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Guidelines on the Implementation of the Basic Safety Standards in Nuclear Medicine

(Draft for review by cosponsoring International Organizations and Professional Bodies)

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FOREWORD

The International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS), cover the application of ionizing radiation for all practices and interventions and are, therefore, basic and general in nature. Users of radiation sources have to apply these basic requirements to their own particular practices. This requires a degree of 'interpretation' by the user, which can result in varying levels of regulatory compliance and inconsistencies between applications of the BSS to similar practices. In this context, the preamble of the BSS states that: *"The Regulatory Authority may need to provide guidance on how certain regulatory requirements are to be fulfilled for various practices, for example in regulatory guideline documents."*

In order to guide the user to achieve a good standard of protection and to achieve a consistent national approach to licensing and inspection, some countries have developed practice specific regulatory guidance. National regulatory guidance is tailored to a country's own legislation and regulations for obvious reasons. There would appear, therefore, to be scope for producing internationally harmonized guidance, while bearing in mind that the ultimate responsibility for the regulatory documents rests with the State.

Some regions have taken the initiative of preparing guidance to facilitate the regional harmonization in the application of the Standards for certain common practices (e.g. nuclear medicine). This first initiative was taken under the programme of the Regional Co-operative Agreement for the Promotion of Nuclear Science and Technology in Latin America and the Caribbean (ARCAL) and was recently followed by other initiatives under the Regional Co-operative Agreement for Research, Development and Training Related to Nuclear Science and Technology for Asia and the Pacific (RCA) and the African Regional Co-operative Agreement for Research, Development and Training Related to Nuclear Science and Technology (AFRA). This initiative is to be commended and indicates that there is a global demand for this type of document. In particular, it is felt that Member States, particularly those participating in the IAEA model project on strengthening radiation and waste safety infrastructure, would benefit significantly from the availability of practice specific guidance. Member States could then more readily develop their own guidance tailored to their own national requirements and national needs. This idea led to the development of the present document.

The Action Plan on the Radiological Protection of Patients approved by the IAEA General Conference in September 2002, requires that "The practice-specific documents under preparation should be finalized as guidance rather than regulations, and they should include input from professional bodies, from international organizations and from authorities with responsibility for radiation protection and medical care." Following this request, the only mandatory statements of this document are quotations from the BSS, being complemented with advice on how the BSS requirements can be met.

There are certain BSS requirements that, when applied to specific practices, can be fulfilled through virtually only one practical solution. In these cases, the regulatory authority may need to use a "should" statement for this solution, which implies that licensees should choose this solution or if another option is intended, an equivalent level of safety should be provided. In other cases, there may be more than one option. In these cases the regulatory authority would just mention or describe them.

This guidance is intended for both regulators and users of radiation sources in nuclear medicine. Regulators may use the guidance for reviewing applications for authorization and during the inspection of facilities. Registrants/licensees may wish to follow the guidance in

order to comply with BSS requirements or equivalent national requirements. Experts recruited on IAEA missions to advise on the implementation of the BSS for the practice of nuclear medicine are expected to use this regulatory guidance document rather than their own national guidance. Working safely is important and contributes to gain overall confidence and credibility in the practice of nuclear medicine itself.

Regulatory authorities and professional bodies (nuclear medicine, medical physics and radiation protection experts) are invited to provide feedback on this draft document. The UN organizations co-sponsoring the BSS, with an interest in radiological protection in medical practices, as well as the relevant professional bodies (WFNMB, IOMP, IRPA) are invited also to co-sponsor and collaborate in the preparation of the final document.

EDITORIAL NOTE

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

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

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1. INTRODUCTION

1.1. Background

The International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (the 'BSS') were published as IAEA Safety Series No. 115 in 1996 [1]. This publication was the culmination of efforts over the past decades towards harmonization of radiation protection and safety standards internationally, and was jointly sponsored by the Food and Agriculture Organization of the United Nations (FAO), the International Atomic Energy Agency (IAEA), the International Labour Organization (ILO), the Nuclear Energy Agency of the Organization for Economic Co-operation and Development (OECD/NEA), the Pan American Health Organization (PAHO) and the World Health Organization (WHO). The purpose of the BSS was 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 (hereinafter called 'radiation safety'). The requirements are based on the principles set out in the Safety Fundamentals, published as IAEA Safety Series Nos. 110 and 120 [2, 3].

The BSS can only be implemented through an effective radiation safety infrastructure that includes adequate laws and regulations, an efficient regulatory system, supporting experts and services, and a 'safety culture' shared by all those with responsibilities for protection, including both management and workers.

IAEA published TECDOC 1067, Organization and Implementation of a National Regulatory Infrastructure Governing Protection against Ionizing Radiation and Safety of Radiation Sources [4], which provides detailed guidance on how to establish or improve national radiation safety infrastructure in order to implement the requirements of the BSS. The TECDOC covers the elements of a national radiation safety infrastructure needed to apply the BSS to radiation sources such as those used in medicine, agriculture, research, industry and education. It also provides advice on approaches to the organization and operation of the infrastructure aimed at achieving its maximum efficiency.

The BSS cover the application of ionizing radiation for all practices and interventions and are, therefore, basic and general in nature. Users must apply these basic requirements to their own particular practices. In this context, the preamble of the BSS states that: "The Regulatory Authority may need to provide guidance on how certain regulatory requirements are to be fulfilled for various practices, for example in regulatory guideline documents."

1.2. Objective

The objective of this document is to assist Regulatory Authorities in monitoring compliance with the Basic Safety Standards (or equivalent national regulations) with regard to nuclear medicine practice and ensuring proper and consistent application of the BSS. This document will also be helpful to users of radionuclides in nuclear medicine in meeting the regulatory requirements. It is one of a series of IAEA regulatory guidance documents. Separate documents have been prepared for diagnostic and interventional radiology [5] and radiotherapy [6].

1.3. Scope

These model regulations are applicable to all established uses of ionizing radiation sources in the practice of nuclear medicine, to the facilities where the sources are located, and to the individuals involved. They cover occupational, public, medical and potential exposure situations, providing guidance on the implementation of the BSS for medical practitioners, professional staff and hospital administrators. It is not intended here to simply reproduce basic requirements from the BSS (or the equivalent national regulations), but to supplement them with further requirements specific to nuclear medicine.

2. PRINCIPAL REQUIREMENTS

2.1. Administrative requirements

2.1.1. Authorization of practices

The BSS require that legal persons apply to the Regulatory Authority for an authorization, which should take the form of a registration or a license. The BSS further clarify that practices that *"Typical practices that are amenable to registration are those for which: (a) safety can largely be ensured by the design of the facilities and equipment; (b) the operating procedures are simple to follow; (c) the safety training requirements are minimal; and (d) there is a history of few problems with safety in operations. Registration is best suited to those practices for which operations do not vary significantly."*

Given the complexity of "in vivo" nuclear medicine, the risks involved, especially in therapeutic applications, the substantial training required and the fact that its safety depends largely on human performance, demonstration of safety requires a safety assessment for each facility and therefore its authorization should take the form of a licence rather than a registration. The process can be however simplified by standardized training, a relatively standardized quality assurance programme in modular form to take account of different levels of complexity, equipment and sources for each facility, and by establishing a simple mechanism to provide evidence of both training and quality assurance are met.

A nuclear medicine department involves the construction of facilities, which are later difficult to modify. Regulatory authorities may choose a two-stage process of authorization, i.e., to require initial application when construction is about to begin, especially for facilities that include therapeutic application of radionuclides. A good way to implement the two-stage process is for the regulatory authority to get a picture of the intended applications and the facility design [reference to TECDOC 1067]. Allowance for evolving new procedures should be given, provided that they fit into the shielding and the facility design.

Substantial modifications of the nuclear medicine facilities, sources and procedures may have safety implications, which need verification of compliance with regulations. The regulatory authority may also require an application for this. The same is true for partial or total decommissioning of a nuclear medicine facility.

The legal person applying for an authorization shall refrain from carrying out any of the actions of the practice until the registration or license, as appropriate, has been granted.

2.1.1.1. Renewal of authorization

Regulatory Authorities may require that the authorization be renewed periodically. Periods of renewal are based on safety criteria[1]. The advantages of a renewal or revalidation approach are described in TECDOC 1067 [4], as well as the factors that influence the frequency of revalidation. These factors include the inspection frequency, the safety record of the facility, and the stability of the user's operation. Considering these factors, a suitable period for nuclear medicine may be of the order of five years. Consultation between the regulatory and health authority in this respect may be advisable.

2.1.1.2. Inspection

The registrant and licensee shall permit inspection by the Regulatory Authority of the facilities and records. An example of the items for commissioning and regular inspection is provided in Appendix A.

2.1.2. ***Personal accreditation***[2]

The BSS require that [BSS para. 2.30]:

"(a) all personnel on whom protection and safety depend be appropriately trained and qualified so that they understand their responsibilities and perform their duties with appropriate judgement and according to defined procedures;"

In nuclear medicine practice, the following individuals carry responsibility for protection and safety, by virtue of tasks involving decisions, operation or handling of sources or equipment, which could lead to an accidental exposure:

- medical practitioners working with radionuclides (e.g. nuclear medicine physicians, and other appropriately trained clinical specialists);
- medical physicists in nuclear medicine (qualified experts in nuclear medicine physics);
- other health professionals involved in the clinical use of radionuclides (e.g. radiopharmacists, nuclear medicine technologists);
- radiation protection officer (RPO); and
- staff performing special tasks (e.g. contamination tests, some of the quality control tests).

To comply with the above BSS requirements in relation with the above staff, evidence of education and training relevant to their duties in relation with protection and safety should be demonstrated. The accreditation on the relevant profession is necessary, together with that on radiation protection, since radiation protection alone does not entitle to take responsibilities in the practice of nuclear medicine.

For nuclear medicine specialists, radiopharmacists, medical physicists, nuclear medicine technologists and radiation protection officers, typical documentary evidence indicated above, i.e., qualification credentials, should consist of:

(a) a degree relevant to the profession, issued by the competent education and examining authorities as required in the country and accreditation required in the

[1] The frequency of revalidation is influenced by several factors, described in IAEA-TECDOC-1067 [4], in view of which a reasonable period for nuclear medicine is five years.

[2] Regulations in a number of countries require a personal accreditation as formal recognition of the holder's competency to do the job safely.

country to exercise the profession, granted by the competent authorities or other institutions;

(b) a course on radiation protection for which the contents, methodology and teaching institution are approved by the regulatory authority. This course may be integrated into the curricula of the professional education under (b) provided that it meets the training criteria for radiation protection specified by the Regulatory Authority, (with regard to medical exposure the training criteria should be established by the Regulatory Authority in consultation with relevant professional bodies [BSS para. II.1 (f)]);

(c) before working without supervision, on-the-job training supervised by accredited professionals with experience, as required in the country.

Evidence of competence for maintenance and servicing of medical equipment may consist of the following:

(a) certification, ideally by the manufacturer, of having completed a training programme on the type of authorized equipment;

(b) course on radiation protection for which the contents, the methodology and the teaching institution are approved by the Regulatory Authority

Personal accreditation or authorization may need to be renewed periodically. The Regulatory Authority may provide guidance on qualification requirements for each category of job found in particular practices.

It may be appropriate and convenient for the Regulatory Authority to recognize certain training centres and courses for their quality and suitability. Such recognition can be formally conferred by a process of accreditation. The requirements for accreditation of training centres and courses should be defined by the Regulatory Authority. These standards should establish requirements for training facilities, teaching staff, content, material and methods for training, examination procedures and training records.

The following staff do not require personal accreditation but do require instruction on radiation protection:

– nurses handling patients with therapeutic amounts of radioactivity and nurses in a nuclear medicine department;

– maintenance, engineering and cleaning staff working nuclear medicine laboratories.

2.1.3. Authorization of other activities related to nuclear medicine

According to the BSS [1], the activities listed below also require authorization,:

- import, distribution, sale or transport of radioactive sources, and equipment;
- individual monitoring;
- disposal of radioactive sources.

Regulatory Authorities may require the registrant and licensee of a nuclear medicine practice to contract any of the following services only to enterprises authorized by the Regulatory Authority. The requirements applying to these activities should have been established by national regulations complemented by regulatory guidance documents.

2.2. Radiation protection requirements

The principles of radiation protection and safety on which the safety standards are based are those developed by the ICRP. These principles are reflected in requirements of the BSS:

BSS 2.23 **(justification of practices):** "No practice or source within a practice should be authorized unless the practice produces sufficient benefit to the exposed individuals or to society to offset the radiation harm that it might cause; that is: unless the practice is justified, taking into account social, economic and other relevant factors.".

BSS. 2.23 **(limitation of doses to individuals):** "The normal exposure of individuals shall be restricted so that neither the total effective dose nor the total equivalent dose to relevant organs or tissues, caused by the possible combination of exposures from authorized practices, exceeds any relevant dose limit specified in Schedule II, … Dose limits shall not apply to medical exposures from authorized practices."

BSS.2.24 **(optimization of protection):** "In relation to exposures from any particular source within a practice, except for therapeutic medical exposures, protection and safety shall be optimized in order that the magnitude of individual doses, the number of people exposed and the likelihood of incurring exposures all be kept as low as reasonably achievable, economic and social factors being taken into account, within the restriction that the doses to individuals delivered by the source be subject to dose constraints." For diagnostic medical exposure, optimization of protection is achieved by keeping the exposure of patients to the minimum necessary to achieve the required diagnostic objective; in therapeutic medical exposure, optimization is done by keeping exposure of normal tissue as low as reasonably achievable consistent with delivering the required dose to the planning target volume [BSS appendix II].

Table 1 summarizes the principles as applied to occupational and public exposure and to medical exposure.

TABLE 1 PRINCIPLES OF RADIATION PROTECTION AS APPLIED TO OCCUPATIONAL AND PUBLIC EXPOSURE AND TO MEDICAL EXPOSURE

Principles of protection	
Application to occupational and public exposure	**Application to medical exposure**
Justification of practices a practice that entails exposure to radiation should only be adopted if it yields sufficient benefit to the exposed individuals or to society to outweigh the radiation detriment	**Justification** 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
Limitation of doses to individuals (for occupational and public exposure)	**Dose limitation** not applicable to medical exposure
Optimization of protection. Providing the best available protection and safety measures under the prevailing circumstances, so that the magnitudes and likelihood of exposures and the numbers of individuals exposed be as low as reasonably achievable, …	**Optimization of protection**: in diagnostic medical exposure, keeping the exposure of patients to the minimum necessary to achieve the required diagnostic objective; in therapeutic medical exposure, keeping exposure of normal tissue as low as reasonably achievable consistent with delivering the required dose to the planning target volume

Dose constraints are used for optimizing protection in the planning stage for each radiation source. Anticipated individual doses should be compared with the appropriate dose constraints and choose protective measures that predict doses below dose constraints. The BSS definition of dose constraint is: "*For occupational exposures, dose constraint is a source-related value of individual dose used to limit the range of options considered in the process of optimization"*. When choosing dose constraints for the sources involved in a nuclear medicine facility, consideration needs to be given to the fact that medical and paramedical staff often work in more than one hospital, i.e. two institutions in two working shifts.

As indicated under the section on occupational exposure, pregnant workers hall be protected in such a way that ensures that the embryo or foetus is afforded the same broad level of protection as required for members of the public.

Table 2 summarizes individual dose limits as established in the BSS.

TABLE 2 SUMMARY OF DOSE LIMITS (SEE BSS SCHEDULE II)

	Occupational exposure	**Apprentices of 16 to 18 years of age, who are in training for employment and for students of 16 to 18 years**	**Public exposure**
Effective dose	20 mSv per year averaged over five consecutive years; 50 mSv in a single year	6 mSv in a year	1 mSv in a year in special circumstances, an effective dose of up to 5 mSv in a single year provided that the average dose over five consecutive years does not exceed 1 mSv per year
Equivalent dose to the lens of the eye	150 mSv in a year	50 mSv in a year	15 mSv in a year
Equivalent dose to the extremities (hands and feet) or the skin[3]	500 mSv in a year	150 mSv in a year	50 mSv in a year

2.3. Managerial requirements

2.3.1. Managerial commitment and policy statement

The BSS 2.28 establish that *"A safety culture shall be fostered and maintained to encourage a questioning and learning attitude to protection and safety and to discourage complacency"*. To comply with this requirement, hospital management needs to be committed to an effective protection and safety policy, particularly at the senior level, and by demonstrable support for those persons with responsibility for radiation protection. The commitment can be demonstrated by a written policy that, in addition to recognize that the objective of the practice is the diagnosis, treatment and well-being of the patients, assigns the required importance to protection and safety in nuclear medicine. This unambiguous statement should be made known to the hospital personnel and should be followed by establishing a radiation protection programme, which includes fostering a safety culture in the hospital.

