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No. 40

Applying Radiation Safety Standards in Nuclear Medicine

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APPLYING
RADIATION SAFETY STANDARDS
IN NUCLEAR MEDICINE

SAFETY REPORTS SERIES No. 40

APPLYING RADIATION SAFETY STANDARDS IN NUCLEAR MEDICINE

JOINTLY SPONSORED BY THE
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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 in similar practices. In this context, the preamble of the BSS states that: “The [regulatory body] 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, while others have developed practice specific regulations. National regulatory guidance is tailored to a country’s own legislation and regulations for obvious reasons. This can lead to problems if the guidance is used in other States without appropriate modification to take local requirements into account. There would appear, therefore, to be scope for producing internationally harmonized guidance, while bearing in mind that the ultimate responsibility for regulatory documents rests with States.

Some regions have taken the initiative of preparing guidance to facilitate the regional harmonization of regulatory control of certain common practices (for example, nuclear medicine). A number of draft regulatory guidance publications for the main practices involving the use of ionizing radiation have already been prepared. In particular, it is felt that countries participating in the IAEA’s technical cooperation model project on Upgrading 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 requirements and needs. This idea led to the development of the present report.

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 in this report are quotations from the BSS, including requirements.

There are certain BSS requirements that, when applied to specific practices, can be fulfilled mainly through one practical solution. In these cases, the regulatory body may need to use a 'should' statement, 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 body would simply mention or describe them.

This guidance is intended for both regulators and users of radiation sources in nuclear medicine. Regulators may use it 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 regulations. 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 report rather than their own national guidance. Working safely is important and contributes to gaining overall confidence and credibility in the practice of nuclear medicine itself.

This report has been prepared by the IAEA with contributions from the International Labour Office, the Pan American Health Organization, the World Health Organization, the World Federation of Nuclear Medicine and Biology, and the International Organization for Medical Physics.

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

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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 ‘Standards’ or 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 Organisation for Economic Co-operation and Development (OECD/NEA), the Pan American Health Organization (PAHO) and the World Health Organization (WHO). The purpose of the Standards is to establish basic requirements for protection against the risks associated with exposure to ionizing radiation and for the safety of radiation sources that may deliver such exposure (hereinafter called ‘radiation safety’). The requirements are based on the principles set out in the Safety Fundamentals publications. The fundamentals on radiation protection are published as IAEA Safety Series No. 120 [2].

The Standards 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.

The 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. In this context, the preamble of the BSS states that:

“The [regulatory body] may need to provide guidance on how certain regulatory requirements are to be fulfilled for various practices, for example in regulatory guideline documents.”

This report provides guidance and does not contain requirements other than those quoted from the BSS, and therefore the only mandatory statements in the ‘shall’ form are those from BSS quotations. Any additional material is in the ‘should’ form or simply in the present tense, the latter indicating a way to comply with the standards.

1.2. OBJECTIVE

The objective of the present safety report is to assist regulatory bodies in preparing regulatory guidance on the proper and consistent application of basic requirements of the BSS, by the legal persons responsible for the nuclear medicine practice. This report will be, therefore, also useful to registrants and licensees in meeting the regulatory requirements. It is one of a series of IAEA Safety Reports. Separate reports have been prepared for diagnostic and interventional radiology [3] and radiotherapy [4].

1.3. SCOPE

This report is applicable to all the established uses of ionizing radiation sources employed in the practice of nuclear medicine, to the facilities where the sources are located and used, and to the individuals involved. The guidance covers occupational, public, medical, and potential and emergency exposure situations.

2. PRINCIPAL REQUIREMENTS

2.1. ADMINISTRATIVE REQUIREMENTS

2.1.1. Authorization of practices

The BSS require that legal persons apply to the regulatory body for an authorization, which should take the form of a registration or a licence. The BSS further clarify 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 an assessment for each facility. Therefore, authorization should take the form of a licence rather than a registration. The process of authorization can be simplified, however, by establishing standardized training programmes, by a relatively standardized quality assurance programme in modular form to take account of different levels of complexity, by providing equipment and sources for each facility, and by establishing a simple mechanism to provide evidence that both training and quality assurance requirements are met.

A nuclear medicine department involves the construction of facilities which are difficult to modify later. Regulatory bodies may choose a two stage process of authorization, i.e. to require the 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 body to obtain an overview of the intended applications and the facility design [5]. Allowance for evolving new procedures should be made, provided that they fit into the shielding and facility design.

Substantial modifications of nuclear medicine facilities, sources and procedures may have safety implications, which need verification of compliance with regulations. The regulatory body 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 licence, as appropriate, has been granted.

2.1.1.1. Renewal of authorization

Regulatory bodies may require that the authorization be renewed periodically. Periods of renewal are based on safety criteria¹. The advantages of a renewal or revalidation approach are described in IAEA-TECDOC-1067 [5] and in Safety Guide GS-G-1.6 [6], 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.

¹ The frequency of revalidation is influenced by several factors, described in IAEA-TECDOC-1067 [5], in view of which a reasonable period for renewal of a nuclear medicine authorization is five years.

Considering these factors, a suitable period for renewal of a nuclear medicine authorization may be of the order of five years. Consultation between the regulatory and health authorities in this respect may be advisable.

2.1.2. Inspection

Basic Safety Standard para. 1.10 requires that the “principal parties shall permit duly authorized representatives of the [regulatory body], ..., to inspect their protection and safety records and to carry out appropriate inspections of their authorized activities.” A sample list of the main items for inspection of nuclear medicine is provided in Appendix I.

2.1.3. Personal accreditation²

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 (for example, nuclear medicine physicians³ and other appropriately trained clinical specialists);
- Medical physicists in nuclear medicine (qualified experts in nuclear medicine physics);

² Regulations in a number of countries require a personal authorization as formal recognition of the holder’s competence.

³ The medical practitioner responsible for using radionuclides for diagnosis or therapy, depending on the objectives of the procedure. He/she decides the course to be followed in the case of each patient in order to best meet the needs specified by the referring physician, taking into account the possibilities associated with the various techniques of diagnosis and treatment with radiopharmaceuticals and the doses involved. The nuclear medicine specialist holds a nationally accepted medical degree, has, in addition, completed a nationally prescribed programme of training in the discipline of radiology and has credentials awarded by a national medical speciality certifying agency.

- Other health professionals involved in the clinical use of radionuclides (for example, radiopharmacists and nuclear medicine technologists⁴);
- Radiation protection officers (RPOs);
- Staff performing special tasks (for example, contamination tests and some quality control tests).

To comply with the above BSS requirements in relation to the above staff, evidence of education and training relevant to their duties in relation to protection and safety should be provided. Training in radiation protection is necessary, but by no means sufficient, to practice in radiotherapy. As a precondition, gaining the qualifications and certification of the profession as such is indispensable. These are usually not defined by radiation protection regulations nor granted by the regulatory body, but by academic institutions and by boards or societies. In the particular case of qualified experts the BSS defines them as:

“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 a relevant field of specialization, e.g. medical physics, ...”.

For nuclear medicine specialists, radiopharmacists, medical physicists, nuclear medicine technologists and RPOs, 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 the accreditation, granted by the competent authorities or other institutions, required in the country to exercise the profession.
- (b) A certificate for a course on radiation protection of which the contents, methodology and teaching institution are recognized or approved by the regulatory body. This course may be integrated into the curricula of the education of professionals under (a) provided that it meets the training criteria specified by the regulatory body.

⁴ Specialized staff responsible, under medical supervision, for the preparation, administration and measurement of radiopharmaceuticals, for ensuring patient identification, providing patient records and helping to ensure radiation protection. Under the supervision of the qualified expert in nuclear medicine physics, such staff carry out basic quality control tests.

- (c) On-the-job training supervised by accredited experienced professionals, as required by national standards, before working without supervision.

Evidence of competence in the 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) Certification for a course on radiation protection of which the contents, methodology and teaching institution are approved by the regulatory body.

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

Courses and syllabi required in professional education and training are generally defined by national departments of health and/or education authorities together with professional bodies. An approach is suitable in which the training criteria for radiation protection for medical exposure, specified by the regulatory body in consultation with the relevant professional bodies⁵ (BSS para. II.1(f)), are incorporated into the professional education and training.

It may be appropriate and convenient for the regulatory body to recognize certain training centres and courses for their quality and suitability in connection with radiation protection requirements. For example, it can identify (a) radiation oncology departments which have been accredited as training centres for the profession (if any) and facilities, (b) syllabi and qualifying bodies that are responsible for training and accreditation in nuclear medicine, and recognize them for training in radiation protection as well. Such recognition can be formally conferred by a process of accreditation based on the training criteria referred to above. The evaluation for accreditation should involve training facilities, teaching staff, contents and methods for training, examination procedures and training records.

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

- Nurses handling patients with therapeutic amounts of radioactivity and nurses in nuclear medicine departments;

⁵ In countries in which a national professional body does not exist, either a regional body or international professional organization may be consulted for advice.

- Maintenance, engineering and cleaning staff working in nuclear medicine laboratories.

2.1.4. Authorization of other practices related to nuclear medicine

Considering that the BSS require that the activities listed below be subject to authorization, regulatory bodies may require the licensee of a nuclear medicine practice to award contracts only to enterprises authorized by the regulatory body for any of the following services:

- Import, distribution, sale or transfer of radioactive sources;
- Installation and maintenance of nuclear medicine equipment;
- Disposal of radioactive materials and waste.

The requirements to carry out these practices 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 International Commission on Radiation Protection (ICRP). These principles are reflected in the following requirements of the BSS:

BSS para. 2.20 (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 para. 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 para. 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 achieved by keeping exposure of normal tissue as low as reasonably achievable consistent with delivering the required dose to the planned target volume (BSS Appendix II).

Table 1 summarizes the principles of radiation protection as applied to occupational and public exposures in comparison with medical exposure.

Dose constraints are used for optimization of protection in the planning stage for each radiation source. Anticipated individual doses should be compared with the appropriate dose constraints, and protective measures chosen with predicted 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 required in Appendix I of the BSS and indicated in Section 4, pregnant workers shall be protected in a way that ensures that the embryo or foetus is afforded the same broad level of protection required for members of the public.

