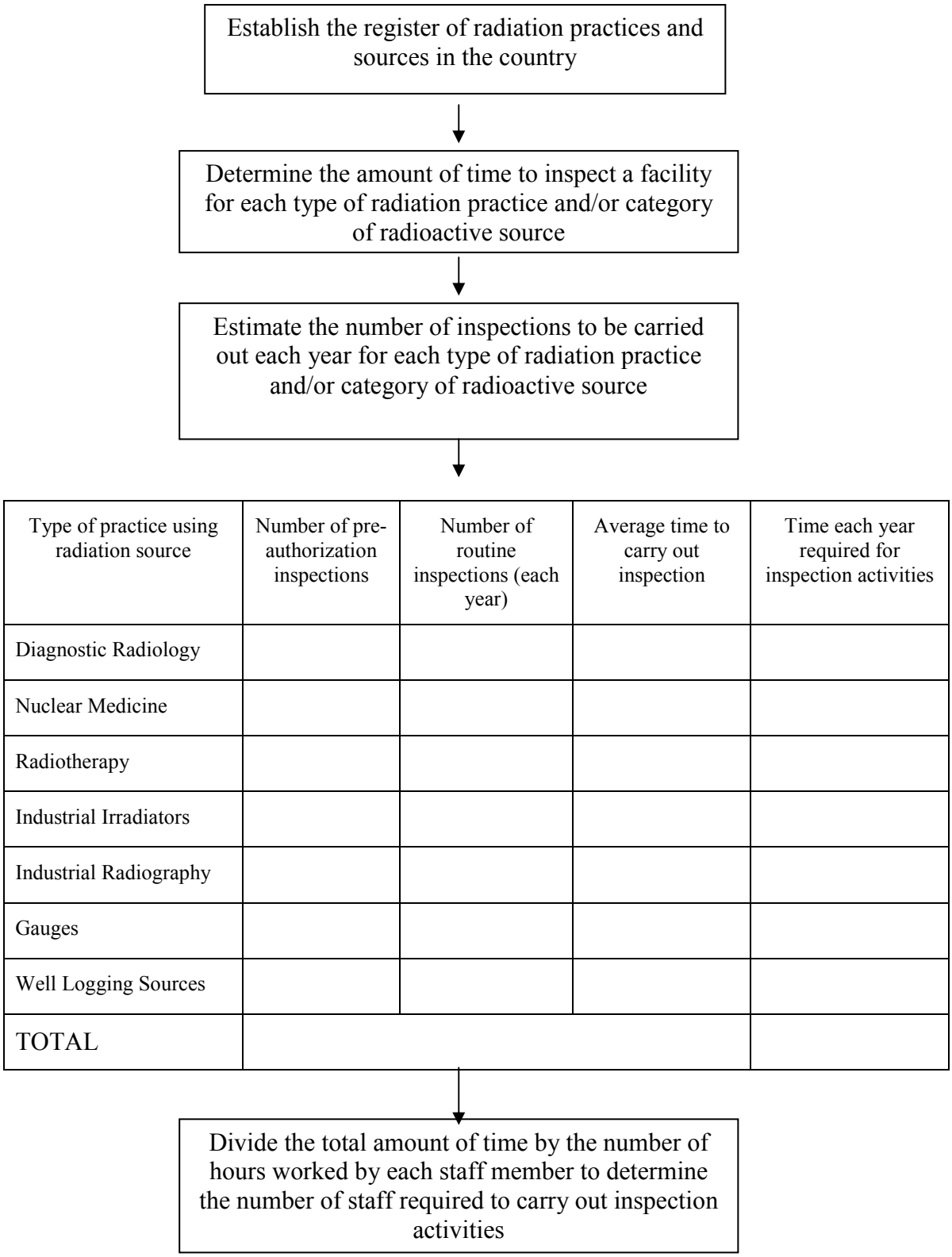

FIG. 1. Process to determine the number of staff required for inspection activities.

4. PERFORMANCE OF INSPECTIONS

4.1. USE OF CHECKLISTS BY INSPECTORS

An inspection entails a visit to the authorized facility or to a field site (e.g. industrial radiography or well logging) to assess compliance with the regulations and the conditions of the authorization.

The use of an inspection checklist contributes to the efficiency of the inspection process and allows procedures to be reviewed in a systematic manner, provided that the inspector's behaviour is not limited to put a series of ticks over a printed form. It identifies the key features of a radiation practice that are to be checked by an inspector to determine regulatory compliance and are developed from the regulatory body's code of practice or regulatory guide (i.e. practice specific regulations). Examples of checklists for different radiation practices are provided in Appendices A to G of Annex IV.

As on-site inspections are the component of the regulatory regime closest to actual practices with radiation sources, and the principal means for direct contact between operators and the regulatory body's staff, it is in the compliance monitoring where the greatest proportion of regulatory resources (i.e. in staff and budget) should be allocated.

A flow chart setting out the inspection process is presented in Figure 2.

4.2. PREPARATION FOR AN INSPECTION

Prior to an on-site inspection, the inspector should:

- receive from his/her supervisor the indication whether a specific inspection should be announced;
- review the authorization certificate and radiation protection programme;
- examine previous inspection reports;
- note the status of any allegations or incidents;
- analyse the response to previous items of non-compliance, note items marked for follow-up during this inspection and have a look on eventual past violations;
- identify unresolved issues from last inspection;
- plan the inspection;

identify whether other personnel will take part as well as their respective roles during the inspection; (***Note:*** *Inspectors who have a private or business relationship to an operator or with its senior (management) personnel should make that relationship known to their supervisor at the time he/she is designated as a regulatory body's officer. The supervisor should avoid the officer participating in the inspection and authorization processes of the relevant operator and, perhaps, of performing any other tasks related to the same radiation practice).*

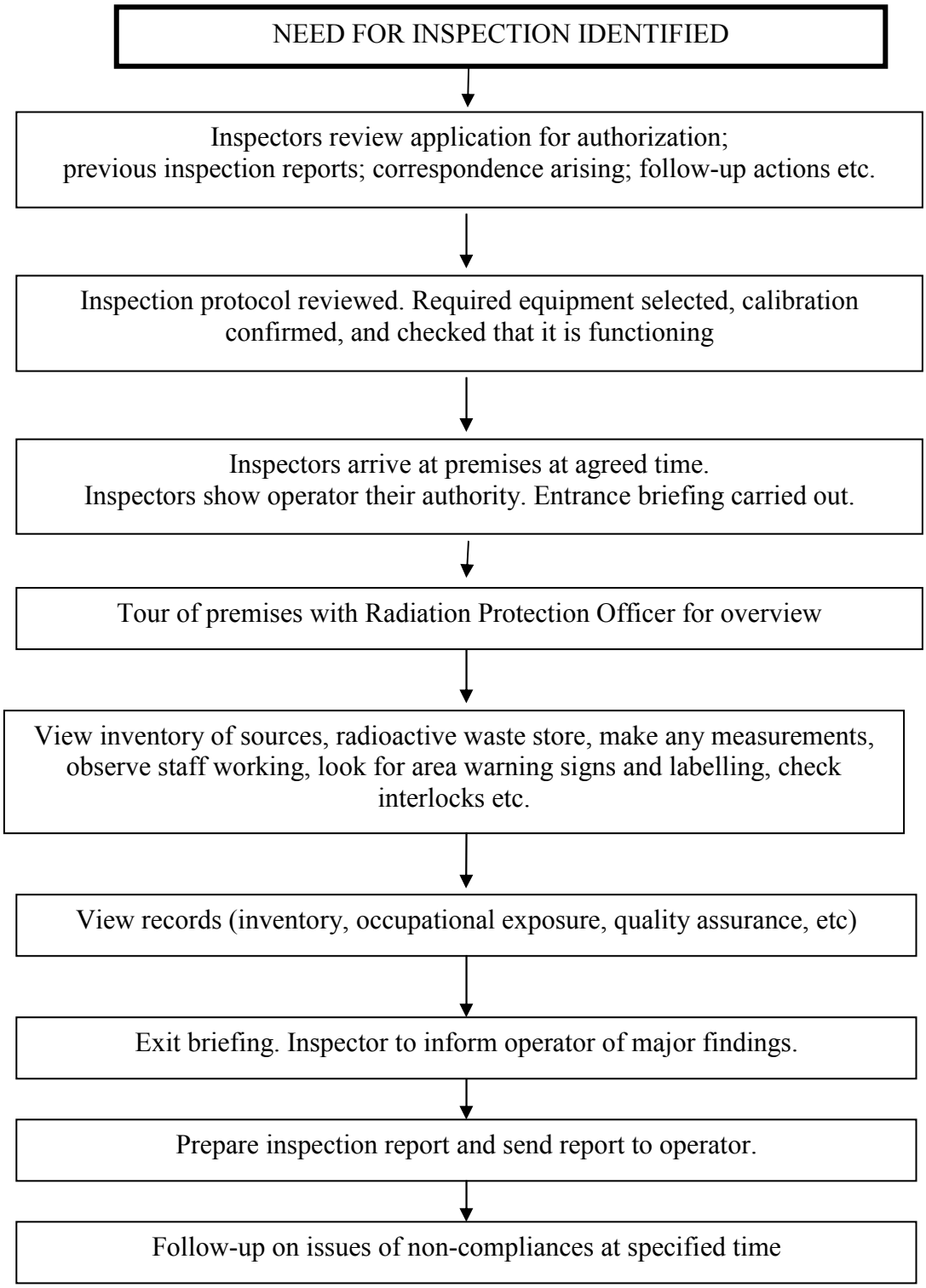

FIG. 2. Flowchart for inspection process.

- identify the equipment necessary for the inspection (***Note:*** *In selecting appropriate survey meters or other necessary measuring equipment, inspectors must ensure they are functional, duly calibrated and appropriate for the radiation types and energies that may need to be measured or detected, and the potential exposure rates that will be encountered during the inspection*). The inspector is not to use the equipment of the operator during the inspection;
- obtain copies of the relevant inspection procedures and checklist(s), copies of the legislation and relevant codes of practice or regulatory guides, and copies of the authorization certificate with the conditions of authorization issued to the operator. The inspector will take their own copies of such documents and not rely on using those held by the operator;
- ensure they are taking their own personal dosimeter; and
- ensure they are carrying their accreditations as official representatives of the regulatory body.

Depending on the particular circumstances and the nature of the facility, the inspector might also take:

- safety glasses, safety shoes, hard-hat, etc.; and
- a camera to record matters of non-compliance or to support findings in the written report.

4.3. INDICATORS OF DEGRADED PERFORMANCE

The ultimate goal of an inspection is to determine that radiation practices and sources are being used safely. This requires the inspector to be alert for details beyond regulatory compliance because they can be indicators of the potential for degraded or deteriorating safety performance. The most common indicators are:

- lack of senior management commitment to, or involvement with, the facility's radiation protection programme;
- minimal radiation protection officer's oversight or the Radiation Protection Officer (hereinafter, 'RPO') is too busy with other assignments;
- insufficient staff trained to conduct an effective radiation protection programme;
- lack of discussion on radiation safety issues by the appropriate responsible officers;
- the quality assurance programme fails to detect small radiation safety breaches;
- poor housekeeping;
- failures to follow procedures although non-related to radiation safety;
- operational production procedures take precedence over the radiation protection programme;
- minor problems repeated;
- poor record keeping;
- financial instability;
- frequent resignation of staff and consequent high staff turnover;
- inability to perform radiation safety tasks on time;
- lack of documentation on staff training;
- failure to assess the effectiveness of training;
- lack of refreshing training;
- concern on elementary radiation safety matters shown by radiation workers during inspections;

- poor accounting for, or control of, radiation sources;
- major changes in the internal organizational structure; having influence in radiation safety and;
- excessive on-site accumulation of radioactive wastes; and
- lack of emergency preparedness.

These factors, even where no breach of regulations or additional requirements is detected, will influence the conclusions of an inspection and may lead to a variation in the frequency of future inspections for the particular operator.

4.4. METHODS OF INSPECTION

While important, examination of records should not be considered the most essential part of the inspection programme. Observations of activities in progress, equipment, facilities and work areas, etc., are a better indicator of the overall radiation protection programme than a review of records alone.

Some sections of the procedures described below instruct the inspector to verify the adequacy of certain aspects of the radiation protection programme. Whenever possible, verification should be through direct observations of normal work activities; interviews and discussions with managers, radiation protection officers and workers; on-site measurements of radiation and contamination levels, and review of records.

Records such as surveys, receipt, use, transfer of radioactive sources and training should be examined to ensure they are current at the date of inspection and also randomly for earlier periods until the inspector is satisfied that they are properly maintained and complete. Other records that more closely relate to direct radiation safety (i.e. such as inventory of radiation sources, occupational exposure records, calibration and periodic checking of monitoring equipment, and incident reports) should be examined in greater detail. In the case of medical exposures, the existence of records on necessary data to allow retrospective assessment of radiopharmaceuticals and activities administrated, and of the whole data on patients' radiotherapy treatment plans, should be examined as appropriate (***Note;*** *see Basic Safety Standards [4] for details*).

The inspectors may need to ask for copy of documents held by the operator that support a finding of non-compliance or which otherwise may be necessary to hold on the authorization file (i.e. to clarify or explain a particular point). Copies of records required to support alleged non-compliance should be obtained while on site (i.e. and in presence of relevant personnel interviewed to ensure that the evidence gathered complies with the regulatory body's procedures). For prosecutions, the original documents may also be required. Obviously, inspectors should not ask for copies or retain documents unnecessarily, but a negative response from the operator to their request should be considered a breach to the legislation. Such a fact should be mentioned to the relevant personnel interviewed and included in the inspection report.

From time to time, inspectors will identify a safety problem that requires immediate action, e.g. significant safety hazards, willful non-compliance and other potentially significant enforcement issues. The regulatory body should have protocols in place for such eventualities that clearly identify the actions that may be taken. However, in unforeseen circumstances,

inspectors should discuss the matter with their supervisor by the most expeditious way before taking any action.

Portable or mobile radiation sources (e.g. industrial radiography and well logging) generally should be inspected at field sites and often with an unannounced inspection. However, rather than wasting time in what might be a fruitless exercise traveling to perhaps inactive field sites for unannounced inspections, officers can use their time more efficiently by contacting said type of operators at random intervals seeking details of current field sites. Inspections might not necessarily follow every enquiry but provide information and remind operators that the regulatory body is an active force in the workplace. Enquiries of this nature in themselves can help effect an improvement in safe working practices, provided work site inspections also take place

4.5. ENTRANCE BRIEFING

In consideration of the operator's time, inspectors should not be late for announced inspections. Unless otherwise arranged, and for all types of inspection, the inspectors should present themselves at the operator's reception area and request to meet the operator's most senior manager. Following introductions and production of their accreditation to the operator, the inspector taking the lead role should give an outline of the objectives of the inspection and the anticipated duration. In addition, the inspector and the operator's representative need to identify and schedule personnel to be interviewed. Scheduling interviews enhances efficiency and gives the operator the opportunity to identify the most knowledgeable individuals to respond to questions.

For unannounced inspections (e.g. particularly at field sites used for industrial radiography) the inspector may first decide to assess work practices without the knowledge of the workers using the radiation sources. This would require liaison with the owners of the site, who would be asked to provide information on the purpose of the use of radiation sources on the site. The inspectors need to take care so as not to put themselves in any physical danger. Following initial observations, the inspectors should announce themselves to the radiation workers performing their duties at the field site, review the practices as being undertaken on the site and proceed as for an announced inspection.

4.6. OPERATING ORGANIZATION AND RESPONSIBLE STAFF

The inspector should:

- confirm that there have not been any unauthorized changes in ownership or of personnel who occupy the positions of Radiation Protection Officer (RPO), Qualified Expert, etc;
- verify that the RPO is knowledgeable about the radiation protection programme and ensure that radiation work is performed in accordance with approved procedures, the regulations and any conditions imposed on the authorization certificate;
- review organizational changes that might affect responsibilities (e.g. the responsible medical practitioner[1] for nuclear medicine, medical X ray diagnosis and all types of radiotherapy) and reporting chains;

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[1] Among others, a responsibility for this Medical Practitioner should be the justification of medical exposures. The Basic Safety Standards [4] state that *"Medical exposures should be justified by weighing the diagnostic or therapeutic benefits they produce against the radiation detriment they might cause, taking into account the benefits and risks of available alternative techniques that do not involve medical exposure"*. One means

- inspect in detail the implementation of the radiation protection programme; the frequency of internal audits; the use of qualified experts; procedures for recording deficiencies, reporting to management and correcting deficiencies in a timely manner, to verify whether everything conform to those described in the authorization application; and
- confirm that the RPO has appropriate authority to implement corrective actions, including stopping use of a radiation source if there are significant threats to health and safety. The inspector should pay special attention to any changes that may reduce the ability of the RPO to resolve concerns or issues related to the safe conduct of the radiation protection programme.

4.7. INITIAL OVERVIEW

At the start of the inspection, the inspector would ask to be taken on an overview tour of the facility. The inspector should be alert to any work practices or facilities that may indicate poor safety standards and note them for follow-up later during the inspection.

The inspector also should verify that the facility is as described in the application for authorization and that any subsequent modifications of significance have been approved by the regulatory body.

Inspectors also should be alert to potential non-radiation safety hazards (e.g. industrial, electrical, chemical, occupational, etc.) for referral to the appropriate regulatory agencies, especially when they can have a particular influence on the radiation safety of the facility.

4.8. QUALIFICATION AND TRAINING OF STAFF USING RADIATION SOURCES

The inspector should firstly verify the presence of the person responsible for the use of relevant radiation sources at the facility, which has been named as such in the authorization application.

The initial authorization application may additionally list the facility's radiation workers but changes in personnel will inevitably occur between granting the authorization certificate and subsequent renewal applications. Regulatory bodies should set minimum standards for the qualifications, training and experience of radiation workers and should not need to be kept informed of or approve inconsequential personnel changes.

The radiation protection programme should include the facility's employment criteria for radiation workers and this should be verified from records and by discussions with personnel. If required by the law or by conditions on the authorization certificate, it should also be verified that workers are supervised as required.