2.3.2. Organization and responsibilities

The BSS paragraphs 1.6 and 1.7 establish that…. "The principal parties having the main responsibilities for the application of the Standards shall be:

- registrants or licensees; and
- employers.

"Other parties shall have subsidiary responsibilities for the application of the Standards. These parties may include, as appropriate:

[3] The equivalent dose limits for the skin apply to the average dose over 1 cm^2 of the most highly irradiated area of the skin. Skin dose also contributes to the effective dose, this contribution being the average dose to the entire skin multiplied by the tissue weighting factor for the skin.

- suppliers;
- workers;
- radiation protection officers;
- medical practitioners;
- other (non-medical) health professionals;
- qualified experts;
- ethical review committees; and
- any other party to whom a principal party has delegated specific responsibilities."

The BSS also establish that it is the responsibility of principal parties,

"(b) to develop, implement and document a protection and safety programme commensurate with the nature and extent of the risks associated with the practices … under their responsibility and sufficient to ensure compliance with the requirements of the Standards…".

An effective way to ensure compliance with the programme is the appointment of a committee and a radiation protection officer, with authority to communicate with management regarding compliance with regulations and licence provisions. Since a representative of the management is usually a member of the radiation protection committee, communication to him/her may be the most appropriate. The committee should be assigned the responsibility of developing and reviewing the radiation protection programme and the supervision to ensure compliance with this programme. A suggested list of items for the programme is given in appendix A.

According to the BSS requirements for medical exposure (see section 5 on medical exposure) the advice of qualified experts in nuclear medicine physics is necessary; a suitable persons need to be appointed on part-time or a full-time basis as required, depending on the size of the nuclear medicine department. The tasks of qualified experts include imaging and quality assurance (including quality control) and optimization of protection, which should involve patient dosimetry. A suggested list of items for the radiation protection programme is given in appendix A.

2.3.3. Quality assurance

The International Organization for Standards defines quality assurance as all planned and systematic actions needed to provide confidence that a structure, system or component will perform satisfactorily in service. Satisfactory performance in diagnostic nuclear medicine service implies the optimum quality of the entire process- i.e., the "consistent production of adequate diagnostic information with minimum exposure of both patients and personnel". For therapeutic uses of unsealed radionuclides quality assurance refers to "all those procedures that ensure consistency of the medical prescription and the safe fulfilment of that prescription."

BSS 2.29 requires the licensee to establish quality assurance (QA) to ensure that the specific requirements related to protection and safety are satisfied and quality control mechanisms and procedures are in place for reviewing and assessing overall effectiveness of protection measures.

It is an extended and growing practice, that hospitals implement a quality assurance system for the entire medical care throughout the treatment, i.e. covering the overall nuclear medicine practice. This system involves a quality assurance committee. The radiation protection and

the quality assurance committees have many functions in common, especially with regard to medical exposure (namely, quality control of physical and clinical factors, as established in the BSS), and also members of both committees will be the same: an administrator representing the management, the chief nuclear medicine physician, a qualified expert (medical physicist), a nuclear medicine technologist, and possibly a maintenance engineer. Harmonization of the work of both committees is needed to ensure that radiation protection issues are given the importance required by regulations and direct reporting to management is ensured. An effective QA programme demands a strong commitment from the departmental and institutional leadership to provide the necessary resources of time, personnel and budget.

The programme should cover the entire process from the initial decision to adopt a particular procedure through to the interpretation and recording of results and should include ongoing auditing, both internal and external, as a systematic control methodology. The maintenance of records is an important part of QA. One important aspect of any QA programme is continuous quality improvement (CQI). It implies a commitment of the staff to strive for continuous improvement in the use of unsealed sources in diagnosis and therapy based on new information learned from their QA programme and new techniques developed by the nuclear medicine community at large. Feedback from operational experience and lessons learned from accidents or near misses can help identify potential problems and correct deficiencies, and therefore should be used systematically, as part of the CQI.

Quality assurance should cover:

- the prescription of the procedure by the medical practitioner and its documentation;
- appointment and patient information;
- clinical dosimetry;
- optimization of examination protocol;
- record keeping and report writing;
- quality control (QC) of radiopharmaceuticals and radionuclide generators;
- acceptance and commissioning;
- QC of equipment and software;
- waste management procedures;
- training and continuing education of staff;
- clinical audit; and
- general outcome of nuclear medicine service.

The WHO has published guidelines on QA in nuclear medicine [8], covering the organization of services, the training of personnel, the selection of procedures, QC requirements for instrumentation and radiopharmaceuticals, and the interpretation and evaluation of results. Quality control of nuclear medicine instruments has been described by the IAEA for recommended schedules [9].

2.3.4. Human factors

BSS 2.30 establishes that "Provision shall be made for reducing as far as practicable the contribution of human error to accidents and other events that could give rise to potential exposures, by ensuring that: (a) all personnel on whom protection and safety depend be appropriately trained and qualified so that they understand their responsibilities and perform their duties with appropriate judgement and according to defined procedures"...

2.3.4.1. Staffing

To comply with this requirement the licensee shall appoint a number of professionals, each possessing a recognized form of accreditation (see Section 2.1.2), sufficient to ensure that all activities relevant to QA, radiation protection and safety are undertaken in accordance with the BSS. Resource requirements should be reviewed as workload increases or as new techniques and new equipment are incorporated into the facility. The table in Appendix C [10] gives an example of staffing levels for medical physicists in nuclear medicine, but this may need to be adapted to allow for differing roles and responsibilities in some cultures. It may not be appropriate for a document on radiation protection to give timing for tasks, which may be more appropriate for other professional documents. However, given as an example may be OK.

2.3.4.2. Education and training

A number of requirements in the BSS refer to the availability of qualified personnel: BSS 2.14 establish that the legal person responsible for sources to be used for medical purposes shall include in the application of the authorization the qualifications in radiation protection of the medical practitioners who are to be so designated by name in the authorization. BSS II. (c) requires that medical and paramedical personnel with appropriate training be available as needed. BSS 2.31 requires that qualified experts shall be identified and made available and in particular, BSS II.2 requires that for diagnostic uses of radiation the imaging and quality assurance requirements of the Standards be fulfilled with the advice of a qualified expert in either radiodiagnostic physics or nuclear medicine physics, as appropriate.

To comply with these requirements, the licencee should ensure that only staff with the credentials specified in Section 2.1.2 fill these positions and that they are aware of :

- the conditions and limitations of the licence;
- the institutional radiation protection policies and procedures (including practice drills);
- their own individual (subsidiary) responsibilities
- the use and operation of equipment;
- the local quality assurance programme and quality control procedures, which should be in an accessible manual);
- review and analysis of incidents and accidents that have occurred in the institution or documented from elsewhere; and
- instructions provided to patients and caregivers.

The professional education and the training to obtain the necessary qualifications as mentioned above need to have been completed before commencement of duties and continued subsequently as part of the professional development and as required by the Regulatory Authority. Furthermore, the instruction of personnel is required whenever significant changes occur in duties, regulations, the terms of the licence or radiation safety procedures.

The licensee should establish a policy that encourages and provides continuing professional development programme, with the aim to improve staff skills, maintain familiarity with current practices and foster a safety culture throughout the institution. Such training and development schemes can be accomplished through informal meetings of the nuclear medicine department, seminars, accredited continuing education programmes or other means.

In addition to the staff needing formal credentials, the following staff needs to be provided with specific instructions on radiation protection:

- nurses attending patients under therapy;
- staff who do not belong to the nuclear medicine practice but need to enter controlled areas; and
- staff who transport radioactive materials within the institution.

Personnel with duties in the vicinity of radioactive sources used in nuclear medicine shall be informed of the radiation effects, details of the specific uses, and the radiation protection programme. The licensee needs to keep documented the initial and periodic instruction of personnel as part of the records of the Radiation Protection Committee. The licensee shall prepare and keep a record of the initial and periodic training of personnel. These records should be kept for at least five years after the expiry of the corresponding authorization.

3. SAFETY OF SOURCES, EQUIPMENT AND FACILITIES

Defence in depth is a safety approach, the purpose of which is a single equipment fault or human error should not directly result in an accident. Defence in depth is defined in the glossary of the BSS as “the application of more than a single protective measure for a given safety objective such that the objective is achieved even if one protective measure fails”. The BSS establish the following requirement for defence in depth [BSS para. 2.35]:

“A multilayer (defence in depth) system of provisions for protection and safety commensurate with the magnitude and likelihood of the potential exposures involved shall be applied to sources such that a failure at one layer is compensated for or corrected by subsequent layers, for the purposes of:

(a) preventing accidents that may cause exposure;

(b) mitigating the consequences of any such accident that does occur; and

(c) restoring sources to safe conditions after any such accident.”

3.1. Design

The BSS (BSS II.11–12) establish, with regard to design of equipment that:

"II.11. The requirements for the safety of sources specified in other parts of the Standards shall also apply to sources used in medical exposure, where relevant, and, in particular, equipment used in medical exposure shall be so designed that:

(a) failure of a single component of the system be promptly detectable so that any unplanned medical exposure of patients is minimized; and

(b) the incidence of human error in the delivery of unplanned medical exposure be minimized.

II.12. Registrants and licensees shall:

(a) taking into account information provided by suppliers, identify possible equipment failures and human errors that could result in unplanned medical exposures;

(b) take all reasonable measures to prevent failures and errors, including the selection of suitably qualified personnel, the establishment of adequate procedures for the calibration, quality assurance and operation of diagnostic and therapeutic equipment, and the provision to personnel of appropriate training and periodic retraining in the procedures, including protection and safety aspects;

(c) take all reasonable measures to minimize the consequences of failures and errors that may occur; and

(d) develop appropriate contingency plans for responding to events that may occur, display plans prominently, and periodically conduct practice drills."

3.1.1. Radiopharmaceuticals

Radiopharmaceuticals should be manufactured according to good manufacturing practice following relevant international standards [11–15] for:

- radionuclide purity;
- specific activity;
- radiochemical purity (see appendix B);
- chemical purity; and
- pharmaceutical aspects — toxicity, sterility, pyrogenicity.

The registrant and licensee should store, handle and use materials in a safe manner in accordance with manufacturer's instructions and regulatory requirements. The registrant and licensee should provide appropriate equipment to contain, store and dispense unsealed sources, having due regard to radiation safety and limitation of contamination. This includes, where appropriate, shielded containers, bench top shields, remote handling tools, syringe shields and protective clothing.

3.1.2. Facilities and ancillary equipment

Should we elaborate more details on design of laboratories, examination rooms, waiting rooms, wards and ancillary equipment, enclosures and extraction systems, and protective clothing, as well as procedures for handling radionuclides in laboratories and procedures in wards as well as decontamination? Or should we refer to other type of documents, such as practical manuals?

The shielding should be designed using the principles of optimization of protection and the design of the facility should take into consideration the classification of the areas within it

(Section 4.2), the type of work to be done and the radionuclides (and their activity) intended to be used. A safety assessment should be performed in order to determine the special needs concerning ventilation, plumbing, and materials used in walls, floors and workbenches.

The floors of controlled areas with the potential for contamination should be finished in an impermeable material, which is washable and resistant to chemical change. A sign such as recommended by ISO [16] should be posted on doors as an indicator of radiation.

A nuclear medicine practice should have a radionuclide activity meter and equipment for workplace monitoring including contamination monitoring. The calibration of these instruments should be traceable to a certified standards laboratory, and should be maintained by a regular quality control programme. Equipment for continuous monitoring of external exposure should be considered in rooms assigned for preparation of radiopharmaceuticals. The manufacturer's operating manual should be available in a language understood by the operators.

Fume hoods are required for use, as appropriate, for volatile radioactive substances. The exhaust of the fume hood shall not exceed the regulatory limit of release. A source storage area and an area for temporary storage of radioactive waste shall be provided with appropriate protection. When designing the facility, the licensee should consider access control when determining source storage areas and rooms for hospitalized patients undergoing radionuclide therapy. (See Section 6.4).

3.2. Maintenance

The licensee should ensure that adequate maintenance (preventive and corrective) is performed as necessary to ensure that equipment used in nuclear medicine retains its design specifications for image quality, radiation protection and safety for its useful life. The licensee needs, therefore, to establish the necessary arrangements and co-ordination with the manufacturer's representative before initiating operation.

All maintenance procedures should be included in the QA programme at a frequency recommended by the manufacturer of the equipment and the relevant professional body. Servicing should include a report describing the equipment fault, the work done and the pieces replaced and adjustments made, which should be filed as part of the QA programme.

3.2.1. Electrical and mechanical safety

The electrical and mechanical safety aspects of the nuclear medicine systems are an important part of the maintenance programme, and can have direct or indirect effects on radiation safety. This work shall be performed by authorized persons who are aware of the specification of the systems. Electrical and mechanical maintenance should be included in the quality assurance programme at a frequency recommended by the manufacturer. Servicing shall include a written report describing the findings. These reports shall be archived as part of the QA programme.

3.3. Security of sources

The objective of source security is to ensure continuity in the control and accountability of each source at all times in order to meet BSS requirement 2.28. Specific provisions shall be made for situations in which loss of control could lead to accidents. To comply with this

requirement, the licensee needs to develop procedures to ensure the safe receipt and movement of radioactive sources within the institution, and establish controls to prevent theft, loss, unauthorized withdrawal or entrance of unauthorized personnel to the controlled areas.

4. OCCUPATIONAL EXPOSURE

The requirements of Sections I.1 to I.20 of the BSS as well as the recommendations of the Safety Guidance on Occupational Radiation Protection, RS-G-1.1 and 1.3 [14,15], should be applied to nuclear medicine practices.

4.1. Responsibilities and conditions of service

The parties responsible for occupational exposure are not only registrants and licensees but also employers. In some cases the employer and registrant and licensee are the same legal person, but in other cases they may be different. For example, the employer of a maintenance engineer may be the maintenance company, while maintenance engineers work in many nuclear medicine departments, each one under a different licensee.

4.2. The use of dose constraints in nuclear medicine

Dose constraints can be used for optimizing protection in the planning stage for each radiation source. Anticipated individual doses should be compared with the appropriate dose constraints and choose protective measures that predict doses below dose constraints. The BSS definition of dose constraint is: *"For occupational exposures, dose constraint is a source-related value of individual dose used to limit the range of options considered in the process of optimization"*.

Since dose constraints are source related, the source to which they relate should be specified, e.g., when choosing source-related dose constraints for the sources involved in a nuclear medicine facility, consideration should be given to the fact that medical and paramedical staff may work in more than one hospital and are exposed to the sources from two nuclear medicine departments (for example in one hospital in the morning and in another hospital in the evening).

4.3. Pregnant workers

The BSS establish that:

"I.16. A female worker should, on becoming aware that she is pregnant, notify the employer in order that her working conditions may be modified if necessary.

I.17. The notification of pregnancy shall not be considered a reason to exclude a female worker from work; however, the employer of a female worker who has notified pregnancy shall adapt the working conditions in respect of occupational exposure so as to ensure that the embryo or foetus is afforded the same broad level of protection as required for members of the public."

4.4. Classification of areas

Relevant areas of a practice can be classified as *controlled* or *supervised* [BSS requirements I.21–25]. A controlled area is any area in which specific protection measures and safety provisions are or could be required for controlling normal exposures … and preventing or limiting the extent of potential exposures. Controlled areas are typically the rooms for storage, preparation and injection of the radiopharmaceuticals, and also due to the potential risk of contamination, the imaging rooms and waiting areas as well as the area housing a patient to whom therapeutic amounts of activity have been given.