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

2.3. MANAGERIAL REQUIREMENTS

2.3.1. Managerial commitment and policy statement

Basic Safety Standard para. 2.28 establishes that “A safety culture shall be fostered and maintained to encourage a questioning and learning attitude to

TABLE 1. SUMMARY OF RADIATION PROTECTION PRINCIPLES AS APPLIED TO OCCUPATIONAL AND PUBLIC EXPOSURES IN COMPARISON WITH MEDICAL EXPOSURE

Applications in general	Applications to medical exposure
<p><i>Justification of practices:</i> 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.</p>	<p><i>Justification:</i> By weighing the diagnostic or therapeutic benefits produced by exposures against the radiation detriment they might cause, taking into account the benefits and risks of available alternative techniques that do not involve medical exposure.</p>
<p><i>Limitation of doses:</i> Doses to individuals are limited (for occupational and public exposure).</p>	<p><i>Limitation of doses:</i> Not applicable to medical exposure.</p>
<p><i>Optimization of protection:</i> 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, economic and social factors being taken into account.</p>	<p><i>Optimization of protection:</i> In diagnostic medical exposure, keeping the exposure of patients to the minimum necessary to achieve the required diagnostic objective. In therapeutic medical exposure, keeping the exposure of normal tissue as low as reasonably achievable consistent with delivering the required dose to the planned target volume.</p>

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 which, in addition to recognizing 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 implemented by establishing a quality assurance programme that provides for compliance with radiation protection requirements and fosters safety culture in the hospital.

TABLE 2. SUMMARY OF INDIVIDUAL DOSE LIMITS^a

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

^a See BSS Schedule II.

^b The equivalent dose limits for the skin apply to the average dose over 1 cm² 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.

2.3.2. Organization and responsibilities

Basic Safety Standard paras 1.6 and 1.7 establish that:

“The principal parties having the main responsibilities for the application of the Standards shall be:

- (a) registrants or licensees; and
- (b) employers.

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

- (a) suppliers;
- (b) workers;
- (c) radiation protection officers;
- (d) medical practitioners;
- (e) health professionals;
- (f) qualified experts;
- (g) Ethical Review Committees; and
- (h) any other party to whom a principal party has delegated specific responsibilities.”

Basic Safety Standard para. 1.9 also establishes 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”.

For the programme to be effective, the licensee needs to provide for its implementation, including the resources necessary to comply with this programme and arrangements to facilitate cooperation between all relevant parties.

An effective way to supervise compliance with the programme is the appointment of a committee for radiation protection. 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 members of the radiation safety committee should include an administrator representing the management, the chief nuclear medicine physician, a qualified expert in nuclear medicine physics (medical physicist), the RPO, a nuclear medicine technologist, possibly a nurse for patients undergoing therapy with radiopharmaceuticals and a maintenance engineer. A suggested list of items for the programme is given in Appendix I.

For the day-to-day oversight of the radiation protection programme an RPO, who should report to the committee, is necessary. The licensee should provide the PRO with the time and resources required to supervise the programme, and with the authority to communicate not only periodically with

the committee but also, in case of breaches of compliance which may compromise safety, with the licensee.

According to the BSS requirements for medical exposure (Section 5), the imaging and quality assurance activities should be performed with the advice of a qualified expert in nuclear medicine physics; suitable persons need to be appointed on a part-time or a full-time basis as required, depending on the size of the nuclear medicine department. The tasks of the qualified experts involve participation in the preparation of technical purchase specifications, performance of acceptance tests, quality control, participation in the radiation safety and quality assurance committee and optimization of protection, which should include patient dosimetry.

2.3.3. Quality assurance

The International Organization for Standardization (ISO) 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 implies the optimum quality of the entire process [7], 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.”

Basic Safety Standard para. 2.29 requires the licensee to have quality assurance programmes that provide “adequate assurance that the specified requirements relating to protection and safety are satisfied” and “quality control mechanisms and procedures for reviewing and assessing the overall effectiveness of protection and safety measures.”

It is a common and growing practice that hospitals implement a quality assurance system for the entire medical care throughout diagnosis and treatment, i.e. covering the overall nuclear medicine practice. This system involves a quality assurance committee. The radiation safety and 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 the membership 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 that direct reporting to management is ensured. An effective quality assurance programme requires 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 quality assurance. One important aspect of any quality assurance programme is continuous quality improvement. This 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 quality assurance 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 continuous quality improvement.

Quality assurance should cover:

- The prescription of the procedure by the medical practitioner and its documentation (supervising if there is any error or contraindication),
- Appointments and patient information,
- Clinical dosimetry,
- Optimization of examination protocol,
- Record keeping and report writing,
- Quality control of radiopharmaceuticals and radionuclide generators,
- Acceptance and commissioning,
- Quality control of equipment and software,
- Waste management procedures,
- Training and continuing education of staff,
- Clinical audit,
- General outcome of the nuclear medicine service.

The WHO has published guidelines on quality assurance in nuclear medicine [8], covering the organization of services, the training of personnel, the selection of procedures, quality control requirements for instrumentation and radiopharmaceuticals, as well as the interpretation and evaluation of results. Quality control of nuclear medicine instruments has been described by the IAEA for recommended schedules [9, 10].

2.3.4. Human factors

Basic Safety Standard para. 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 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 judgment and according to defined procedures.”

2.3.4.1. Staffing

To comply with requirement BSS para. 2.30 indicated above, the licensee has to appoint a number of professionals, with personal accreditation for the tasks described in Section 2.1.2, sufficient to ensure that all activities relevant to protection and safety are carried out in accordance with regulations and the radiation protection programme. Each of these professionals should possess a recognized form of accreditation (Section 2.1.2), sufficient to ensure that all activities relevant to quality assurance, radiation protection and safety are undertaken in accordance with the BSS. Resources should be reviewed as workload increases or as new techniques and new equipment are incorporated into the facility. In Ref. [8], the WHO emphasizes the importance of staffing for patient safety and quality of diagnosis, and Ref. [11] elaborates on the importance of having support by qualified experts in nuclear medicine physics and provides advice on the appropriate support needed for all nuclear medicine facilities, regardless of their size.

2.3.4.2. Education and training

A number of requirements in the BSS refer to the availability of qualified personnel; BSS para. 2.14 establishes that:

“The legal person responsible for a source to be used for medical exposure shall include in the application for authorization:

- (a) the qualifications in radiation protection of the medical practitioners who are to be so designated by name in the registration or licence; or

- (b) a statement that only medical practitioners with the qualifications in radiation protection specified in the relevant regulations or to be specified in the registration or licence will be permitted to prescribe medical exposure by means of the authorized source.”

Basic Safety Standard para. 2.31 requires that “Qualified experts shall be identified and made available” and, in particular, BSS para. II.2 requires that “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 nuclear medicine physics”, and BSS para. II.1(c) requires that “medical and paramedical personnel be available as needed, and either be health professionals or have appropriate training adequately to discharge assigned tasks.”

To comply with these requirements, the licensee 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 compiled in an accessible manual;
- Reviews and analyses of incidents and accidents that have occurred in the institution or are documented from elsewhere;
- Instructions provided to patients and caregivers.

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

A typical list of topics for this training is given in Appendix III. The licensee should establish a policy that encourages and provides a 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 accreditation, the following staff need 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,
- Staff who transport radioactive materials within the institution.

Registrants and licensees need to keep documentation about the initial and periodic instruction of personnel as part of the records. These records should be kept for at least five years after the expiry of the corresponding authorization.

3. SAFETY OF RADIOACTIVE MATERIALS, EQUIPMENT AND FACILITIES

Defence in depth is a safety approach, the purpose of which is that 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.”

Major parts of the design and operating advice of this section are adapted from Ref. [11].

3.1. DESIGN

The BSS (paras II.11 and II.12) establish, with regard to the 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 [13–17] for:

- Radionuclide purity;
- Specific activity;
- Radiochemical purity (Appendix III);
- Chemical purity;

– Pharmaceutical aspects: toxicity, sterility and pyrogenicity.

Registrants and licensees should store, handle and use materials in a safe manner in accordance with the 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. Equipment

Unlike diagnostic radiology and radiotherapy, nuclear medicine technology, with the exception of cyclotrons for positron emission tomography (PET) and generators for therapy nuclides, does not incorporate equipment that generates ionizing radiation. Nevertheless, adherence to International Electrotechnical Commission (IEC) standards or nationally recognized equivalent standards for gamma cameras, activity meters and other nuclear medicine equipment should be required, since equipment has an influence on the activity to be administered to the patient in order to obtain the desired diagnosis or treatment [18, 19].

For PET installations, which operate a cyclotron for radionuclide production, the regulatory body should require that the registrant or licensee complies with the guidelines for preparation and control of radiopharmaceuticals in hospitals. As the cyclotrons are not directly involved in the exposure of the patient, they do not need to meet the standards for radiation generators and irradiation installations used for medical diagnosis and treatment. However, the regulatory body should require that the registrant or licensee follow safety standards for cyclotrons similar to those used in the industrial production of radionuclides.

Activity meters used to measure the amount of activity of a radiopharmaceutical to be administered to the patient, for both diagnostic tests and therapeutic purposes, should be designed in such a way that they exhibit the performance required for that purpose, and that the effect of background radiation on the instruments be minimized [18].

3.1.3. Facilities

A typical nuclear medicine department requires the following areas: a source storage and preparation (radiopharmacy) area, an area for radiopharmaceutical administration to patients, waiting areas, imaging areas (in

vivo), sample measurement (in vitro) areas, changing areas and toilets, radioactive waste storage, disposal and decontamination areas, and patient wards for therapeutic treatments with unsealed radionuclides. In addition, there are areas in which radioactive materials are not expected to be found, such as office and reporting areas, and staff rooms, including cloakrooms, showers and toilets.

The issues to be considered for design are: optimize the exposure to external radiation and contamination, maintain low radiation background levels to avoid interference with imaging equipment, meet pharmaceutical requirements, and ensure safety and security of sources (locking and control of access).

The shielding should be designed using the principles of optimization of protection and taking into consideration the classification of the areas within it (Section 4.4), the type of work to be done and the radionuclides (and their activity) intended to be used. It is convenient to shield the source, where possible, rather than the room or the person. Structural shielding is in general not necessary for most of the areas of a nuclear medicine department. However, the need for wall shielding should be assessed, for example in the design of a therapy ward (to protect other patients and staff) and in the design of rooms housing sensitive instruments (to keep a low background in, for example, well counters and gamma cameras).

A secure and shielded storage for radioactive substances should be provided. This may be a room or separate space outside the work area or it may be a locked cupboard or safe, or a locked refrigerator, freeze or safe situated in the work area. Separate radiopharmaceutical storage compartments and an area for temporary storage of radioactive waste should be provided with appropriate protection.

Special consideration should be given to avoiding interference with work in adjoining areas, such as imaging or counting procedures, or where fogging of films stored nearby can occur. Imaging rooms are usually not controlled areas.