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for achieving this include providing written guidelines for MPs to assist them in determining the most appropriate diagnostic procedure(s) under given clinical conditions. (*Referral Guidelines have been published by various radiological bodies around the world*.). For potentially high radiation dose procedures (e.g. such as those involving the use of fluoroscopy, CT, etc.) but also for examinations of children, hospitals or practices might also require examination requests to be first reviewed by a Radiologist. If the request doesn't meet internal guidelines, the Radiologist might discuss the matter with the referring MP and advise on more appropriate alternatives.

The inspector should examine the periodic re-training programme and randomly examine records of personnel training and examinations or tests (i.e. if applicable) to the extent that the inspector is satisfied that the training programme is being implemented as required. Where examinations are required, the inspector should review some of the examination questions to ascertain that they are indicative of what the worker is required to know in order to safely to carry out his/her responsibilities.

4.9. INVENTORY OF RADIATION SOURCES

4.9.1. Facilities with radioactive sources

The inspector should examine the source inventory in sufficient detail to be satisfied that radioactive sources are properly identified including their present location.

The inventory records should detail**:**

- the radionuclide, physical form and activity (i.e. in Bq.) of each *sealed source*. It should also be confirmed that the types of *unsealed sources* on the premises comply with any restrictions that may be imposed on the authorization certificate and that the maximum activities of unsealed sources on the premises do not exceed the maximum activities at any time prescribed by the authorization certificate;
- the manufacturer's name, model, serial number (i.e. if appropriate) of devices containing radioactive material;
- the location of each sealed source and devices containing sources; and
- the date that the inventory was last updated.

The inventory should be confirmed by physically checking the radioactive sources actually held by the authorized legal person.

Note: *Radioactive sources used at field sites remote from the principal premises (e.g. for industrial radiography) should be accounted for in a source movement register, which clearly identifies its present location. Similar requirements might be appropriate for some types of sources even if used only on the principal premises.*

The authorization certificate should identify the purpose for which the radioactive sources are required. It should be verified from records and by discussions with personnel that use is restricted to the purpose for which the authorization certificate was granted.

Section 2.34 of the Basic Safety Standards [4] requires radiation sources to be kept secure so as to prevent theft or damage and to prevent any unauthorized person from carrying out any of the actions specified in the General Obligations for Practices of the Standards.

The inspector should verify that procedures have been established to maintain an appropriate level of control of radioactive sources and that these procedures are understood and implemented.

4.9.2. Facilities with X ray equipment and linear accelerators

The inventory for X ray equipment, linear accelerators, etc. should state the manufacturer’s name, model, serial number, maximum output power (e.g. kVp and mA), purpose and location on the premises.

The inspector should verify that**:**

- the equipment is properly authorized and located as described in the inventory and in the plan of the premises attached to the application for authorization *(**Note:** see item on portable sources below);*
- the equipment is used for the prescribed purposes;
- there is appropriate control and safety for mobile and portable sources (e.g. those used at field sites away from the principal premises). Controls should include an utilization log to indicate when such sources are taken from and returned to their storage area; and

4.10. RADIATION DETECTION AND QUALITY ASSURANCE EQUIPMENT

The inspector should verify that any portable radiation detection, counting, sampling and quality assurance test equipment at the facility is appropriate, functioning, calibrated, adequately maintained and conforms to any relevant regulations or with conditions that may be imposed on the authorization certificate.

The inspector should:

- randomly select instruments of each type and examine them to verify their function and, if applicable, alarm settings. These may include portable survey instruments, fixed monitoring equipment, constant air monitors, portable air samplers, pocket dosimeters, alarming dosimeters and quality assurance equipment;
- review the most recent calibration records of the instrument(s) selected for inspection to assure that the calibration and maintenance programme (e.g. change of batteries) for these instruments complies with any relevant regulations or conditions of the authorization certificate;
- verify that a system is in place (e.g. an inventory) that identifies all radiation detection equipment and when they are due for calibration, functional testing or maintenance; and
- verify that the radiation detection equipment are appropriate for the types of radiation sources at the facility.

4.11. OCCUPATIONAL PROTECTION

4.11.1. Working rules and emergency procedures

Working rules and emergency procedures should be contained in the radiation protection programme (and in the application for authorization). Working rules may range from explicit step-by-step procedures to more generalized safety guidelines.

The inspector should verify that the working rules are followed by observing personnel performing their routine tasks. Through discussions with the responsible personnel and radiation workers, it should be verified that personnel understand and can implement the established emergency procedures and are aware of any procedural revisions.

4.11.2. Classification of areas

The inspector will verify the classification of controlled and supervised areas, including that suitable warning signs are displayed at access points to these areas, and that access to controlled areas is restricted.

4.11.3. Monitoring of the workplace

The inspector should verify that the nature and frequency of workplace monitoring is sufficient to enable:

- evaluation of the radiological conditions in all workplaces;
- exposure and, when applicable, contamination assessment in controlled areas and supervised areas; and
- review of the classification of controlled and supervised areas.

The inspector should also verify that:

- schedules for periodic surveys of work areas of the facility site have been established;
- surveys are conducted using approved procedures by reviewing a random selection of survey records to see whether surveys are being performed according to schedules;
- survey results are reviewed by an appropriate person; and
- corrective action is taken as may be appropriate.

Inspectors should additionally perform some spot area measurements at representative points with their own survey equipment, and include their results and, if possible, a sketch of locations measured in the report.

4.11.4. Personnel dosimetry

Through discussions with the RPO and by direct observation of radiation workers, the inspector should verify that:

- personal dosimetry devices are worn by designated personnel on the appropriate part of the body, according to their design characteristics and foreseen use (e.g. chest, front, wrist, fingers, etc.);
- the devices are appropriate to the type and energy of the radiation to which the radiation workers are exposed;
- dosimeters are obtained from a service provider approved by the regulatory body;
- workers are periodically advised of their doses; and
- records of personal monitoring are maintained and preserved, checking that all individual annual doses are below the annual dose limits (Note: Should the last not be the case, the inspector shall continue the inquire up to know which has been the decision taken on the subject).

4.11.5. Personal protective equipment

The inspector needs to verify that appropriate personal protective equipment is available.

4.12. MEDICAL EXPOSURE

4.12.1. Responsibilities

The inspector will verify that the operating organization has established a mechanism to ensure that medical exposures are prescribed by a medical practitioner, and that the obligation for patient protection is assigned to an appropriately qualified medical specialist e.g. radiation oncologist, nuclear medicine specialist, radiologist.

The inspector will verify that responsibility for conducting or supervising calibration of beam and sources, clinical dosimetry, imaging and quality assurance is assigned to a qualified expert (e.g. medical physics, diagnostic radiology physics, nuclear medicine physics, radiotherapy physics). The inspector will verify that all personnel using radiation sources have appropriate qualifications and training. The inspector will verify that additional training is provided when needed e.g. new equipment, new techniques.

4.12.2. Justification

The inspector will verify that medical practitioners follow justification procedures for medical exposures.

4.12.3. Optimization of protection

The inspector will verify that the operating organization has established and maintains:

- provisions for optimization of protection; to ensure that exposure of patients is the minimum required to achieve the intended diagnostic objective during diagnostic procedures, taking into account the relevant guidance levels for medical exposures; and exposure of normal tissue during radiotherapy is kept to as low as reasonable achievable consistent with delivering the required dose to the planning target volume, and organ shielding is used when feasible and appropriate,
- a program for acceptance testing according to national or international standards for radiological equipment, nuclear medicine equipment and radiotherapy equipment,
- a program for the calibration of radiation beams and sources used for medical exposure;
- a comprehensive quality assurance program is in place, based on an accepted and proven protocols.

The inspector will verify that**:**

- therapy irradiation beams are calibrated by qualified experts in accordance with recognized protocols and procedures and within the time-lines required by the regulatory body, and that such calibrations are checked routinely as specified in the codes of practice or regulatory guides;
- an activity meter is available for measuring activity in syringes or vials, and the imaging equipment is subject to a quality control programme, in a nuclear medicine facility;
- the operating organization or qualified experts appointed by the operating organization have established and implemented a quality control programme for the testing of X ray equipment for compliance with design and performance criteria. For X ray equipment used for diagnostic purposes, the quality control programme would also cover image processing equipment and dose measurements for comparison with appropriate patient dose guidance or reference levels (i.e. matters which may be specified in regulations, codes, guides or conditions of authorization certificate). The regulatory body should not undertake comprehensive testing of this nature on behalf of operators. However, on some occasions it may be desirable for the inspector to perform random checks, particularly on some of the fundamental patient and safety parameters in medicine.

4.12.4. Constraints for comforters and visitors

The inspector will verify that the operating organization ensures that comforters, visitors and members of households of the patient during a course of treatment with radionuclides receive written instructions on radiation protection precautions so that their exposure does not exceed the dose constraint established by the regulatory body (para. II.9, ref. [4]).

4.12.5. Investigation of accidental medical exposures

The inspector will verify that the operating organization has procedures to investigate and report:

- any treatment delivered to the wrong patient or the wrong tissue, or using the wrong radiopharmaceutical, with a dose or dose fractionation differing substantially from the values prescribed by the medical practitioner or which may lead to undue secondary effects;
- any diagnostic exposure substantially greater than that intended or resulting in doses repeatedly and substantially exceeding established guidance levels;
- any equipment failure, accident, error, mishap or other unusual occurrence with the potential of causing patient exposure significantly different from that intended;
- provisions to estimate the doses received, indicate corrective measures to prevent recurrence, implement corrective actions, submit a report to the regulatory body and inform the patient.

Further information on protection of patients can be found in IAEA Safety Report Series No. 38 "Applying Radiation Safety Standards in Radiotherapy" [8], IAEA Safety Report Series No. 39 "Applying Radiation Safety Standards in Diagnostic Radiology and Interventional Procedures using X rays" [9], and IAEA Safety Report Series No. 40 "Applying Radiation Safety Standards in Nuclear Medicine [10].

4.13. PROTECTION AGAINST PUBLIC EXPOSURE

The inspector should verify provisions for protection of the public:

- consideration given to public exposure in the shielding design (see section 4.14.3);
- control of access for the public and visitors, and warning signs are displayed;
- there are procedures for segregating and disposing of radioactive waste; and
- disused sources are stored safely and securely (see section 4.15.4).

4.14. SAFETY OF RADIATION SOURCES

4.14.1. Area warning signs and labeling

The inspector should determine whether suitable warning (or caution) signs are displayed at required locations. Random checks should also be made of the labeling on packages or other containers to determine that proper information (e.g. radionuclide, quantity, and date of measurement) is recorded.

The inspector should also examine locations where notices to workers are posted. Applicable documents, notices or forms (i.e. in the local language) should be posted in locations that

ensure they will be seen by the affected workers. Important safety issues should also be drawn directly to the attention of workers during formal training sessions or in brief meetings.

4.14.2. Interlocks

The inspector should verify that appropriate interlocks are fitted where required and that they function correctly. Interlocks will usually be required for radiotherapy equipment, industrial irradiators and at enclosed industrial radiography sites.

4.14.3. Shielding

In addition to performing spot area measurements to confirm those taken by the operator, the inspector should be alert to inadequacies in the design and construction of radiation shielding, whether this is structural (e.g. walls, door leafs and frames, lead glass windows, location of air conditioning and electrical conduits, floor, ceilings, etc.) or mobile, such as a protective screen in a diagnostic radiology room. While protective screens ideally should be labeled with the lead equivalence (i.e. at a specified energy) the inspector should undertake spot checks of any barrier that appears inadequate. Measurements at the above mentioned locations should be taken under the worst irradiation condition relevant to each site.

4.14.4. Surfaces

Operators using unsealed radioisotopes (e.g. in vitro medical pathology tests, nuclear medicine laboratories, research laboratories, etc.) require facilities that are designed to minimize problems with contamination. Work surfaces should be constructed or finished so that decontamination can be readily carried out. Inspectors should be alert to poor quality finishes including, where appropriate, that of floors and nearby walls (i.e. especially those tiled).

4.14.5. Ventilation

Where volatile substances are being handled (including gases, aerosols and powders) appropriate ventilation will be required which may include forced exhaust systems and/or fume cupboards. Inspectors should verify the correct operation of ventilation systems, including noting where exhaust ducts lead and confirming that they leave the building envelope and exhausted air is not drawn back into the building.

4.14.6. Leak testing of sealed radioactive sources

The inspector should verify that leak tests of sealed sources are performed at required frequencies and in accordance with approved procedures.

If records of a leak test result show contamination in excess of the regulatory requirements, the inspector should verify that appropriate notification has been given to the regulatory body, the eventual resulting air or surface contamination has been eliminated, and the source removed from service.

4.14.7. Incident notifications

Through discussions with personnel and by reviewing representative records the inspector should verify that workers are aware that specified incidents and accidents with radiation sources must be reported to the regulatory body.

The inspector should also verify that the RPO and other designated personnel have ready access to the regulatory body's emergency response telephone number.

Note: *Discretion should be exercised if a radiation worker discloses an unreported incident or accident. Failure to ensure confidentiality during later investigations might jeopardise the worker's continued employment. In such a case, therefore, the inspector should sharpen his wits to make reference to the unreported information, whenever possible, during the exit briefing as he would have discovered it by himself.*

4.15. RADIOACTIVE WASTE MANAGEMENT

4.15.1. Waste storage and disposal of unsealed sources

In premises where unsealed sources are in use, the inspector should:

- review the records in the detail necessary to verify compliance with the waste storage and disposal procedures approved in the radiation protection programme;
- confirm that the procedures are readily available to all persons with responsibility for low-level waste classification and for the preparation and transfer of wastes to land disposal sites or other facilities;
- verify that the waste is suitably protected from fire and that appropriate packaging is used;
- verify that the waste storage area is properly ventilated (i.e. where appropriate) and that adequate controls are in place to minimize the risk from other hazardous materials; and
- verify that there are appropriate methods in place to track items in storage.

4.15.2. Discharges

The inspector should:

- review and verify that waste handling, monitoring equipment and administrative controls are appropriate so that radioactive discharges are within the discharge limits established by regulations or in the conditions of authorization certificate; and
- be satisfied that effluent monitoring systems (i.e. if required) and the associated analytical equipment are appropriate to detect and quantify effluents with sufficient sensitivity and that they are maintained, calibrated, and operated in accordance with the manufacturers' recommendations and good practices.

4.15.3. Transfer of waste

The inspector should review procedures for transfer of waste and ascertain if the procedures ensure that the recipients of radioactive wastes are authorized for that purpose.

4.15.4. Disused sealed sources

The inspector will determine if disused sealed sources are stored safely and securely. The inspector will discuss with the operator the proposed arrangements for the disposal of disused sealed sources.

4.15.5. Records

Records should be maintained of the disposal of radiation sources. The inspector should review these records in sufficient detail to be satisfied that disposal of radiation sources is made in accordance with the applicable regulations and that the records are complete and accurate.

4.16. TRANSPORT OF RADIOACTIVE SOURCES

The transport of radioactive sources is subject to national regulations, which should be in consistent with the requirements of the IAEA Regulations for the Safe Transport of Radioactive Material (IAEA Safety Standard Series No. TS-R-1).

The inspector should review, if applicable:

- training on the handling of radioactive sources;
- labelling of packages and associated documentation;
- vehicles (i.e. including placarding, cargo blocking and bracing, etc.); and
- shipping papers.

The inspector should take particular note if suitable procedures are in place for the transport of portable devices containing radioactive sources (e.g. for industrial radiography, well logging, etc).

4.17. EMERGENCY PREPAREDNESS AND RESPONSE

The inspector will verify that the operating organization has developed procedures for emergency preparedness and response for any reasonable foreseeable operating mishap or accident, and that the staff of the operating organization demonstrates appropriate knowledge of the emergency procedures.

4.18. EXIT BRIEFING

On completion of the inspection an exit briefing should be held, with either the operator's representative before whom the inspector had presented his accreditation when arriving to the facility, his substitute (i.e. officially informed to the inspector during the inspection) or the RPO, in this order. If none of them are available, the inspector may choose to hold a preliminary exit briefing with an appropriate person on site but a formal briefing should be held as soon as practical after the inspection (e.g. by telephone), mainly in case that some non-compliance has been detected. The reason for these circumstances should of course be clarified in the inspection report.

The briefing should outline:

- preliminary findings from the inspection;
- any matters of non-compliance with regulatory requirements;
- safety-related concerns;
- unresolved items identified during the inspection; and
- the status of any previously identified non-compliant items.

If safety concerns or items of non-compliance are identified that affect safe operation of the facility, the operator must be directed to initiate prompt corrective action. The inspector should not leave the site unless satisfied that the concerns are fully understood and corrective action initiated. If there is disagreement over the significance of the matters or the potential impact on the facility's operations, the inspector's supervisor should be notified immediately.

Although deficiencies identified in some areas are not always items of non-compliances, the inspector should also bring such deficiencies to the attention of the operator at the exit briefing. These subjects should also be referred to in the subsequent letter dealing with the inspection, as well as any specific comment or answer from the operator or its representatives.

4.19. INSPECTION REPORT

"Regulatory inspectors shall be required to prepare reports of their inspection activities and findings, which shall be fed back into the regulatory process" (Ref. [1], para. 5.17).

"The purpose of the inspection report is to:

(a) Record the results of all inspection activities relating to safety, including actions taken on recommendations made following previous inspections;
(b) Document an assessment of the operator's activities in relation to safety;
(c) Provide a basis for notifying the operator of the findings of the inspection and of any non-compliance with regulatory requirements, and to provide a record of any enforcement actions taken;
(d) Document any recommendations by inspectors for future actions by the operator or the regulatory body." (Ref. [6], para. 3.65).

Inspection reports typically should include:

(a) An identification of the operator inspected, the purpose and date of the inspection and the inspector's name;
(b) Reference to applicable regulations and authorization certificate conditions;
(c) Details of the radiation sources that were inspected;
(d) Details of the qualification and training of the personnel who use the radiation sources;
(e) Details of the management of the radioactive waste generated by the operator;
(f) A record of any deficiencies or violations found in the regulatory inspections, including a record of any regulations or authorization conditions that have been contravened;
(g) A record of the findings and conclusions of the regulatory inspector, including any corrective or enforcement actions that should be taken; and
(h) a record of the recommendations for future actions made by the inspector.