4.5. Local rules and supervision

"Employers, registrants and licensees shall, in consultation with workers, through their representatives, if appropriate" (BSS I.26):

"(a) establish in writing such local rules and procedures as are necessary to ensure adequate levels of protection and safety for workers and other persons;

(b) include in the local rules and procedures the values of any relevant investigation level or authorized level, and the procedure to be followed in the event that any such value is exceeded;

(c) make the local rules and procedures and the protective measures and safety provisions known to those workers to whom they apply and to other persons who may be affected by them;

(d) ensure that any work involving occupational exposure be adequately supervised and take all reasonable steps to ensure that the rules, procedures, protective measures and safety provisions be observed; and

(e) when required by the Regulatory Authority, designate a radiation protection officer."

In a nuclear medicine department, these local rules should include: procedures for wearing, handling, and storing personal dosimeters; actions to minimize radiation exposure during unusual events (e.g. accidental contamination); means and methods for decontamination of persons, equipment and surfaces; limitations on activities that are permitted in source storage and handling areas (e.g. no eating, drinking, or smoking); and procedures for the control of sources (e.g. prompt removal of sources from transport containers), checking the integrity of containers, checking the correctness of labels and checking for contamination. The work should be planned and performed in a way that minimizes the spread of contamination in air and on surfaces. Work with unsealed sources should be restricted to a minimum number of locations.

For practices performing positron emission tomography (PET) studies, the local rules should ensure that:

- when handling radionuclides in the cyclotron room and in the radiopharmacy, the dose to the operator is minimized;
- shielding design should consider where appropriate the high energy (511 keV) of the annihilation radiation in PET energy.

4.6. Protective equipment and tools

(BSS I.28) Employers, registrants and licensees shall ensure that:

(a) workers be provided with suitable and adequate personal protective equipment which meets any relevant standards or specifications, …" This should include

- movable shields, bench top shields and shields for syringes and vials to be used when handling unsealed sources;
- protective clothing, gloves and tools for handling of sources to be used during the work with unsealed sources; and
- fume hoods, shielded containers for temporary segregation and storage of radioactive waste.

Containers utilized for the transfer and transport of radioactive sources outside (we should also address transport inside Hospital?) the institution shall conform with the requirements established in the IAEA's Regulations for the Safe Transport of Radioactive Material [21].

4.7. Individual monitoring and exposure assessment

The purpose of monitoring and dose assessment is, inter-alia, to provide information of the actual exposure of workers and confirmation of good working practices. It contributes to reassurance and motivation. The BSS requires individual monitoring for any worker who is normally employed in a controlled area and may receive significant occupational exposure. BSS 1.33 establishes that "For any worker who is normally employed in a controlled area, or who occasionally works in a controlled area and may receive significant occupational exposure, individual monitoring shall be undertaken where appropriate, adequate and feasible". Workers to be monitored include nuclear medicine physicians, physicists, technologists, ward nurses and radiopharmacists. Other users of radioisotope sources, such as clinical specialists, research staff and ancillary workers who frequently work in controlled areas, should also be individually monitored.

In nuclear medicine, exposure from both external radiation and internal contamination are relevant. Individual external doses should be determined by using individual monitoring devices such as thermoluminescent dosimeters, film badges or other devices. The individual monitoring device should be typically worn on the front of the upper torso. When there is a possibility of high exposure to the hands, such as in the preparation and administration of radiopharmaceuticals, extremity dosimeters should also be worn (if compatible with good clinical practice). The exchange of dosimeters and receipt of the dose reports shall be for the period specified by the Regulatory Authority.

Because evaluation of dose is an essential part of the RPP, it is important that workers return dosimeters on time for processing. Delays in the evaluation of a dosimeter can result in the loss of the stored information. Licensees should make every effort to recover any missing dosimeters. If an individual's dosimeter is lost, the RPO should perform and document an evaluation of the dose the individual received and add it to the worker's dose record. If a dosimeter has been lost, the most reliable method for estimating an individual's dose is to use his/her recent dose history. In those cases where the individual performs non-routine types of work, it may be better to use doses to co-workers as the basis for the dose estimate. Individual monitoring devices shall be calibrated and this calibration shall be traceable to a standards dosimetry laboratory.

BSS I.36 establish that employers "shall arrange for appropriate monitoring to the extent necessary to demonstrate the effectiveness of the protection provided and to assess the intake of radioactive substances or the committed doses, as appropriate". In nuclear medicine this requirement is typically met by assessing iodine intake for individuals handling large

activities of radioiodine by monitoring the thyroid with an external detector.

A female worker should notify the licensee if she is pregnant as soon as she knows of her condition, or if she is breast-feeding, so that radiation protection requirements for foetus and baby as a member of the public (BSS I.17) can be met respectively.

4.8. Monitoring the workplace

The BSS require licensees to develop programmes for monitoring the workplace [BSS paras I.37–I.40].

"*I.38. The nature and frequency of monitoring of workplaces shall:*

(a) be sufficient to enable:

(i) evaluation of the radiological conditions in all workplaces;

(ii) exposure assessment in controlled areas and supervised areas; and

(iii) review of the classification of controlled and supervised areas; and

(b) depend on the levels of ambient dose equivalent and activity concentration, including their expected fluctuations and the likelihood and magnitude of potential exposures.

I.39. The programmes for monitoring of the workplace shall specify:

(a) the quantities to be measured;

(b) where and when the measurements are to be made and at what frequency;

(c) the most appropriate measurement methods and procedures; and

(d) reference levels and the actions to be taken if they are exceeded."

The Standards require licensees in cooperation with employers to develop programmes for monitoring the workplace [BSS paras I.37–I.40].

Periodic monitoring with a survey meter and contamination monitor or by wipe tests shall be conducted for controlled and supervised areas. Continuous monitoring with an area monitor should be considered for source storage and handling areas. If a package containing radioactive sources is damaged upon arrival, a survey of removable contamination and external radiation field should be carried out.

All radiation monitors shall be calibrated. Their operability and those of their warning devices should be checked prior to each day of use (BSS I.37–39).

4.9. Investigation levels

Investigation levels are a tool used to provide a "warning" on the need for reviewing procedures and performance, investigate what is not working as expected and take timely corrective action. BSS I.26 establish that "Employers, registrants and licensees shall, in consultation with workers, through their representatives if appropriate

…

(b) include in the local rules and procedures the values of any relevant investigation level or authorized level, and the procedure to be followed in the event that any such value is exceeded;"

The BSS glossary defines investigation level as "the value of a quantity such as equivalent dose, intake, or contamination per unit area or volume at or above which an investigation should be conducted." Investigation levels are, therefore, a means for reviewing procedures and performance; exceeding an investigation level should prompt a review of the situation to determine the cause. In nuclear medicine, a suitable quantity for use as an investigation level is the monthly individual effective dose. The dose to the hands of staff who directly handle radiation sources can also be used as a quantity for an investigation level for staff in nuclear medicine. Monthly values higher than 0.5 mSv recorded by personal dosimeters worn on the trunk or values higher than 12 mSv recorded by finger dosimeters are examples of investigation levels.

BSS IV.18 requires registrants and licensees to conduct formal investigations as specified by the Regulatory Authority if an investigation level is exceeded or any accident, error, mishap or other unusual event or circumstance occurs which has the potential for causing a quantity to exceed any relevant limit or operating restriction.

Further, BSS IV.19-20 requires to initiate the investigation as soon as possible following the event, and a report written concerning its cause, including determination or verification of any doses received, corrective actions, and instructions or recommendations to avoid recurrence. The report of any formal investigation, including exposures greater than a dose limit, shall be submitted to the Regulatory Authority and other concerned bodies as required, as soon as possible after the investigation.

4.10. Health surveillance

[BSS I.41] Employers and licensees shall make arrangements or agreements to provide medical surveillance for workers as specified by the regulatory authority or by other local requirements. The primary purpose of medical surveillance is to assess the initial and continuing fitness of employees for their intended tasks. Health surveillance programmes shall be based on the general principles of occupational health. It should be rare for the radiation component of the working environment to significantly influence the decision about the fitness of a worker to undertake work with radiation, or to influence the general conditions of service (see RS-G-1.1, 7.6).

Counselling should be available to workers [para 7.14 of RS-G-1.1], such as women who are or may be pregnant, or are breast-feeding a child, individual workers who have or may have been exposed substantially in excess of dose limits, and workers who may be worried about their radiation exposure.

Under normal working conditions, the doses incurred in a nuclear medicine department are substantially lower than the dose limits. No specific radiation-related medical examinations are normally required for persons who are occupationally exposed to ionizing radiation, as there are no diagnostic tests which yield information relevant to exposures that are close to or below dose limits. It is therefore rare for the radiation component of the working environment of a nuclear medicine department to significantly influence the decision about the fitness of a worker to undertake work with radiation or the influence the general conditions of service.

However, in the case of exposure to high doses (of the order of magnitude of 0.2-0.5 Sv or higher), specific radiation-related medical investigation are necessary.

4.11. Records

[BSS I.44] Employers and licensees shall maintain and preserve exposure records for each worker. The exposure records shall include information on the general nature of the work involving occupational exposure; information on doses, and the data upon which the dose assessments have been based; when a worker is or has been occupationally exposed while in the employ of more than one employer, information on the dates of employment with each employer and the doses, exposures and intakes in each such employment; and records of any doses due to emergency interventions or accidents, which shall be distinguished from doses, during normal work.

Employers and licensees shall provide for access by workers to information in their own exposure records; and give due care and attention to the maintenance of appropriate confidentiality of records.

5. MEDICAL EXPOSURE

The detailed requirements given in Appendix II of the BSS are applicable, in particular, to nuclear medicine sources. In addition, the Safety Guide on Radiological Protection of Patients describes strategies to involve organizations outside the regulatory framework, such as professional bodies, whose co-operation is essential to ensure compliance with the BSS requirements for medical exposures. Examples that may illustrate this point include acceptance testing for nuclear medicine equipment, calibration of activity meters, establishing guidance levels for diagnostic exposure and reporting of medical overexposure.

As an overall remark, it is important to note that the principles justification and optimization of protection requirements also apply to medical exposure but not the dose limitation. Further, dose constraints do not apply to exposure of patients as part of their own diagnosis and treatment but specific dose constraints shall be defined to comforters and to medical exposure to individuals exposed for medical research if these individuals do not benefit directly from the exposure.

5.1. Responsibilities

With regard to responsibilities for medical exposure, the BSS require that:

“II.1. Registrants and licensees shall ensure that:

(a) no patient be administered a diagnostic or therapeutic medical exposure unless the exposure is prescribed by a medical practitioner;

(b) medical practitioners be assigned the primary task and obligation of ensuring overall patient protection and safety in the prescription of, and during the delivery of, medical exposure;

(c) medical and paramedical personnel be available as needed, and either be health professionals or have appropriate training adequately to discharge assigned tasks in the

conduct of the diagnostic or therapeutic procedure that the medical practitioner prescribes; …

II.02. Registrants and licensees should ensure that for diagnostic uses of radiation the imaging and quality assurance requirements of the Standards be fulfilled with the advice of a qualified expert in either radiodiagnostic physics or nuclear medicine physics, as appropriate.”.

In addition, as stated in the BSS (see section of this document), subsidiary parties with responsibilities for compliance with safety standards can also be workers, radiation protection officers, health professionals, or any other party to whom a principal party has delegated specific responsibilities. Each individual should take actions within his or her area of responsibility, as established in the radiation protection programme, to prevent inappropriate exposures to patients.

All persons involved in delivery of medical exposure should:

(a) follow the applicable rules and procedures for the protection and safety of patients, as specified by the licensee; and

(b) be aware that prescription of treatment and treatment plan need to be signed by the medical practitioner prior to initiation of treatment.

Furthermore, the BSS require that the licensee shall ensure that:

“(e) the exposure of individuals incurred knowingly while voluntarily helping (other than in their occupation) in the care, support or comfort of patients undergoing medical diagnosis or treatment be constrained as specified in Schedule II; and

(f) the training criteria be specified or be subject to approval, as appropriate, by the regulatory authority in consultation with relevant professional bodies.”

“II.3. Medical practitioners shall promptly inform the registrant or licensee of any deficiencies or needs regarding compliance with the Standards in respect of protection and safety of patients and shall take such actions as may be appropriate to ensure the protection and safety of patients”.

??? To comply with these requirements it is indispensable that registrants and licensees establish an internal mechanism to ensure that medical exposure be prescribed by medical practitioner, that the obligation for the overall patient protection is assigned to a nuclear medicine specialist or equivalent, that medical and paramedical staff be available, that advice of qualified experts in nuclear medicine physics and that only staff with the necessary training be in charge of exposing patients for diagnosis and treatment.

5.2. Justification

Pursuant to paragraph II.4 of the BSS, justification of medical exposure is required “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.” The licensee should ensure that medical practitioners follow a justification procedure that is documented and signed. The medical practitioner should consider the efficacy, benefits and risks of alternative treatment modalities, such as ultrasound or magnetic resonance imaging (MRI). In justifying each type of diagnostic nuclear medicine examination, relevant guidelines should be taken into account, such as those established by the WHO [23, 24].

Some diagnostic examinations, particularly of children, can be performed better with the assistance of a helper or comforter (e.g. a relative in the case of a paediatric patient or a relative or friend for a disabled patient). In these circumstances, the helper will be exposed (usually at a low dose).

As children are at greater risk of incurring stochastic effects, paediatric examinations should require special consideration in the justification process. Thus the benefit of some high dose examinations should be carefully weighed against the increased risk.

The justification of examinations in pregnant women requires special consideration. Due to the higher radiosensitivity of the foetus, the risk may be substantial, so the licensee shall ascertain whether the female patient is pregnant before considering use of a radionuclide for diagnosis or for therapy. In these cases, the advice of a medical physics expert should be required and a foetal dose and nominal foetal risk estimation performed before deciding whether the examination should be undertaken.

Certain iodine-131 and phosphorus-32 radiopharmaceuticals can rapidly cross the placenta. It is therefore necessary to exclude the possibility of pregnancy in a female patient *before radionuclides are administered for therapy.* As a rule, a pregnant woman should not be subject to therapy with a radioactive substance unless the application is life saving. Otherwise, the therapeutic application should be deferred until after the pregnancy and after any period of breast-feeding. The International Commission on Radiological Protection (ICRP) in Publication 84 on Pregnancy and Medical Radiation advises that "Termination of pregnancy is an individual decision affected by many factors. Foetal doses below 100 mGy should not be considered a reason for terminating a pregnancy. At foetal doses above this level, there can be foetal damage, the magnitude and type of which is a function of dose and stage of pregnancy" [25].

Important additional information for the medical practitioner prescribing or conducting nuclear medicine examinations is the range of typical doses per examination. This could help in the process of justification. A good way to apply the justification criteria in nuclear medicine is to use the referral criteria published by different scientific societies.

With respect to medical research, [BSS II.8] require that:

"The exposure of humans for medical research is deemed to be not justified unless it is:

(a) in accordance with the provisions of the Helsinki Declaration[16] and follows the guidelines for its application prepared by Council for International Organizations of Medical Sciences (CIOMS)[17] and WHO[18]; and

(b) subject to the advice of an Ethical Review Committee (or any other institutional body assigned similar functions by national authorities) and to applicable national and local regulations."

Footnotes from the BSS corresponding to the above quotation:

"[16]Adopted by the 18th World Medical Assembly, Helsinki, 1974, and as amended by the 29th World Medical Assembly, Tokyo, 1975, the 35th World Medical Assembly, Venice, 1983, and the 41st World Medical Assembly, Hong Kong, 1989; available from the World Medical Association, F-01210 Ferney-Voltaire, France."

"[17]Adopted by the 18th World Medical Assembly, Helsinki, 1974, and as amended by the 29th World Medical Assembly, Tokyo, 1975, the 35th World Medical Assembly, Venice, 1983, and the 41st World Medical Assembly, Hong Kong, 1989; available from the World Medical Association, F-01210 Ferney-Voltaire, France."

"[18]WORLD HEALTH ORGANIZATION, Use of Ionizing Radiation and Radionuclides on Human Beings for Medical Research, Training and Non-Medical Purposes, Technical Report Series No. 611, WHO, Geneva (1977)."

Medical exposure for biomedical research is subject to specific dose constraints when the exposed individual does not benefit from the exposure (see 5.)