Areas where radioactive substances are handled, such as the source preparation area, should have [12]:

- (a) Means to prevent access by unauthorized persons;
- (b) Adequate storage space for equipment used in the laboratory to be available at all times, to minimize the potential for spreading contamination to other areas;
- (c) A contained workstation for easy decontamination;
- (d) Shielded storage for radioactive substances;
- (e) Shielded temporary storage for solid radioactive waste and places designated for the disposal of liquid radioactive waste, directly connected to the main sewer;

- (f) Shielding to protect workers where significant external exposure may occur; a wash-up area for contaminated articles, such as glassware;
- (g) An entry area where protective clothing can be put on, taken off and kept when not in use, and where washing and contamination monitoring can be performed.

The wash-up sink should be located in a low traffic area adjacent to the work area. Taps should be operable without direct hand contact and disposable towels or a hot air dryer should be available. An emergency eyewash should be installed near the hand washing sink and there should be access to an emergency shower for decontamination of persons in or near the laboratory.

Drainpipes from the radioisotope laboratory sink should go as directly as possible to the main building sewer and should not connect with other drains within the building, unless those other drains also carry radioactive material. This is to minimize the possibility of a 'backup' contaminating other, non-controlled, areas. The final plans of the drainage system, which are supplied to maintenance personnel, should show which drains are from radioisotope laboratories. Pipelines through which radioactive materials flow should be marked to ensure that monitoring precedes any maintenance.

Some countries require that drainpipes from the nuclear medicine department and especially from isolation wards for patients undergoing radionuclide therapy terminate in a delay tank. Requirements on this issue differ very much among countries. The ICRP has set up a working group to harmonize recommendations, which may in future influence international and national standards (see Section 6 on criteria for clearance for waste disposal of non-radioactive substances, and IAEA-TECDOC-1000 [19] about the methodology for estimating public exposure).

The floors of areas with the potential for contamination should be finished in an impermeable material which is washable and resistant to chemical change, curved to the walls, with all joints sealed and glued to the floor. The walls should be finished in a smooth and washable surface, for example painted with washable, non-porous paint. A sign such as that recommended by the ISO [21] should be posted on doors as an indicator of radiation. The surfaces of the room where radionuclides are used or stored, such as benches, tables and seats, should be smooth and non-absorbent, so that they can be cleaned and decontaminated easily. Supplies (for example, gas, electricity and vacuum equipment) should not be mounted on bench tops, but on walls or stands.

The floor and benches, including worktops, should be strong enough to support the weight of any necessary shielding materials or of radionuclide

generators. The need for lifting equipment for radionuclide generators should be assessed.

Laboratories in which radioactive aerosols or gases may be produced or handled should have an appropriate ventilation system that includes a fume hood, laminar air flow cabinet or glovebox. The fume hood should be constructed of material that is smooth, impervious, washable and resistant to chemicals. The working surface should have a slightly raised lip to contain any spills. The ventilation system should be designed such that the laboratory is at negative pressure relative to surrounding areas.

The airflow should be from areas of minimal likelihood of airborne contamination to areas where such contamination is likely. All air from the laboratory should be vented through a fume hood and should not be recirculated either directly, in combination with incoming fresh air in a mixing system, or indirectly, as a result of proximity of the exhaust to a fresh air intake. For reasons of asepsis, some radiopharmacies may require a positive rather than a negative pressure. In this case, the pressure gradient can be obtained by placing other workstations requiring negative pressure next to the radiopharmacy workstation.

Control of access is required to source storage and preparation areas and to rooms for hospitalized patients undergoing radionuclide therapy (Section 6.2). A separate toilet room for the exclusive use of therapy patients is recommended. A sign requesting patients to flush the toilet well and wash their hands should be displayed to ensure adequate dilution of excreted radioactive materials and minimize contamination. The facilities shall include a wash-up sink as a normal hygiene measure. Washrooms designated for use by nuclear medicine patients should be finished in materials that are easily decontaminated. Hospital staff should not use the patient washing facilities, as it is likely that the floors, toilet seats and sink tap handles will frequently be contaminated.

A radionuclide activity meter and equipment for workplace monitoring including contamination monitoring should be available. 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.

3.1.4. Therapeutic treatment and wards

Rooms for high activity patients should have separate toilet and washing facilities. The design of safe and comfortable accommodation for visitors is important. Floors and other surfaces should be covered with smooth, continuous and non-absorbent surfaces that can be easily cleaned and decontaminated. Shielding should be designed using source related source constraints for the staff and public. Secure areas should be provided with bins for the temporary storage of linen and waste contaminated with radioactive substances. Storage areas should be clearly marked, using the radiation sign.

3.1.5. Ancillary and protective equipment, tools and clothing

Laboratories and other work areas for manipulation of unsealed radioactive substances should be provided with equipment kept specifically for this purpose, which should include:

- (a) Tools for maximizing the distance from the source, for example tongs and forceps;
- (b) Shielded syringes;
- (c) Containers for radioactive substances, with shielding as close as possible to the source;
- (d) Double walled containers (the outer being unbreakable) for liquid samples;
- (e) Drip trays for minimizing the spread of contamination in the case of spillage;
- (f) Disposable tip automatic pipettes (alternatively, hypodermic syringes to replace pipettes);
- (g) Lead walls or castles for shielding;
- (h) Lead barriers with lead glass windows;
- (i) Barriers incorporating Perspex for work with beta emitters;
- (j) Radiation and contamination monitoring equipment;
- (k) Carrying containers, wheeled if necessary, for moving radioactive substances from place to place;
- (l) Equipment to deal with spills.

Protective clothing should be used in work areas where there is a likelihood of contamination, such as radiopharmaceutical preparation areas. The clothing serves both to protect the body of the wearer and to help to prevent the transfer of contamination to other areas. The clothing should be monitored and removed before leaving designated areas; however, when

moving between supervised areas such as the camera room and the injection area, it may not be necessary to change the protective clothing unless a spill is suspected. Protective clothing should be removed prior to going to other areas such as staff rooms. The protective clothing may include laboratory gowns, waterproof gloves, overshoes, and caps and masks for aseptic work. When beta emitters are handled, the gloves should be thick enough to protect against external beta radiation.

3.2. OPERATING PROCEDURES

Work procedures should be formulated so as to minimize exposure from external radiation and contamination, to prevent spillage from occurring and, in the event of spillage, to minimize the spread of contamination. All manipulation for dispensing radioactive materials should be carried out over a drip tray, in order to minimize the spread of contamination due to breakages or spills.

No food or drink, cosmetic or smoking materials, crockery or cutlery should be brought into an area where unsealed radioactive substances are used. They should not be stored in a refrigerator used for unsealed radioactive substances. Handkerchiefs should never be used in these areas; an adequate supply of paper tissues should be provided. Before a person enters an area where radioactive substances are handled, any cut or break in the skin should be covered. Dressings should incorporate a waterproof adhesive strapping.

When an area is classified as controlled on account of the potential for contamination, anyone working in or visiting the area should wear protective clothing identified as necessary in a prior risk assessment. Protective clothing is unlikely to be necessary for persons accompanying patients into gamma camera rooms. On leaving the controlled area, protective clothing should be monitored and placed in an appropriate container. The method of removing gloves should be based on the surgical technique, in order to avoid transferring activity to the hands.

Staff leaving a controlled area, classified as such on account of the potential for contamination, should, after removal of their protective clothing, wash their hands and then monitor their hands, clothing and body. Mild liquid soap should be provided unless aseptic considerations require an alternative cleaner. Non-abrasive nail brushes should only be used if contamination persists after simple washing.

Pipettes should never be operated by mouth. Syringes used for handling radioactive liquids should be shielded wherever practicable. The distance

between the fingers and the radioactive substance should be as large as can be achieved.

The work area should be kept tidy and free from articles not required for work. It should be monitored periodically and be cleaned often enough to ensure minimal contamination. Cleaning and decontamination should be simplified by covering benches and drip trays with disposable material such as plastic backed absorbent paper.

Shielding close to the sources should be preferred, and appropriate shielding should be considered for any radioactive source. A variety of materials can be used for this purpose, such as lead, lead glass and lead composite. Shielding incorporating acrylic is more suitable for beta emitters, as it lowers the amount of bremsstrahlung produced. Lead should be painted to provide a cleanable surface.

A question frequently asked is whether lead aprons are useful for nuclear medicine work. Most of the exposure comes from ^{99m}Tc , which emits 140 keV gamma rays. The attenuation of a lead apron at this energy is modest. In some hospitals where 0.35–0.5 mm thick lead aprons are used, it has been found that the readings of personal dosimeters are reduced by a factor of about 2, compared with an attenuation of about 20–50 or even higher for the photon energies found in diagnostic radiology. It is therefore a matter of judgment whether this dose reduction compensates for the effort of wearing an apron. In some hospitals in Sweden, for example, lead aprons are used in the case of prolonged injections and high activity [22]. The following protective approaches can reduce occupational exposure significantly:

- (a) For preparation and dispensing of radiopharmaceuticals, working behind a lead glass bench shield, and using shield vials and syringes;
- (b) For administration of radiopharmaceuticals to patients, using lead aprons in the case of prolonged injection and high activity, and using a syringe shield;
- (c) During examinations, when the distance to the patient is short, using a movable transparent shield.

Radioactive substances should be clearly labelled, indicating the radionuclide, chemical form and activity at a given date and time. Batch number and expiry date and time should be added as appropriate. Records of stocks, administrations and disposals should be kept.

3.2.1. Specific operating procedures in therapy wards

Ward nurses should be informed when a patient may pose a radioactive hazard, and advice and training should be provided. The training should include radiation protection and specific local rules, in particular, for situations where there is a risk of significant contamination from, for example, urine, faeces or vomiting. Appropriate training should also be given to night staff.

In the case of high activity patients, only essential nursing should be carried out. Other nursing should be postponed for as long as possible after administration, to take full advantage of the reduction of activity by decay and excretion. Also, there should be minimum handling of contaminated bed linen, clothing, towels, crockery, etc. during the initial period and the instructions on how long these precautions should be maintained should be documented.

Rooms with radiotherapy patients should be controlled areas, and both a radiation sign and a warning sign should be posted. The nursing staff should be familiar with the implications of the procedure, the time and date of administration, and any relevant instructions to visitors.

Values of ambient dose equivalent at suitable distances should be determined. This information will assist in deriving appropriate arrangements for entry by visitors and staff. These arrangements should be made in writing in the local rules.