Inspection reports should be distributed according to established procedures in order to:

(a) Provide a basis for future regulatory action;
(b) Document the regulatory history of a facility by the maintenance of a record of inspections and their findings and conclusions;

(c) Provide a basis for identifying major or generic issues that necessitate special inspections, changes to inspection plans or regulatory action;
(d) Provide a basis for the periodic review of the findings of inspections, including trends and root causes;
(e) Inform the regulatory staff responsible for the development of requirements for authorizations or new regulations;
(f) Provide a means of passing information to governmental bodies or to interested parties; and
(g) To provide a basis for self-assessment activities.

Inspection findings should be submitted to the operator for any necessary corrective action. Whenever corrective action is needed, a formal communication including the inspection findings should be sent to the operator as part of the enforcement procedure.

5. ORGANIZATION AND MANAGEMENT OF THE ENFORCEMENT PROCESS

5.1. MANAGEMENT OF THE ENFORCEMENT PROCESS

Enforcement actions are the means by which the regulatory body can respond to non-compliance with the law or with specified conditions of the authorization certificate and should be commensurate with the possible consequences of non-compliance. Actions may range from written directions requiring corrective action within a specified time-frame to confiscation of a radiation source or, in situations where the violation implies a breach of the common law, even to prosecution by taking the responsible person to Court.

The legislation should specify the nature and scope of administrative sanctions, which may be imposed by the regulatory body (e.g. formal warnings, the maximum applicable fine, the suspension of an authorization certificate, its definitive cancellation and the confiscation of a radiation source). In addition, the regulatory body should - at a very early stage of the inspection and enforcement program - list all foreseeable breaches to the legislation, with indication of the applicable sanctions to violators corresponding to each type of breach in accordance to the grade of risk.

In most situations, operators should be formally requested to correct matters of non-compliance (i.e. which may also require a follow-up review and confirmation by the appointed qualified expert and/or a regulatory body inspector) and report to the regulatory body within the specified time-frame. Depending on the gravity of the matter, the regulatory body might also require an investigation into why the non-compliance occurred to identify measures to prevent a recurrence.

The regulatory body should ensure that it has internal procedures in place so that any directions given to the operator are followed up within the specified time-frame. Depending on the potential hazards associated with the matters of non-compliance, the regulatory body should consider if an immediate review inspection is called for or (i.e. and assuming satisfactory notification of correction has been received) if the file should just be marked so that those matters are checked at the next scheduled inspection.

The enforcement policy should provide a response, which is commensurate with the alleged offence. In no case a sanction can be applied ‘on the spot’ for an inspector, for the principle

that nobody may be sanctioned before giving him/her the possibility of depositions should be followed. All breaches will require consideration by the senior regulatory body personnel (i.e. the organizational position of which should be clearly determined in the authority's internal procedures) as to whether they may deserve an administrative sanction or if the alleged breaches should be referred for prosecution.

5.2. LAWS AND REGULATIONS FOR ENFORCEMENT

The law should empower the regulatory body to**:**

- Impose sanctions that will deter deliberate or careless deviations from regulatory requirements;
- Revoke, suspend or modify an authorization or to prohibit use of a source;
  - Confiscate a radiation source in specified circumstances;
  - Levy fines for non-compliance commensurate with the nature of the infractions; and
  - Indicate that deliberate or attempted violations of regulations and requirements and some breaches due to evident negligence should be matters considered for prosecution.

The legislation should also establish a procedure for appealing decisions of the regulatory body.

5.3. LEGAL SUPPORT FOR PROSECUTION

In the case of serious breaches that might result in prosecution, the regulatory body requires access to legal support services that are able to present the case for prosecution. In some countries legal support services may be external to the regulatory body, perhaps in the same government agency to which the regulatory body may be attached, or in another government agency. In others, the regulatory body may be required to place follow-up investigations and legal action in the hands of the police.

If the regulatory body obtains its legal support from within its own government agency, the protocols and procedures to be followed in legal enforcement actions may be those set down for a wider range of legal infringements than just radiation safety**.** A special case may occur if the legal infringement was produced by such governmental agency. The regulations should foresee those situations and make clear by which way the regulatory body will be able to impose the sanctions.

An example of a policy document for investigation and enforcement is given in Attachment II that in practice should be tailored to be coherent with the national legislation. The example assumes that where the regulatory body decides to prosecute, its officers will prepare the evidence for action by its legal support services, whether that support service is internal or external to the organization.

5.4. FACTORS IN DETERMINING ENFORCEMENT ACTIONS

The factors to be taken into account by the regulatory body in deciding which enforcement action is appropriate in each case should include:

(a) The safety significance of the deficiency and the complexity of the corrective action that is needed;
(b) The seriousness of the violation;

(c) Whether the violation is a repeat violation of a less serious nature;
(d) Whether there has been a wilful violation of the limits and conditions specified in the authorization certificate or in regulations;
(e) Who identified and reported the non-conformance;
(f) The past performance of the operator and its trend; and
(g) The need for consistency and openness in the treatment of operators.

The regulatory body should anticipate and consider possible unintended effects that enforcement actions might produce. In some circumstances the actions might have a greater negative impact on economic, health and safety issues than the improvement gained through the enforcement action.

5.5. METHODS OF ENFORCEMENT

5.5.1. Written warning or directive

"Deviations from, or violations of, requirements, or unsatisfactory situations which have minor safety significance, may be identified at facilities or in the conduct of activities. In such circumstances, the regulatory body shall issue a written warning or directive to the operator which shall identify the nature and regulatory basis of each violation and the period of time permitted for taking remedial action" (Ref. [1], para. 5.19). This is the most common form of enforcement action and will, in most cases, suffice to remedy the safety issue.

In such situations normal operations can generally continue while the corrective actions are taken. Examples might include failure to appoint a RPO after personnel changes, inadequate warning signs, a radiation worker not using his personal dosimeter, a radiation source which was not placed into its shielded box while not in use, etc.

5.5.2. Orders to curtail specific activities

"If there is evidence of a deterioration in the level of safety, or in the event of serious violations which in the judgment of the regulatory body pose an imminent radiological hazard to workers, public or environment, the regulatory body shall require the operator to curtail activities and to take any further action necessary to restore an adequate level of safety" (Ref. [1], para. 5.20).

5.5.3. Modification, suspension or revocation of the authorization certificate

"In the event of continual, persistent or extremely serious non-compliance, or a significant release of radioactive material to the environment due to serious malfunctioning at or damage to a facility, the regulatory body shall direct the operator to curtail activities and may suspend or revoke the authorization. The operator shall be directed to eliminate any unsafe conditions" (Ref. [1], para. 5.21). In considering the withdrawal of an authorization certificate, the regulatory body should ensure that activities important to safety continue to be performed by an authorized operator.

A partial suspension might apply, for example, to a company authorized to perform well logging and use radioactive tracers but which fails to satisfactorily comply with its own radiation protection programme while using unsealed radioactive tracers. The authorization certificate might then be suspended in respect of those unsealed radiation sources while

allowing the operator to continue operating with sealed sources only, if the regulatory body so deems appropriate.

An example where a operator may be directed to curtail activities and the authorization certificate be revoked might be that of a company authorized for industrial radiography that, under pressure to meet contracted deadlines, employs untrained and unaccompanied workers to operate gamma radiography sources at field sites.

5.5.4. Penalties

The regulatory body should have the authority to impose or to recommend penalties, for example fines on the operator, as a corporate body or individuals, or to institute prosecution through the legal process, depending on the legal system and the authorization practices of the States. The use of penalties is usually reserved for serious violations, for repeated violations of a less serious nature, or for willful non-compliance. Experience in some States suggests that imposing penalties on the operator (i.e. the legal person) rather than on individual workers is preferable and is more likely to lead to an improved safety performance.

5.6. FOLLOWING-UP ENFORCEMENT ACTIONS

The delay between inspection and follow-up correspondence should be kept to a minimum. Immediate written notification should be given to the authorized operator where the regulatory body considers there is any proved, suspected or highly probable breach of the legislation. Prevention of occurrence shows an authority's attitude more positive than waiting up to being able to sanction an offence against the legislation. Issues that were discussed during the exit interview or pointed out during the inspection, whether minor or major, should also be confirmed in writing. Any minor issue which would not be pointed out in good time by the regulatory body may lead to a progressive and dangerous decline in the radiation safety conditions at the premises.

Notifications for corrective actions should always include a timeframe for compliance. Therefore, where a follow-up action is required, the regulatory body must ensure that it has a system in place to flag correspondence or to send an inspection for review immediately after the end of the prescribed time. Lacking in the verification of compliance in time of its own requirements is one of the most quickly ways for the regulatory body to lose credibility, prestige and therefore authority. In the same direction, the regulatory body should never establish a requirement, which it is not technically able to verify compliance with.

Examples of letters notifying different corrective actions are given in Attachment III.

The regulatory body has to be capable of enforce its administrative sanctions according to its written enforcement policy, particularly in cases of government agencies or economical very powerful enterprises reticent to satisfy any deadline or comply with any requirement. Resignation in accepting its legal authority not being recognized, leads the regulatory body in many cases to full discredit, making it to become a bureaucratic agency without any practical action on ensuring national radiation safety.

ANNEX I.
EXAMPLE OF A CODE OF CONDUCT FOR INSPECTORS

I-1. RADIATION CONTROL LEGISLATION

REGULATORY AUTHORITY PROCEDURAL MEMORANDUM

CODE OF CONDUCT FOR INSPECTION STAFF

- Where an inspection involves two or more officers, the supervisor should inform which officer will take the lead role in discussions and interviews.
- Officers will refrain from any public display of dissent.
- Inspectors will identify themselves by showing their ID card
- ID cards or other appropriate identification is to be worn at all times when conducting an inspection unless site health and safety considerations require otherwise.
- A professional appearance will be presented.
- A firm but courteous attitude must be adopted at all times.
- Irrelevant discussion should be avoided as it can irritate busy personnel.
- Questions to radiation workers and managers should be courteous and carefully considered to ensure relevant information is obtained. Open questions preferably should be used provided that the answer received includes the expected information on the specific subject of interest.
- Where practicable, issues should be discussed as they arise.
- Avoid open criticism of individuals especially in the presence of operator colleagues.
- Inspection staff should not act as consultants on means of achieving regulatory requirements. (However, in countries where there may be limited radiation protection expertise, regulatory body personnel may need to provide assistance on practical implementation, particularly if written guidance has not yet been developed by the regulatory body). Advice to operators as to how compliance can be achieved may be given but, while doing it, it should be stressed that the practical actions necessary are, and will continue to be, the responsibility of the authorized legal person.

ANNEX II.
EXAMPLE OF A REGULATORY BODY'S ENFORCEMENT POLICY

II-1. ENFORCEMENT (INVESTIGATION AND PROSECUTION) POLICY

II-1.1. PURPOSE

To establish and document policies for the enforcement of the legislation administered by the regulatory body and provide advice for prioritizing investigation and enforcement work so that:

- the number and scope of tasks can be effectively managed;
- resources are applied principally to priority activities in terms of radiation safety and established policy;
- tasks are completed within an appropriate time.

The regulatory body administers the following legislation:

- Radiation Protection Act or Law
- Radiation Protection Rules and Regulations
- Safe Transport of Radioactive Substances Regulations

II-1.2. INVESTIGATION AND ENFORCEMENT

One role of the regulatory body is to investigate and enforce suspected breaches of the legislation in accordance with the priorities and procedures outlined in this policy.

Officers designated by the Radiation Protection Act (or Law) for constituting the regulatory body have a routine enforcement role defined by the legislation. The regulatory body's legal support services will provide assistance as may be necessary for them to carry out their duties ensuring compliance with legal principles of general law.

In carrying out their tasks, designated officers are expected to apply these same principles to their own routine regulatory and enforcement work. Where they might also identify issues with implications to the preservation of radiation safety of workers, the public and, in case of medical uses, the patients, they should bring the matter to the attention of their supervisors.

Officers assigned to the regulatory body's legal support services must have completed a training program to become aware of the special difficulties involved in what is used to be called the "Nuclear Law".

II-1.2.1. Principles

Decision to investigate

From time to time matters will be drawn to the attention of officers, which appear to be in breach of the legislation. In some cases and despite appearances, there may actually be no breach, particularly where intent is argued to be a factor.

The purpose of an investigation is to establish whether an offence has been committed and if so, by whom. The investigator is expected to carry out an objective assessment of the matter of concern with a view to determining these facts.

An investigation is therefore a search for the facts in the interests of justice and the radiation safety improvement in accordance with the specifications of the law. The investigator's task is to be an objective gatherer of any evidence that will demonstrate the guilt or innocence of those under investigation. Nevertheless, the main aim of a regulatory body's investigation shall be the determination of facts and facts sequence as to know what and why happen for avoiding its recurrence at the investigated and other premises.

Where an officer finds a potential breach during an inspection it is incumbent on that person to forthwith investigate the circumstances in accordance with this policy so that evidence is gathered and interviews are conducted in accordance with established legal principles, including that of natural justice. Failure to do so may prevent use of the evidence and interviews in any legal action.

Priorities are discussed further below. Generally, resources should be committed to an investigation when an alleged offence falls within the following priority criteria:

- Risk of death, serious injury or illness
- Significant worker, public and, in cases of medical uses, patient health risk
- Serious breaches of the law (i.e. ***serious*** *implies some potential risk to worker, public and patient health**;** fraudulent or misleading practices; or potential harm to the credibility or integrity of the law or the regulatory body*.
- Significant degree of negligence, culpability, or repeated or persistent offending.

All alleged offences should in principle be investigated trying to avoid, as stated above, the recurrence of the same breach at same or other premises. The decision on how to investigate must be taken on the merits of the individual case, but in any circumstance the regulatory body shall at least request an investigation to the authorization holder.

When deciding whether an investigation is appropriate to be performed by the regulatory body **with the aim of supporting a criminal prosecution**, the following matters will also be considered**:**

- Whether the regulatory body is, according to the general law, the state agency which shall initiate the case or whether the regulatory body will send the papers resulting from the investigation to the Director of Public Prosecutions, the attorney-general's office or otherwise;
- The gravity and nature of the offence, mainly when as a consequence of the breach there are serious injuries or death of the affected person(s);
- The likely availability of evidence of sufficient quality to support a prosecution;
- The resources necessary to conduct a thorough and exhaustive prosecution;
- The time frame in which the offence could reasonably be expected to be investigated, based on the probable availability of evidence;
- The apparent or likely degree of culpability of the alleged offender; and
- The date of the alleged offence[2];

[2] In many countries the law requires legal action to be commenced within a fixed period from the date that the alleged offense is first brought to attention of the responsible authority.

II-1.3. Prosecution guidelines

A decision on whether to carry out an investigation and to initiate a prosecution is to be made in accordance with the principles and priorities in the government's *Prosecution Guidelines*[3].

As a general rule the more serious the alleged offence the more appropriate it will be to investigate and prosecute rather than to deal with it by some other process. *The decision to investigate, or not, must not be influenced by political concerns or by public or media pressure alone.* However, public concern may be a factor to be considered when prioritizing.

Once the decision to investigate has been taken and the investigation reveals that the matter meets the criteria for prosecution in the *Prosecution Guidelines* then, in general, a prosecution should follow.

An officer must not allow his judgment to be affected by concern about the personal or business circumstances of an alleged offender. It is particularly important that an officer conducting an investigation does not prejudge the outcome until all facts are gathered. All investigations should be undertaken so that any evidence or exhibits collected are not compromised and will be admissible should there be a decision to prosecute.

An officer who has any relationship to the person or organization under investigation (e.g. business, family, friendship, etc.) should promptly declare that relationship to their supervisor and should take no further part in the investigation.

II-1.4. Warning letter policy

In some circumstances it will become apparent that the alleged offence reported is of a nature that suggests it would be more appropriate to seek compliance from the alleged offender or just follow the procedures to apply an administrative sanction rather than proceed with a prosecution.

In such circumstances a warning letter may be appropriate. Warning letters are not to be sent when the regulatory body has any doubt as to the activity concerned and who is responsible. Warning letters are also not to be sent in circumstances where it is apparent from the nature of the offence that a prosecution is warranted.

In general, a warning is appropriate where there is reason to believe the alleged offender did not intend a breach, would willing rectify the matter, and had not acted irresponsibly or negligently.

In circumstances where it is appropriate to proceed by way of warning, such a letter may be sent to the alleged offender as an alternative to an investigation with a view to prosecution. The letter must clearly identify the concerned breach of the legislation, the offence involved and the penalty applicable.

The letter must also outline what corrective action is expected and an appropriate time-frame in which to achieve it.

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[3] It is assumed that Governments in all countries have prepared Guidelines for use by its agencies and statutory authorities.

If a satisfactory response is received and the corrective action has been verified by inspection, it shall be filed and the matter considered closed. Where matters are investigated and resolved by means of a warning letter, they would not necessarily also be the subject of any subsequent legal action, provided that the breach has not been so important as to deserve some administrative sanction according to the regulatory body's written enforcement policy. However, details of previous warnings should be relevant in considering action on subsequent offences.

II-1.5. Brief of evidence

Once an investigation has shown that an offence has been committed and a person or entity has been identified who can be held accountable for the offence in Court, the investigating officer will submit a complete brief of the evidence through his supervisor to the regulatory body's legal support service. It is the investigating officer's responsibility to ensure that the brief contains all available evidence in relation to the alleged offence. This will include, where relevant, copies of the application for authorization, the authorization certificate itself together with any attached conditions, the inspection report detailing the breach discovery, and any other relevant correspondence and reports. The legal support service will ensure that the evidence provided in the brief is sufficient to satisfy a prosecution.

II-1.6. Referral to the authority's legal support services

It is the responsibility of the regulatory body's legal support service to decide if the matter should proceed to a prosecution. In reaching this decision the above considerations and the *Prosecution Guidelines* will be taken into account. If necessary, the legal support services should be consulted for further advice on whether to pursue a prosecution.