5.3. Optimization for medical exposures in nuclear medicine

5.3.1. Operational considerations for diagnostic procedures

The BSS requires "II.17. Registrants and licensees shall ensure for nuclear medicine that:

(a) the medical practitioners who prescribe or conduct diagnostic applications of radionuclides:

  (i) ensure that the exposure of patients be the minimum required to achieve the intended diagnostic objective;

  (ii) take into account relevant information from previous examinations in order to avoid unnecessary additional examinations; and

  (iii) take into account the relevant guidance levels for medical exposure;

(b) the medical practitioner, the technologist or other imaging staff, as appropriate, endeavour to achieve the minimum patient exposure consistent with acceptable image quality by:

  (i) appropriate selection of the best available radiopharmaceutical and its activity, noting the special requirements for children and for patients with impairment of organ function;

  (ii) use of methods for blocking the uptake in organs not under study and for accelerated excretion when applicable;

  (iii) appropriate image acquisition and processing;

(c) administration of radionuclides for diagnostic or radiotherapeutic procedures to women pregnant or likely to be pregnant be avoided unless there are strong clinical indications;

(d) for mothers in lactation, discontinuation of nursing be recommended until the radiopharmaceutical is no longer secreted in an amount estimated to give an unacceptable effective dose to the nursling[4]; and

(d) administration of radionuclides to children for diagnostic procedures be carried out only if there is a strong clinical indication, and the amount of activity administered be reduced according to body weight, body surface area or other appropriate criteria."

Further, for therapeutic procedures BSS II.18 requires that:

[4] Examples of good practice are at least 3 weeks for ^{67}Ga, ^{111}In, ^{131}I and ^{201}Tl, at least 2 days for ^{123}I and at least 12 hours for ^{99m}Tc.

"(c) administration of radionuclides for therapeutic procedures to women who are pregnant or likely to be pregnant or who are nursing be avoided unless there are strong clinical indications;"

Measures to achieve these requirements include:

5.3.1.1. For diagnostic procedures

Equipment should be operated within the conditions established in the technical specifications and in the licence requirements, ensuring that it will operate satisfactorily at all times, in terms of both the tasks to be accomplished and radiation safety, so that optimal image acquisition and processing can be achieved with the minimum patient exposure.

Registrants and licensees should also establish constraints on the dose to comforters and caregivers and provide instruction on actions to take to limit their exposure while visiting or caring for a patient who has received radionuclide therapy. Registrants and licensees should provide written as well as verbal instructions to patients who have received radionuclide therapy on actions to take to limit exposure to comforters, caregivers and members of the public when leaving the hospital. These instructions should include minimizing prolonged contact with the spouse, other family members, minors and potentially pregnant women.

The following applies to individual patients:

- An effective system for correct identification of patients.
- Written protocol for each diagnostic procedure, designed to maximize the clinical information to be obtained from the study, taking into consideration the appropriate guidance level for the procedure.
- Correct recording of patient details
- Selection of the data acquisition conditions, such that the exposure is the minimum necessary to achieving the intended diagnostic objective. The choice of collimator, energy window, matrix size, acquisition time, angulation of collimator, SPECT or PET parameters, and zoom factor shall be such as to obtain optimum quality image.
- For dynamic studies, the number of frames, time interval and other parameters shall be chosen to obtain optimum quality of image sequence.
- Care shall be taken to ensure that there is no contamination on the collimator surface or elsewhere as this may might impair the quality of the result.

5.3.1.2. For therapeutic application of radionuclides

- An effective system for identification of patiens
- Verbal and written instructions to the patien to minimize exposure to family members and the public
- Special attention to prevent spread of contamination due to patient vomit and excreta.
- Observance of national regulations on release of patients after administration of therapeutic doses of radiopharmaceuticals

5.3.1.3. Breast feeding

Registrants and licensees should ascertain beforehand whether the female patient is breast-feeding. Cessation of breast-feeding is recommended during most nuclear medicine procedures as many radiopharmaceuticals are excreted in breast milk. Appendix I is taken from a recent journal article and gives guidance on cessation of breast feeding following administration of some common radiopharmaceuticals [27].

5.3.1.4. Conception after therapeutic administration of radionuclides

Following treatment with a therapeutic radionuclide, a female patient should be advised to avoid pregnancy for an appropriate period. A table of periods after administration of a radionuclide administered for therapeutic purposes during which conception should be avoided is given in Appendix E. It may be noted that these times have been derived with a view to the need for further therapy, not to the risk of genetic effects It is not considered that males who have been administered normal doses of diagnostic radiopharmaceuticals need to be given any advice concerning avoidance of conception.

The administration of therapeutic doses of relatively long-lived radionuclides in ionic chemical forms is, however, a possible source of concern because of the appearance of larger quantities of these radionuclides in ejaculate and in sperm. It may be prudent to advise sexually-active males who have been treated with [^{131}I] iodine, [^{32}P] phosphate or [^{89}Sr] strontium chloride to avoid fathering children for a period of four months after treatment. The period of four months is suggested as it is longer than the life of a sperm cell [28].

5.3.2. Calibration

BSS II.19 requires that registrants and licensees shall ensure that (BSS II.19):

"(a) the calibration of sources used for medical exposure be traceable to a Standards dosimetry laboratory;

…

(e) unsealed sources for nuclear medicine procedures be calibrated in terms of activity of the radiopharmaceutical to be administered, the activity being determined and recorded at the time of administration;"

Registrant and licensees should ensure that an activity meter is available for measuring the activity in syringes or vials in a nuclear medicine department. The validity of measurements should be ensured by regular quality control of the instrument, including periodic assessment of its calibration, traceable to secondary standards [reference to the Safety Guide RS-G-1.5 paragraph 4.11]. (More advice is needed because secondary standards are not available in most countries; we could refer to the conclusions of the recent Symposium in Dosimetry). The calibration of the instruments should be maintained by a regular quality control programme. The licensee should participate in a regular intercomparison programme.

5.3.3. Clinical (patient) dosimetry

In addition to the requirement to calibrate and record of the activity to be admistered at the time of the administration, (BSS II.20 requires that registrants and licensees shall ensure that the following items be determined and documented: " (d) in diagnosis or treatment with unsealed sources, representative absorbed doses to patients;" The Regulatory Authority should require that registrants and licensees make available a list of representative values for absorbed dose or effective dose to typical patients for each type of diagnostic investigation carried out within the department. Registrant and licensees should obtain these values by calculation or from tables using internationally accepted methods or compilation of standard data. These values should be included in the manual of procedures. In special cases, for example doses to an embryo or foetus, it may be necessary to calculate dose values specifically for relevant cases [RS-G-1.5].

In relation with therapeutic applications the BSS further requires that: (e) in all radiotherapeutic treatments, absorbed doses to relevant organs" need to be evaluated. The advice of a qualified expert is needed to perform individual dose calculations for therapeutic procedures and each therapeutic dose should be calculated and recorded.

5.3.4. Quality assurance for medical exposures

As indicated in Section 2.3.3, the licensee needs to establish a comprehensive QA programme. With regard to medical exposure, BSS II.22 requires that programme shall be established with the participation of appropriate qualified experts in the relevant fields, such as nuclear medicine physics and radiopharmacy, taking into account the principles established by the WHO and the PAHO. The programme shall include:

(a) measurements of the physical parameters of … imaging devices … at the time of commissioning and periodically thereafter;

(b) verification of the appropriate physical and clinical factors used in patient diagnosis or treatment;

(c) written records of relevant procedures and results;

(d) verification of the appropriate calibration and conditions of operation of dosimetry and monitoring equipment; …"

To comply with these requirements, the following should be included in the programme (copy from the safety guide) Mention TECDOC 602. Compliance with these requirements should not lead to contradict or unnecessarily overlap with other aspects of the quality system of the nuclear medicine department as a whole. There should be an harmonization between the requirements of the quality system based on medical grounds and the requirements for radiation protection [RS-G-1.5].

Quality assurance activities have bee often restricted to testing equipment performance. A comprehensive QA programme, however, should embrace the entire process of nuclear medicine. The International Organization for Standards defines quality assurance as all planned and systematic actions needed to provide confidence that a structure, system or component will perform satisfactorily in service. Applying this definition to diagnostic nuclear medicine, WHO points out that satisfactory performance in service implies that optimal quality can be obtained in the whole process of diagnostic, i.e., in any moment, an adequate diagnostic information is provided with minimal exposure to patient and staff. The programme should address not only equipment performance but also image quality assessments, analysis of poor images, finding the causes of poor quality taking corrective actions and controlling radiation doses. The complete quality cycle has to be gone through with feedback mechanism for rectification of malfunction of equipment but also improving operator performance.

After equipment installation, it is necessary to conduct acceptance tests in order to verify that the equipment conforms to technical specifications certified by the manufacturer. Purchasing conditions should clearly establish the responsibility of suppliers for resolving non-conformities identified during acceptance testing. A qualified expert on the equipment e.g. medical physicist should define the technical specifications and do the acceptance testing of the equipment. For equipment operation, the manufacturer's operating manual, and the institutions procedural manual should be followed.

Acceptance tests, should be performed by the manufacturer's representative in the

presence of authorized local personnel (e.g. a qualified expert in nuclear medicine physics) representing the user to decide on acceptance. Commissioning includes all parameters and situations intended for clinical use under clinical conditions and establish the base line for constancy tests. Quality control needs to be co-ordinated with maintenance programmes. Tests may need to be performed after any maintenance on the equipment that may affect its imaging and/or radiation characteristics [ref to PAHO/WHO 1997 book under revision].

The Regulatory Authority should encourage registrants and licensees to work with professional bodies in the development of such programmes. As the development of a national programme may not be feasible in many Member States, a well-established and proven international or national programme may be followed.

5.4. Guidance levels

The principal requirements of the BSS establish that:

"2.27. Guidance levels for medical exposure shall be established for use by medical practitioners. The guidance levels are intended:

(a) to be a reasonable indication of doses for average sized patients;

(b) to be established by relevant professional bodies in consultation with the Regulatory Authority following the detailed requirements of Appendix II and the guidance levels given in Schedule III;

(c) to provide guidance on what is achievable with current good practice rather than on what should be considered optimum performance;

(d) to be applied with flexibility to allow higher exposures if these are indicated by sound clinical judgement; and

(e) to be revised as technology and techniques improve."

Appendix II of the BSS further establishes the following detailed requirements:

"II.24. Registrants and licensees should ensure that guidance levels for medical exposure be determined as specified in the Standards, revised as technology improves and used as guidance by medical practitioners, in order that:

(a) corrective actions be taken as necessary if doses or activities fall substantially below the guidance levels and the exposures do not provide useful diagnostic information and do not yield the expected medical benefit to patients;

(b) reviews be considered if …activities exceed the guidance levels as an input to ensuring optimized protection of patients and maintaining appropriate levels of good practice; and

(c) …, the guidance levels be derived from the data from wide scale quality surveys which include … activities of radiopharmaceuticals administered to patients for the most frequent examinations in nuclear medicine…".

II.25. In the absence of wide scale surveys, performance of … nuclear medicine equipment should be assessed on the basis of comparison with the guidance levels specified in Schedule III, Tables III-I to III-V. These levels should not be regarded as a guide for

ensuring optimum performance in all cases, as they are appropriate only for typical adult patients, and therefore, in applying the values in practice, account should be taken of body size and age."

The Regulatory Authority should encourage professional associations and registrants and licensees to perform surveys of administered activity for typical adult patients in common diagnostic procedures. An assessment of administered activity may be implemented gradually and should always be undertaken in parallel with image quality assessments.

Deviations from the normally used amounts may be necessary under a variety of physical and pathological conditions. These cases should be given special consideration by the physicians performing the procedure.

5.5. Dose constraints

Dose constraints do not apply to the exposure of patients as a result of their own medical diagnostic or therapeutic procedure. Further, BSS II.26 further establishes that "The Ethical Review Committee or other institutional body assigned similar functions on the subject by national authorities shall specify dose constraints to be applied on a case by case basis in the optimization of protection for persons exposed for medical research purposes if such medical exposure does not produce direct benefit to the exposed individual."

With regards to patient's comforters and visitors, BSS II.27 establish that: "Registrants and licensees shall constrain any dose to individuals incurred knowingly while voluntarily helping (other than in their occupation) in the care, support or comfort of patients undergoing medical diagnosis or treatment, and to visitors to patients who have received therapeutic amounts of radionuclides or who are being treated with brachytherapy sources, to a level not exceeding that specified in Schedule II, para. II-9."

Schedule II of the BSS establish that, "the dose of any such comforter … of patients shall be constrained so that it is unlikely that his or her dose will exceed 5 mSv during the period of a patient's diagnostic examination or treatment."

5.6. Maximum activity for patients in therapy on discharge from hospital

BSS II.28 establish that *"In order to restrict the exposure of any members of the household of a patient who has undergone a therapeutic procedure with sealed or unsealed radionuclides and members of the public, such a patient shall not be discharged from hospital before the activity of radioactive substances in the body falls below the level specified in Schedule III, Table III-VI. Written instructions to the patient concerning contact with other persons and relevant precautions for radiation protection shall be provided as necessary."*

Table III-VI only includes the value for Iodine-131 and sets 1100 MBq as the guidance level for maximum activity for patients in therapy on discharge from hospital. (The ICRP has an ongoing Task Group with the remit of developing guidance that includes other radionuclides). To comply with this requirement, registrant and licensees should have a system to measure or estimate the activity in patients prior to discharge. The result should be recorded. When deciding on the appropriate discharge activity for a particular patient, the licensee should take into account the transport and the living conditions of the patient, such as the extent to which the patient can be isolated from other family members and the requirement to dispose safely of the patient's contaminated excreta. In some cases such as for

the elderly or children, it may be necessary to discuss the precautions to be taken with other family members.

Further guidance on radiation protection following I-131 therapy can be found in the recommendations from the European Commission [29]. Patients under bone pain palliation therapies shall be discharged based on local rules, which take into account the external exposure rate, the risk of contamination and the patient's condition. Special consideration shall be given to the case of incontinent patients (BSS II.28).

5.7. Investigation of accidental medical exposure

[BSS paragraph., II.29 and 30] require

"II.29.Registrants and licencees shall promptly investigate any of the following incidents:

(a) any therapeutic treatment delivered to either the wrong patient or the wrong tissue, or using the wrong pharmaceutical, or with a dose or dose fractionation differing substantially from the values prescribed by the medical practitioner or which may lead to undue acute secondary effects; ..

(b) any diagnostic exposure greater than intended or resulting in doses repeatedly and substantially exceeding the established guidance levels; and

(c) any equipment failure, accident, error, mishap or other unusual occurrence with the potential for causing a patient exposure significantly different from that intended.

II.30. Registrants and licensees shall, with respect to any investigation required under para. II.29:

(a) calculate or estimate the doses received and their distribution within the patient;

(b) indicate the corrective measures required to prevent recurrence of such an incident;

(c) implement all the corrective measures that are under their own responsibility;

(d) submit to the regulatory authority, as soon as possible after the investigation or as otherwise specified by the regulatory authority, a written report which states the cause of the incident and includes the information specified in (a) to (c), as relevant, and any other information required by the regulatory authority; and

(e) inform the patient and his or her doctor about the incident."

Appendix H provides, for illustration, a short description of the major reported events occurred in nuclear medicine.

5.8. Records for medical exposure

Registrants and licensees shall keep for a period specified by the Regulatory Authority and make available, as required, records concerning types of radiopharmaceuticals administered and their activities and exposure of volunteers in medical research (BSS II.32)

5.9. Gradual transition from basic to advance stages of BSS implementation with regard to medical exposure

The requirements of the BSS are comprehensive and need time and organization for full implementation, which requires a step-by-step process; the Action Plan on the Radiological

Protection of Patients has requested to include “advice about the gradual transition from basic to advanced stages of implementation” in this guideline document. It also recognizes that many developing countries do not have at present have the resources or expertise necessary for fully meeting them and, therefore, requests providing support for Member States in this transition.

Full compliance implies performing periodical image quality assessments and surveys of administered activities; having a full QA programme and arrangements for rectification of equipment malfunction; surveys of patient doses; and a mechanism for education and training of medical and paramedical personnel. To achieve this stage the following steps are envisaged:

For countries with no previous experience in assessment and documentation of image quality, the first step is a question of initiation and developing capability for evaluating image quality, exercising in searching for causes for poor quality and preparing the ground for a subsequent QA program, based on the needs of the country. Formal patient dose assessment is not included at this stage but recording of administered activity together with image quality should be included.