Visitors comforting patients are not subject to dose limits, but all other visitors are members of the public for radiation protection purposes. Procedures for identifying and advising possibly pregnant visitors and comforters should be in place in consultation with the RPO. Visitors should be informed of the necessary safety precautions to be taken when entering the room of a patient treated with unsealed radioactive sources.

Persons working with unsealed sources or nursing high activity patients should wash their hands before leaving the work area. Patients treated with high activity should use designated toilets. Simple precautions such as laying plastic backed absorbent paper on the floor around the toilet bowl and instructions to flush the toilet twice after each use will help to minimize exposure to external radiation and contamination.

Particular attention and measures to limit spread of contamination are required in the case of incontinent patients and, in cases of oral administration, if there are reasons for believing that the patient may vomit. Contaminated bedding and clothing should be changed promptly and retained for monitoring.

Crockery and cutlery may become contaminated. Local rules should specify washing up and segregation procedures, except for disposable crockery and cutlery.

If the medical condition of a patient deteriorates such that intensive nursing care becomes necessary, the advice of the RPO should be sought immediately. While urgent medical care is a priority and should not be delayed, it may be necessary to restrict the maximum time that individual health professionals should spend with a patient.

Female patients should be advised that breast feeding is contraindicated after therapeutic administration of radionuclides, and females as well as males should be advised concerning the avoidance of conception after therapeutic administrations.

Precautions may be required after the death of a patient to whom radioactive substances have been administered, for autopsy, embalming, burial or cremation. These precautions should be determined by the RPO, based on a generic safety assessment of the need for monitoring personal who carry out these procedures, the need for monitoring the premises and the need for minimizing external radiation exposure and the potential for contamination. In addition to whole body monitoring, finger monitoring may be required for autopsy and embalming personnel, as contamination and radioactive waste are likely to be generated.

3.2.2. Decontamination of persons

Hands should be washed if contamination is suspected, on completing work with unsealed radioactive substances and on leaving an area that is controlled, due to the potential for contamination. If detectable contamination remains on the hands after simple washing, use of a surfactant or chelating agent specific to the chemical form of the contamination may be more successful.

The RPO should be consulted when contamination of parts of the body other than the hands is suspected, or when the procedures for decontamination of the hands are ineffective. Special care needs to be taken in the decontamination of the face to restrict entry of radioactive material into the eyes, nose or mouth.

If the skin is broken or a wound is sustained under conditions where there is a risk of radioactive contamination, the injury should be irrigated with water as soon as appropriate, taking care not to wash contamination into the wound. As soon as the first aid measures have been taken, the person should seek further treatment, including decontamination if necessary.

Contaminated clothing should be removed as soon as practicable, taking care not to spread contamination.

All staff working with unsealed sources should be trained in the procedures for dealing with accidents, spills or contaminated persons, with refresher training at appropriate intervals.

3.3. 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 coordination with the manufacturer's representative before initiating operations.

All maintenance procedures should be included in the quality assurance programme at the 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 parts replaced and adjustments made, which should be filed as part of the quality assurance programme. A record of maintenance carried out should be kept for each item of equipment: this should include information on any defects found by users (a fault log), remedial actions taken (both interim and subsequent repairs) and the results of testing before equipment is reintroduced to clinical use.

After any modifications or maintenance, the person responsible for maintenance should immediately inform the person responsible for use of the equipment before it is returned to clinical use. The latter should decide whether further quality control tests are needed with regard to image quality and whether alterations of protocols are involved, especially in the amount of administered activity. The advice of a qualified expert in nuclear medicine physics may be required.

3.3.1. 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 specifications 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 quality assurance programme.

3.4. SECURITY OF SOURCES

Basic Safety Standard para. 2.34 requires that:

“Sources shall be kept secure so as to prevent theft or damage and to prevent any unauthorized legal person⁶ from carrying out any of the actions specified in ..., by ensuring that:

- (a) control of a source not be relinquished without compliance with all relevant requirements specified in the registration or licence and without immediate communication to the [regulatory body], ..., of information regarding any decontrolled, lost, stolen or missing source;
- (b) a source not be transferred unless the receiver possesses a valid authorization; and
- (c) a periodic inventory of movable sources be conducted at appropriate intervals to confirm that they are in their assigned locations and are secure.”

The objective of source security is to ensure continuity in the control and accountability of each source at all times in order to meet the requirement in BBS para. 2.34. Specific provisions are required for avoiding loss of control in the following situations (see Appendix III to this report, on accidents caused by failure to do so):

- Receipt,
- Storage,
- Movement inside the hospital,
- Storage of radioactive waste.

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 of radioactive materials or entrance of unauthorized personnel to the controlled areas. Procedures to stimulate proactive behaviour should be in

⁶ A legal person is defined in the BSS as “Any organization, corporation, partnership, firm, association, trust, estate, public or private institution, group, political or administrative entity or other persons designated in accordance with national legislation, who or which has responsibility and authority for any action taken under these Standards”.

writing, for example, to trigger a search when a delivery of radiopharmaceuticals is not received at the expected time.

4. OCCUPATIONAL EXPOSURE

Detailed requirements for protection against occupational exposure are given in the BSS, and recommendations on how to meet these requirements are given in the Safety Guidance on Occupational Radiation Protection, RS-G-1.1, 1.2 and 1.3 [23–25], which apply to nuclear medicine practice. In this section, a summary of the requirements most relevant to nuclear medicine is given.

4.1. RESPONSIBILITIES AND CONDITIONS OF SERVICE

The BSS require that:

“I.1. Registrants and licensees and employers of workers who are engaged in activities involving normal exposures or potential exposure shall be responsible for:

- (a) the protection of workers from occupational exposure; and
- (b) compliance with any other relevant requirements of the Standards.

“I.2. Employers who are also registrants or licensees shall have the responsibilities of both employers and registrants or licensees.”

The parties responsible for occupational exposure are, therefore, not only registrants and licensees but also employers. Registrants and licensees and employers of workers are responsible for ensuring that exposure is limited, that protection and safety are optimized and that appropriate radiological protection programmes are set up and implemented [23]. The BSS (para. I.9) further require that “Employers, registrants and licensees shall facilitate compliance by workers with the requirements of the Standards.”

The BSS (para. I.10) also establish the subsidiary responsibilities of workers:

“Workers shall:

- (a) follow any applicable rules and procedures for protection and safety specified by the employer, registrant or licensee;
- (b) use properly the monitoring devices and the protective equipment and clothing provided;
- (c) cooperate with the employer, registrant or licensee with respect to protection and safety and the operation of radiological health surveillance and dose assessment programmes;
- (d) provide to the employer, registrant or licensee such information on their past and current work as is relevant to ensure effective and comprehensive protection and safety for themselves and others;
- (e) abstain from any wilful action that could put themselves or others in situations that contravene the requirements of the Standards; and
- (f) accept such information, instruction and training concerning protection and safety as will enable them to conduct their work in accordance with the requirements of the Standards.”

Workers are also responsible for providing feedback to the management⁷. The BSS (para. I.11) require that “If for any reason a worker is able to identify circumstances that could adversely affect compliance with the Standards, the worker shall as soon as feasible report such circumstances to the employer, registrant or licensee” and also prescribe (para. I.12) that management “shall record any report received from a worker that identifies circumstances which could affect compliance with the Standards, and shall take appropriate action.”

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 for nuclear medicine equipment (‘itinerant workers’) may be the maintenance company, while maintenance engineers work in many nuclear medicine departments, each one under a different licensee. There is a need for cooperation between the employers, workers and managements of hospitals.

The BSS (para. I.30) require that:

“If workers are engaged in work that involves or could involve a source that is not under the control of their employer, the registrant or

⁷ The responsibilities are placed on the management of the organizations of registrants, licensees or employers. For simplicity, Safety Guide RS-R-1.1 uses the term ‘management’ to denote registrants, licensees or employers.

licensee responsible for the source and the employer shall cooperate by the exchange of information and otherwise as necessary to facilitate proper protective measures and safety provisions.”

The organizational structure should reflect the assignment of responsibilities and the commitment of the organization to protection and safety. The management structure should facilitate cooperation between the various individuals involved. The radiation protection programme should be designated in such a way that the relevant information is provided to the individuals in charge of the various aspects of the work [23].

A self-employed person is regarded as having the duties of both an employer and a worker, as specified in the BSS definition of ‘worker’ (see definitions). This situation is very much applicable to nuclear medicine, because in some private nuclear medicine departments the head of the department is self-employed and can be an occupationally exposed worker.

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 only protective measures that predict doses below dose constraints should be chosen. 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.”

Dose constraints are not intended to be applied retrospectively to check compliance with protection requirements, but to assess individual doses at the design and planning stages. Since dose constraints are source related, it is necessary to specify the source to which they relate, for example 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 may be exposed to sources from two nuclear medicine departments (for example in one hospital in the morning and in another hospital in the evening). Further discussion of dose constraints can be found in paras 4.17–4.21 of Ref. [23].

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.”

The limitation of the dose to the conceptus does not mean that it is necessary for pregnant women to avoid work with radiation, but it does imply that the employer has to carefully review the exposure conditions with regard to both normal exposure and potential exposure. For example, ICRP Publication 84 [26] suggests that a pregnant worker “can be restricted from spending a lot of time in the radiopharmacy or working with solutions of radioiodine”. With regard to the exposure assessment of the foetus from external radiation, ICRP Publication 84 further indicates that foetal doses are not likely to exceed 25% of the personal dosimeter measurement. This value depends on the penetration of the radiation, i.e. on the photon energy of the radionuclides in use. The energy of the photon emitted in the decay of ^{99m}Tc is 140 keV, while that of the primary photon emitted from ^{131}I is higher (364 keV).

Special consideration should be given to assigning a pregnant woman duties in which accidents are very unlikely and avoiding her intervention in an emergency, such as those described in Section 7 and Appendices VII and VIII (for example, in relation to an incident with a radioactive spill from a patient). Counselling for pregnant workers should be available as indicated in Section 4.11.

4.4. CLASSIFICATION OF AREAS

Relevant areas of a practice can be classified as controlled or supervised (BSS paras I.21–I.25). A controlled area is any area “in which specific protection measures or safety provisions are or could be required for: (a) controlling normal exposures ... and (b) preventing or limiting the extent of potential exposures.” Controlled areas are typically the rooms for storage,

preparation and injection of the radiopharmaceuticals, as well as areas housing patients to whom therapeutic amounts of activity have been given. Measurements of typical diagnostic nuclear medicine waiting rooms have shown that their classification as controlled areas is not merited [12].