If the legal support services believe is recommendable not to prosecute, written reasons for that position will be provided promptly to the regulatory body. The regulatory body will consider those reasons, but if it believes that a prosecution should nevertheless proceed, it shall inform the legal support services accordingly.

If it is considered that further enquiries or evidence are necessary, the investigating officer shall as far as possible comply with requests to investigate further.

II-1.7. Referral to, and collaboration with, other agencies

In some circumstances, it may be apparent that although the activity of concern allegedly breaches public health or similar legislation, the activity may be more appropriately investigated by another agency. Consumer fraud is one example. In some instances Police or Customs may also be more appropriate enforcement agents. Investigating officers must be prepared to collaborate with other agencies when they have information that may be helpful to other investigators.

ANNEX III.
EXAMPLES OF CORRECTIVE ACTION LETTERS

RADIATION REGULATORY AUTHORITY
Government of COUNTRY

Example 1

Your Ref
Our Ref 1234/02
Enquiries Mrs. S. Mollah 222 3335

Dr. M. Rahman
Department of Radiology
City Radiology
Box 5678 Post Office
CAPITAL CITY 01234

Dear Dr. Rahman

I enclosed a copy of the report of the inspection of your practice on 23 October 2003.

A number of points of non-compliance with the regulations and/or the *Code of Practice for the Safe Use of X rays in Medical Diagnosis* have been identified. In accordance with the Authority's policy, remedial action to correct these deficiencies must be completed by **30 November 2003**.

Matters requiring repair or re-calibration of X ray equipment may only be carried out by an approved service agency. The completed remedial action should be reviewed by your Qualified Expert and a copy of the report submitted to me as evidence that the work has been satisfactorily completed.

If you require further information, please let me know. The Authority's staff will be pleased to discuss the report with your Qualified Expert.
Yours sincerely

Dr. H. Hamzah
Director

28 October 2003

Letters: Box X999 Post Office, Capital City 01234
Telephone: (880) 222 3333
Fax: (880) 222 3334
E-mail: rra@isp.gov.country

RADIATION REGULATORY AUTHORITY

Government of COUNTRY

Example 2

Your Ref
Our Ref 1234/02
Enquiries Mrs. S. Mollah 222 3335

Dr. M. Rahman
Department of Radiology
City Radiology
Box 5678 Post Office
CAPITAL CITY 01234

Dear Dr. Rahman

I refer to my letter of 28 October 2003 and the report that was enclosed on the inspection of your practice on 23 October 2003. Although you were asked to take remedial action in respect of a number of points of non-compliance by 30 November 2003 and to notify me when this work was completed, no response has yet been received.

The date for completing the work has now been extended by 14 days. Would you please provide confirmation by 12 December 2003, together with evidence from your Qualified Expert, that the matters identified in the report have been corrected.

Through a comprehensive inspection and enforcement program, the Regulatory Authority ensures that facilities using ionizing radiation operate in compliance with strict safety standards. During the authorization process, regulatory requirements and applicant obligations are incorporated into the authorization certificate conditions. A condition of all authorization certificates is that operators must demonstrate and maintain compliance with the appropriate Code of Practice. The conditions of the authorization certificate have the same force in law as the regulations to the Act.

Failure to address the notified points of non-compliance by the due date will lead to a breach of the conditions in the authorization certificate. The Authority may then be obliged to consider a number of enforcement actions, which can range from suspension or cancellation of the authorization certificate, to prosecution.

Yours sincerely

Dr. H. Hamzah
Director

30 November 2003

Letters: Box X999, Post Office, Capital City 01234
Telephone: (880) 222 3333
Fax: (880) 222 3334
E-mail: rra@isp.gov.country

ANNEX IV.
INSPECTION PROCEDURES AND RECORDS OF RADIATION SOURCES

APPENDIX A.

INSPECTION PROCEDURES AND RECORDS OF RADIATION SOURCES IN DIAGNOSTIC RADIOLOGY

INSPECTION RECORD SUMMARY

DIAGNOSTIC RADIOLOGY (PART 1)

	Inspection number	
	Authorization Number	
Name of the facility		
Address (location of the facility)		
Telephone Number		
Radiation Protection Officer		
Operator's representative for the inspection		
Date of LAST Inspection	_____/_____/_____	
Date of THIS Inspection	_____/_____/_____	
Starting time:	**Exit time:**	
Type of Inspection Pre-authorization	☐	
Routine	☐	
Investigation	☐	
Termination	☐	
Recommended Date of NEXT Inspection	_____/_____/_____	
Summary of Findings and Actions		
NO items of non-compliance found	☐	
Items of non-compliance found	☐	(to be detailed in Comments)
Follow-up on previous non-compliance	☐	(to be detailed in Comments)
Inspector (1) name & signature Date		
Inspector (2) name & signature Date		
Report approved by supervisor	**Yes** ☐ **No** ☐ Comments (if **No)**	
Supervisor's signature		
Comments (*to be signed and dated*)		

INSPECTION RECORD

DIAGNOSTIC RADIOLOGY (PART 1)

This inspection record/checklist is to be used by the inspector to assist with the performance of the inspection. Note that all areas will not necessarily be applicable to each authorized facility. In addition, with supervisory approval, the inspector may choose not to review a particular program area during each inspection. However, for those areas ***not examined*** *or* ***not relevant*** *during the inspection a notation such as "Not Reviewed" or "Not Applicable" should be made in the relevant section and a brief explanation as to why the area was not reviewed should be provided, where applicable.*

All areas investigated during the inspection should be documented in sufficient detail to describe the activities and procedures observed and/or demonstrated. In addition, the types of records that were reviewed and the time periods covered by those records should be noted. If the operator demonstrates any work practices at the inspector's request, describe those demonstrations. The observations and demonstrations described in this report, along with measurements and the records reviewed, should substantiate your inspection findings. Attach copies of all relevant documents and records required to support item(s) of non-compliance.

This inspection record/checklist is divided into THREE parts*. The first deals with matters common to dental and medical radiology. The second with matters more relevant to dental practices (intraoral, panoramic and cephalometric radiology) and the third with medical radiology. i.e. radiology practices, hospitals, GP practices, etc. Medical radiology practices may also possess dental X ray equipment. The officer should use the* ***common*** *first part plus either the* ***second or third*** *part as applicable to the authorized use.*

1. AMENDMENTS AND PROGRAM CHANGES *Prior to the inspection, list for review any amendments submitted by the operator and approved by the regulatory body since the last inspection*

2. INSPECTION AND ENFORCEMENT HISTORY

Prior to the inspection, list for review any items of non-compliance identified during previous 2-3 inspections

DATE	INSPECTOR	VIOLATIONS

3. INCIDENT / EVENT HISTORY

Prior to the inspection, list for review any incidents or events reported by the operator to the Regulatory Body since the last inspection

4. ORGANIZATION AND SCOPE OF THE PROGRAM

Briefly describe the present scope of activities, including types of procedures, frequency of use, staff size, etc. (Note deviations from the licence or registration)

5. TRAINING AND INSTRUCTION OF WORKERS *Training and retraining requirements and documentation; interviews and observations of routine work; staff knowledge of all routine activities; and emergency response*		
	Yes	**No**
All personnel using or responsible for the use of the X ray equipment have prescribed qualifications and/or training?		
All occupationally exposed personnel are provided with initial safety training?		
Refresher radiation safety training is provided periodically?		
Appropriate supervision of personnel (e.g. technologists, nurses, etc.) is provided by designated practitioners?		
Training records maintained for each worker?		
Interviews with personnel demonstrate an adequate level of understanding regarding safe working procedures?		
Discussion with the RPO demonstrates an appropriate knowledge of the Regulatory Body, the authorization certificate, the legislation, conditions, safe working procedures, etc?		
Does the RPO have appropriate resources (time, personnel) and authority (to take independent action to remedy urgent safety issues) to properly perform the role?		
Comments:		

6. INTERNAL AUDITS AND REVIEWS		
	Yes	**No**
Operator reviews the radiation protection program at appropriate intervals?		
Audits of the facilities, X ray equipment inventory and working rules performed at appropriate intervals?		
Audits conducted by		
Frequency		
Records of program reviews and audits maintained?		
Comments		

7. AREA RADIATION SURVEYS *Radiological surveys*		
	Yes	**No**
Operator possesses appropriate, functioning survey instrument(s)?		
Suitable function checks are performed on instruments prior to use?		
Survey meter calibrations are current?		
Survey meter calibration is performed by an approved facility?		
Name of facility		
Area exposure rate surveys are performed at appropriate intervals?		
Records of calibrations, surveys, etc. are maintained?		
Comments:		

8. PERSONNEL RADIATION MONITORING *Radiation protection program with ALARA provisions; dosimetry; exposure evaluations; dose and survey records and reports; notifications to workers] [BSS – Schedule II]*		
	Yes	**No**
Operator provides personal dosimeters to all radiation workers?		
Dosimetry supplier is an authorized provider?		
Name of provider		
Dosimeters provided are appropriate for the radiation type and energy?		
Dosimeters are exchanged at the prescribed period?		
Dosimetry reports are promptly reviewed by the RPO?		
Is it evident that personal dosimeters are being worn by workers?		
Individual workers are informed of their monitoring results when each monitoring report is received (regardless of the dose measured)?		
Personnel monitoring records are maintained?		
Inspector reviewed personnel monitoring records for the period from/ to		
Comments *(include the maximum doses to workers during this review period*)		

9. NOTIFICATIONS AND REPORTS *Reporting and follow-up of theft; loss; incidents; overexposures; safety-related equipment failures; change in RPO, and radiation dose reports to workers. [BSS - Section 3.12]*		
	Yes	**No**
Have any program changes been implemented that required (but have not received) approval by the Regulatory Body?		
Have any notifiable incidents or accidents occurred since the last inspection?		
If yes, have they been reported to the Regulatory Body? (*If no, list the incidents or accidents in Comments)*		
Have any significant structural or other safety related changes been made to the facilities or X ray equipment without approval of the Regulatory Body		
If yes, was a safety assessment performed by a Qualified Expert?		
Comments		

10. WARNING SIGNS AND LABELLING *Proper warning signs in use areas and labelling of containers with radioactive material [BSS-Section I.23]*		
	Yes	**No**
Controlled areas have appropriate warning signs (in the local language)?		
Entry to X ray rooms posted appropriately?		
Illuminated warning signs/lights functioning (where required)?		
Notices to workers are displayed as required?		
Comments		

11. INDEPENDENT AND CONFIRMATORY MEASUREMENTS		
	Yes	**No**
Inspector made area and other measurements for comparison to operator's		
Comments: *Describe the types and results of measurements taken. Identify the instruments used by the inspector (make, model, last calibration)*		

12. ITEMS OF NON-COMPLIANCE AND OTHER SAFETY ISSUES *List any breaches noted during the inspection (what, when, where and who).*

13. PERSONNEL CONTACTED *Identify the personnel contacted during the inspection*

INSPECTION RECORD

DIAGNOSTIC RADIOLOGY — MEDICAL (PART 2)

This inspection record/checklist deals with matters relevant to medical radiology

1. RESPONSIBILITIES *Justification and Optimization [BSS Apex II]*		
	Yes	**No**
Examinations with X ray are authorized by appropriately Qualified Practitioners?		
Has an appropriately Qualified Practitioner been designated as having overall responsibility for patient protection and safety?		
If yes, practitioner's name?		
Does this Qualified Practitioner ensure that exposures are justified?		
If yes, how the Qualified Practitioner says is this achieved?		
Has the operator established Dose Guidance (or Reference) Levels?		
Have dose measurements been made at the facility for comparison to these levels?		
If yes, by whom, at what frequency and when last made?		
Does the facility undertake research involving exposure of humans to radiation?		
If yes, are procedures in place ensuring compliance with the Helsinki Declaration, and guidelines observing the requirements of the Council for International Organizations of Medical Sciences and of the World Health Organization?		
Are such exposures subject to the advice of an Ethics Committee or similar body within the facility?		
Does the facility conduct any screening programs?		
If yes, are standards available and followed?		
Are satisfactory procedures in place to properly identify patients?		
Are satisfactory procedures in place to identify potentially pregnant patients and, if clinically appropriate, to defer or modify the X ray examination?		
Are satisfactory steps taken to minimize the radiation dose during X ray examinations of the lower trunk of pregnant women (i.e. of the abdomen, pelvis, lumbar spine, etc.) when such examinations cannot be deferred?		

2. FACILITIES AND EQUIPMENT *Facilities as described; uses; control of access; engineering controls; shielding [BSS Section 2.34]*		
	Yes	**No**
Are the facilities as described in the application?		
Is access to the X ray equipment adequately controlled to prevent unauthorized use?		
Are adequate means (barriers, signs, procedures) used to prevent unauthorized individuals from entering controlled areas?		
Are X ray examinations performed with appropriate (purpose designed) equipment?		
EQUIPMENT COMPLIANCE AND MAINTENANCE (Quality Control)		
Is the X ray equipment subject to periodic testing (a QC program) to ensure the design and operating characteristics comply with the IEC/ISO or other requirements of the Regulatory Body?		
If so, at what frequency; by whom; date of the last test?		
Is the X ray equipment subject to routine maintenance by authorized service agents?		
Records confirm testing and maintenance?		
FILM, INTENSIFYING SCREENS, PROCESSING		
Is the speed of image receptors (intensifying screens and/or film) the highest commensurate with the required image quality?		
Does the X ray film spectral sensitivity match that of the intensifying screens?		
Is the darkroom light tight?		
Is the safe lighting appropriate to the film type(s) in use (colour and wattage)?		
For manual processing of X ray film		
- are appropriate facilities provided (tanks, temperature control, etc.)?		
- is the developer in use suitable for the films being developed?		
- is a suitable developer timer and developer thermometer available?		
- is the correct time-temperature chart for the developer and film displayed?		
- is time-temperature development routinely practised?		
- is the temperature of the developer kept within the bounds specified by the manufacturer?		
- are the storage conditions of undeveloped X ray film stocks satisfactory?		
Are appropriate quality control checks performed on the film/image processing equipment at regular intervals?		
Radiation Protection Officer routinely reviews quality control checks and maintains records?		

PROTECTIVE DEVICES		
Appropriate numbers of lead protective aprons and gloves in good order?		
Protective screens for control console position provided where appropriate and in good order?		
Appropriate patient (eyes, gonads, etc) protective devices available and in good order?		
Is it apparent that these protective devices are being used routinely?		
Comments:		

INSPECTION RECORD

DIAGNOSTIC RADIOLOGY — DENTAL (PART 3)

This inspection record/checklist deals with matters relevant to dental radiology (facilities with intra-oral, panoramic (tomographic) or cephalometric X ray equipment).

3. RESPONSIBILITIES

Justification and Optimization [BSS Apex II]

	Yes	No
Examinations with X ray are authorized by appropriately Qualified Practitioners?		
Has an appropriately Qualified Practitioner been designated as having overall responsibility for patient protection and safety?		
If yes, practitioner's name?		
Does this practitioner ensure that exposures are justified?		
If yes, how is this achieved?		
Has the operator established Dose Guidance (or Reference) Levels?		
Have dose measurements been made at the facility for comparison to these levels?		
If yes, by whom, at what frequency and when last made?		
Are satisfactory procedures in place to properly identify patients?		
Does the facility undertake research involving exposure of humans to radiation?		
If yes, are procedures in place ensuring compliance with the Helsinki Declaration, and guidelines observing the requirements of the Council for International Organizations of Medical Sciences and of the World Health Organization?		
Are such exposures subject to the advice of an Ethics Committee or similar body?		
Does the facility conduct any screening programs?		
If yes, are standards available and followed?		

4. FACILITIES AND EQUIPMENT *Facilities as described; uses; control of access; engineering controls; shielding [BSS Section 2.34]*		
	Yes	**No**
Are the facilities as described in the application?		
Is access to the X ray equipment adequately controlled to prevent unauthorized use?		
Are adequate means (barriers, signs, procedures) used to prevent unauthorized individuals from entering controlled areas?		
Are X ray examinations performed with appropriate (purpose designed) equipment?		
EQUIPMENT COMPLIANCE AND MAINTENANCE (Quality Control)		
Is the X ray equipment subject to periodic testing (a QC program) to ensure the design and operating characteristics comply with the IEC/ISO or other requirements of the Regulatory Body?		
If so, at what frequency; by whom; date of the last test?		
Is the X ray equipment subject to routine maintenance by authorized service agents?		
Records confirm testing and maintenance?		
FILM, INTENSIFYING SCREENS, PROCESSING		
Is the speed of image receptor (intra-oral film and film used with intensifying screens) the highest commensurate with the required image quality?		
For film-screen combinations, does the X ray film spectral sensitivity match the intensifying screens?		
Is the darkroom (or dental processing unit) light tight?		
Is the safe lighting appropriate to the film type(s) in use (colour and wattage)?		
For manual processing of X ray film		
- are appropriate facilities provided (tanks, temperature control, etc)?		
- is the developer in use suitable for the films being developed?		
- is a suitable developer timer and developer thermometer available?		
- is the correct time-temperature chart for the developer and film displayed?		
- is time-temperature development routinely practised?		
- is the temperature of the developer kept within the bounds specified by the manufacturer?		
- are the storage conditions of undeveloped X ray film stocks satisfactory?		
Are appropriate quality control checks performed on the film/image processing equipment at regular intervals?		
Radiation Protection Officer reviews quality control checks and maintains records?		

PROTECTIVE DEVICES		
Patient protective apron(s) available and in good order?		
Operator's operator can stand at least 2 m from the patient and X ray tube during exposures?		
If no, is other satisfactory shielding in place?		
Patient holds intra-oral films during exposures?		
Is it apparent that these protective measures are being used routinely?		
Comments:		

APPENDIX B.