After developing capabilities for evaluating image quality, countries are in a position of developing a quality assurance programme that would give emphasis to parameters depending on their contribution to image quality, derived from the study. The programme should include image quality and quality control of equipment and operator performance. These countries should develop availability of service facility for rectification of equipment malfunction. The availability of service should lead to a report on frequency of malfunction and actions taken and their impact on image quality. At this stage, provisions for sustainable training should be made.

Finally, countries having completed the two previous steps would be able to perform assessment of patient dose and establish guidance level. At the end of the process a comprehensive quality assurance and sustainable training mechanism for medical and paramedical staff should be in place.

6. PUBLIC EXPOSURE

6.1. Responsibilities

Registrants and licensees are responsible for controlling public exposure resulting from a nuclear medicine practice. Public exposure is controlled by proper shielding design, by minimizing contamination and by controlling access and ensuring that radiation sources are secured (e.g., located in a locked area) to prevent unauthorized access or use. Presence of members of the public in and near the nuclear medicine department shall be considered when designing shielding of storage and use facilities.

Registrants and licensees should:

- develop and implement use, storage and transport measures for ensuring the safety and security of radiopharmaceuticals to control public exposures in accordance with the requirements of the regulatory authority; and

- control and maintain constant surveillance of licensed material that is not in storage (e.g., when nuclear medicine sources are being transported or used for treatment) and secure stored licenced material from unauthorized access, removal, or use (e.g., the storage facility shall be locked at all times).

Registrants and licensees are responsible for ensuring that the optimization process for measures to control the discharge of radioactive substances from a source to the environment is subject to dose constraints established or approved by the Regulatory Authority.

6.2. Control of access of visitors

Registrants and licensees shall (BSS III.5):

(a) "ensure that visitors be accompanied in any controlled area by a person knowledgeable about the protection and safety measures for that area;

(b) provide adequate information and instruction to visitors before they enter a controlled area so as to ensure appropriate protection of the visitors and of other individuals who could be affected by their actions;

(c) ensure that adequate control over entry of visitors to a supervised area is maintained and that appropriate signs are posted in such areas."

Arrangements should be made to control access of visitors to patients undergoing radionuclide therapy and provide adequate information and instruction to these persons before they enter the patient´s room so as to ensure appropriate protection.

6.3. Radioactive contamination

Registrants and licensees shall ensure that for sources for which they are responsible, measures optimized in accordance with the requirements of the Regulatory Authority are taken, as appropriate, for restricting public exposure to contamination in areas accessible to the public (BSS III.7).

6.4. Radioactive waste

The registrant and the licensee shall (BSS III.8):

- develop and implement a programme for safe disposal of radioactive waste or return of sources when their use is discontinued, as required by the Regulatory Authority;
- ensure that the activity and volume of any radioactive waste resulting from the sources for which they are responsible are kept to the minimum practicable, and that the waste is managed in accordance with the requirements of the Regulatory Authority;
- ensure that the discharge of radioactive wastes to the public waste treatment system and to the sewage system is within the limits specified by the Regulatory Authority; and
- maintain responsibility for all other sources until provisions have been made to transfer the sources to an appropriate licensee or to an authorized waste disposal facility at the end of use.

This section does not provide practical advise on how to implement these requirements. The minimum that it should do is to give some good reference to help the reader.

6.5. Monitoring of public exposure

The registrant and licensee shall, as appropriate (BSS III.13):

(a) establish and carry out a monitoring programme sufficient to ensure that the requirements of the Regulatory Authority regarding public exposure to radioactive sources are satisfied and to assess such exposure;

(b) establish and carry out a monitoring programme sufficient to ensure that the requirements that the Regulatory Authority for discharges of radioactive substances to the environment are satisfied; and

(c) keep appropriate records of the results of the monitoring programmes.

Again, no practical advise on the type of monitoring

7. POTENTIAL EXPOSURE AND EMERGENCY PLANS

This section focuses on identification, prevention, preparation for and mitigation of emergency situations or accidents. Requirements for the safety of sources and facilities are set out in Section 3.

7.1. Safety assessment

The registrant and licensee needs to conduct a safety assessment applied to all stages of the design and operation of the nuclear medicine facility, and present the report to the Regulatory Authority if required. The safety assessment shall include, as appropriate, a systematic critical review of identification of possible events leading to accidental exposure (BSS IV.3–7). Basically, the safety assessment deals with finding “what can go wrong” and how it can be prevented and in case it occurs, how it can be mitigated. A good basis is provided by collection of information of accidents that aleady occur but it should not stop there, and should make an effort to anticipate other events that have not previously occurred or not been reported.

The safety assessment needs to be documented and, if appropriate, independently reviewed, within the QA programme. Additional reviews shall be performed as necessary whenever:

(a) safety may be compromised as a result of modifications of the facilities or of the procedures;

(b) operational experience or information on accidents or errors indicates that a review is necessary; or

(c) any significant changes to relevant guidelines or standards are envisaged or have been made.

Any consequential modifications shall be made cautiously and only after a favourable assessment of all the implications for protection and safety.

Appendix I of this TECDOC provides identified causes of contributing factors to accidents in nuclear medicine and examples of accidental exposures (misadministration) of radiopharmaceuticals that have been reported.

7.2. Prevention of accidents and mitigation of their consequences

The registrant and licensee shall incorporate within the RPP (BSS IV.10–12):

(a) defence in depth measures to cope with identified events, and an evaluation of the reliability of the safety systems (including administrative and operational procedures, and equipment and facility design); and

(b) operational experience and lessons learned from accidents and errors. This information should be incorporated into the training, maintenance and QA programmes;

The registrant and licensee shall promptly inform the Regulatory Authority of all reportable events, and make suitable arrangements to limit the consequences of any accident or incident that does occur.

7.3. Emergency plans

On the basis of events identified by the safety assessment, the registrant and licensee shall prepare emergency procedures (BSS V.2–6).

The procedures should be clear, concise and unambiguous and shall be posted visibly in places where their need is anticipated.

An emergency plan shall, as a minimum, list/describe:

- predictable incidents and accidents and measures to deal with them;
- the persons responsible for taking actions, with full contact details;
- the responsibilities of individual personnel in emergency procedures (nuclear medicine physicians, medical physicists, nuclear medicine technologists, etc.);
- equipment and tools necessary to carry out the emergency procedures;
- training and periodic rehearsal;
- recording and reporting system;
- immediate measures to avoid unnecessary radiation doses to patients, staff and public;
- measures to prevent access of persons to the affected area; and
- measures to prevent spread of contamination.

APPENDIX A: ITEMS FOR A RADIATION PROTECTION AND SAFETY PROGRAMME IN NUCLEAR MEDICINCE

Compliance with administrative requirements

- Is there an authorization granted by the Regulatory Authority?
- Are there specific conditions in the authorization, in addition to the requirements in the regulations (or BSS)? Which ones?
- Are there safety concerns in inspection reports? Which ones? Have they been addressed?

Security of sources

- Is there an inventory of all radioactive sources, equipment and facilities?
- To whom are responsibilities assigned for keeping the inventory?
- Indicate the means to prevent unauthorized access and use of the radioactive sources

Radiation protection and safety programme

- Is a radiation protection and safety programme in place supported and signed by the licensee (the legal person)?
- Is there a radiation protection committee? Who are the members of the committee? (An administrator representing the management, the chief nuclear medicine phyisician, the qualified expert in nuclear medicine physics, a radiographer, a radiation protection officer)[5].
- Are functions and responsibilities well defined? (For nuclear medicine physicians, technologists, qualified experts in nuclear medicine physics, maintenance engineers and radiation protection officer?
- Are these responsibilities understood by the responsible persons?
- Are there provisions to ensure that only qualified and accredited staff assumes the responsibilities for using radiation (nuclear medicine physicians, technologists …)?
- Is there a programme for education and training and continuing professional development? Describe

Rules and procedures

- Is there a procedure for purchasing radioactive sources and nuclear medicine equipment?
- Do the procedures include consideration to protection and safety aspect, including complying with standards?
- Procedure for use the radioactive sources and equipment?
- Individual exposure monitoring (see occupational protection)?

[5] In small nuclear medicine departments several of these functions can be assumed by the same person: for example, in many countries, in a small private nuclear medicine practice, the chief nuclear medicine specialist may also be the representative of the management or the manager (the licensee him/herself).

- Workplace monitoring (see occupational protection)?
- Equipment repairs and return to use?
- Safe handling of radiation sources (preparation, dispensing and administration of radiopharmaceuticals, such as ^{99}Mo/^{99m}Tc generator)?
- Receipt, storage, and disposal of radioactive sources?

Protection from occupational exposure

Conditions of service

Are there provisions to encourage pregnant workers to notify pregnancy and to adapt her working conditions so as to ensure that the embryo or foetus is protected afforded the same broad level of protection as required for members of the public, without excluding the female worker from work?

Classification of areas

- Are areas classified? Are source storage and preparation rooms, examination rooms, patient wards for therapy patients classified as controlled areas?

Local rules and supervision

- Are there procedures for ensuring adequate levels of protection and safety of workers?
- Are these procedures, the protective measures and safety provisions known to those workers to whom they apply and to other persons who may be affected by them?
- Is supervision to ensure observance of the procedures carried out?
- Are investigation levels included?

Personal protective equipment

- Is there shielded workplace for handling radionuclides available?
- Are other devices such as remote handling devices available?

Co-operation between the employer and the licensee

- Are there provisions to exchange information with other employers and use specific exposure restrictions, if staff works in another place using radiation?

Individual monitoring and exposure assessment

- Are there arrangements to provide individual monitoring provided by an accredited and authorized service in place?
- Are staff members requiring individual monitoring identified?
- Are the monitoring period, frequency for reading, recording the accumulated doses and rules for returning and changing dosimeters established?
- Are there arrangements to ensure that doses are made available to the staff?
- Rules for estimating the worker’s dose if a personal dosimeter is lost or damaged?

- Does personal monitoring include provision for assessing internal exposure?

Monitoring of the workplace

- Are there provisions for keeping the workplace under supervision and the monitoring at a frequency that enables assessment in controlled areas and supervised areas?

Health surveillance

- Are there arrangements for health surveillance according to the rules of the Regulatory Authority in place?
- Is counselling for pregnant women available?

Records

- Are exposure and medical surveillance records available?

Protection for medical exposure

Responsibilities

- Is the responsibility for prescribing medical exposure (nuclear medicine procedure) well defined and established? Is there a provision to prevent administration of a medical exposure without the prescription of a medical practitioner?
- Is the overall responsibility for patient protection and safety assigned to a medical practitioner?
- Are there arrangements to ensure that the imaging and quality assurance requirements of the Standards be fulfilled with the advice of a qualified expert in nuclear medicine physics?

Justification of medical exposure

- Is there a formal procedure for the prescription and administration of medical exposure to ensure that these are justified?
- Is there a formal provision to justify research involving application of radiation on humans, according to the declaration of Helsinki?

Optimization: Design and testing

- Is there a programme for formal acceptance of equipment in place? Describe
- Is it carried out according to international or national standards for nuclear medicine equipment, for example activity meters, such as IEC standards?

Optimization: Operational considerations

- Is there a provision for formal optimization ensure that the exposure of patients be the minimum required to achieve the intended diagnostic objective; take into account relevant information from previous examinations in order to avoid unnecessary additional examinations; and take into account the relevant guidance levels for medical exposure;

Optimization: Calibration

- Are unsealed sources for nuclear medicine procedures calibrated in terms of activity of the radiopharmaceutical to be administered, the activity being determined and recorded at the time of administration?

Optimization: Clinical dosimetry

- Is there a provision to determine in diagnosis or treatment with unsealed sources, representative absorbed doses to patients?

Optimization: Quality assurance

- Is a quality assurance programme established?
- Method to write new procedures and for changing and documenting the changes?
- Is the programme based on an accepted and proven protocol?
- Are all tasks of the programme assigned to trained persons?
- Is there a maintenance strategy, arrangements and procedures (consider giving an example of strategy)?

Do we need some specific details on QA here?

Investigation of accidental medical exposure

- Is there a provision in place to investigate and report:
- any therapeutic treatment delivered to either the wrong patient or the wrong tissue, or using the wrong pharmaceutical, or with a dose or dose fractionation differing substantially from the values prescribed by the medical practitioner or which may lead to undue acute secondary effects;
- any diagnostic exposure substantially greater than intended or resulting in doses repeatedly and substantially exceeding the established guidance levels; and
- any equipment failure, accident, error mishap or other unusual occurrence with the potential for cause a patient exposure significantly different from that intended
- Is there a provision to estimate the doses received and indicate and implement corrective measures?

Protection from public exposure

- Is the public considered in the shielding design?
- Is control of access of public and visitors in place?
- Are pathways designed to minimize interference of public with console control space and examination rooms to avoid potential exposure?
- We need to add on contamination and waste

APPENDIX B: QUALITY ASSURANCE PROGRAMME FOR “IN VIVO” PRACTICES

Nuclear medicine has three major concerns: efficacy, quality of life and safety. A quality assurance (QA) programme should be implemented in every facility for “in vivo” nuclear medicine. Only an integrated QA approach to nuclear medicine, taking into account medical, physical and radiation safety aspects, can improve nuclear medicine to achieve an adequate image quality at the lowest reasonable doses to patients. Co-ordinated with the RPP (RPP) (Appendix D), the QA programme ensures good medical practice and radiation protection of the staff, patients and the public. Experience has shown that the frequency of accidental exposures in “in vivo “ applications is directly related to the absence or inadequacy of an established QA programme in the department. A QA committee shall be responsible for systematically reviewing and auditing the entire QA programme in order to determine whether the activities conducted to obtain images of good quality are consistent with current good medical practice and are carried out in a safe manner and in accordance with the regulations and the terms of the authorization.

In hospitals with several departments using radiation, e.g. radiology, radiotherapy and nuclear medicine, representatives from these departments could be integrated in a single QA committee. For small establishments such as stand-alone nuclear medicine clinics, the RPP and QA committees may be combined.

The following components merit special attention in a QA programme.

GENERAL

Component	Factors affecting quality
Request	Recording of patient history Appropriateness of procedure Contraindications Experience and competence of referring specialist
Scheduling	Administrative routines Workload of the department
Patient care	Patient identification Patient preparation Instructions and information provided to patient Waiting time
Patient examination/treatment	Reliable supply of radiopharmaceuticals Quality of radiopharmaceuticals Storage of radiopharmaceuticals Preparation of radiopharmaceuticals Administration of radiopharmaceuticals

	Equipment performance and maintenance Data acquisition protocol Optimization of the examination/treatment Clinical dosimetry Procedure manuals Training and experience of staff
Report	Equipment performance Processing protocols Training and experience of operators. Expertise of nuclear medicine physician
Radiation protection	Design of facility Safe receipt and storage of unsealed sources Safe handling of unsealed sources Management of radioactive waste Safety equipment Personal monitoring Health surveillance Workplace monitoring Emergency procedures Local rules Training and experience of staff

An analysis of the general outcome of the Nuclear medicine service should include the dose to staff and patients, the satisfaction of the patient and the referring physician, workload indicators, records and clinical audit.

QUALITY CONTROL OF RADIOPHARMACEUTICALS

Radiopharmaceuticals must comply with both radiation and pharmaceutical standards in order to ensure their safe and efficacious use. The *in vivo* behaviour of the radiopharmaceutical is dependent upon its quality, which demands high standards of radionuclide, radiochemical and chemical purity and, in the case of suspensions, of particle size and uniformity. Injections have to satisfy additional standards for sterility, apyrogenicity and freedom from foreign particulate matter.

Radionuclide purity

Radionuclide purity is defined as the percentage of the radioactivity of the required

radionuclide to the total radioactivity of the source. Standards for radionuclidic purity are laid down in the European Pharmacopoeia (EP) [12], the British Pharmacopoeia (BP) [13] and the United States Pharmacopoeia (USP) [14]. The reason for seeking radionuclidic purity in a radiopharmaceutical is primarily to avoid unnecessary radiation dose to the patient, to avoid degradation of image quality, and to limit errors on measurements *in vivo.* It should be noted that measured radionuclidic purity will not be constant, but will depend upon the half-lives of the radionuclides involved. Contaminants with longer half-lives than the specified radionuclide are potentially more hazardous because they will progressively reduce the purity and may significantly effect the radiation dose to the patient. They may also affect the detection and imaging processors. It is therefore very important to strictly control the levels of radionuclidic impurities in radiopharmaceuticals.