A supervised area is “any area not already designated as a controlled area but where occupational exposure conditions need to be kept under review even though specific protection measures and safety provisions are not normally needed.” Supervised areas may include examination imaging rooms (with gamma cameras) and waiting rooms where there are patients who have been injected with radiopharmaceuticals.

4.5. LOCAL RULES AND SUPERVISION

The BSS (para. I.26) require that:

“Employers, registrants and licensees shall, in consultation with workers, through their representatives if appropriate:

- (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 body], designate a radiation protection officer.”

Basic Safety Standards para. I.27 requires that:

“Employers, in cooperation with registrants and licensees, shall:

- (a) provide to all workers adequate information on the health risks due to their occupational exposure, whether normal exposure or

- potential exposure, adequate instruction and training on protection and safety, and adequate information on the significance for protection and safety of their actions;
- (b) provide to female workers who are liable to enter controlled areas or supervised areas appropriate information on:
 - (i) the risk to the embryo or foetus due to exposure of a pregnant woman;
 - (ii) the importance for a female worker of notifying her employer as soon as she suspects that she is pregnant; and
 - (iii) the risk to an infant ingesting radioactive substances by breast feeding;
 - (c) provide to those workers who could be affected by an emergency plan appropriate information, instruction and training; and
 - (d) keep records of the training provided to individual workers.”

In a nuclear medicine department, these local rules include:

- Procedures for wearing, handling and storing personal dosimeters;
- Actions to minimize radiation exposure during unusual events (for example, accidental contamination);
- Means and methods for decontamination of persons, equipment and surfaces;
- Limitations on activities that are permitted in source storage and handling areas (for example, no eating, drinking or smoking);
- Procedures for the control of sources (for example, prompt removal of sources from transport containers);
- Checking the integrity of containers;
- Checking the correctness of labels;
- 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 PET studies, the local rules are aimed at ensuring that:

- When handling radionuclides in the cyclotron room and in the radiopharmacy, the dose to the operator is minimized.
- The shielding design includes consideration, where appropriate, of the energy (511 keV) of the annihilation radiation from the positrons.

4.6. PROTECTIVE EQUIPMENT AND TOOLS

The BSS (para. I.28) require that “Employers, registrants and licensees shall ensure that workers be provided with suitable and adequate personal protective equipment ...” In a nuclear medicine department, this includes bench top shields, fume hoods, shields for syringes and vials, tools to maximize distance to the sources when handling them, protective clothing, and containers for segregation and storage of radioactive materials and waste and for moving radioactive materials inside the institution. Considerations on the possible use of mobile shielding and lead aprons in nuclear medicine, as well as more details about ancillary equipment and tools, are given in Section 3.

Containers for the transfer of sources outside the institution shall conform with the requirements established in the IAEA’s Regulations for the Safe Transport of Radioactive Material [27].

4.7. INDIVIDUAL MONITORING AND EXPOSURE ASSESSMENT

The BSS (paras I.32–34) establish that:

“I.32. The employer of any worker, as well as self-employed individuals, and the registrants and licensees shall be responsible for arranging for the assessment of the occupational exposure of workers, on the basis of individual monitoring where appropriate, and shall ensure that adequate arrangements be made with appropriate dosimetry services under an adequate quality assurance programme.

“I.33. 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. In cases where individual monitoring is inappropriate, inadequate or not feasible, the occupational exposure of the worker shall be assessed on the basis of the results of monitoring of the workplace and on information on the locations and durations of exposure of the worker.

“I.34. For any worker who is regularly employed in a supervised area or who enters a controlled area only occasionally, individual monitoring shall not be required but the occupational exposure of the worker shall be assessed. This assessment shall be on the basis of the results of monitoring of the workplace or individual monitoring.”

Those most likely to require individual monitoring are: nuclear medicine physicians, qualified experts in nuclear medicine physics, RPOs, nuclear medicine technologists, radiopharmacists and those involved in the preparation, dispensing and administering of radiopharmaceuticals to patients for diagnosis and therapy, staff dealing with radioactive waste, maintenance staff, and any nursing or other staff who spend time with therapy patients.

The BSS (para. I.35) state that “The nature, frequency and precision of individual monitoring shall be determined with consideration of the magnitude and possible fluctuations of exposure levels and the likelihood and magnitude of potential exposures.” The typical monitoring period specified by regulatory bodies in many countries is one month. In addition, the period between the dosimeters being received by the dosimetry provider and the dose reports being returned typically does not exceed one month or as specified by the regulatory body.

The operational dosimetric quantity required for external radiation exposure in the BSS and in Safety Guide RS-G-1.3 [25] is the personal dose equivalent $H_p(d)$. For weakly penetrating radiation and for strongly penetrating radiation the recommended depths (d) are 0.07 and 10 mm, respectively. The gamma radiation used in nuclear medicine is usually relatively strongly penetrating, and therefore $d = 10$ mm. Other depths may be appropriate in particular cases, for example 3 mm for the lens of the eye, in cases that the dose to the eye is higher than that to the rest of the body and requires, therefore, specific assessment. Safety Guide RS-G-1.3 states that $H_p(10)$ is used to provide an estimate of effective dose that avoids both underestimation and excessive overestimation.

Monitoring includes more than just making measurements. It includes interpretation, assessment and investigation, which may lead to corrective measures, if needed. In nuclear medicine, exposures from both external radiation and internal contamination are relevant. Individual external doses are assessed by the use of individual monitoring devices such as thermoluminescent dosimeters, film badges or other devices. Individual monitoring devices should typically be 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 body. Each dosimeter is for use by only the person to whom it is issued.

The BSS (para. 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 the iodine intake of individuals handling large activities of radioiodine by monitoring the thyroid with an external detector. Contamination monitoring is required for staff, especially on leaving the radiopharmacy.

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 para. I.17) can be met respectively.

4.8. MONITORING OF 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.”

Periodic monitoring with a survey meter and contamination monitor or by wipe tests should 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 the external radiation field should be carried out.

Laboratories and other areas in which work with unsealed sources is undertaken should be monitored, both for external radiation and for surface contamination, on a systematic basis. Contamination monitoring is required for:

- (a) All working surfaces (including the interior of enclosures), tools, equipment, the floor and any items removed from this area. Monitoring is also required during maintenance of contained workstations, ventilation systems and drains.
- (b) Protective and personal clothing, and shoes, particularly when leaving an area that is controlled due to the risk of contamination (monitors should be available near the exit).
- (c) Clothing and bedding of therapy patients.

4.9. INVESTIGATION LEVELS FOR STAFF EXPOSURE

The BSS (paras IV.18–20) establish that:

“IV.18. Registrants and licensees shall conduct formal investigations as specified by the [regulatory body] if:

- (a) a quantity or operating parameter related to protection or safety exceeds an investigation level or is outside the stipulated range of operating conditions; or
- (b) any equipment failure, 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.

“IV.19. The investigation shall be conducted as soon as possible after the event and a written report produced on its cause, with a verification or determination of any doses received ... and recommendations for preventing the recurrence of similar events.

“IV.20. A summary report of any formal investigation relating to events prescribed by the [regulatory body], including exposures greater than a dose limit, shall be communicated to the [regulatory body] as soon as possible and to other parties as appropriate.”

The BSS glossary defines the investigation level as “the value of a quantity such as an 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.

4.10. PROTECTION OF WORKERS IN INTERVENTIONS (EMERGENCIES)

Section 7 describes the role of safety assessment in identifying potential exposure, so that preventive measures and contingency plans for mitigation can be designed. Appendices VII and VIII identify and provide a short description of emergency situations in nuclear medicine, their prevention, and preparation for and mitigation of them. These emergencies involve loss of nuclear medicine sources, spillage of radioactive substances and emergency care to patients with therapeutic amounts of radioactive substances, for example in the case of vomits or strokes.

Nuclear medicine workers will be involved in the mitigation actions. Although dose limits for practices do not apply to interventions, the safety guide on occupational protection [23] points out that the exposure of workers in interventions cannot be considered an unexpected exposure but rather is deliberate and controlled, and the dose limits for workers should be assumed to apply unless there is an overriding reason not to apply them, such as the need to save life after an accident or to prevent catastrophic conditions.

In emergency situations, contingency plans based on the events identified by the safety assessment for a nuclear medicine department include allocation of responsibilities and provide for the training of the relevant staff in executing the mitigation measures, which should be periodically rehearsed. These actions are, therefore, deliberate and controlled, and there is, generally, no overriding reason for not applying the occupational dose limits to these situations. Most of these situations, for example, decontamination of spillage on work surfaces, can be executed in a planned manner so that doses can be kept low. The only exceptional, life saving, situations are those medical emergencies involving immediate care of patients in the case of strokes or similar situations, when

large amounts of radioactive material have been incorporated (of the order of 2 GBq of ¹³¹I). Even in the case of urgent surgery, rotation of personnel may be performed if the surgical procedure is lengthy, to help in maintaining optimized occupational protection for this situation, with the assistance of the RPO (Section 7).

4.11. HEALTH SURVEILLANCE

The BSS (para. 1.41) states that “Employers, registrants and licensees shall make arrangements for appropriate health surveillance in accordance with the rules established by the [regulatory body].” The primary purpose of health surveillance is to assess the initial and continuing fitness of employees for their intended tasks. Health surveillance programmes should be based on the general principles of occupational health.

No specific health surveillance related to exposure to ionizing radiation is necessary for staff involved in nuclear medicine procedures. Only in the case of overexposed workers at doses much higher than the dose limits (e.g. 0.2–0.5 Sv or higher) would special investigations involving biological dosimetry and further extended diagnosis and medical treatment be necessary (RS-G-1.1, para. 7.18). Under normal working conditions, the doses incurred in a nuclear medicine department are low and no specific radiation related examinations are normally required for persons who are occupationally exposed to ionizing radiation, as there are no diagnostic tests which yield information relevant to normal exposure. It is therefore rare for the radiation component of the work environment of a nuclear medicine department to significantly influence a decision about the fitness of a worker to undertake work with radiation or the general conditions of service (RS-G-1.1, para. 7.6).

Counselling should be available to workers (RS-G-1.1, para. 7.14) such as women who are or may be pregnant, 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.