INSPECTION PROCEDURES AND RECORDS OF RADIATION SOURCES IN NUCLEAR MEDICINE

INSPECTION RECORD SUMMARY
NUCLEAR MEDICINE

Inspection number	
Authorization number	

Name of the facility	
Address (location of the facility)	
Telephone Number	
Name of Radiation Protection Officer	
Name of Medical (or Hospital) Physicist	
Operator's representative for the inspection	
Date of LAST Inspection	_____/_____/_____
Date of THIS Inspection	_____/_____/_____
Starting time:	**Exit time:**
Type of Inspection Pre-authorization Routine Investigational Termination	☐ ☐ ☐ ☐
Recommended Date of NEXT Inspection	_____/_____/_____
Summary of Findings and Actions NO items of non-compliance found Items of non-compliance found Follow-up on previous non-compliance	 ☐ ☐ ☐
Inspector (1) name & signature Date	
Inspector (2) name & signature Date	
Supervisor's signature	

Report approved by supervisor	**Yes** ☐ **No** ☐ Comments (if **No)**
Comments (*to be signed and dated*)	

INSPECTION RECORD

NUCLEAR MEDICINE

This inspection record/checklist is to be used by the inspector to assist with the performance of the inspection. Note that all areas will not necessarily be applicable to each authorized facility. In addition, with supervisory approval, the inspector may choose not to review a particular program area during each inspection. However, for those areas ***not examined*** *or* ***not applicable*** *during the inspection a notation such as "Not Reviewed" or "Not Applicable" should be made in the relevant section and a brief explanation as to why the area was not reviewed should be provided, where applicable.*

All areas investigated during the inspection should be documented in sufficient detail to describe the activities and procedures observed and/or demonstrated. In addition, the types of records that were reviewed and the time periods covered by those records should be noted. If the operator demonstrates any work practices at the inspector's request, describe those demonstrations. The observations and demonstrations described in this report, along with measurements and the records reviewed, should substantiate your inspection findings. Attach copies of all relevant documents and records required to support item(s) of non-compliance.

1. AMENDMENTS AND PROGRAM CHANGES

Prior to the inspection, list for review any licence amendments submitted by the operator and approved by the Regulatory Body since the last inspection

2. INSPECTION AND ENFORCEMENT HISTORY

Prior to the inspection, list for review any items of non-compliance identified during previous 2-3 inspections

DATE	INSPECTOR	VIOLATIONS

3. INCIDENT / EVENT HISTORY *Prior to the inspection, list for review any incidents or events reported to the Regulatory Body since the last inspection*

4. ORGANIZATION AND SCOPE OF THE PROGRAM *Briefly describe the present scope of activities, including types and maximum activities at any time of authorized unsealed sources, frequency of use, staff size, etc. (Note deviations from the authorization certificate)*

5. RESPONSIBILITIES *Justification and Optimization [BSS App. II]*		
	Yes	**No**
Procedures are authorized by appropriately Qualified Practitioners, in accordance with the medical speciality for which the radioactive material is going to be applied to patients? (e.g. cardiologists, endocrinologists, nephrologists, etc.)		
Has an appropriately Qualified Practitioner been designated as having overall responsibility for patient protection and safety?		
If yes, practitioner's name?		
Does this practitioner ensure that procedures are justified?		
If yes, how the practitioner says is this achieved?		
Is the activity of radio-pharmaceuticals administered to patients within the range considered acceptable by the profession and the regulatory body?		
At what frequency is this reviewed, by whom and when reviewed last?		
Does the facility undertake research involving exposure of humans to radiation?		
If yes, are procedures in place ensuring compliance with the Helsinki Declaration, and guidelines observing the requirements of the Council for International Organizations of Medical Sciences and of the World Health Organization?		

Are such procedures subject to the advice of an Ethics Committee or similar body within the facility?		
Are satisfactory procedures in place to properly identify patients before treatment?		
Are satisfactory procedures in place to identify potentially pregnant patients and, if clinically appropriate, to defer or modify the procedure?		
Comments:		

6. TRAINING AND INSTRUCTION OF WORKERS *Training and retraining requirements and documentation; interviews and observations of routine work; staff knowledge of all routine activities, and emergency response*		
	Yes	**No**
All persons working with radiation have prescribed qualifications and/or training?		
All occupationally exposed personnel are provided with initial safety training?		
Refresher radiation safety training is provided periodically?		
Adequate supervision of workers (technologists and lab assistants) by medical practitioners?		
Are training records maintained for each worker?		
Do interviews with personnel demonstrate an adequate level of understanding regarding safety and emergency procedures?		
Discussion with the RPO demonstrates an appropriate knowledge of the regulatory body, the authorization, the legislation, conditions, safe working procedures, etc?		
Does the RPO have appropriate resources (time, personnel) and authority (to take independent action to remedy urgent safety issues) to properly perform the role?		
Comments:		

7. **INTERNAL AUDITS AND REVIEWS**		
	Yes	No
Operator reviews the radiation protection program at appropriate intervals?		
Audits of the facilities, source utilization log book, working rules and emergency procedures performed at appropriate intervals?		

Audits conducted by		
Frequency		
Records of program reviews and audits maintained?		
Comments		

8. FACILITIES AND EQUIPMENT

Facilities as described; uses; control of access; engineering controls; calibration facilities; shielding [BSS Section 2.34]

	Yes	**No**
Are the facilities as described in the application for authorization?		
Access to radioactive material adequately controlled?		
Radioactive material is secured to prevent unauthorized removal?		
Adequate methods used to prevent unauthorized individuals from entering controlled areas?		
Adequate fire protection?		
Operator possesses and uses a radionuclide activity meter?		
Quality control checks (constancy, linearity, accuracy, geometry) of the radionuclide activity meter are conducted as specified by the manufacturer?		
Corrections factors calculated and used to accurately measure β emitting radio-pharmaceuticals (e.g. ^{89}Sr, ^{32}P, ^{153}Sm)		
Is the imaging equipment subject to QC testing to ensure the design and operating characteristics comply with the IEC/ISO or other requirements of the Regulatory Body?		
If so, at what frequency; by whom; date of the last test?		
RPO maintains records and ensures that appropriate personnel (the medical physicist etc.) reviews results of quality control checks?		
Comments:		

9. UNSEALED RADIATION SOURCES		
	Yes	**No**
Radionuclides, chemical form, maximum activities at any time, and uses as authorized and confirmed by the source utilization log book?		
Operator obtains prepared doses from an authorized radio- pharmaceutical supplier?		
Supplier's name, address		
Operator obtains and uses $^{99}Mo/^{99m}Tc$ generators?		
^{99}Mo breakthrough tests performed as required?		
Comments:		

10. RECEIPT AND TRANSFER OF RADIATION SOURCES		
	Yes	**No**
Radioactive package opening procedures established and followed?		
Incoming radioactive packages surveyed for damage, dose rates and potential radioactive contamination before opening?		
Records of packaging surveys, source receipt and transfer maintained?		
Comments		

11. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL *Radiological surveys; leak tests; source existence checks; handling of radioactive materials; records; contamination control [BSS - Section I.38]*		
	Yes	**No**
Operator possesses appropriate, functioning survey instrument(s)?		
Suitable function checks are performed on instruments prior to use?		
Survey meter calibrations are current?		
Survey meter calibration is performed by an approved facility?		
Name of facility		
Area exposure rate surveys are performed at appropriate intervals?		
Surveys for removable contamination, including fume cupboards, conducted as required?		
Records of calibrations, contamination surveys, etc. maintained?		

Comments:

12. PERSONNEL RADIATION MONITORING

Radiation protection program with ALARA provisions; dosimetry; exposure evaluations; dose and survey records and reports; notifications to workers] [BSS – Schedule II]

	Yes	**No**
Operator provides personal dosimeters to all radiation workers?		
Dosimetry supplier is an authorized provider?		
Name of provider		
Dosimeters provided are appropriate for the radiation type and energy?		
Dosimeters are exchanged at the prescribed period?		
Dosimetry reports are promptly reviewed by the RPO?		
Is it evident that personal dosimeters are being worn by workers?		
Individual workers are informed of their monitoring results when each monitoring report is received (regardless of the dose measured)?		
Does the operator apply the optimization principle (ALARA) to occupational exposure?		
Potential for exposure of workers to airborne radioactive material exists?		
Monitoring for airborne radioactivity conducted?		
For radioactive gases (e.g. ^{133}Xe) ventilation rates checked to ensure negative pressure in use areas?		
Spilled gas clearance times calculated and posted as appropriate?		
Bioassay program established and implemented as appropriate?		
Personnel monitoring records are maintained?		
Inspector reviewed personnel monitoring records for the period from/ to		
Comments *(include the maximum doses to workers during this review period*)		

13. RADIO-PHARMACEUTICAL THERAPY		
	Yes	**No**
Appropriate written safety instructions are provided to patients and nursing staff commensurate with the therapy administered?		
The safety precautions at the facility include appropriate administration/treatment rooms, patient toilet facilities, warning signs, controlled visiting times, patient safety guidance, release and contamination controls?		
Discharge of patients complies with approved procedures?		
Patient treatment rooms are surveyed for contamination following patient release?		
Appropriate procedures have been established in case of premature death of patients undergoing treatment (including post mortem, cremations, etc)?		
Thyroid uptake measured on workers involved with administration of radioiodine?		
Records of procedures, treatments and other measurements maintained?		
Comments:		

14. RADIOACTIVE WASTE MANAGEMENT *Disposal or transfer of sources; packaging, control, and tracking procedures; records [BSS Section III.8]*		
	Yes	**No**
Radioactive effluents released to unrestricted area?		
Releases comply with regulatory requirements?		
Decay-in-storage method used?		
Storage facilities comply with regulations?		
Control and fire safety satisfactory?		
Warning and notification signs (in local language) satisfactory?		
Inventory of store contents checked at acceptable intervals?		
Disposals in accordance with regulatory requirements?		
Records maintained?		
Comments:		

15. TRANSPORT OF RADIOACTIVE SOURCES

IAEA Regulations for the Safe Transport of Radioactive Material-Safety Standard Series No. TS-R-1

	Yes	No
Does transport of radioactive material (from supplier, by operator) comply with IAEA regulations?		
Approved packages used?		
Packages properly labelled and marked?		
Supplier's vehicles, if used for transport, comply with regulations?		
Shipper's declaration papers have correct details and used when shipping sources?		
Comments		

16. NOTIFICATIONS AND REPORTS

Reporting and follow-up of theft; losses; incidents; overexposures; safety-related equipment failures; change in RPO, and radiation dose reports to workers [BSS – Section 3.12]

	Yes	No
Have any program changes been implemented that required (but have not received) approval by the Regulatory Body?		
Have any notifiable incidents or accidents occurred since the last inspection?		
If yes, have they been reported to the Regulatory Body? (*If no, list the incidents or accidents in Comments)*		
Have any significant structural or other safety related changes been made to the facilities without approval of the Regulatory Body?		
If yes, was a safety assessment performed by a Qualified Expert?		
Comments		

17. WARNING SIGNS AND LABELLING *Proper warning signs in use areas and labelling of containers with radioactive material [BSS-Section I.23]*		
	Yes	**No**
Controlled areas have appropriate warning signs (in the local language)?		
Containers of radioactive material are properly labelled?		
Notices to workers are displayed as required?		
Radiopharmaceutical syringes, vials, storage areas, etc. are labelled as appropriate?		
Comments		

18. INDEPENDENT AND CONFIRMATORY MEASUREMENTS		
	Yes	**No**
Inspector made area and other measurements for comparison to operator's		
Comments: *Describe the types and results of measurements taken. Identify the instruments used by the inspector (make, model, last calibration).*		

19. ITEMS OF NON-COMPLIANCE AND OTHER SAFETY ISSUES *List any breaches noted during the inspection (what, when, where and who).*

20. PERSONNEL CONTACTED *Identify the personnel contacted during the inspection*

APPENDIX C.

INSPECTION PROCEDURES AND RECORDS OF RADIATION SOURCES IN RADIOTHERAPY

INSPECTION RECORD SUMMARY

RADIOTHERAPY (PART 1)

Inspection number	
Authorization number	

Name of the Facility	
Address (location of the facility)	
Telephone Number	
Name of Radiation Protection Officer	
Name of the Medical (or Hospital) Physicist	
Operator's representative for the inspection	
Date of LAST Inspection	_____/_____/_____
Date of THIS Inspection	_____/_____/_____
Starting time:	**Exit time:**
Type of Inspection Pre-authorization	☐
Routine	☐
Investigational	☐
Termination	☐
Recommended Date of NEXT Inspection	_____/_____/_____
Summary of Findings and Actions	
NO items of non-compliance found	☐
Items of non-compliance found	☐
Follow-up on previous non-compliance	☐
Inspector (1) name &signature	
Date	

Inspector (2) name & signature Date	
Supervisor's signature	
Report approved by supervisor	**Yes** ☐ **No** ☐ Comments (if **No)**

Comments (*to be signed and dated*)

INSPECTION RECORD

RADIOTHERAPY (PART 1)

This inspection record/checklist is to be used by the inspector to assist with the performance of the inspection. Note that all areas will not necessarily be applicable to each authorized facility. In addition, with supervisory approval, the inspector may choose not to review a particular program area during each inspection. However, for those areas ***not examined*** *or* ***not applicable*** *during the inspection a notation such as "Not Reviewed" or "Not Applicable" should be made in the relevant section and a brief explanation as to why the area was not reviewed should be provided, where applicable.*

All areas investigated during the inspection should be documented in sufficient detail to describe the activities and procedures observed and/or demonstrated. In addition, the types of records that were reviewed and the time periods covered by those records should be noted. If the operator demonstrates any work practices at the inspector's request, describe those demonstrations. The observations and demonstrations described in this report, along with measurements and the records reviewed, should substantiate your inspection findings. Attach copies of all relevant documents and records required to support item(s) of non-compliance.

This inspection record/checklist is divided into THREE parts*. The first deals with matters generally common to radiotherapy. The second with specific issues for X ray and electron therapy and cobalt teletherapy and the third with brachytherapy (implants and devices). The officer should use the* ***common*** *first part plus the relevant* ***second or third*** *parts as applicable to the authorized use and each type of radiation source****.***

1. AMENDMENTS AND PROGRAM CHANGES

Prior to the inspection, list for review any amendments submitted by the operator and approved by the Regulatory Body since the last inspection

2. INSPECTION AND ENFORCEMENT HISTORY

Prior to the inspection, list for review any items of non-compliance identified during previous 2-3 inspections

DATE	INSPECTOR	VIOLATIONS

3. INCIDENT/EVENT HISTORY *Prior to the inspection, list for review any incidents or events reported to the Regulatory Body since the last inspection*

4. ORGANIZATION AND SCOPE OF THE PROGRAM *Briefly describe the present scope of activities, including types and quantities of use involving authorized sources, frequency of use, staff size, etc. (Note deviations from the authorization certificate)*

5. RESPONSIBILITIES

Justification [BSS App. II]

	Yes	**No**
All treatments authorized by appropriately Qualified Practitioners?		
An appropriately Qualified Practitioner is designated as having overall responsibility for patient protection and safety?		
If yes, practitioner's name?		
Does this Qualified Practitioner ensure that procedures are justified?		
If yes, how is this achieved?		

All patient have an individual treatment planning performed by a Medical Physicist?		
If yes, Medical (or hospital) Physicist's name?		
Is always at least one radiotherapist present at the facility while patients are being irradiated?		
Are satisfactory procedures in place to properly identify patients before treatment?		
Does the facility undertake research involving exposure of patients to radiation?		
If yes, are procedures in place ensuring compliance with the Helsinki Declaration, and guidelines observing the requirements of the Council for International Organizations of Medical Sciences and of the World Health Organization?		
Are such procedures subject to the advice of an Ethics Committee or similar body within the facility?		
Comments:		

6. TRAINING AND INSTRUCTION OF WORKERS

Training and retraining requirements and documentation; interviews and observations of routine work; staff knowledge of all routine activities, and emergency response

	Yes	**No**
All personnel using radiation sources have recognized qualifications?		
All occupationally exposed personnel are provided with initial safety training?		
Refresher radiation safety training is provided periodically?		
Supervision of personnel (e.g. technologists) by specialist Medical Practitioners is satisfactory?		
Training records kept for each worker?		
Interviews with workers demonstrate an appropriate knowledge of safe working rules and emergency procedures (e.g. source recovery?)		
Discussion with the RPO demonstrates an appropriate knowledge of the Regulatory Body, the authorization certificate, the legislation, conditions, safe working procedures, etc?		
Does the RPO have appropriate resources (time, personnel) and authority (to take independent action to remedy urgent safety issues) to properly perform the role?		
Comments		

7. INTERNAL AUDITS AND REVIEWS		
	Yes	No
Operator reviews the radiation protection programme at appropriate intervals?		
Audits of the facilities, source inventory, working rules and emergency procedures performed at appropriate intervals?		
Audits conducted by		
Frequency		
Records of program reviews and audits maintained?		
Comments		

8. FACILITIES AND RADIATION SOURCES *Facilities as described; uses; control of access; engineering controls; calibration facilities; shielding [BSS Section 2.34]*		
	Yes	**No**
FACILITIES		
Facilities are as described in the authorization application?		
Radiation sources are secured so as to prevent unauthorized use and removal?		
Access to controlled areas by unauthorized persons properly supervised?		
Suitable emergency equipment for radioactive source recovery is available?		
Fire protection satisfactory?		
COMPLIANCE, MAINTENANCE, AND REPAIR (Quality Control)		
The design and performance characteristics of radiation devices, whether using radioactive sources or electrically generated radiation, comply with relevant IEC/ISO standards or other requirements of the Regulatory Body?		
Radiation devices are subject to regular QC tests to ensure continued compliance?		
If so, at what frequency; by whom; date of last test?		
Radiation devices are subject to routine maintenance by authorized service agents?		
If so, at what frequency, by whom; date last maintenance		
Records of compliance tests, maintenance, inspection and service maintained?		