It is the manufacturer's duty to examine his products in detail, and especially to examine preparations of short-lived radionuclides for long-lived impurities after a suitable period of decay.

When a parent-daughter generator system is used, a check must be made on each eluate to ensure that any breakthrough of the parent into the eluate is below the limit as specified in the pharmacopoeia at the time of patient administration. Where the physical half-lives of impurity radionuclides are known and the radionuclidic purity of the radiopharmaceutical has been measured at a given time, the radionuclidic purity at subsequent times, e.g., by the time of administration to patients. can be determined by calculation.

Radiochemical purity

Radiochemical purity is the percentage of the radionuclide present in the desired chemical form. Radiochemical impurities are detected and quantified following separation of the radioactive chemical species. The most commonly used separation technique is chromatography.

In a nuclear medicine department, many routine procedures will be carried out either by the use of ready-to-administer radiopharmaceuticals from the manufacturer or by the preparation of radiopharmaceuticals through the reconstitution of mass-produced non-radioactive kits, by adding a radionuclide (e.g. sodium pertechnetate[^{99m}Tc], indium[^{111}In] chloride). The manufacture of ready-to-inject radiopharmaceuticals and of non-radioactive kits shall be subject to quality control. It is, therefore, not normally necessary to carry out radiochemical analysis of radiopharmaceuticals immediately prior to patient administration. Failure to maintain the required radiochemical quality may result in poor tissue specificity of the radiopharmaceutical with consequent poor quality results and avoidable irradiation of non-target organs.

Chemical purity and content

Chemical purity refers to the proportion of the preparation which is in the specified chemical form(s) regardless of the presence of radioactivity, and may be determined by normal methods of chemical analysis. In general, chemical impurities in preparations of radiopharmaceuticals are objectionable only if they are toxic or if they modify the physiological processes which are under study. An important aspect of the chemical purity of many non-radioactive cold kits intended to be reconstituted by the addition of sodium pertechnetate[^{99m}Tc] is the oxidation of stannous ions to stannic ions. It is important that the content of stannous ion remains sufficient to ensure the reduction of pertechnetate[^{99m}Tc] and to yield a radiopharmaceutical of high radiochemical purity.

The content of the specified chemical components of the radiopharmaceutical or cold kit shall be within the specified mass limit(s). Chemical content may be determined by quantitative chemical analysis.

pH

The pH of radiopharmaceutical injections and solutions shall be within the specified range.

Specific activity

Specific activity is defined as the radioactivity per unit mass of a particular chemical species taking into account the radioactive and non-radioactive forms of that species (e.g. MBq/mg). Radionuclides produced by nuclear reactions followed by chemical separation are referred to as "carrier free" or "no carrier added", and are of high specific activity. However, the presence of elevated levels of pertechnetate[^{99}Tc] in the sodium pertechnetate[^{99m}Tc] eluted from generators where there has been an extended period since the previous elution may result in the inadequate labelling of sensitive cold kits containing a small quantity of stannous ions.

Control of specific activity is particularly important in exchange radiolabelling e.g. in the labelling of an iodo compound by exchange with ^{123}I or ^{131}I.

Pharmaceutical aspects

All preparations intended for parenteral administration must be tested to ensure that they comply with the pharmacopoeia test for sterility.

A particular responsibility falls upon the manufacturer of such products to validate the sterilization process by all suitable measures, which may include careful and frequent calibration of sterilizers and the use of biological and chemical indicators of the efficiency of the sterilization process.

Because short lived radiopharmaceuticals, including all ^{99m}Tc preparations, cannot be tested prior to administration, emphasis is placed on quality control of the process and procedures. Thus, all operating procedures must be documented and strictly observed, and accurate records must be kept in accordance with the requirements of a quality system. There shall be routine monitoring of the production environment with respect to microbiological, particulate and radioactive contamination. All equipment used in a radiopharmacy shall be subject to routine planned preventive maintenance, and all instruments shall be regularly calibrated.

The manufacturer also bears a particular responsibility to ensure that all substances used in the preparation of such products are of the specified quality and handled in a manner, which ensures that they are free from pyrogens.

All radiopharmaceutical preparations shall have proper package labelling. The label should show:

- the radionuclide and chemical form of the preparation;
- the total activity present;
- the reference time for the activity measurement;
- radiochemical impurity analysis;
- the name and location of the manufacturer;

- the expiry date;
- a number or other indication by which the history of the product may be traced, for example, batch or lot number;
- in the case of solutions, the total volume of the solution; and
- any other specified parameter e.g. the presence or absence of an antimicrobial agent or preservative.

The documentation for a radiopharmacy should cover pharmaceutical, physical and safety aspects. It must include records of starting materials and acceptance tests, stocks of radioactive materials, the production process, the distribution of products and the disposal of radioactive waste. Records are also required for environmental particulate monitoring, radiation monitoring, workstation performance, the calibration of radiation monitors and staff radiation doses.

QUALITY CONTROL OF EQUIPMENT

Quality control of an instrument begins with its selection. The user must decide what functionality and performance are required and these requirements must be checked against the manufacturer's specifications. It should be understood how the performance is going to be assessed, and appropriate radionuclide sources, phantoms and any necessary measuring instruments should be acquired. The supply of spare parts, inclusion of service manuals and provision of maintenance should also be considered, and arrangements made for servicing during the expected lifetime of the equipment.

For many large items of equipment, the siting and installation must be carefully controlled, taking into account such factors as electrical power requirements, background radiation levels, shielding requirements, and environmental constraints, including temperature and humidity.

Perhaps the most critical step towards the maintenance of quality is the carrying out of acceptance tests, preferably before completing payment for the purchase of the instrument. Not only should this ensure that the performance initially meets the required specification, but the results of these tests, duly recorded, will also serve as a reference for future performance comparisons.

For most equipment, it is desirable to define smaller sets of routine tests, falling into two categories: operational tests to be undertaken every time the instrument is used and periodic measurements of performance at appropriate intervals, for example weekly, monthly or quarterly, depending upon the anticipated reliability. Information concerning the quality control of radionuclide activity meters, sample counting system, gamma cameras, PET systems and computer systems is provided below. More detailed information can be found in [9]. A quality control manual should be available for each type of equipment, specifying the methods and frequency of testing.

In spite of the increasing use of computer displays, the final image in diagnostic nuclear medicine is most commonly produced on photographic film. It is essential that appropriate protocols are used for the quality control of the film processor in order to ensure optimum transfer of the image information to the display medium.

Instrument	**Acceptance and reference tests**	**Operational checks**
Radionuclide activity meter	Precision	Reproductibility

	Accuracy Linearity of activity response Geometrical response Background	 Background
Sample counting system	Scaler/timer function Energy calibration Energy resolution Sensitivity Counting precision Linearity of energy response Background Linearity of activity response Geometrical response Preset analyser facilities	 Analyser peak setting Background
Gamma camera including SPECT-system and computer system	PHA window settings Energy resolution Linearity of energy response Intrinsic uniformity System uniformity Intrinsic linearity Intrinsic spatial resolution System spatial resolution Count-rate performance Sensitivity Whole body uniformity Whole body resolution Head shielding leakage Pixel size Computer timing Centre of rotation Tomographic uniformity Tomographic spatial resolution Total SPECT performance	 PHA window settings Uniformity Sensitivity Background Centre of rotation Collimator
Film Processor	Base fog level Speed Sensitivity	Base fog level
PET	Calibration check Uniformity Spatial Resolution (in and out-of-plane) Scatter fraction Sensitivity Count rate losses and randoms Scanner cross calibration Drifts in coincidence timing Drifts in energy thresholds Mechanical movement of detector rings Removable septa positioning Laser alignment Attenuation correction accuracy	Calibration check Normalization Blank scan Scanner cross calibration

	Dead time correction accuracy Scatter correction accuracy Random coincidence correction accuracy

PPENDIX C: EXAMPLE OF STAFFING LEVELS

The following should be considered only as an example:

GUIDELINES FOR THE PROVISION OF PHYSICS SUPPORT TO NUCLEAR MEDICINE

Recommended staffing levels: Core duties only (hours per week).

	Small DGH*	**Medium-sized DGH**	**Large DGH**	**Small TH**	**Large TH**
	1 camera, 1500 investigations mixed	2 cameras 2400 investigations + in vitro + therapy	2 or more cameras, 5000 investigations + in vitro + therapy	2 or more cameras, 5000 ininvestigations + in vitro + therapy	3 or more cameras, 7000-10000 investigations + in vitro + therapy
Equipment management	1.5	2.5	4	4.5	5.5
Diagnostic procedures support	4.5	7.75	14.5	17.5	22.5
Radionuclide therapy support	0	1.75	2.5	2.75	4
Service development	2.25	3.5	5.5	6.75	10
Research support	1.5	2.5	6.75	9	12.25
QA	1.5	2.25	3	3	4
Computer system administration	1.5	2.5	4	6	9
Radiation protection	1.5	2.5	4.5	5	5.5
Management of scientific services	2	3	4	5.5	7
Audit	1	1.75	2	2.5	4
Administration	1.5	2.5	3.5	4.5	7
ARSAC support	0.5	1	1.5	2	2.25
CPD	0.5	1	1.5	2	3
Professional activities	0.5	1	1.5	2	3
Training	1.5	2	3	5	7
Staff meeting	0.5	1	1.5	2	3

	Small DGH*	Medium-sized DGH	Large DGH	Small TH	Large TH
Total hours[a]	22.25	38.5	63.25	80	109
Total sessions[a,b]	6	11	18	23	31

Note: this table excludes non-core duties, funded research and formal teaching and training. Additional staff would be required for these duties.

[a] Additional hours will be required to cover for study and annual leave.

[b] Assuming 3.5 h per session and 10 sessions per week.

*Abbreviations: DGH — district general hospital; TH — teaching hospital; CPD — continuing professional development; ARSAC — administration of radioactive substances advisory committee.

APPENDIX D: TRAINING PROGRAMME FOR RADIATION PROTECTION (IMPLEMENTATION OF THE BSS IN NUCLEAR MEDICINE)

Personnel shall be instructed in radiation protection before assuming duties with, or in the vicinity of, radioactive materials. Annual refresher training should be conducted whenever there is a significant change in duties, regulations, terms of the licence, or type of radioactive material or therapy device used.

The following is a list of broad topics related to radiation protection, safety and quality assurance for professionals in nuclear medicine such as: medical practitioners, medical physicists, RPOs, technologists, nurses and maintenance staff. The degree of detail needed for each of these professionals will necessarily differ. Curricula for training must be developed in consultation with the appropriate professional bodies.

The training should include the following subjects, as applicable to the duties and responsibilities of the individual:

PART 1: BIOLOGICAL EFFECTS OF IONIZING RADIATION

Objective: To become familiar with the mechanisms of different types of biological effects following exposure to ionizing radiation, results of epidemiological studies of exposed population to ionizing radiation. To be aware of the models used to derive risk coefficients for estimating the radiation detriment

Module	Content
I.1 Biological Effects of Ionizing Radiation	Basic concepts on radiobiology Deterministic and stochastic effects Radio sensitivity Factors affecting radiosensitivity Dose-effect response curve
I.2 Epidemiological studies and risk assessment	Whole body response: acute radiation syndrome (BMS, GI and CNS) Effects of antenatal exposure Delayed effects of radiation
	Risks and weighting factors Type of epidemiological studies (retrospective, prospective..)
	Confounding factors/Definition of risk
	Risk perception/Risk estimates /Risk models
	Historical overview of exposed population (in medical field)
	The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR)

PART 2: RADIATION PHYSICS

Objective: To become familiar with the basic knowledge in radiation physics, dosimetric quantities and units to perform related calculations, different types of radiation detectors and their characteristics, their operating principles, and limitations.

Module	Content
2.1 The atomic structure	Atomic basic structure
2.2 Interactions of electrons with matter	Bremsstrahlung production Characteristic X-rays production Primary and secondary ionization Elastic scattering of electrons
2.3 Interactions of photons with matter	Types of interaction Photo-electric effect Compton scattering Photon attenuation Half value thickness Beam attenuation and half value thickness
2.4 Interaction of neutrons with matter	Relevant to cyclotrons, producing ^{8}F, ^{13}N, etc.
2.5 Radiation quantities and Units	Electronic structure Quantities and units Exposure and exposure rate Absorbed dose and KERMA Mean Absorbed Dose in a tissue Equivalent dose H Effective Dose Tissue weighting factors
2.6 Radiation detectors and dosimeters	Basic principles in detection of ionizing radiation (gas filled detectors, scintillation detectors, semiconductor detectors). Personnel dosimetry systems e.g. TLD Types of monitoring instruments Operating principles and limitations Workplace monitoring

PART 3: PRINCIPLES OF RADIATION PROTECTION AND THE INTERNATIONAL FRAMEWORK AND REGULATORY REQUIREMENTS

Objective: To become aware of the ICRP's conceptual framework and the Iinternational Basic Safety Standards requirement (BSS) and related Safety Guides in radiation protection in medical field.

Module	Content
3.1 Principles of radiation protection	International Commission of Radiological Protection Concept and aims of Radiation Protection The framework of Radiation Protection System of Radiation Protection Justification Dose Limitation OptimizationLimitation
3.2 International basic safety standards (the BSS)	Preamble and Principal Requirements Detailed requirements; Occupational, medical and public exposures,Potential exposure, Emergency exposure situation, Chronic exposure
3.3 Regulatory control	Establishment of Regulatory Authority System of notification, authorization, inspection and enforcement Guidelines for implementation of the BSS in nuclear medicine

PART 4. SAFETY OF SOURCES AND DESIGN OF FACILITIES

Objective: To become familiar with the types of sources used in nuclear medicine. To become familiar with international safety regulations for the medical use of radionuclides e.g. pharmacopoeia. To become aware of how the basic principles of defence in depth, safety of sources and optimization are applied to the design of a nuclear medicine facility. To get basic information about shielding calculations.

Module	Content
4.1. Introduction	Principles of safety of sources and security of sources. The concepts of defence in depth and categorization of hazard
4.2. Sources	Relevant international safety standards. Examples of the unsealed and sealed sources used in therapeutic and diagnostic nuclear medicine
4.3. Building requirements	Room design, ventilation, plumbing, washing, toilets, shielding, and safe storage of unsealed sources. Fume hoods. Special requirements in radionuclide therapy wards
4.4. Safety equipment	Shielding of sources and shielding calculations,

PART 5: OCCUPATIONAL PROTECTION (PROTECTION OF THE WORKER)

Objective: To become familiar with the BSS detailed requirement and the Safety Guide on occupational exposures for radiation protection of workers in nuclear medicine

Module	Content
5.1 Responsibilities and conditions of service	Responsibilities of licensees, employers and workers. Special compensatory arrangements, pregnant workers, and conditions for young persons
5.2 Classification of areas	Definition of controlled and supervised areas. Examples of classification of the different rooms in a nuclear medicine department
5.3 Sources of exposure	External and internal exposure. The radioactive patient. Typical dose rates from patients and sources
5.4 Personal protective equipment in NM. Safe handling of sources	Time, distance and shielding. Correct design and use of shields for vials and syringes. Tools for remote handling of sources. Contamination and decontaminaation. Special requirements in the care of hospitalized patients undergoing radionuclide therapy
5.5 Individual and workplace monitoring	Methods of individual monitoring. Instruments for workplace monitoring. Monitoring procedures. Decommissioning of therapy wards.
5.6 Local rules and supervision	Define the procedures and applications that need to be transformed into local rules Example of local rules
5.7 Health surveillance	Design of a health surveillance program for radiation workers.
5.8 Records	Type and content of records to be kept for workers. ILO code of practice regarding records to be kept

PART 6: MEDICAL EXPOSURE

Objective: To become familiar with the BSS detailed requirement and Safety Guide for medical exposure in particular nuclear medicine: responsibilities, justification, optimization, and guidance level, dose constraints, requirements for discharge of therapy patients, investigation of accidental exposure and medical records

Module	Content
6.1 Responsibilities	Define the responsibilities of the referring physician, the nuclear medicine specialist, the medical physicist and the nuclear medicine technologist in accordance with BSS and other IAEA documents
6.2 Justification and optimization	The principle of justification and optimization applied to exposure of the patient and biomedical research
6.3 Guidance level of activity	Presentation and discussion on reference levels of activity Investigation of accidental exposure
6.5 Medical Records	BSS requirements of medical records to be kept

PART 7: OPTIMIZATION OF PROTECTION IN MEDICAL EXPOSURE: DIAGNOSTIC PROCEURES

Objective: To be able to apply the principles of radiation protection including design, operational considerations, calibration, clinical dosimetry and quality control for diagnostic procedures using these major types of equipment: Activity meter, monitoring equipment, probes, scanners, gamma cameras, SPECT-system including coincidence option, and PET.