4.12. RECORDS

The BSS (para. I.44) state that “Employers, registrants and licensees shall maintain and preserve exposure records for each worker.” The exposure records should include information on the general nature of the work involving occupational exposure, and 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, the exposure records should include information on the dates of employment with each employer and the doses, exposures and intakes in each such employment, as well as any doses due to emergency interventions or accidents, which should be distinguished from doses incurred 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. In addition, Safety Guide RS-G-1.5 [28] describes strategies to involve organizations outside the regulatory framework, such as professional bodies, whose cooperation is essential to ensure compliance with the BSS requirements for medical exposures. Examples that may illustrate this point include the adoption of protocols for calibration of unsealed sources and for quality assurance and for reporting accidental medical exposure.

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 (Table 1). Furthermore, dose constraints do not apply to exposure of patients as part of their own diagnosis and treatment, but specific dose constraints are to be defined for comforters and for 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, BSS para II.1 requires that:

“Registrants and licensees shall ensure that:

- (a) no patient be administered a diagnostic 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;
-
- (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) training criteria be specified or be subject to approval, as appropriate, by the [regulatory body] in consultation with relevant professional bodies.”

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

In addition, the BSS identify subsidiary parties (Section 2.3) with responsibilities for compliance with safety standards, who can be workers, RPOs, health professionals or any other party to whom a principal party has delegated specific functions. Each individual should take actions within his or her area of responsibility, as established in the radiation protection programme, to prevent inappropriate exposures of 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;
- (b) Be aware that the prescription of treatment and the treatment plan need to be signed by the medical practitioner prior to initiation of treatment.

The BSS (para. II.2) require that:

“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.”

It is not feasible, and it is also not required, to have full-time medical physicists for all nuclear departments. However, the regulatory body should require that registrants and licensees obtain advice for the function required in the BSS. Arrangements can be made for a medical physics group from a larger nuclear medicine department to provide the required advice to smaller departments on a part-time basis.

The BSS (para. II.3) require that:

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

5.2. JUSTIFICATION

Pursuant to para. II.4 of the BSS, a 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 both documented and signed. The medical practitioner should consider the efficacy, benefits and risks of alternative treatment modalities, such as ultrasound or magnetic resonance imaging. In justifying each type of diagnostic nuclear medicine examination, relevant guidelines should be taken into account, such as those established by the WHO [29, 30].

Some diagnostic examinations, particularly of children, can be better performed with the assistance of a helper or comforter (for example 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 to a low dose). This exposure is also considered to be medical exposure.

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. When a nuclear medicine examination is proposed for a pregnant woman, care has to be taken to ascertain that the examination is indeed indicated for a medical condition that requires prompt therapy. The possibility of performing the examination by reducing the administered activity, i.e. with longer imaging time, should be considered. In these cases, the advice of a qualified expert in nuclear medicine physics should be required to estimate foetal dose.

Most diagnostic procedures with ^{99m}Tc do not cause high foetal doses. For radionuclides that do not cross the placenta, foetal dose is derived from the radioactivity in maternal tissues. Some radiopharmaceuticals (such as iodine isotopes) that do cross the placenta and concentrate in a specific organ or tissue can pose a significant risk to the foetus. To avoid unintentional radiation exposures of the embryo and foetus, patients should be interviewed to assess the likelihood of pregnancy [26]. To reduce the frequency of unintentional exposures of the embryo or foetus, advisory notes should be posted at several places within the nuclear medicine department, particularly in its reception area.

Certain ^{131}I and ^{32}P 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 [26, 31]. Radioiodine will easily cross the placenta, and the foetal thyroid begins to accumulate iodine at about ten weeks of gestation. Treatment of cancer can be delayed until after pregnancy; in general, if any therapy is to be performed during pregnancy, it will be surgery during the second or third semester. Treatment of hyperthyroidism can be delayed until after pregnancy and the patient in the interim can be treated with drugs [26].

An important remark in ICRP Publication 84 [26] 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.”

With respect to medical research, BSS para. II.8 requires 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 Declaration¹⁶ and follows the guidelines for its application prepared by Council for International Organizations of Medical Sciences (CIOMS)¹⁷ and WHO¹⁸; 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.

¹⁶ Adopted by the 18th World Medical Assembly, Helsinki, 1964, 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 COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES in collaboration with WORLD HEALTH ORGANIZATION, International Ethical Guidelines for Biomedical Research Involving Human Subjects, CIOMS, Geneva (1993).

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 (Section 5.5).

5.3. OPTIMIZATION FOR MEDICAL EXPOSURES IN NUCLEAR MEDICINE

The BSS (para. II.17) require that:

“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 nursling¹⁹; and
- (e) 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.

¹⁹ Examples of good practice are at least 3 weeks for ⁶⁷Ga, ¹¹¹In, ¹³¹I and ²⁰¹Tl, at least 2 days for ¹²³I and at least 12 hours for ^{99m}Tc.”

Furthermore, for therapeutic procedures BSS para. II.18 requires that:

“(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 will now be discussed (Sections 5.3.1–5.3.5).

5.3.1. Optimization 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 of patient exposure.

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

The following points apply to individual patients:

- (a) There should be an effective system for correct identification of patients.
- (b) There should be a 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.
- (c) Patient details must be correctly recorded.
- (d) Data acquisition conditions should be selected such that the exposure is the minimum necessary for achieving the intended diagnostic objective. The choice of collimator, energy window, matrix size, acquisition time, angulation of collimator, single photon emission computed tomography (SPECT) or PET [32, 33] parameters and zoom factor shall be such as to obtain an optimum quality image.
- (e) For dynamic studies, the number of frames, time interval and other parameters should be chosen in a way that provides optimum quality of image sequence.
- (f) Care should be taken to ensure that there is no contamination on the collimator surface or elsewhere as this might impair the quality of the result.
- (g) Hydration of patients is an effective means to reduce exposure from radiopharmaceuticals that are excreted by the kidneys. Patients, particularly in the case of children, should be encouraged to void frequently, especially in the immediate interval following the examination.

- (h) The storage or retention of radiopharmaceuticals within specific organs can be influenced by drugs such as diuretics or gall bladder stimulants, whenever they do not interfere with the procedure. This method is sometimes used to increase the specificity of the examination, but has also a positive influence on radiation protection.⁸

5.3.1.1. Breast feeding

Breast feeding is usually stopped for three weeks after diagnostic procedures with ^{131}I and ^{125}I radiopharmaceuticals (except hippurate), and after procedures with ^{22}Na , ^{67}Ga and ^{201}Tl . It is stopped for 12 hours after procedures with iodine labelled hippurates and all $^{99\text{m}}\text{Tc}$ compounds. More detailed advice is given in Appendix IV.

A case of accidental exposure with the administration of 180 MBq of ^{131}I for a whole body scan of a breast feeding mother led to a thyroid dose to the child of 300 Gy. The child will require hormone medication for life (case 6 in Appendix VII).

5.3.1.2. Pregnancy

Diagnostic nuclear medicine procedures with $^{99\text{m}}\text{Tc}$ and radiopharmaceuticals that do not cross the placenta do not cause high foetal doses. Protection of the foetus can be optimized by using smaller administered activities and longer imaging times. This is feasible if the patient is able to remain still.

Specific assessment of individual foetal doses is not usually necessary after diagnostic nuclear medicine studies involving $^{99\text{m}}\text{Tc}$ radiopharmaceuticals. In the case of inadvertent administration of other radiopharmaceuticals (such as iodine or gallium), calculation of dose to the individual foetus and risk estimation may be necessary.

In the case of radiopharmaceuticals that are rapidly eliminated by the maternal kidneys, the urinary bladder is the major source of foetal irradiation. After the administration of such radiopharmaceuticals, maternal hydration and frequent voiding should be encouraged. Some radiopharmaceuticals, for example radioactive iodides, including those administered for diagnostic

⁸ An example is kidney examination: if the time-activity curve shows a continuous accumulation of activity, administration of diuretics is appropriate. When the curve drops, this means that the accumulation was not due to an obstruction of the urethra.

purposes, cross the placenta freely and are taken up by the foetal tissues, for example the thyroid. Failure to ascertain whether a patient is pregnant when administering ^{131}I for a scan, for example, may lead to a severe accidental exposure of the foetus.

5.3.2. Optimization for therapeutic application of radionuclides

The following provisions should be in place:

- (a) An effective system for identification of patients;
- (b) Procedures to find out, before administration of the radiopharmaceutical, whether patients are pregnant or breast feeding;
- (c) Verbal and written instructions to patients to minimize exposure to family members and the public;
- (d) Special attention to preventing spread of contamination due to patient vomit and excreta;
- (e) Observance of national regulations on release of patients after administration of therapeutic doses of radiopharmaceuticals.

5.3.2.1. Breast feeding

Registrants and licensees should ascertain beforehand whether a female patient is breast feeding. Cessation of breast feeding is recommended during most nuclear medicine procedures, as many radiopharmaceuticals are excreted in breast milk. This is particularly true when therapeutic doses are administered. Appendix IV is taken from a recent journal article and gives guidance on cessation of breast feeding following administration of some common radiopharmaceuticals [34].

5.3.2.2. Pregnancy and conception after therapeutic administration of radionuclides

In Section 5.2 the need to exclude the possibility of pregnancy *before radionuclides are administered for therapy* was emphasized. As a rule, pregnant women should not be subject to therapy with a radioactive substance unless the application is life saving.

Following treatment with a therapeutic activity of a radionuclide, female patients 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 V. It may be noted that these times have been derived with a view to the need for further therapy.

The administration of therapeutic doses of relatively long lived radionuclides in ionic chemical forms to males is 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 (iodide), ^{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 [31].

5.3.3. Calibration

The BSS (para. II.19) require that registrants and licensees shall ensure that:

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

.....

(d) 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.”

Registrants and licensees should ensure that an activity meter is available for measuring activity in syringes or vials in the nuclear medicine unit. The validity of measurements should be assured by regular quality control of the instrument, including periodic reassessment of its calibration, traceable to secondary standards. The licensee should participate in a regular intercomparison programme.

5.3.4. Clinical (patient) dosimetry

In addition to the requirement to calibrate and record the activity to be administered at the time of the administration, BSS para. 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 body should require that registrants and licensees prepare and 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. Registrants and licensees should obtain these values by calculation or from tables using internationally accepted methods or compilations 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.

In relation to therapeutic applications BSS para. II.20 further requires that “(e) in all radiotherapeutic treatments, the 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.

5.3.5. Quality assurance for medical exposures

As indicated in Section 2.3.3 the licensee needs to establish a comprehensive quality assurance programme. With regard to medical exposure, BSS para. II.22 requires that:

“Registrants and licensees, in addition to applying the relevant requirements for quality assurance specified elsewhere in the Standards, shall establish a comprehensive quality assurance programme for medical exposures with the participation of appropriate qualified experts in the relevant fields, such as radiophysics or radiopharmacy, taking into account the principles established by the WHO²¹⁻²³ and the PAHO²⁴.