OPERATING CHECKS AND CALIBRATION		
Appropriate checks of the performance and functionality of radiation devices and their associated safety equipment have been prescribed by a medical physicist and are carried out daily and at other suitable periods (where relevant to the device)?		
These checks are performed by the Medical Physicist or the results of these checks are reviewed by him/her within the day?		
Radiation devices are calibrated using acceptable protocols?		
A complete calibration of each device is performed		
- before the device is first used for patient treatment?		
- routinely at prescribed intervals acceptable to the Regulatory Body?		
- if routine operating checks show output variations outside established limits?		
- after major repair or modification?		
- using instruments with calibrations traceable to an approved standard?		
- by a Medical Physicist recognized by the Regulatory Body?		
Records of operating checks and calibrations are maintained?		
STORAGE OF RADIOACTIVE SOURCES		
Storage facilities for radioactive sources complies with regulations?		
Control and fire safety satisfactory?		
Warning and notification signs satisfactory?		
Inventory of store contents checked at acceptable intervals?		
RADIATION SOURCES		
Radioactive sources (cobalt unit, sealed sources) at the facility are as authorized?		
X ray equipment (interstitial, superficial, deep X ray therapy), linear accelerators, etc. at the facility are as authorized?		
Leak tests are performed on sealed radioactive sources at prescribed intervals?		
Procedures are in place for appropriate action to be taken in the event of an unacceptable leak test?		
Operator confirms the inventory of radiation sources at acceptable intervals?		
Records of radioactive source leak tests and source inventory maintained?		
Comments:		

9. RECEIPT AND EVENTUAL DISPOSAL OF RADIATION SOURCES		
	Yes	**No**
Radioactive package opening procedures established and followed?		
Incoming radioactive packages surveyed for damage, dose rates and potential		

radioactive contamination before opening?		
Satisfactory procedures are in place for the disposal of radiation sources that are no longer required (whether radioactive sources or devices that generate radiation electrically) e.g. disposal only to authorized persons (indicate to whom in "Comments"); notification to the Regulatory Body, etc.?		
Records of packaging surveys, source receipt and disposal maintained?		
Comments		

10. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL

Radiological surveys; leak tests; inventories; handling of radioactive materials; records; contamination control [BSS - Section I.38]

	Yes	**No**
Operator possesses appropriate, functioning survey instrument(s)?		
Suitable function checks are performed on instruments prior to use?		
Survey meter calibrations are current?		
Survey meter calibration is performed by an approved facility?		
Name of facility		
Area exposure rate surveys are performed at appropriate intervals?		
Surveys for removable contamination conducted as required?		
Records of calibrations, contamination surveys, etc. maintained?		
Comments:		

11. PERSONNEL RADIATION MONITORING

Radiation protection program with ALARA provisions; dosimetry; exposure evaluations; dose and survey records and reports; notifications to workers] [BSS – Schedule II]

	Yes	**No**
Operator provides personal dosimeters to all radiation workers?		
Dosimetry supplier is an authorized provider?		
Name of provider		
Dosimeters provided are appropriate for the radiation type and energy?		
Dosimeters are exchanged at the prescribed period?		
Dosimetry reports are promptly reviewed by the RPO?		

Is it evident that personal dosimeters are being worn by workers?		
Individual workers are informed of their monitoring results when each monitoring report is received (regardless of the dose measured)?		
Does the operator apply the optimization principle (ALARA) to occupational exposure?		
Personnel monitoring records are maintained?		
Inspector reviewed personnel monitoring records for the period from/ to		
Comments *(include the maximum doses to workers during this review period*)		

12. TRANSPORT OF RADIOACTIVE SOURCES

IAEA Regulations for the Safe Transport of Radioactive Material-Safety Standard Series No. TS-R-1

	Yes	**No**
Does transport of radioactive material (from supplier, by operator) comply with IAEA transport regulations?		
Approved packages used?		
Packages properly labeled and marked?		
Transporter's vehicles, if used for transport, comply with regulations?		
Shipper's declaration papers have correct details and used when shipping sources?		
Comments		

13. NOTIFICATIONS AND REPORTS

Reporting and follow-up of theft; losses; incidents; overexposures; safety-related equipment failures; change in RPO and Medical (or hospital)Physicist, and radiation dose reports to workers [BSS - Section 3.12]

	Yes	**No**
Have any program changes been implemented that required (but have not received) approval by the Regulatory Body?		
Have any notifiable incidents or accidents occurred since the last inspection?		
If yes, have they been reported to the Regulatory Body? (*If no, list the incidents or accidents in Comments)*		

Have any significant structural or other safety related changes been made to the facilities or the radiation devices without approval of the Regulatory Body?		
If yes, was a safety assessment performed by a Qualified Expert?		
Comments		

14. WARNING SIGNS AND LABELING

Proper warning signs in use areas and labeling of containers with radioactive material [BSS-Section I.23]

	Yes	**No**
Controlled areas have appropriate warning signs (in the local language)?		
Containers of radioactive sources are properly labeled?		
Notices to workers are displayed in the local language?		
Entry to treatment rooms has appropriate warning signs?		
Comments		

15. INDEPENDENT AND CONFIRMATORY MEASUREMENTS

	Yes	**No**
Inspector made area and other measurements for comparison to operators		
Comments: *Describe the types and results of measurements taken. Identify the instruments used by the inspector (make, model, last calibration).*		

16. ITEMS OF NON-COMPLIANCE AND OTHER SAFETY ISSUES *List any breaches noted during the inspection (what, when, where and who)*

17. PERSONNEL CONTACTED *Identify the personnel contacted during the inspection*

Comments:

INSPECTION RECORD

RADIOTHERAPY– X RAYS/TELETHERAPY (PART 2)

This inspection record/checklist deals with matters relevant to superficial X ray therapy, deep X ray therapy, linear accelerators and cobalt teletherapy. Record each device on a separate Inspection Record,

Authorization Number	
Device Manufacturer	
Device Model	
Device Serial Number	
For ^{60}Co teletherapy unit: Total Activity & Activity Calibration Date	
Location on premises	

	Yes	**No**
FACILITIES. Where relevant, are the following operational		
- room entrance barrier/door interlock system?		
- waning signs satisfactory?		
- photon/electron selection and any other beam parameter interlocks?		
- area radiation monitor(s)?		
- beam ON indication?		
- patient viewing and intercom systems?		
OPERATION		
Is the device restricted to particular orientations and/or gantry angles?		
If so, is operation prevented in other orientations?		
OPERATING PROCEDURES		
Operating procedures (in the local language) located at the control console?		
Procedures include response to emergencies or abnormal situations?		
Emergency response telephone numbers clearly displayed?		
Patient is sole occupant in the treatment room during treatment?		
All patients have an individual dosimetric treatment planning performed by the Medical Physicist?		
Qualified staff (Medical Physicist, Radiation Oncologist etc.) physically present throughout all treatments with a gamma stereotactic/radiosurgery devices?		

OPERATIONAL CHECKS AND CALIBRATION		
Were operational checks performed before use today (or when last used)?		
Was any operational fault detected at that check?		
If yes, was appropriate corrective action taken?		
Date last fully calibrated?		
Records confirm checks, calibrations and related actions?		

Comments

INSPECTION RECORD

RADIOTHERAPY– BRACHYTHERAPY (PART 3)

This inspection record/checklist deals with matters pertaining to devices which use radioactive sources for brachytherapy, e.g. afterloaders, high dose rate therapy (HDR), etc. Record each on a separate Inspection Record.

Authorization Number	
Device Manufacturer	
Device Model	
Device Serial Number	
Radionuclide, Total Activity, Activity Calibration Date	
Number & Type of Sealed Sources	
Types of Treatments	
Location on premises	

	Yes	**No**
FACILITIES. Where relevant, are the following operational		
- room entrance barrier/door interlock system?		
- waning signs satisfactory?		
- area radiation monitor(s)?		
- source ON indication?		
- patient viewing and intercom systems?		
- appropriate emergency source recovery and storage equipment available?		
PROCEDURES		
For devices containing sources (e.g. afterloaders, HDR, etc) operating procedures (in the local language) are located at or near the control?		
Safe nursing procedures (in the local language) are available and explained to all relevant personnel including controlling patients and visitors, contamination control and the size/appearance of sources, emergency procedures?		
Emergency response telephone numbers clearly displayed?		
Functional survey meter immediately available?		
Survey meter's last calibration date?		
Patient is sole occupant in the treatment room?		
Portal alarm at room entrance?		

Medical Physicist		
- performs patient's individual dosimetric treatment planning?		
- surveys patients immediately after implant completed?		
- surveys patients immediately after removal of implant and confirms source inventory before patient leaves treatment area?		
- is physically present throughout all patient treatments with a gamma stereotactic/radiosurgery devices?		
- is physically present when patient treatment with remote afterloaders initiated?		
OPERATIONAL AND DOSE RATE CHECKS		
If a radiation device,		
- are operational checks performed before use on patients?		
- was any operational fault detected at that check?		
If yes, was appropriate corrective action taken?		
Date of dose rate last re-assessment by medical physicist?		
Records confirm checks, dose rate assessment and related actions?		

Comments

APPENDIX D.

INSPECTION PROCEDURES AND RECORDS OF RADIATION SOURCES IN INDUSTRIAL RADIOGRAPHY

INSPECTION RECORD SUMMARY

INDUSTRIAL RADIOGRAPHY

Inspection number	
Authorization number	

Name of the authorized legal person	
Address of Legal Person's principal premises:	
Address (location of the site inspected if other than principal premises)	
Telephone Number	
Name of Radiation Protection Officer	
Name of legal person's representative for the inspection	
Date of LAST Inspection	_____/_____/_____
Date of THIS Inspection	_____/_____/_____
Starting time:	**Exit time:**
Type of Inspection Pre-authorization	☐
Routine	☐
Investigational	☐
Termination	☐
Recommended Date of NEXT Inspection	_____/_____/_____
Summary of Findings and Actions	
NO items of non-compliance found	☐
Items of non-compliance found	☐
Follow-up on previous non-compliance	☐
Inspector (1) name & signature	

Date	
Inspector (2) name & signature Date	
Supervisor's signature	
Report approved by supervisor	**Yes** ☐ **No** ☐ Comments (if **No)**

Comments (*to be signed and dated*)

INSPECTION RECORD

INDUSTRIAL RADIOGRAPHY

This inspection record/checklist is to be used by the inspector to assist with the performance of the inspection. Note that all areas will not necessarily be applicable to each licensed facility. In addition, with supervisory approval, the inspector may choose not to review a particular program area during each inspection. However, for those areas ***not examined*** *or* ***not relevant*** *during the inspection a notation such as "Not Reviewed" or "Not Applicable" should be made in the relevant section and a brief explanation as to why the area was not reviewed should be provided, where applicable.*

All areas investigated during the inspection should be documented in sufficient detail to describe the activities and procedures observed and/or demonstrated. In addition, the types of records that were reviewed and the time periods covered by those records should be noted. If the operator demonstrates any work practices at the inspector's request, describe those demonstrations. The observations and demonstrations described in this report, along with measurements and the records reviewed, should substantiate your inspection findings. Attach copies of all relevant documents and records required to support item(s) of non-compliance.

1. AMENDMENTS AND PROGRAM CHANGES *Prior to the inspection, list for review any licence amendments submitted by the operator and approved by the Regulatory Body since the last inspection*

2. INSPECTION AND ENFORCEMENT HISTORY *Prior to the inspection, list for review any items of non-compliance identified during previous 2-3 inspections*		
DATE	**INSPECTOR**	**VIOLATIONS**

3.	**INCIDENT / EVENT HISTORY** *Prior to the inspection, list for review any incidents or events reported to the Regulatory Body since the last inspection*

4.	**ORGANIZATION AND SCOPE OF THE PROGRAM** *Briefly describe the present scope of activities, including types and quantities of use involving licensed sources, frequency of use, staff size, etc. (Note deviations from the authorization certificate)*

5.	**TRAINING AND INSTRUCTION OF WORKERS** *Training and retraining requirements and documentation; interviews and observations of routine work; staff knowledge of all routine activities, and emergency response*		
		Yes	**No**
	Do all Industrial Radiographers have a suitable level of training?		
	Do all industrial radiography assistants have a suitable level of training?		
	Refresher radiation safety training is provided periodically?		
	Are radiography assistants directly supervised by a competent person at all times?		
	Are training records maintained for each worker?		
	Do interviews with Industrial Radiographers and assistants demonstrate an appropriate level of understanding of safe working rules and emergency procedures (e.g. source recovery?)		
	Discussion with the RPO demonstrates an appropriate knowledge of the Regulatory Body, the authorization certificate, the legislation, conditions, safe working procedures, etc.?		
	Does the RPO have appropriate resources (time, personnel) and authority (to take independent action to remedy urgent safety issues) to properly perform the role?		
	Comments:		

6. INTERNAL AUDITS AND REVIEWS		
	Yes	No
Operator reviews the radiation protection program at appropriate intervals?		
Audits of the facilities, source inventory, working rules and emergency procedures performed at appropriate intervals?		
Frequency		
Operator conducts regular audits of employees working at field sites?		
Audits conducted by		
Records of program reviews and audits maintained?		
Comments		

7. FACILITIES AND EQUIPMENT *Facilities as described; uses; control of access; engineering controls; calibration facilities; shielding [BSS Section 2.34]*		
	Yes	**No**
At the principal authorized premises		
- are the facilities as described in the application for authorization?		
- is access to radiation sources restricted to authorized persons only?		
- are radiation sources properly secured to prevent unauthorized removal?		
- is a source (x and γ) movement register maintained and up to date?		
- is the store for radiation sources (all types) secure?		
- does the store for radioactive sources bear appropriate warning signs (in the local language)?		
- are fire protection measures adequate?		
- are adequate methods used to prevent unauthorized individuals from the enclosures for radiography?		
- appropriate emergency equipment is available in order to properly deal with the retrieval of jammed sources, etc.?		
At the inspected field site		
- are adequate methods used to prevent unauthorized individuals from entering irradiation zones?		
- is access to irradiation zone restricted to authorized persons only?		
- are radiation sources properly secured to prevent unauthorized removal?		
- is the transitory store for radiation sources secure?		
- does the store for radioactive sources bear appropriate warning signs (in the local language)?		

- are fire protection measures adequate?		
- appropriate emergency equipment is available in order to properly deal with the retrieval of jammed sources, etc.?		

8. RADIATION SOURCES	**Yes**	**No**
Radiation sources and uses are as authorized?		
Leakage tests are periodically performed on sealed sources (other than those subject to frequent replacement such as ^{192}Ir)? e.g. ^{137}Cs crawler control sources, ^{60}Co, etc.?		
Inventory of sealed sources maintained? (inspector to confirm)		
Decayed radiation sources (e.g. ^{192} Ir) disposed of where?		
Records of leakage tests and inventory maintained?		
Are the source containers, X ray equipment and crawler control sources subject to periodic testing to ensure the design and operating characteristics comply with the IEC/ISO or other requirements of the Regulatory Body?		
Collimating devices are provided with every radiation source (x and γ) and used whenever practicable?		
If so, at what frequency; by whom; date of the last test?		
Radioactive source containers		
- are properly labelled (as radioactive, details of the contained source, contacts)?		
- have key locks and, if not in immediate use, are locked?		
- meet the minimum length requirement for wind-out and delivery cables?		
- are subject to wear testing, source disconnect checks and maintenance procedures in compliance with the manufacturer's requirements?		
X ray equipment		
- is key operated?		
- meets the minimum length requirements for connecting cables?		
- is fitted with filtration appropriate to the task?		
- for crawler equipment, is fitted with appropriate exposure warning device (e.g. klaxon)?		
- for crawler equipment, is fitted with a safety shut-off switch to be activated prior to removal of the equipment from the pipe?		
RPO keeps records of testing, compliance and maintenance?		
Comments:		

9. RECEIPT AND TRANSFER OF RADIATION SOURCES		
	Yes	**No**
Radioactive package opening procedures established and followed?		
Incoming radioactive packages surveyed for damage, dose rates and potential radioactive contamination before opening?		
Satisfactory procedures are in place for the disposal of radiation sources that are no longer required. e.g. disposal only to authorized persons; notification to the Regulatory Body, etc.?		
Records of packaging surveys, source receipt and transfer maintained?		
Comments		

10. AREA RADIATION SURVEYS *Radiological surveys; leak tests; inventories; handling of radioactive materials; records; [BSS – Section I.38]*		
	Yes	**No**
Operator possesses appropriate, functioning radiation survey instrument(s) suitable for the detection and measurement of x and/or γ radiation as appropriate?		
Operator performs proper function checks on instruments prior to use?		
Survey meter calibrations are current?		
Survey meter calibration is performed by an approved facility?		
Name of facility		
Sufficient functional survey meters are available for each radiography operation? (i.e. for each Industrial Radiographer and assistant team)		
Direct reading pocket dosimeters performance checked at appropriate intervals?		
Sufficient functional direct reading pocket dosimeters are available for each radiography worker?		
Area exposure rate surveys are performed at appropriate intervals?		
Is it evident that workers always use a survey meter at the conclusion of every exposure to confirm that the radioactive source has been returned to its container?		
Surveys for removable contamination conducted as required?		
Records of calibrations, contamination surveys, etc. maintained?		
Comments:		

11. PERSONNEL RADIATION MONITORING *Radiation protection program with ALARA provisions; dosimetry; exposure evaluations; dose and survey records and reports; notifications to workers] [BSS – Schedule II]*		
	Yes	**No**
Operator provides personal dosimeters to all radiation workers?		
Dosimetry supplier is an authorized provider?		
Name of provider		
Dosimeters provided are appropriate for the radiation type and energy?		
Dosimeters are exchanged at the prescribed period?		
Dosimetry reports are promptly reviewed by the RPO?		
Is it evident that personal dosimeters are being worn by workers?		
Individual workers are informed of their monitoring results when each monitoring report is received (regardless of the dose measured)?		
Does the operator apply the optimization principle (ALARA) to occupational exposure?		
Personnel monitoring (reading pocket dosimeters and personal dosimeters) records are maintained?		
Dosimetric results of both systems are in acceptable agreement?		
Inspector reviewed both personnel monitoring records for the period from/to		
Comments *(include the maximum doses to workers during this review period*)		

12. TRANSPORT OF RADIOACTIVE SOURCES *IAEA Regulations for the Safe Transport of Radioactive Material-Safety Standard Series No. TS-R-1]*		
	Yes	**No**
Does transport of radioactive material (from supplier, by operator) comply with IAEA transport regulations?		
Approved packages used?		
Packages properly labelled and marked?		
Operator's vehicles, if used for transport, comply with regulations?		
Shipper's declaration papers have correct details and used when shipping sources?		
Comments		

13. NOTIFICATIONS AND REPORTS

Reporting and follow-up of theft; loss; incidents; overexposures; safety-related equipment failures; change in RPO, and radiation dose reports to workers [BSS - Section 3.12]

	Yes	No
Have any program changes been implemented that required (but have not received) approval by the Regulatory Body?		
Have any notifiable incidents or accidents occurred since the last inspection?		
If yes, have they been reported to the Regulatory Body? (*If no, list the incidents or accidents in Comments)*		
Have any significant structural or other safety related changes been made to the principal facilities or to radiation devices without approval of the Regulatory Body?		
If yes, was a safety assessment performed by a Qualified Expert?		
Comments		

14. WARNING SIGNS AND LABELLING

Proper warning signs in use areas and labelling of containers with radioactive material [BSS - Section I.23]

	Yes	No
Controlled areas, including field sites (if relevant for this inspection), have appropriate barriers and warning signs (in the local language)?		
Devices containing radiation sources are properly labelled?		
Notices to workers (in the local language) are displayed as required?		
Comments		

15. INDEPENDENT AND CONFIRMATORY MEASUREMENTS		
	Yes	**No**
Inspector made area and other measurements for comparison to operators		
Comments: *Describe the types and results of measurements taken. Identify the instruments used by the inspector (make, model, last calibration).*		

16. ITEMS OF NON-COMPLIANCE AND OTHER SAFETY ISSUES *List any breaches noted during the inspection (what, when, where and who).*

17. PERSONNEL CONTACTED *Identify the personnel contacted during the inspection*

APPENDIX E.