Module	Content
7.1 Activity meter and calibration of sources	Principles of operation. Operational considerations and quality control. Traceability. Record keeping of administered activity
7.2 Monitoring instruments	Principles of operation. Operational considerations and quality control
7.3 In vivo and in vitro probes and counters	Principles of operation. Operational considerations and quality control
7.4 Equipment for morphological and functional studies	Scanners, gamma cameras, SPECT, PET and coincidence systems: principles of operation. Operational considerations

	and quality control
7.5 Clinical dosimetry	Methods of calculating the absorbed dose to the patient. (See also Part 3 module 3.4)
	Internal dosimetry :MIRD and ICRP concepts on internal dosimetry

PART 8: OPTIMIZATION OF PROTECTION IN MEDICAL EXPOSURE: THERAPEUTIC PROCEURES

Objective: To be able to apply the principle of optimization of radiation protection to therapeutic procedures including design, operational consideration (particular attention to discharge of patients, conception), quality control and clinical dosimetry.

Module	Content
8.1 Radionuclide therapy	Operational consideration, calibration, clinical dosimetry, quality control.
	Instructions to the patient concerning spread of contamination . Minimizing exposure to the family members.
	Conception after therapy
	Requirements for discharge

PART 9: RADIOACTIVE WASTE

Objective: To be aware of the general principles of the handling and the safety of radioactive waste. To be able to identify, store and dispose of the different types of waste generated in a nuclear medicine department.

Module	Content
9.1 Basic requirements	The general principles for the safety of waste as stated in the BSS and related publications from the IAEA
9.2 Types and quantities	Types of waste generated in the hospital. Methods of collection and segregation
9.3 Storage	Storage for decay, facility for interim storage
9.4 Disposal	Identify the different procedures for final disposal of the waste (sewage system, open air, landfills, transport to a national plant for radioactive waste)

PART 10: QUALITY ASSURANCE

Objective: To become familiar with the concepts of Quality Assurance, radiation protection in nuclear medicine and procedures for reviewing and assessing the overall effectiveness of radiation protection

Module	Content
10.1 Definition	Definition of the concept of QA and its application to radiation protection and safety in nuclear medicine
10.2 Organization	Responsibilities and duties
10.3 Administrative routines	Request, scheduling, patient identification and information, diagnostic report. Ordering and receipt of radioactive material. Records. Local rules. Procedure manuals
10.4 Purchase of instruments	General rules for purchase of an instrument (purchase specifications, bid analysis, warranty, vendor selection, acceptance testing)
10.5 Maintenance	The need of preventive maintenance and corrective actions. Organization.
10.6 Education and training	The different professionals needed in a nuclear medicine department and their formal education. Program for continuing education.

PART 12: POTENTIAL EXPOSURE AND EMERGENCY PREPAREDNESS

Objective: To able to identify hazardous situations which can result in accidental exposure and to take the necessary corrective actions. Case studies on accidental exposures and lessons learned.

Module	Content
12.1 Potential exposure	The basic principles of safety assessments in order to identify the potential exposures in the handling and use of unsealed sources for diagnosis and therapy
12.2 Accident prevention	Examples of accidents and incidents and discussion of the actions that should be taken. Lessons learned

PART 13: PROTECTION OF THE GENERAL PUBLIC

Objective: To become aware of the BSS requirements for the protection of public exposure and how these are applied to restrictions in the care of the radioactive patients as well as the design and operation of a nuclear medicine facility

Module	Content
13.1 Dose limits	Dose limits for the general public
13.2 Design considerations	Safe storage, prevent spread of contamination
13.3 The radio-active patient	Release of patients from the hospital. Visiting restrictions. Restricted contact with children and pregnant women.
13.4 Special problems	Handling of radioactive cadavers
13.5 Transportation	Information about the international rules on safe transports. Principles of internal transports.

APPENDIX E: RECOMMENDATIONS FOR CESSATION OF BREAST FEEDING FOLLOWING ADMINISTRATION OF A RADIOPHARMACEUTICAL

Radiopharmaceutical	Administered Activity, MBq (mCi)	Counselling Needed?	Advice
Class A Radiopharmaceuticals			
Ga-67 Citrate	185 (5.0)	Yes	Cessation
Tc-99m DTPA	740 (20)	No	
Tc-99m MAA	148 (4)	Yes	12 hr
Tc-99m Pertechnetate	185 (5)	Yes	4 hr
I-131 NaI	5550 (150)	Yes	Cessation
Class B Radiopharmaceuticals			
Cr-51 EDTA	1.85 (0.05)	No	
Tc-99m DISIDA	300 (8)	No	
Tc-99m glucoheptonate	740 (20)	No	
Tc-99m HAM	300 (8)	No	
Tc-99m MIBI	1110 (30)	No	
Tc-99m MDP	740 (20)	No	
Tc-99m PYP	740 (20)	No	
Tc-99m RBC's in vivo labelling	740 (20)		12 hr

Radiopharmaceutical	Administered Activity, MBq (mCi)	Counselling Needed?	Advice
Tc-99m RBC's in vitro labelling	740 (20)	No	
Tc-99m Sulphur Colloid	**444 (12)**	**No**	
In-111 WBC's	0.5 (18.5)	No	
I-123 NaI	14.8 (0.4)	Yes	Cessation
I-123 OIH	74 (2)	No	
I-123 mIBG	370 (10)	Yes	48 hr
I-125 OIH	0.37 (0.01)	No	
I-131 OIH	11.1 (0.3)	No	
Tl-201	111 (3)	Yes	96 hr

Tc-99m DTPA Aerosol	**37 (1)**	**No**	
Class C Radiopharmaceuticals			
Tc-99m WBC's	185 (5)	Yes	**48 hr**
Tc-99m MAG3	370 (10)	No	
Xe-133 gas		No	

APPENDIX F: TIME RECOMMENDED AVOIDING PREGNANCY FOLLOWING THERAPY WITH RADIONUCLIDES

NUCLIDE & FORM	FOR TREATMENT OF	ALL ACTIVITIES UP TO (MBq)	AVOID PREGNANCY (months)
^{198}Au-colloid	malignant disease	10 000	2
^{131}I-iodide	thyrotoxicosis	800	4
^{131}I-iodide	thyroid cancer	5000	4
^{131}I-MIBG	phaeochromocytoma	5000	4
^{32}P-phosphate	polycythemia, etc.	200	3
^{89}Sr-chloride	bone metastases	150	24
^{90}Y-colloid	arthritic joints	400	0
^{90}Y-colloid	malignancy	4000	1
^{169}Er-colloid	arthritic joints	400	0

Note: Pregnancy should be avoided for the period indicated in column four even when the activity administered was smaller than shown in column three.

APPENDIX G: GUIDANCE LEVELS FOR DIAGNOSTIC PROCEDURES

TABLE III-V. GUIDANCE LEVELS OF ACTIVITY FOR PROCEDURES IN NUCLEAR MEDICINE FOR A TYPICAL ADULT PATIENT

(Adapted from the BSS)

Test Procedure	**Radionuclide**	**Chemical form (a)**	**Maximum usual activity per procedure (b) (MBq)**
Bone			
Bone imaging	^{99m}Tc	Phosphonate and Phosphate compounds	600
Bone imaging by single photon emission computerized tomography (SPECT)	^{99m}Tc	Phosphonate and Phosphate compounds	800
Bone marrow imaging	^{99m}Tc	Labelled colloid	400
Brain			
Brain imaging: blood brain barrier (BBB) permeability (planar)	^{99m}Tc	TcO_4^-	500
	^{c99m}Tc	Diethylenetriaminepenta-acetic acid (DTPA), or glucoheptonate GH	500
Brain imaging: BBB permeability (SPECT)	^{99m}Tc	TcO_4^-	800
	^{99m}Tc	DTPA, or GH	800
Brain Imaging: cerebral blood flow (SPECT)			

	^{99m}Tc	Hexametyl propylene amine oxime (HM-PAO) or ethly cysteinate dimer (ECD)	700
Cisternography	^{111}In	DTPA	40
Lacrimal			
Lacrimal drainage	^{99m}Tc	TcO_4^-	4
	^{99m}Tc	Labelled colloid	4
Thyroid			
Thyroid imaging	^{99m}Tc	TcO_4^-	100

	^{123}I	I^-	20
Total body scan for the visulaization of thyroid metastases (after ablation)	^{131}I	I^-	370
Test Procedure	**Radionuclide**	**Chemical form (a)**	**Maximum usual activity per procedure (b) (MBq)**
Parathyroid imaging	$^{201}T1$	T1 chloride	80
Lung			
Lung ventilation imaging			
	^{99m}Tc	DTPA-aerosol	80
Lung perfusion imaging			
	^{99m}Tc	Human albumin (macroagregates – MAA- or microspheres)	100
Lung perfusion imaging (with venography)	^{99m}Tc	Human albumin (MAA or microspheres)	160
			200
Lung imaging (SPECT)	^{99m}Tc	MAA	200
Liver and spleen			
Liver and spleen imaging	^{99m}Tc	Labelled colloid	80
Functional biliary system imaging	^{99m}Tc	Iminodiacetates and equivalent agents	150
Spleen imaging	^{99m}Tc	Labelled denaturated red	100

		blood cells	
Liver imaging (SPECT)	^{99m}Tc	Labelled colloid	200
Cardiovascular			
First pass blood flow studies	^{99m}Tc	TcO_4^-	800
	^{99m}Tc	DTPA	800
	^{99m}Tc	Macroaggregated globulin 3	400
Blood pool imaging (equilibrium gated imaging)	^{99m}Tc	Labelled red blood cell	800
Cardiac and vascular imaging/probe studies	^{99m}Tc	Labelled red blood cell	800

Test Procedure	**Radionuclide**	**Chemical form (a)**	**Maximum usual activity per procedure (b) (MBq)**
Myocardial imaging of necrotic areas in the acute phase	^{99m}Tc	Phosponate and phosphate compounds	600
Myocardial imaging	^{99m}Tc	compounds that reflects myocardial perfusion	400
	^{201}TI	Tl^{+} chloride	100
Myocardial imaging(SPECT)	^{99m}Tc	compounds that reflects myocardial perfusion	800
Stomach, gastrointestinal tract			
Stomach/salivary gland imaging	^{99m}Tc	TcO_4^-	100
Meckel's diverticulum imaging	^{99m}Tc	TcO_4^-	400
Gastrointestinal bleeding	^{99m}Tc	Labelled colloid	400
	^{99m}Tc	Labelled normal red blood cells	400
Oesophageal transit and reflux	^{99m}Tc	Labelled colloid	40
	^{99m}Tc	Non-absorbable compounds	40
Gastric emptying	^{99m}Tc	Non-absorbable compounds	12
	^{111}In	Non-absorbable compounds	12
	^{113}In^{m}	Non absorbable compounds	12

Kidney, urinary system and adrenals			
Renal imaging:static	^{99m}Tc	Dimercaptosuccinic acid	160
Renal imaging/renography	^{99m}Tc	DTPA, gluconate and glucoheptonate	350
	^{99m}Tc	Macroaggregated globulin 3	100
	^{123}I	O-iodohippurate	20

Test Procedure	Radionuclide	Chemical form (a)	Maximum usual activity per procedure (b) (MBq)
Adrenal imaging	^{75}Se	Selenorcholesterol	8
Miscellaneous			
Tumour or abscess imaging	^{67}Ga	Citrate	300
	^{201}TI	Chloride	100
Tumour imaging	^{99m}Tc	Dimercaptosuccinic acid penta	400
Neuroectodermal tumour imaging	^{123}I	Meta-iodo-benzyl guanidine	400
	^{131}I	Meta-iodo-benzil guanidine	20
Lymph node imaging	^{99m}Tc	Labelled nanocolloid	80
Abscess imaging	^{99m}Tc	Exametazime labelled white cells	400
	^{111}In	Labelled white cells	20
Thrombus imaging	^{111}In	Labelled platelets	20

(a) In some countries, some of the compounds are considered obsolete;

(b) In some countries, the typical values are lower than those indicated in the table.

Note that the maximal usual activity for each procedure can vary according also to the patients' clinical conditions, clinical question, protocol and instrumentation used. For paediatric patients the dosage should be modified according to the age and/or weight .

APPENDIX H: EXAMPLES OF ACCIDENTAL EXPOSURES IN NUCLEAR MEDICINE

Event No. 1: Treatment of the wrong patient because two patients had the same names

A therapeutic dose of 370 MBq of iodine-131 was prescribed to a patient for treatment of hyperthyroidism. The physician who was familiar with the patient was not available and asked another physician to administer the isotope. In arranging for transportation, a porter noted that the patient was listed as being assigned to a bed that she believed was occupied by another patient. The porter asked the nuclear medicine secretary to check the discrepancy. The secretary referred to a list for the patient's name, obtained the bed assignment area from a computer file, and changed the request form. The secretary did not know that there were two patients in the hospital with the same first and last names, one for iodine administration and the other for treatment of a lung disease. Moreover, the secretary did not know that the computer program that generated the patient list did not print (and in fact deleted) duplicate entries: the name of the patient who was to undergo treatment for hyperthyroidism was thus not printed on the list. The physician who administered the dose picked up the request form and the iodine-131 dosage, and went to the nursing station on the floor of the patient with the lung problem. The physician did not inform the nursing staff that he was about to administer a therapeutic dose to one of their patients and went to the patient's room. There, he asked the patient's name and verified the name on the wristband, but did not crosscheck the patient's identification number on the wristband with the number on the request form. The physician completed the request form and returned the patient's folder to the nurses' station.

Within five minutes of the administration of iodine-131, the nurses discovered the error and informed the physician and the radiation protection officer. As a remedy, a dose of 1000 mg of potassium iodide was administered immediately, and three subsequent doses of 1000 mg each, given at 4-hour intervals. The estimated radiation dose to the patient’s thyroid was between 1.2 and 1.4 Gy.

Initiating event

- Incorrect patient identification.

Contributing factors

  - Two patients in the hospital had the same first and last names.
  - Computer software, designed to avoid duplicate entries, deleted the name of one patient.
  - Administration of iodine-131 treatments was not restricted to designated rooms or wards where nursing staff had specialized training.
- Deficient procedures or non-compliance with procedures:
  - The physician did not communicate with the nursing staff at the ward, but went directly to the patient's room to administer the iodine.
  - Hospital protocol for identification of patients was not followed with regard to verifying the patient’s hospital number.

Event No. 2: Iodine-131 treatment of wrong patient

A therapy dose of 333 MBq of iodine-131 was given inadvertently to the wrong patient (patient A instead of patient B). Patient A was to receive 740 MBq of technetium-99m for a diagnostic bone scan; the technetium-99m was administered and the patient was seated in the waiting room. Patient B, who was scheduled to receive an iodine-131 hyperthyroidism treatment, arrived, completed an interview, signed a consent form, and sat in the waiting room pending the iodine treatment. The technologist prepared a dose of 333 MBq of iodine-131 and called patient B; however, patient A responded. The technologist explained the iodine-131 treatment, scheduled a follow-up appointment, and administered the dose to patient A. The patient then questioned the technologist, and it became evident that the wrong patient had been treated. Patient A was immediately informed of the error, and his stomach was pumped, retrieving 118 MBq of the material. The patient was given potassium perchlorate and Lugol's solution to release iodine-131 trapped in the thyroid and to block further uptake. Patient A's dose to the thyroid was estimated at 8.2 Gy.

Initiating event

- Incorrect patient identification.

Contributing factors

- Ineffective communication: a patient responded to another patient's name.
- Non-compliance with procedures: patient identification procedures were not followed.

Event No. 3: Wrong dose of iodine-131

A 60-year-old woman was referred to the nuclear medicine department for thyroid ablation following a thyroidectomy for cancer. The physician prescribed 6475 MBq of iodine-131 to be administered orally.