²¹ WORLD HEALTH ORGANIZATION, Quality Assurance in Diagnostic Radiology, WHO, Geneva (1982).

²² WORLD HEALTH ORGANIZATION, Quality Assurance in Nuclear Medicine, WHO, Geneva (1982).

²³ WORLD HEALTH ORGANIZATION, Quality Assurance in Radiotherapy, WHO, Geneva (1988).

²⁴ PAN AMERICAN HEALTH ORGANIZATION, Publicación Científica No. 499, Control de Calidad en Radioterapia: Aspectos Clínicos y Físicos, PAHO, Washington DC (1986).”

Furthermore, BSS para. II.23 requires that:

“Quality assurance programmes for medical exposures 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.”

Compliance with these requirements should not lead to contradiction or unnecessarily overlap with other aspects of the quality system of the nuclear medicine department as a whole. There should be a harmonization between the requirements of the quality system based on medical grounds and the requirements for radiation protection.

Quality assurance activities have often been restricted to testing equipment performance. A comprehensive quality assurance programme, however, should embrace the entire process of nuclear medicine. The ISO 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, the WHO points out that satisfactory performance in service implies that optimal quality can be obtained throughout the whole process of diagnostic use, i.e. that adequate diagnostic information is provided at any moment with minimal exposure of patients and staff. The programme, therefore, should address not only equipment performance assessments but also image quality assessments, analysis of poor images, determination of the causes of poor quality, corrective actions and control of radiation doses. The complete quality cycle should include the feedback mechanism, from results of quality control, through rectification of malfunction of equipment to improvement of operator performance, as appropriate.

After equipment installation, it is necessary to conduct acceptance tests in order to verify that the equipment conforms to the technical specifications certified by the manufacturer. The purchasing conditions should clearly establish the responsibility of suppliers for resolving any non-conformities identified during acceptance testing. A qualified expert on the equipment, for example, a medical physicist, should define the technical specifications and carry out the acceptance testing of the equipment. For equipment operation, the manufacturer’s operating manual and the institution’s procedural manual should be followed.

Acceptance tests should be performed by the manufacturer’s representative in the presence of authorized local personnel (for example, a qualified expert in nuclear medicine physics) who represent the user and decide on acceptance. Commissioning includes all the parameters and situations intended for clinical use under clinical conditions and establishment

of the baseline for constancy tests. Quality control needs to be coordinated with maintenance programmes. Tests may need to be performed after any maintenance on the equipment that may affect its imaging and/or radiation characteristics.

The regulatory body 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 body] 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 body 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.

Basic Safety Standards Schedule III, Tables III-I to III-V, referred to in para. II.25 above, is reproduced in Appendix VI. The values in the tables correspond to the time at which the BSS were written, i.e. the early 1990s. Since then, nuclear medicine has evolved and, as a result, some new procedures have emerged and some of the listed radiopharmaceuticals may have been replaced or the activities given may no longer be up to date (see, for this purpose, the footnotes added to Appendix VI).

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. Furthermore, BSS para. 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 regard to patient comforters and visitors, BSS para. II.27 establishes 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 ..., to a level not exceeding that specified in Schedule II, para. II-9.”

Schedule II, para. II-9 of the BSS establishes 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.”⁹ A task group of the ICRP is currently working on the maximum activity level for discharge from hospital and is likely to have completed its report by 2004 (if the ICRP document is published before this Safety Report, the reference has to be included). The draft of this report recommends that infants and young children as well as casual visitors be excluded from the 5 mSv dose constraint and be limited to the public dose constraint (1 mSv).

Registrants and licensees should ensure that comforters, visitors and members of the households of patients during the course of treatment with radionuclides (for example, ¹³¹I for hyperthyroidism and thyroid carcinoma, ⁸⁹Sr, ¹⁸⁶Re for pain palliation) receive sufficient written instruction on relevant radiation protection precautions (for example, time and proximity to the patient) so that they do not exceed the dose constraint given in the BSS.

5.6. MAXIMUM ACTIVITY FOR PATIENTS IN THERAPY ON DISCHARGE FROM HOSPITAL

In order to restrict the exposure of any members of the households of patients who have undergone a therapeutic procedure with sealed or unsealed radionuclides and of members of the public, such patients should be discharged

⁹ The dose of 5 mSv from the BSS paragraph refers to effective dose.

from hospital only when the constraint of 5 mSv for the patient's comforters can be met. The limit for children and casual visitors throughout the complete treatment time is 1 mSv. Written instructions to the patient concerning contact with other persons and relevant precautions for radiation protection shall be provided as necessary.

To comply with this requirement, registrants and licensees should have a system to measure or estimate the activity in patients prior to discharge and assess the dose likely to be received by members of the household and members of the public. The result should be recorded.

A method to estimate the acceptable activity of radiopharmaceuticals for patients on discharge from hospitals is to calculate the time integral of the ambient dose equivalent rate and compare it with the constraints for patient comforters as indicated in Section 5.5, or for other persons who may spend time close to the patient. For this calculation, either a simple conservative approach based on the physical half-life of the radionuclide or a more realistic one, based on patient-specific effective half-life, can be used. The assumptions made in these calculations with regard to time (occupancy factors) and distance should be consistent with the instructions given to patients and comforters at the time the patient is discharged from hospital.

In the calculation of the effective half-life, the behaviour of ^{131}I can be modelled using two components for the biological half-life: the extrathyroidal (i.e. existing outside the thyroid) iodine and thyroidal iodine following uptake by thyroid tissue. Examples of such calculations are given in Ref. [35].

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 ^{131}I therapy can be found in recommendations from the European Commission [36]. Patients undergoing bone pain palliation therapies should be discharged on the basis of local rules, which take into account the external exposure rate, the risk of contamination and the patient's condition (BSS para. II.28). Special consideration shall be given to the case of incontinent patients.

5.7. INVESTIGATION OF ACCIDENTAL MEDICAL EXPOSURE

The BSS (paras II.29 and II.30) require that:

“II.29. Registrants and licensees 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 substantially 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 body], as soon as possible after the investigation or as otherwise specified by the [regulatory body], 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 body]; and
- (e) inform the patient and his or her doctor about the incident.”

Appendix VII provides, for illustration, a short description of the major reported events that have occurred in nuclear medicine and an exercise on identifying corrective measures for each case.

5.8. RECORDS FOR MEDICAL EXPOSURE

The BSS (para. II.31) require that:

“Registrants and licensees shall keep for a period specified by the [regulatory body] and make available, as required, the following records:

-
- (b) in nuclear medicine, types of radiopharmaceuticals administered and their activities;

.....

 - (d) the exposure of volunteers in medical research.”

This requirement involves, at least, the radiopharmaceuticals, their activities and routes of administration for each individual patient and volunteers in medical research.

5.9. GRADUAL TRANSITION FROM BASIC TO ADVANCED 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, approved by the IAEA General Conference in September 2002, has requested that “advice about the gradual transition from basic to advanced stages of implementation” be included in guidance publications. This plan also recognizes that many developing countries do not at present have the resources or expertise necessary for fully meeting the requirements and, therefore, requests provision of support for Member States during this transition.

Full compliance implies performance of periodic image quality assessments and surveys of administered activities, having a full quality assurance 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 initiating and developing a capability for evaluation of image quality, exercising in searches for causes of poor quality and preparing the ground for a subsequent quality

assurance programme 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 capabilities for evaluation of image quality have been developed, countries will be in a position to develop a quality assurance programme giving emphasis to parameters depending on their contribution to image quality, derived from the study. The programme should include image quality evaluation as well as quality control of equipment and operator performance. These countries should develop service facilities for the rectification of equipment malfunction. The availability of service facilities should lead to a report on the frequency of malfunction, actions taken and the impact on image quality. At this stage, provisions for sustainable training should be made.

Finally, countries that have completed the two previous steps will be able to perform an assessment of patient dose and establish a 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

The BSS (para. III.1) require that: “Registrants and licensees shall apply the requirements of the Standards as specified by the [regulatory body] to any public exposure delivered by a practice or source for which they are responsible”. The registrant or licensee is, therefore, responsible for controlling public exposure resulting from a nuclear medicine practice. The presence of members of the public in and near the radiology department shall be considered when designing the shielding and flow of persons in the department.

To comply with the BSS requirements, registrants and licensees should:

- (a) 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 body;
- (b) Control and maintain constant surveillance of licensed material that is not in storage (for example, when nuclear medicine sources are being transported or used for treatment) and secure stored licensed material

from unauthorized access, removal or use (for example, 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 body.

6.2. CONTROL OF ACCESS OF VISITORS

The BSS (para. III.5) require that:

“Registrants and licensees, in cooperation with employers when appropriate, shall:

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

Arrangements should be made to control access of visitors to patients undergoing radionuclide therapy and to 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

The BSS (para. III.7) require that:

“Registrants and licensees shall ensure that:

- (a) for sources for which they are responsible, measures that are optimized in accordance with the requirements of the Standards be

- taken as appropriate for restricting public exposure to contamination in areas accessible to the public; and
- (b) specific containment provisions be established for the construction and operation of a source that could cause spread of contamination in areas accessible to the public.”

Registrants and licensees should, therefore, take measures for restricting public exposure to contamination in areas accessible to the public.

6.4. RADIOACTIVE WASTE

The BSS (para. III.8) require that:

“Registrants and licensees shall:

- (a) ensure that the activity and volume of any radioactive waste that results from the sources for which they are responsible be kept to the minimum practicable, and that the waste be managed, i.e. collected, handled, treated, conditioned, transported, stored and disposed of, in accordance with the requirements of the Standards and any other applicable standard²⁶; and
- (b) segregate, and treat separately if appropriate, different types of radioactive waste where warranted by differences in factors such as radionuclide content, half-life, concentration, volume and physical and chemical properties, taking into account the available options for waste disposal.

²⁶ See the publications within the IAEA’s RADWASS Programme, Safety Series No. 111, on the safe management of radioactive waste.”

Most radioactive wastes from nuclear medicine are short lived radionuclides, and it is feasible to consider them as non-radioactive waste either directly or after some time for decay. The only exceptions are wastes from some in vitro studies in which the activity is so small that they can also be considered non-radioactive.