INSPECTION PROCEDURES AND RECORDS OF RADIATION SOURCES IN RESEARCH AND INDUSTRIAL IRRADIATORS

INSPECTION RECORD SUMMARY

IRRADIATOR

Inspection number	
Authorization number	

Name of the Facility	
Address (location of the facility)	
Telephone Number	
Name of Radiation Protection Officer	
Legal person's representative for the inspection	
Date of LAST Inspection	_____/_____/_____
Date of THIS Inspection	_____/_____/_____
Starting time:	**Exit time:**
Type of Inspection Pre-authorization	☐
Routine	☐
Investigational	☐
Termination	☐
Recommended Date of NEXT Inspection	_____/_____/_____
Summary of Findings and Actions	
NO items of non-compliance found	☐
Items of non-compliance found	☐
Follow-up on previous non-compliance	☐
Inspector (1) name & signature Date	
Inspector (2) name & signature Date	
Supervisor's signature	

Report approved by supervisor	**Yes** ☐ **No** ☐ Comments (if **No)**

Comments (*to be signed and dated*)

INSPECTION RECORD

IRRADIATOR

This inspection record/checklist is to be used by the inspector to assist with the performance of the inspection. Note that all areas will not necessarily be applicable to each authorized facility. In addition, with supervisory approval, the inspector may choose not to review a particular program area during each inspection. However, for those areas ***not examined*** *or* ***not relevant*** *during the inspection (the form may be adapted to irradiators using either* ***radioactive substances*** *or* ***electrically generated radiation****) a notation such as "Not Reviewed" or "Not Applicable" should be made in the relevant section and a brief explanation as to why the area was not reviewed should be provided, where applicable*

All areas covered during the inspection should be documented in sufficient detail to describe what activities and procedures were observed and/or demonstrated. In addition, the types of records that were reviewed and the time periods covered by those records should be noted. If the operator demonstrated any practices at your request, describe those demonstrations. The observations and demonstrations you describe in this report, along with measurements and some records review, should substantiate your inspection findings. Attach copies of all operator's documents and records needed to support items of non-compliance.

1. AMENDMENTS AND PROGRAM CHANGES *Prior to the inspection, list for review any licence amendments submitted by theoperator and approved by the Regulatory Body since the last inspection*

2. INSPECTION AND ENFORCEMENT HISTORY

Prior to the inspection, list for review any items of non-compliance identified during previous 2-3 inspections

DATE	INSPECTOR	VIOLATIONS

3.	**INCIDENT / EVENT HISTORY** *Prior to the inspection, list for review any incidents or events reported to the Regulatory Body since the last inspection*

4.	**ORGANIZATION AND SCOPE OF THE PROGRAM** *Briefly describe the present scope of activities, including types and quantities of use involving authorized sources, frequency of use, staff size, etc. (Note deviations from the authorization certificate)*

5.	**TRAINING AND INSTRUCTION OF WORKERS** *Training and retraining requirements and documentation; interviews and observations of routine work; staff knowledge of all routine activities, and emergency response*		
		Yes	**No**
	All occupationally exposed personnel are provided with initial safety training?		
	Refresher radiation safety training is provided periodically?		
	Proper supervision of workers by appropriately trained persons?		
	Are training records maintained for each worker?		
	Do interviews with workers demonstrate an adequate level of understanding of safe working rules and emergency procedures?		
	Discussion with the RPO demonstrates an appropriate knowledge of the regulatory body), the authorization certificate, the legislation, conditions, safe working procedures, etc?		
	Does the RPO have appropriate resources (time, personnel) and authority (to take independent action to remedy urgent safety issues) to properly perform the role?		
Comments:			

6. INTERNAL AUDITS AND REVIEWS		
	Yes	No
Operator reviews the radiation protection programme at appropriate intervals?		
Audits of the facilities, source inventory, working rules and emergency procedures performed at appropriate intervals?		
Audits conducted by		
Frequency		
Records of program reviews and audits maintained?		
Comments		

7. FACILITIES AND EQUIPMENT *Facilities as described; uses; control of access; engineering controls; calibration facilities; shielding [BSS Section 2.34]*		
	Yes	**No**
Are the facilities as described in the authorization application?		
Is the irradiator subject to periodic testing to ensure the design and operating characteristics comply with the IEC/ISO or other requirements of the Regulatory Body?		
If yes, by whom, date of last test?		
Do those checks include		
- each aspect of the system controlling access to and emergency exit (e.g. safe life system) from the irradiation room?		
- source position (or beam ON) indication?		
- emergency source return (or beam OFF) control?		
- heat/smoke detectors, fire extinguisher system?		
- assessment of potential radiation damage to electrical wiring?		
- ozone concentration measurement, if needed?		
For radioactive sources		
- confirmation that water circulation system is leak tight?		
- pool water replacement system high and low water indicators?		
- assessment of water volumes added to the pool to determine if there is pool leakage?		
- water conductivity and analysis?		
Is repair and maintenance of the irradiator performed periodically by the manufacturer or other persons specifically authorized by the Regulatory Body?		
If yes, name of organization, date of last maintenance		

Are malfunctions and defects found during inspection and maintenance checks repaired without delay?		
Is access to the radiation source(s) adequately controlled?		
Are radioactive sources secured to prevent unauthorized removal?		
Are adequate procedures in place to prevent unauthorized individuals from entering controlled areas?		
Is the store for radioactive sources secure?		
Does the store bear appropriate warning signs (in the local language)?		
Is the level of fire protection in the store satisfactory?		
RPO keeps records of checks, maintenance and follow up actions?		
Comments		

8. RADIATION SOURCES		
	Yes	**No**
Radioactive sources (radionuclides, activities and uses) at the facility are as authorized?		
Other irradiators (e.g. linear accelerators, etc) at the facility are as authorized?		
Are sealed radioactive sources leak tested at prescribed intervals?		
Are leak tests performed in accordance with approved procedures?		
Have any sealed radioactive sources been found to be leaking?		
If yes, were appropriate actions taken and the Regulatory Body notified?		
Records of leakage tests and inventory maintained?		
Comments:		

9. RECEIPT AND TRANSFER OF RADIATION SOURCES		
	Yes	**No**
Radioactive package opening procedures established and followed?		
Incoming radioactive packages surveyed for damage, dose rates and potential radioactive contamination before opening?		
Satisfactory procedures are in place, if relevant, for the disposal of radiation sources that are no longer required. (e.g. disposal only to authorized persons; notification to the Regulatory Body, etc.)?		
Records of packaging surveys, source receipt and transfer are maintained?		

Comments

10. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL

Radiological surveys; leak tests; inventories; handling of radioactive materials; records; contamination control [BSS – Section I.38]

	Yes	**No**
Operator possesses appropriate functioning survey meters?		
Suitable function checks are performed on survey meters prior to use?		
Survey meter calibrations are current?		
Survey meter calibration is performed by an approved facility?		
Name of facility		
Date of last calibration		
Area exposure rate surveys are performed at appropriate intervals?		
Are appropriate and functioning conductivity meters possessed and used?		
Are conductivity meters calibrated at appropriate intervals?		
Is the location, sensitivity and function of fixed radiation monitor to detect sources that may be carried by the product conveyor system satisfactory?		
Is the location, sensitivity and function of fixed monitor(s) used to detect the presence of high radiation levels in the irradiation room satisfactory?		
Is the function and sensitivity of monitor(s) used to detect contamination of the pool water due to a leaking source satisfactory?		
Is the function of all monitors routinely tested at prescribed intervals?		
Records of calibrations, surveys, tests, conductivity measurements etc. maintained?		
Comments		

11. PERSONNEL RADIATION MONITORING

Radiation protection program with ALARA provisions; dosimetry; exposure evaluations; dose and survey records and reports; notifications to workers] [BSS – Schedule II]

	Yes	**No**
Operator provides personal dosimeters to all radiation workers?		
Dosimetry supplier is an authorized provider?		
Name of provider		
Dosimeters provided are appropriate for the radiation type and energy?		

Dosimeters are exchanged at the prescribed period?		
Dosimetry reports are promptly reviewed by the RPO?		
Is it evident that personal dosimeters are being worn by workers?		
Individual workers are informed of their monitoring results when each monitoring report is received (regardless of the dose measured)?		
Does the operator apply the optimization principle (ALARA) to occupational exposure?		
Personnel monitoring records are maintained?		
Inspector reviewed personnel monitoring records for the period from/ to		
Comments *(include the maximum doses to workers during this review period*)		

12. TRANSPORT OF RADIOACTIVE SOURCES

IAEA Regulations for the Safe Transport of Radioactive Material-Safety Standard Series No. TS-R-1

	Yes	**No**
Does transport of radioactive material (from supplier, by operator) comply with IAEA transport regulations?		
Approved packages used?		
Packages properly labelled and marked?		
Operator's vehicles, if used for any transport, comply with regulations?		
Shipper's declaration papers have correct details and used when shipping sources?		
Comments		

13. NOTIFICATIONS AND REPORTS

Reporting and follow-up of theft; loss; incidents; overexposures; safety-related equipment failures; change in RPO, and radiation dose reports to workers. [BSS - Section 3.12]

	Yes	**No**
Have any program changes been implemented that required (but have not received) approval by the Regulatory Body?		
Have any notifiable incidents or accidents occurred since the last inspection?		
If yes, have they been reported to the Regulatory Body? (*If no, list the incidents or accidents in Comments)*		
Have any significant structural or other safety related changes been made to the facilities or irradiator without approval of the Regulatory Body?		

If yes, was a safety assessment performed by a Qualified Expert?		
Comments		

14. WARNING SIGNS AND LABELLING *Proper warning signs in use areas and labelling of containers with radioactive material [BSS-Section I.23]*		
	Yes	**No**
Controlled areas have appropriate warning signs (in the local language)?		
Containers of radioactive material are properly labelled (with hazard warnings in the local language)?		
Notices to workers are displayed as required?		
High radiation areas properly identified?		
Comments		

15. INDEPENDENT AND CONFIRMATORY MEASUREMENTS		
	Yes	**No**
Inspector made area and other measurements for comparison to operators		
Comments: *Describe the types and results of measurements taken. Identify the instruments used by the inspector (make, model, last calibration).*		

16. ITEMS OF NON-COMPLIANCE AND OTHER SAFETY ISSUES *List any breaches noted during the inspection (what, when, where and who).*

17. PERSONNEL CONTACTED *Identify the personnel contacted during the inspection*

APPENDIX F.

INSPECTION PROCEDURES AND RECORDS OF RADIATION SOURCES IN GAUGES

INSPECTION RECORD SUMMARY

GAUGES (PART 1)

Inspection number	
Authorization number	

Name of the facility	
Address (location of the site inspected)	
Telephone Number	
Name of Radiation Protection Officer	
Operator's representative for the inspection	
Date of LAST Inspection	_____/_____/_____
Date of THIS Inspection	_____/_____/_____
Starting time:	**Exit time:**
Type of Inspection Pre-authorization	☐
Routine	☐
Investigational	☐
Termination	☐
Recommended Date of NEXT Inspection	_____/_____/_____
Summary of Findings and Actions	
NO items of non-compliance found	☐
Items of non-compliance found	☐
Follow-up on previous non-compliance	☐
Inspector (1) name & signature Date	
Inspector (2) name & signature Date	

Supervisor's signature	
Report approved by supervisor	**Yes** ☐ **No** ☐ Comments (if **No)**

Comments (*to be signed and dated*)

INSPECTION RECORD

GAUGES (PART I)

The inspection record/checklist is to be used by the inspector to assist with the performance of the inspection. Note that all areas will not necessarily be applicable to each authorized facility. In addition, with supervisory approval, the inspector may choose not to review a particular program area during each inspection. However, for those areas ***not examined*** *or* ***not relevant*** *during the inspection a notation such as "Not Reviewed" or "Not Applicable" should be made in the relevant section and a brief explanation as to why the area was not reviewed should be provided, where applicable.*

All areas investigated during the inspection should be documented in sufficient detail to describe the activities and procedures observed and/or demonstrated. In addition, the types of records that were reviewed and the time periods covered by those records should be noted. If the operator demonstrates any work practices at the inspector's request, describe those demonstrations. The observations and demonstrations described in this report, along with measurements and the records reviewed, should substantiate your inspection findings. Attach copies of all relevant documents and records required to support item(s) of non-compliance.

This inspection record/checklist is divided into THREE parts*. The first deals with matters common to fixed, portable and in-stream radioactive gauges. The second with specific issues for what may be termed "fixed" gauges i.e. those installed on vessels for level detection, on pipelines and conveyor belts for density and/or weight measurement. That part includes in-stream analysis gauges where the radiation source is immersed in a slurry. The third part deals with portable gauges i.e. neutron moisture/density gauges such as those used in road construction and related activities.*

The officer should use the ***common*** *first part plus either the* ***second or third*** *part as applicable to the authorized use.* ***For fixed or portable X ray gauges*** *(electrically generated X rays), complete the sections and items that are relevant.*

1. AMENDMENTS AND PROGRAM CHANGES *Prior to the inspection, list for review any authorization amendments submitted by the operator and approved by the regulatory body since the last inspection*

2. INSPECTION AND ENFORCEMENT HISTORY

Prior to the inspection, list for review any items of non-compliance identified during previous 2-3 inspections

DATE	INSPECTOR	VIOLATIONS

3. INCIDENT / EVENT HISTORY

Prior to the inspection, list for review any incidents or events reported to the Regulatory Body since the last inspection

4. ORGANIZATION AND SCOPE OF THE PROGRAM

Briefly describe the present scope of activities, including types and quantities of use involving authorized sources, frequency of use, staff size, etc. (Note deviations from the authorization certificate)

5. INTERNAL AUDITS AND REVIEWS		
	Yes	No
Operator reviews the radiation protection program at appropriate intervals?		
Audits of the facilities, source inventory, working rules and emergency procedures performed at appropriate intervals?		
Operator conducts regular audits of employees working at field sites?		
Audits conducted by		
Frequency		
Records of program reviews and audits maintained?		
Comments		

6. RECEIPT AND TRANSFER OF RADIATION SOURCES		
	Yes	**No**
Radioactive package opening procedures established and followed?		
Incoming radioactive packages surveyed for damage, dose rates and potential radioactive contamination before opening?		
Satisfactory procedures are in place for the disposal of radiation sources that are no longer required. e.g. disposal only to authorized persons; notification to the Regulatory Body, etc.?		
Records of packaging surveys, source receipt and transfer maintained?		
Comments		

7. TRANSPORT OF RADIOACTIVE SOURCES *IAEA Regulations for the Safe Transport of Radioactive Material-Safety Standard Series No. TS-R-1*		
	Yes	**No**
Does transport of radioactive sources (from supplier, by operator) comply with IAEA transport regulations?		
Approved packages used?		
Packages properly labeled and marked?		
Operator's vehicles, if used for transport, comply with regulations?		
Shipper's declaration papers have correct details and used when shipping sources?		

Comments

8. WARNING SIGNS AND LABELLING

Proper warning signs in use areas and labeling of containers with radioactive material [BSS-Section I.23]

	Yes	No
Controlled areas have appropriate warning signs (in the local language)?		
Gauges housings are properly labeled (hazard warning in the local language)?		
Notices to workers are displayed in the local language?		

Comments

9. NOTIFICATIONS AND REPORTS

Reporting and follow-up of theft; loss; incidents; overexposures; safety-related equipment failures; change in RPO, and radiation dose reports to workers. [BSS - Section 3.12]

	Yes	No
Have any program changes been implemented that required (but have not received) approval by the Regulatory Body?		
Have any notifiable incidents or accidents occurred since the last inspection?		
If yes, have they been reported to the Regulatory Body? (*If no, list the incidents or accidents in Comments)*		
Have any significant structural or other safety related changes been made to the facilities or radiation sources without approval of the Regulatory Body?		
If yes, was a safety assessment performed by a Qualified Expert?		