The hospital received from the distributor the patient's prescribed amount of iodine-131 in one vial, together with a second vial containing 5180 MBq of iodine-131. A technologist assayed both vials and placed them together in a fume hood located in the nuclear pharmacy. Both vials were in their original lead shields with contents correctly labelled.

When the physician was ready to administer the iodine-131, the technologist who had assayed the vials was not available and another technologist went to the pharmacy to obtain the radiopharmaceutical. The administering technologist picked up both vials and, without reviewing the labels, assumed that both vials were required for the proper dose. The technologist did not consider the use of two vials for one administration to be unusual since this was a common occurrence at this facility. After reviewing the dosage record, the physician instructed the technologist to administer the iodine-131. Without reviewing the labels on the containers, the physician assumed that the use of two vials was correct.

The mistake was discovered the next day when the nuclear pharmacist received a request for 925 MBq of iodine-131 and could not find the second vial. The resulting investigation determined that the vial had been used the previous day.

Initiating event

- Two unsealed sources were administered in place of one.

Contributing factors

- Ineffective communication: improper identification of radionuclides, starting with the receipt of the material, through the preparation of doses, to administration.
- Insufficient safety provisions (defence in depth): there was no independent check of the material to be administered.

Event No. 4: Radiopharmacy error

A patient was referred for treatment of Graves' disease with 555 MBq of iodine-131. The radiopharmacist assumed that the dosage to be delivered was 1073 MBq rather than 555 MBq, since a 1073 MBq dose was routinely used for Graves' disease in that hospital. Therefore, he requested a 1073 MBq dose from a commercial radiopharmacy. The dose received was 1058 MBq, labelled as such. When the radiopharmacist logged the dosage into the computer after it had been measured by a dose calibrator, he failed to take note of the dose of 550 MBq in the referring physician's prescription. In addition, the physician who administered the isotope did not check the prescription. As a result, the patient's thyroid received about 319 Gy instead of the intended 167 Gy, an overdose of 91%.

Initiating event

- The wrong source was administered: incorrect activity of iodine-131.

Contributing factors

- Insufficient awareness/alertness: the radiopharmacist assumed that the prescribed dose was the usual dose, without verification.
- Lack of or ineffective procedures, protocols and documentation:
  - The radiopharmacist failed to verify the dose received against that prescribed.
  - The nuclear medicine physician failed to verify the activity before he administered the isotope.

Event No. 5: Confusion regarding activity of iodine-131

A patient was prescribed 370 MBq of iodine-131 for a thyroid treatment. A capsule containing 370 MBq was ordered but the distributor shipped a capsule containing 444 MBq. Personnel receiving the capsule did not note the discrepancy. Prior to administration, the capsule was assayed in a dose calibrator. However, because the technnologist was expecting a reading of 370 MBq, he misread 444 MBq as 370 MBq. The administration of 444 MBq resulted in an overdosage of 20%.

Initiating event

- Incorrect source for patient treatment: the supplier shipped a capsule with an activity higher than had been ordered (i.e. sent with a different calibration date).

Contributing factors

- Lack of or ineffective procedures, protocols and documentation:
  - Hospital staff did not check the activity stated by the supplier against the activity ordered.

- The calibrator scale was misread.

- Insufficient safety provisions (defence in depth): lack of independent verification of dose of iodine-131 against the prescription.

Event No. 6: Dose to ineligible patient

A patient was administered 180 MBq of iodine-131 for a whole-body scan. The scan indicated an unusually high breast uptake of iodine-131 and it was discovered that the patient was a nursing mother. Before administering the dose, both the physician and nuclear medicine technologist failed to confirm that the patient was not breastfeeding. Consequently, the infant received an estimated 300 Gy to the thyroid and 0.17 Gy to the whole body and will require thyroid hormone medication for life to ensure normal growth and development. There was a staff shortage that day.

Initiating event

- A therapy dose of iodine-131 was given to a nursing mother.

Contributing factors

- Insufficient awareness: the technologist was distracted and forgot to ask the patient a standard list of questions.

- There was a staff shortage on the day of administration.

Event No. 7: Radioactive spills from a patient during resuscitation efforts

A therapy dose of 7400 MBq of iodine-131 was administered to an 87-year old patient, in an effort to relieve esophageal compression caused by metastatic thyroid carcinoma. The patient had a gastrostomy tube and a Foley catheter in place. Approximately 34 hours after receiving the dose, the patient had a cardiopulmonary arrest. Sixteen staff members attempted to resuscitate the patient; their efforts included insertion of a pacemaker. Blood and urine contaminated with radioactivity were spilled but the clothing of those present was not checked for activity. Although contamination was extensive, subsequent thyroid bioassays showed no uptakes by involved staff. Monitoring of personnel showed that the highest reading was 0.3 mGy for one of the nurses.

Initiating event

- The patient experienced cardiac failure shortly after thyroid ablation therapy.

Contributing factors

- There were no contingency procedures for emergency situations involving patients with radioactivity.

- There had been no training exercises simulating emergencies.

- Shortage of instruments: radiation monitoring instruments and decontamination utensils were not available.

- Radioactive patient not clearly identified.

Event No. 8: Administration of wrong dose of iodine-131

A patient was to be administered 259 MBq of iodine-131. The isotope was in the form of two capsules, 130 MBq each, which were labelled correctly. Previous doses of this level had been administered in the form of one capsule. When the vial was inverted by the technologist, only one of the two capsules fell out and she assumed that this was the entire dose. Later, when disposing of the vial shield, the technologist discovered the other capsule. As a result, the patient received only 50% of the prescribed dose.

Initiating event

- One of two iodine-131 capsules remained stuck in the vial.

Contributing factors

- Deficiencies in procedures or procedures were not followed:
    - Staff failed to check the vial label to ascertain the number of vials and the prescribed dose.
    - There was no measurement of the vials before and after administering the dose.

APPENDIX I: SUMMARY OF TYPICAL CAUSES AND CONTRIBUTING FACTORS TO ACCIDENTAL EXPOSURE IN NUCLEAR MEDICINE

- Communication errors, transmission of information and misunderstanding of prescription and protocols, or use of obsolete protocols
- Errors in the identification of the patient
- Using the wrong source, the wrong radiopharmaceutical or the wrong activity
- Calibration errors
- Maintenance errors

The following factors may influence the frequency and severity of incidents and accidents:

- Insufficient training and expertise of nuclear medicine physician, medical physicist or nuclear medicine technologist.
- No reassessment of staffing after purchasing new equipment, hiring new technologists or increasing workload.
- Inadequate QA and lack of defence-in-depth
- Lack of a programme for acceptance tests
- Lack of a maintenance programme
- Poor, misunderstood, or violated procedures
- Lack of operating documents in a language understandable to the users
- Misunderstanding of displays or software messages
- Inattention
- Inconsistent use of different quantities and units

In most of the accidents there was a combination of several contributing factors, which can be summarized as:

- Lack of commitment of the licensee (hospital administrators and managers of the departments)
- Staff insufficiently briefed or trained
- Insufficient QA

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GLOSSARY

Absorbed dose

The fundamental dosimetric quantity D, defined as:

$$D = \frac{d\varepsilon}{dm}$$

where is the mean energy imparted by ionizing radiation to matter in a volume element and dm is the mass of matter in the volume element. The energy can be averaged over any defined volume, the average dose being equal to the total energy imparted in the volume divided by the mass in the volume. The SI unit of absorbed dose is the joule per kilogram (J/kg), termed the gray (Gy).

Accident

Any unintended event, including operating errors, equipment failures or other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection or safety.

Applicant

Any legal person who applies to the Regulatory Authority for authorization to undertake any of the actions described in the General Obligations for practices of the Standards (see paras 2.7 and 2.8).

Approved

Approved by the Regulatory Authority. An authority or authorities designated or otherwise recognized by a government for regulatory purposes in connection with protection and safety.

Authorization

A permission granted in a document by the Regulatory Authority to a legal person who has submitted an application to carry out a practice or any other action described in the General Obligations for practices of the Standards (see paras 2.7 and 2.8). The authorization can take the form of a registration or a licence.

Authorized

Granted an authorization by the Regulatory Authority.

Controlled area: A controlled area is any area in which specific protection measures and safety provisions are or could be required for:

(a) controlling normal exposures or preventing the spread of contamination during normal working conditions; and

(b) preventing or limiting the extent of potential exposures.

Dose constraint

A prospective and source related restriction on the individual dose delivered by the source which serves as a bound in the optimization of protection and safety of the source. For occupational exposures, dose constraint is a source related value of individual dose used to limit the range of options considered in the process of optimization. For public exposure, the dose constraint is an upper bound on the annual doses that members of the public should receive from the planned operation of any controlled source. The exposure to which the dose constraint applies is the

annual dose to any critical group, summed over all exposure pathways, arising from the predicted operation of the controlled source. The dose constraint for each source is intended to ensure that the sum of doses to the critical group from all controlled sources remains within the dose limit. For medical exposure the dose constraint levels should be interpreted as guidance levels, except when used in optimizing the protection of persons exposed for medical research purposes or of persons, other than workers, who assist in the care, support or comfort of exposed patients.

Dose limit

The value of the effective dose or the equivalent dose to individuals from controlled practices that shall not be exceeded.

Effective dose

The quantity E, defined as a summation of the tissue equivalent doses, each multiplied by the appropriate tissue weighting factor:

$$E = \sum_T w_T \cdot H_T$$

where H_T is the equivalent dose in tissue T and W_T is the tissue weighting factor for tissue T. From the definition of equivalent dose, it follows that:

$$E = \sum_T w_T \cdot \sum_R w_R . D_{T \cdot R}$$

where W_R is the radiation weighting factor for radiation R and $D_{T,R}$ the average absorbed dose in the organ or tissue T. The unit of effective dose is $J.kg^{-1}$, termed the sievert (Sv).

Emergency plan

A set of procedures to be implemented in the event of an accident.

Employer

A legal person with recognized responsibility, commitment and duties towards a worker in his or her employment by virtue of mutually agreed relationship. (A self-employed person is regarded as being both an employer and a worker).

Ethical review committee

A committee of independent persons to advise on the conditions of exposure and the dose constraints to be applied to the medical exposure of individuals exposed for biomedical research purposes when there is no direct benefit to the exposed individual.

Guidance level for medical exposure

A value of dose, dose rate or activity selected by professional bodies in consultation with the Regulatory Authority to indicate a level above which there should be a review by medical practitioners in order to determine whether or not the value is excessive, taking into account the particular circumstances and applying sound clinical judgement.

Health professional

An individual who has been accredited through appropriate national procedures to practice a profession related to health (e.g., medicine, dentistry, chiropractic, paediatry, nursing, medical physics, radiation and nuclear medical technology, radiopharmacy, occupational health).

Health surveillance

Medical supervision intended to ensure the initial and continuous fitness of workers for their intended task.

Imaging devices

Electronic equipment used for imaging in diagnostic radiology and Nuclear medicine (e.g., image convertors, gamma cameras).

Intervention

Any action intended to reduce or avert exposure or the likelihood of exposure to sources which are not part of a controlled practice or which are out of control as a consequence of an accident.

Legal person

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

Licence

An authorization granted by the Regulatory Authority on the basis of a safety assessment and accompanied by specific requirements and conditions to be complied with by the Licensee.

Licensee

The holder of a current licence granted for a practice or source who has recognized rights and duties for the practice or source, particularly in relation to protection and safety.

Medical exposure

Exposure incurred by patients as part of their own medical or dental diagnosis or treatment; by persons, other than those occupationally exposed, knowingly while voluntarily helping in the support and comfort of patients; and by volunteers in a programme of biomedical research involving their exposure.

Member of the public

In a general sense, any individual in the population except, for the purposes of the BSS, when subject to occupational or medical exposure. For the purpose of verifying compliance with the annual dose limit for public exposure, the representative individual in the relevant critical group.

Monitoring

The measurement of dose or contamination for reasons related to the assessment or control of exposure to radiation or radioactive substances, and the interpretation of the results.

Normal exposure

An exposure which is expected to be received under normal operating conditions of an installation or a source, including possible minor mishaps that can be kept under control.

Notification

A document submitted to the Regulatory Authority by a legal person to notify an intention to carry out a practice or any other action described in the General Obligations for practices of the BSS (see paras. 2.7 and 2.8).

Occupational exposure

All exposures of workers incurred in the course of their work with the exception of exposures excluded from the BSS and exposures from practices or sources exempted by the Standards.

Potential exposure

Exposure that is not expected to be delivered with certainty but that may result from an accident at a source or owing to an event or sequence of events of a probabilistic nature, including equipment failures and operating errors.

Practice

Any human activity that introduces additional sources of exposure or exposure pathways or extends exposure to additional people or modifies the network of exposure pathways from existing sources, so as to increase the exposure or the likelihood of exposure of people or the number of people exposed.

Preparation table

Working plane surface located within the storage room of a design adequate for safe handling of radioactive sources.

Protection and safety

The protection of people against exposure to ionizing radiation or radioactive substances and the safety of radiation sources, including the means for achieving such protection and safety, such as the various procedures and devices for keeping people's doses and risks as low as can reasonably be achieved and below prescribed dose constraints, as well as the means for preventing accidents and for mitigating the consequences of accidents should they occur.

Protective action

An intervention intended to avoid or reduce doses to members of the public in chronic or emergency exposure situations.

Public exposure

Exposure incurred by members of the public from radiation sources, excluding any occupational or medical exposure and the normal local natural background radiation but including exposure from authorized sources and practices and from intervention situations.

Qualified expert in nuclear medicine physics (medical physicist)

An individual who, by virtue of certification by appropriate boards or societies, professional licences or academic qualifications and experience, is duly recognized as having expertise in nuclear medicine physics.

Quality assurance

All those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality.

Radiation protection officer

An individual technically competent in radiation protection matters relevant for a given type of practice who is designated by the registrant or licensee to oversee the application of the requirements of the Standards.

Radioactive waste

Material, whatever its physical form, remaining from practices or interventions and for which no further use is foreseen (i) that contains or is contaminated with radioactive substances and has an activity or activity concentration higher than the level for clearance from regulatory requirements, and (ii) exposure to which is not excluded from the Standards.

Registrant

An applicant who is granted registration of a practice or source and has recognized rights and duties for such a practice or source, particularly in relation to protection and safety.

Reference air kerma rate

The reference air kerma rate of a source is the kerma rate to air, in air, at a reference distance of one metre, corrected for air attenuation and scattering. This quantity is expressed in $mGy.h^{-1}$ at 1 m.

Regulatory Authority

An authority or authorities designated or otherwise recognized by a government for regulatory purposes in connection with protection and safety.

Risk

A multiattribute quantity expressing hazard, danger or chance of harmful or injurious consequences associated with actual or potential exposures. It relates to quantities such as the probability that specific deleterious consequences may arise and the magnitude and character of such consequences.

Sealed source

Radioactive material that is (a) permanently sealed in a capsule or (b) closely bounded and in a solid form. The capsule or material of a sealed source shall be strong enough to maintain leaktightness under the conditions of use and wear for which the source was designed, also under foreseeable mishaps.

Safety assessment

A review of the aspects of design and operation of a source which are relevant to the protection of persons or the safety of the source, including the analysis of the provisions for safety and protection established in the design and operation of the source and the analysis of risks associated with normal conditions and accident situations.

Safety culture

The assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance.

Unsealed source

A source that does not meet the definition of a sealed source.

Source

Anything that may cause radiation exposure, such as by emitting ionizing radiation or releasing radioactive substances or materials. For example, materials emitting radon are sources in the environment, a sterilization gamma irradiation unit is a source for the practice of radiation preservation of food, an X ray unit may be a source for the practice of radiodiagnosis, and a nuclear power plant is a source for the practice of generating electricity by nuclear power. A complex or multiple installation situated at one location or site may as appropriate be considered a single source for the purposes of application of the Standards.

Standards dosimetry laboratory

A laboratory designated by the relevant national authority for the purpose of developing, maintaining or improving primary or secondary standards for radiation dosimetry.

Storage room

Facility designated for lodging, preparation, control and sterilization of radioactive sources.

Supplier

Any legal person to whom a registrant or licensee delegates duties, totally or partially, in relation to the design, manufacture, production or construction of a source. (An importer of a source is considered a supplier of the source.)

Worker

Any person who works, whether full time, part time or temporarily, for an employer and who has recognized rights and duties in relation to occupational radiation protection. (A self-employed person is regarded as having the duties of both an employer and a worker.)

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