Comments

10. ITEMS OF NON-COMPLIANCE AND OTHER SAFETY ISSUES *List any breaches noted during the inspection (what, when, where and who).*

11. PERSONNEL CONTACTED *Identify the personnel contacted during the inspection*

INSPECTION RECORD

GAUGES – FIXED (PART 2)

This inspection record/checklist *deals with matters pertaining to "fixed" gauges i.e. those installed on vessels for level detection, on pipelines and conveyor belts for density and/or weight measurement. It includes in-stream analysis gauges where the radiation source is immersed in a slurry.*

X ray Gauges *- Complete relevant items for gauges that use electrically generated X rays*

1. TRAINING AND INSTRUCTION OF WORKERS

Training and retraining requirements and documentation; interviews and observations of routine work; staff knowledge of all routine activities, and emergency response

	Yes	No
Is basic radiation safety training provided to all persons who may be required to work in the vicinity of a gauge?		
Is more advanced training given to personnel whose tasks require them to install or work in close proximity to a gauge or where there is the potential for exposure to the useful radiation beam (e.g. during maintenance inside bins or hoppers fitted with level gauges)?		
For in-stream analysis gauges, are workers responsible for replacing protective source windows provided with special training?		
Refresher radiation safety training is provided periodically?		
Are training records maintained for each worker?		
Do interviews with workers demonstrate an adequate level of understanding regarding safety and emergency procedures?		
Discussion with the RPO demonstrates an appropriate knowledge of the Regulatory Body, the authorization certificate, the legislation, conditions, safe working procedures, etc?		
Does the RPO have appropriate resources (time, personnel) and authority (to take independent action to remedy urgent safety issues) to properly perform the role?		
Comments:		

2. FACILITIES AND EQUIPMENT

Facilities as described; uses; control of access; engineering controls; calibration facilities; shielding [BSS Section 2.34]

	Yes	No
Are the facilities as described in the authorization application?		

Is access to gauges in use adequately controlled by		
- appropriate area warning signs (in the local language)?		
- physical barriers, where appropriate?		
Except for in-stream analysis gauges, is access to the useful radiation beam prevented by physical barriers?		
Are adequate controls in place to prevent unauthorized persons from entering controlled areas and from accessing the useful radiation beam?		
Do the design and performance characteristics of the gauges comply with relevant IEC/ISO standards or other requirements of the Regulatory Body?		
Are gauges subject to regular testing to ensure continued compliance?		
If so, at what frequency; by whom; date of last test?		
Are gauges subject to routine maintenance by authorized service agents?		
If so, at what frequency, by whom; date last maintenance?		
Are adequate controls in place to ensure that all gauges are secured from unauthorized removal? e.g. through training of personnel and by ensuring that the RPO is given prior notification of any work requiring a gauge to be removed from its usual site, or of planned work in a bin or hopper to which gauges are fitted?		
Is the store for radioactive gauges currently not in use		
- Properly identified and sign posted (in the local language)?		
- Unlikely to be affected by the storage of other potentially hazardous substances?		
Records of compliance tests, maintenance, inspection and service maintained?		
Comments:		

3. RADIATION SOURCES	**Yes**	**No**
Radionuclides, chemical form, activities and uses as authorized in the authorization certificate, i.e. inventory confirmed? (Also confirm inventory for X ray gauges)		
Leakage tests performed on sealed sources (other than in-stream analysis gauges)?		
For in-stream analysis gauges, is the source protective window routinely checked for contamination by an approved method when replaced?		
Records of leakage tests and inventory maintained?		
Comments:		

4. **PERSONNEL RADIATION MONITORING** *Radiation protection programme with ALARA provisions; dosimetry; exposure evaluations; dose and survey records and reports; notifications to workers] [BSS – Schedule II]*		
	Yes	**No**
Operator provides personal dosimeters to all radiation workers?		
Dosimetry supplier is an authorized provider?		
Name of provider		
Dosimeters provided are appropriate for the radiation type and energy?		
Dosimeters are exchanged at the prescribed period?		
Dosimetry reports are promptly reviewed by the RPO?		
Is it evident that personal dosimeters are being worn by workers?		
Individual workers are informed of their monitoring results when each monitoring report is received (regardless of the dose measured)?		
Does the operator apply the optimization principle (ALARA) to occupational exposure?		
Personnel monitoring records are maintained?		
Inspector reviewed personnel monitoring records for the period from/ to		
Comments *(include the maximum doses to workers during this review period*)		

5. **TRANSPORT OF RADIOACTIVE SOURCES** *IAEA Regulations for the Safe Transport of Radioactive Material-Safety Standard Series No. TS-R-1*		
	Yes	**No**
Does transport of radioactive material (from supplier, by operator) comply with IAEA transport regulations?		
Approved packages used?		
Packages properly labeled and marked?		
Operator's vehicles, if used for transport, comply with regulations?		
Shipper's declaration papers have correct details and used when shipping sources?		
Comments		

6. INDEPENDENT AND CONFIRMATORY MEASUREMENTS		
	Yes	**No**
Inspector made area and other measurements for comparison to operators		
Comments: *Describe the types and results of measurements taken. Identify the instruments used by the inspector (make, model, last calibration).*		

INSPECTION RECORD

GAUGES – PORTABLE (PART 3)

This inspection record/checklist deals with portable gauges i.e. neutron moisture/density gauges such as those used in road construction and related activities.

1. TRAINING AND INSTRUCTION OF WORKERS

Training and retraining requirements and documentation; interviews and observations of routine work; staff knowledge of all routine activities, and emergency response

	Yes	No
All occupationally exposed personnel are provided with initial safety training?		
Refresher radiation safety training is provided periodically?		
Are training records maintained for each worker?		
Do interviews with workers demonstrate an adequate level of understanding regarding safety and emergency procedures?		
Discussion with the RPO demonstrates an appropriate knowledge of the Regulatory Body), the authorization certificate, the legislation, conditions, safe working procedures, etc?		
Does the RPO have appropriate resources (time, personnel) and authority (to take independent action to remedy urgent safety issues) to properly perform the role?		
Is staffing appropriate for the radiation workers to discharge assigned duties safely?		

Comments:

2. FACILITIES AND EQUIPMENT

Facilities as described; uses; control of access; engineering controls; calibration facilities; shielding [BSS Section 2.34]

	Yes	No
Are the ad-hoc controlled areas and devices as described in the authorization application?		
Are adequate controls in place to prevent unauthorized persons from entering those controlled areas?		
Are adequate controls in place to ensure that all gauges are secured from unauthorized removal from either the operator's premises or from a field site or other temporary transport or storage location?		
The design and performance characteristics of the gauges comply with relevant IEC/ISO standards or other requirements of the Regulatory Body?		
Gauges are subject to regular testing to ensure continued compliance?		

If so, at what frequency; by whom; date of last test?		
Gauges are subject to routine maintenance by authorized service agents?		
If so, at what frequency, by whom; date last maintenance		
Records of compliance tests, maintenance, inspection and service maintained?		
Comments:		

3. RADIATION SOURCES		
	Yes	**No**
Radionuclides, chemical form, activities and uses as authorized in the authorization, i.e. inventory confirmed?		
Leakage tests periodically performed on sealed sources by an approved method?		
Records of leakage tests and inventory maintained?		
Comments:		

4. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL *Radiological surveys; leak tests; inventories; handling of radioactive materials; records; contamination control [BSS - Section I.38]*		
	Yes	**No**
Operator possesses appropriate (particularly in case of neutron detection), functioning survey instrument(s)?		
Suitable function checks are performed on instruments prior to use?		
Survey meter calibrations are current?		
Survey meter calibration is performed by an approved facility?		
Name of facility		
Sufficient functional survey meters are available for each field operation?		
Area exposure rate surveys are performed at appropriate intervals?		
Surveys for removable contamination conducted as required?		
Is it evident that workers always use a survey meter at the conclusion of every exposure to confirm that the radioactive source has returned to its container?		
Records of calibrations, contamination surveys, etc. maintained?		
Comments:		

5. PERSONNEL RADIATION MONITORING *Radiation protection programme with ALARA provisions; dosimetry; exposure evaluations; dose and survey records and reports; notifications to workers]. [BSS – Schedule II]*		
	Yes	**No**
Operator provides personal dosimeters to all radiation workers?		
Dosimetry supplier is an authorized provider?		
Name of provider		
Dosimeters provided are appropriate for the radiation type and energy?		
Dosimeters are exchanged at the prescribed period?		
Dosimetry reports are promptly reviewed by the RPO?		
Is it evident that personal dosimeters are being worn by workers?		
Individual workers are informed of their monitoring results when each monitoring report is received (regardless of the dose measured)?		
Does the operator apply the optimization principle (ALARA) to occupational exposure?		
Personnel monitoring records are maintained?		
Inspector reviewed personnel monitoring records for the period from/to		
Comments *(include the maximum doses to workers during this review period*)		

6. TRANSPORT OF RADIOACTIVE SOURCES *IAEA Regulations for the Safe Transport of Radioactive Materials Safety Standard Series No. TS-R-1]*		
	Yes	**No**
Does transport of radioactive material (from supplier, by operator) comply with IAEA transport regulations?		
Approved packages used?		
Packages properly labeled and marked?		
Operator's vehicles, if used for transport, comply with regulations?		
Shipper's declaration papers have correct details and used when shipping sources?		
For gauges transported by the operator's workers e.g. during field operations		
- are vehicles properly labeled?		
- are gauges properly secured for transport?		
- if also used for storage, are the vehicles and gauges secure from theft?		
Comments		

7. INDEPENDENT AND CONFIRMATORY MEASUREMENTS		
	Yes	**No**
Inspector made area and other measurements for comparison to operators		
Comments: *Describe the types and results of measurements taken. Identify the instruments used by the inspector (make, model, last calibration).*		

APPENDIX G.

INSPECTION PROCEDURES AND RECORDS OF RADIATION SOURCES IN WELL LOGGING

INSPECTION RECORD SUMMARY

WELL (BOREHOLE) LOGGING

Inspection number	
Authorization number	

Name of the Operator	
Address of Operator's Main Office	
Address (location of the site inspected)	
Telephone Number	
Name of Radiation Protection Officer	
Operator's representative for the inspection	
Date of LAST Inspection	_____/_____/_____
Date of THIS Inspection	_____/_____/_____
Starting time:	**Exit time:**
Type of Inspection Pre-authorization	☐
Routine	☐
Investigational	☐
Termination	☐
Recommended Date of NEXT Inspection	_____/_____/_____
Summary of Findings and Actions	
NO items of non-compliance found	☐
Items of non-compliance found	☐
Follow-up on previous non-compliance	☐
Inspector (1) name & signature Date	
Inspector (2) name & signature	

Date	
Supervisor's signature	
Report approved by supervisor	**Yes** ☐ **No** ☐ Comments (if **No)**

Comments (*to be signed and dated*)

INSPECTION RECORD

WELL (BOREHOLE) LOGGING

This inspection record/checklist is to be used by the inspector to assist with the performance of the inspection. Note that all areas will not necessarily be applicable to each authorized facility. In addition, with supervisory approval, the inspector may choose not to review a particular program area during each inspection. However, for those areas ***not examined*** *or* ***not relevant*** *during the inspection a notation such as "Not Reviewed" or "Not Applicable" should be made in the relevant section and a brief explanation as to why the area was not reviewed should be provided, where applicable.*

All areas investigated during the inspection should be documented in sufficient detail to describe the activities and procedures observed and/or demonstrated. In addition, the types of records that were reviewed and the time periods covered by those records should be noted. If the operator demonstrates any work practices at the inspector's request, describe those demonstrations. The observations and demonstrations described in this report, along with measurements and the records reviewed, should substantiate your inspection findings. Attach copies of all relevant documents and records required to support item(s) of non-compliance.

1. AMENDMENTS AND PROGRAM CHANGES

Prior to the inspection, list for review any authorization certificate amendments submitted by the operator and approved by the Regulatory Body since the last inspection

2. INSPECTION AND ENFORCEMENT HISTORY

Prior to the inspection, list for review any items of non-compliance identified during previous 2-3 inspections

DATE	INSPECTOR	VIOLATIONS

3. INCIDENT/EVENT HISTORY *Prior to the inspection, list for review any incidents or events reported to the Regulatory Body since the last inspection*

4. ORGANIZATION AND SCOPE OF THE PROGRAM *Briefly describe the present scope of activities, including types and quantities of use involving authorized sources, frequency of use, staff size, etc. (Note deviations from the authorization certificate)*

5. TRAINING AND INSTRUCTION OF WORKERS

Training and retraining requirements and documentation; interviews and observations of routine work; staff knowledge of all routine activities, and emergency response

	Yes	**No**
Occupationally exposed personnel are provided with initial safety training in the hazards associated with both sealed and unsealed radiation sources?		
Refresher radiation safety training is provided periodically?		
Supervision of logging assistants satisfactory?		
Are training records maintained for each worker?		
Do interviews with workers demonstrate an adequate level of understanding regarding safety and emergency procedures?		
Discussion with the RPO demonstrates an appropriate knowledge of the Regulatory Body, the authorization certificate, the legislation, conditions, safe working procedures, etc?		
Does the RPO have appropriate resources (time, personnel) and authority (to take independent action to remedy urgent safety issues) to properly perform the role?		

Comments:

6. INTERNAL AUDITS AND REVIEWS		
	Yes	**No**
Operator reviews the radiation protection programme at appropriate intervals?		
Audits of the facilities, source inventory, working rules and emergency procedures performed at appropriate intervals?		
Operator conducts regular audits of employees working at field sites?		
Audits conducted by		
Frequency		
Records of program reviews and audits maintained?		
Comments		

7. FACILITIES AND EQUIPMENT *Facilities as described; uses; control of access; engineering controls; calibration facilities; shielding [BSS Section 2.34]*		
	Yes	**No**
Are field site facilities as described in the authorization application?		
Is access to radioactive material adequately controlled?		
Are radiation sources secured to prevent unauthorized removal?		
Are adequate methods used to prevent unauthorized individuals from entering controlled areas?		
Is there adequate fire protection?		
RPO reviews results of quality control checks and maintains records of checks?		
Comments:		

8. RADIATION SOURCES		
	Yes	**No**
Radionuclides, chemical form, activities and uses as authorized in the authorization certificate, i.e. inventory confirmed?		
Leakage tests performed on sealed sources?		
Inventory of sealed sources conducted?		
Records of leakage tests and inventory maintained?		
Comments:		

9. RECEIPT AND TRANSFER OF RADIATION SOURCES		
	Yes	**No**
Radioactive package opening procedures established and followed?		
Incoming radioactive packages surveyed for damage, dose rates and potential radioactive contamination before opening?		
Satisfactory procedures are in place for the disposal of radiation sources that are no longer required. e.g. disposal only to authorized persons; notification to the Regulatory Body, etc.?		
Records of packaging surveys, source receipt and transfer maintained?		
Comments		

10. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL *Radiological surveys; leak tests; inventories; handling of radioactive materials; records; contamination control [BSS - Section I.38]*		
	Yes	**No**
Operator possesses appropriate, functioning survey instrument(s)?		
Suitable function checks are performed on instruments prior to use?		
Survey meter calibrations are current?		
Survey meter calibration is performed by an approved facility?		
Name of facility		
Sufficient functional survey meters are available for each field site operation?		
Area exposure rate surveys are performed at appropriate intervals?		

Surveys for removable contamination conducted as required?		
Is it evident that workers always use a survey meter at the conclusion of every exposure to confirm that the radioactive source has been returned to its container or, for unsealed sources that contamination is within prescribed limits?		
Records of calibrations, contamination surveys, etc. maintained?		
Comments:		

11. PERSONNEL RADIATION MONITORING *Radiation protection programme with ALARA provisions; dosimetry; exposure evaluations; dose and survey records and reports; notifications to workers] [BSS – Schedule II]*		
	Yes	**No**
Operator provides personal dosimeters to all radiation workers?		
Dosimetry supplier is an authorized provider?		
Name of provider		
Dosimeters provided are appropriate for the radiation type and energy?		
Dosimeters are exchanged at the prescribed period?		
Dosimetry reports are promptly reviewed by the Radiation Protection Officer?		
Is it evident that personal dosimeters are being worn by workers?		
Individual workers are informed of their monitoring results when each monitoring report is received (regardless of the dose measured)?		
Does the operator apply the optimization principle (ALARA) to occupational exposure?		
Potential for exposure of workers to airborne radioactive substances exists?		
Monitoring for airborne radioactivity conducted?		
Bioassay program has been established and is implemented as appropriate?		
Personnel monitoring records (including bioassay results) are maintained?		
Inspector reviewed personnel monitoring records for the period from/to		
Comments *(include the maximum doses to workers during this review period*)		

12. RADIOACTIVE WASTE MANAGEMENT *Disposal or transfer of sources; packaging, control, and tracking procedures; records [BSS - Section III.8]*		
	Yes	**No**
Decay-in-storage method used?		
Sealed source disposal in accordance with regulatory requirements?		
Unsealed radiation sources disposed of in accordance with regulatory requirements?		
Records maintained?		
Comments:		

13. TRANSPORT OF RADIOACTIVE SOURCES *IAEA Regulations for the Safe Transport of Radioactive Material-Safety Standard Series No. TS-R-1*		
	Yes	**No**
Does transport of radioactive material (from supplier, by operator) comply with IAEA transport regulations?		
Approved packages used?		
Packages properly labelled and marked?		
Operator's vehicles, if used for transport, comply with regulations?		
Shipper's declaration papers have correct details and used when shipping sources?		
Comments		

14. NOTIFICATIONS AND REPORTS *Reporting and follow-up of theft; loss; incidents; overexposures; safety-related equipment failures; change in RPO, and radiation dose reports to workers [BSS - Section 3.12]*		
	Yes	**No**
Have any program changes been implemented that required (but have not received) approval by the Regulatory Body?		
Have any notifiable incidents or accidents occurred since the last inspection?		

If yes, have they been reported to the Regulatory Body? (*If no, list the incidents or accidents in Comments)*		
Have any significant safety related changes been made to the facilities or radiation devices without approval of the Regulatory Body?		
If yes, was a safety assessment performed by a Qualified Expert?		
Comments		

15. WARNING SIGNS AND LABELLING

Proper warning signs in use areas and labelling of containers with radioactive material [BSS-Section I.23]

	Yes	**No**
Controlled areas at field sites have appropriate barriers and warning signs (in the local language)?		
Containers of radioactive material are properly labelled?		
Notices to workers are displayed as required (in the local language)?		
Comments		

16. INDEPENDENT AND CONFIRMATORY MEASUREMENTS		
	Yes	**No**
Inspector made area and other measurements for comparison to operators		
Comments: *Describe the types and results of measurements taken. Identify the instruments used by the inspector (make, model, last calibration).*		

17. ITEMS OF NON-COMPLIANCE AND OTHER SAFETY ISSUES *List any breaches noted during the inspection (what, when, where and who).*

18. PERSONNEL CONTACTED *Identify the personnel contacted during the inspection*

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