The criteria for disposal are:

- (a) For liquid waste, the public exposure due to ingestion is optimized and the individual dose is below the limits (or source related dose constraints). The methodology to optimize and ascertain that an

individual effective dose is below the constraints consists of estimating the dose from the conversion coefficients of committed effective dose per unit of incorporated activity of the chemical substance and ingestion route, and of considering the dilution and amount of intake [20].

- (b) For solid waste, disposal is based on clearance values and reference values [20].

Since waiting for decay until disposal is an essential method in nuclear medicine, a room for interim storage of radioactive waste should be available. The room should be locked, properly marked and ventilated. Records should be kept from which the origin of the waste can be identified. The process requires grouping (segregation) radionuclides according to the expected time for their decay (initial activity and physical half-life), their physical form and their appearance. Examples of different physical forms are: biological waste which may undergo decomposition, infectious waste requiring sterilization prior to disposal, broken glassware, syringes, etc., requiring collection in separate containers to prevent personnel being injured, radionuclide generators, bed linen and clothing from hospital wards (therapeutic applications), and liquid scintillation solutions. Containers to allow segregation of different types of radioactive waste should be available in areas where the waste is generated. The containers should be suitable for their purpose (for example, in volume, shielding and leaktightness).

In practice, it is mainly ^{131}I and the waste from therapy patients that require special radioactive waste precautions. Appropriate storage of radioactive materials to allow for decay will minimize the environmental impact of the release. The majority of diagnostic studies are performed using $^{99\text{m}}\text{Tc}$, which has a physical half-life of 6 h. Following storage of 2.5 days (10 half-lives, i.e. a decay of a factor of more than 1000) most of this waste can be disposed of. The technetium generators contain ^{99}Mo with a half-life of 2.75 days; depending on their initial activity, the decay time at the nuclear medicine facility is 1–2 months.

Following the above considerations, the following summary of practical advice for concrete items used in nuclear medicine can be given:

- (a) *Technetium generators.* There are two options: (1) returning to the supplier after use and (2) waiting for decay and dismantling of the elution column afterwards. After a waiting time of 1.5–2 months, when the activity and the dose rate are so low that the elution column can be removed, the generator can be dismantled and the material be considered as non-radioactive. Labels should then be removed.

- (b) *Used syringes and needles.* These can be collected in a shielded container in the rooms used for preparation and injection of radiopharmaceuticals. When the container is full, it should be sealed and the expected disposal date be marked on it. After this time, the external dose rate can be monitored. The container can be disposed of when the external ambient dose equivalent rate is the same as the background.
- (c) *Vials containing residues of ^{99m}Tc , ^{67}Ga , ^{111}In and ^{201}Tl .* The same procedure should be used as for the syringes, but using a different container.
- (d) *Gloves and cover paper.* These should be collected in plastic bags in the rooms used for preparation and injection of radiopharmaceuticals. When a bag is filled, it should be sealed. After waiting for decay, they can be disposed of as ordinary waste.
- (e) *Sealed sources* for calibration of activity meters, quality control of gamma cameras and counters, and anatomical marking of images. After waiting for decay, the RPO should determine the disposal route according to national regulations and authorization by the regulatory body (clearance).
- (f) *Small activities of ^3H and ^{14}C in organic solutions.* Their activities are usually very small, and can be treated as non-radioactive. However, as these substances are toxic, they should be given to an authorized plant, for example for incineration.
- (g) *Patients' excreta, such as urine with ^{131}I .* For diagnostic patients there is no need for collection of excreta and ordinary toilets can be used. For therapy patients, there are very different policies in different countries, but, in principle, the clearance criteria should follow the dilution and decay criteria until ingested by members of the public [19]. Given these large differences, the ICRP is preparing a document to harmonize the criteria based on pure radiation protection considerations.

6.5. MONITORING OF PUBLIC EXPOSURE

The BSS (para. III.13) require that:

“The registrant and licensee shall, if appropriate:

- (a) establish and carry out a monitoring programme sufficient to ensure that the requirements of the Standards regarding public exposure to sources of external radiation be satisfied and to assess such exposure;

- (b) establish and carry out a monitoring programme sufficient to ensure that the requirements of the Standards for discharges of radioactive substances to the environment and the requirements established by the [regulatory body] in granting the discharge authorization be satisfied and that the conditions assumed in deriving the authorized discharge limits remain valid and sufficient to enable the exposures to critical groups to be estimated;
- (c) keep appropriate records of the results of the monitoring programmes.”

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 or 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 body if required. The safety assessment shall include, as appropriate, a systematic critical review of the identification of possible events leading to accidental exposure (BSS paras IV.3–IV.7). Basically, the safety assessment deals with finding out ‘what can go wrong’ and how this can be prevented and, in case it occurs, how it can be mitigated. A good basis is provided by collection of information about accidents that have already occurred, but such assessments should not stop there and an effort should be made 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 quality assurance 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.
- (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.

Safety assessments in nuclear medicine have to be done for all the steps of the use of unsealed sources for diagnosis and treatment in the nuclear medicine department. This includes asking ‘What can go wrong?’ at every step (the steps include ordering, transport and receipt of unsealed sources, unpacking, storage, preparation and administration of the radiopharmaceuticals to the patient, examination or treatment, care of therapy patients with high amounts of radioactivity, and storage and handling of radioactive waste).

Appendix VIII of this Safety Report lists 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 radiation protection programme (BSS paras IV.10–IV.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);
- (b) Operational experience and lessons learned from accidents and errors. This information should be incorporated into the training, maintenance and quality assurance programmes.

The registrant and licensee shall promptly inform the regulatory body 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 paras V.2–V.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 the following:

- 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 (for example, nuclear medicine physicians, medical physicists and nuclear medicine technologists);
- Equipment and tools necessary to carry out the emergency procedures;
- Training and periodic rehearsals;
- Recording and reporting systems;
- Immediate measures to avoid unnecessary radiation doses to patients, staff and the public;
- Measures to prevent access of persons to the affected area;
- Measures to prevent spread of contamination.

Emergency kits should be kept readily available for use in an emergency. These may include the following:

- Protective clothing, for example overshoes and gloves;
- Decontamination materials for the affected areas, including absorbent materials for wiping up spills;
- Decontamination materials for persons;
- Warning notices;
- Portable monitoring equipment;
- Bags for waste, tape, labels and pencils.

7.4. TYPES OF EMERGENCY SITUATIONS

7.4.1. Lost sources

It is critical for this type of event that an up-to-date inventory exists so that it can be determined immediately which source(s) is (are) missing, what its type and activity are, when and where it was last known to be, and who last took possession of it. A proactive attitude is important for the case that sources

are ordered and not received at the expected time. Making a check for the arrival of a source at the expected receipt time should be part of the procedures. The actions to be part of the contingency plans include:

- Obtain assistance from the RPO.
- Conduct a local search.
- Check and ensure security and control of other sources.
- Check all possibilities in the hospital.
- If still not found, call the company and inform them of the failure so that they can trace the shipment and find out where the radioactive material is.
- If not found, report the loss of the material according to the rules given by the regulatory body.

7.4.2. Damage to ^{99m}Tc generators

Generators contain a relatively large amount of radioactivity. In the event of a ^{99m}Tc generator being damaged, the measures to be taken are:

- Evacuate the area immediately.
- Inform the RPO, who should confirm the spillage and supervise the decontamination and monitoring procedures.
- Record the event and make a report according to the rules given by the regulatory body.

7.4.3. Spillage of small amounts of radioactivity

After such a spillage the following actions should be taken:

- Use protective clothing and disposable gloves.
- Quickly blot the spill with an absorbent pad to keep it from spreading.
- Remove the pad from the spill.
- Wipe with a towel from the edge of the contaminated area towards the centre.
- Dry the area and perform a wipe test.
- Continue the cycle of cleaning and wipe testing until the wipe sample indicates that the spill has been cleaned.
- Use a plastic bag to hold contaminated items. Suitable bags shall be available as well as damp paper towels.

7.4.4. Spillage of large amounts of radioactivity

After such a spillage the following actions should be taken:

- The RPO should immediately be informed and directly supervise the clean-up.
- Throw absorbent pads over the spill to prevent further spread of contamination.
- All people not involved in the spill should leave the area immediately.
- Monitor all people involved in the spill for contamination when leaving the room.
- If clothing is contaminated, remove and place it in a plastic bag labelled ‘RADIOACTIVE’.
- If contamination of skin occurs, wash the area immediately.
- If contamination of an eye occurs, flush with large quantities of water.

7.4.5. Medical emergencies involving radioactive patients

This is particularly important for therapy patients containing large amounts of radioactivity. Medical personnel should proceed with emergency care (for example, when a patient has suffered a stroke), while taking precautions against spread of contamination and minimizing external exposure. The staff should avoid direct contact with the patient’s mouth, and all members of the emergency team should wear impermeable protective gloves. Medical staff are to be informed and trained on how to deal with radioactive patients. Rehearsals of the procedures should be held periodically.

7.4.6. Need for urgent patient attention, including surgery

Radiation protection considerations should not prevent or delay life saving operations in the event that surgery on a patient is required. The following precautions should be observed:

- Notify the operating room staff.
- Modify operating procedures under the supervision of the RPO to minimize exposure and spread of contamination.
- Protective equipment may be used as long as efficiency and speed are not affected.
- Rotation of personnel may be necessary if the surgical procedure is lengthy.

- The RPO should monitor all individuals involved.
- Measure doses to members of staff.

7.4.7. Fires

The normal hospital drill should be observed, with the safe evacuation of patients, visitors and staff being the most important consideration. When the fire brigade attends, they should be informed of the presence of radioactive material. No one is allowed to re-enter the building until it has been checked for contamination.

Appendix I

POINTS FOR CONSIDERATION IN A RADIATION PROTECTION AND SAFETY PROGRAMME IN NUCLEAR MEDICINE

The following is a list of major items to assist in appraisals of radiation protection and safety in radiotherapy. The relative complexity of each facility should be taken into account when assessing compliance. The list is intended only to provide a systematic approach to appraisals, to ensure consistency in these appraisals and to avoid omission of major items. It should not be construed as replacing professional judgment and knowledge of how safety features fit into the operation of a nuclear medicine practice and of how to avoid interference with medical care. The list can be used as guidance by the licensee for self-assessment, by peers when performing an appraisal and by regulators when checking compliance with the BSS.

GENERAL INFORMATION ON THE FACILITY

- Patient workload;
- Number of X ray rooms and types of equipment (with descriptions);
- Number of staff (type, speciality and number of each speciality).

COMPLIANCE WITH ADMINISTRATIVE REQUIREMENTS

- Availability of an authorization granted by the regulatory body to build the facility, import the source and operate the radiotherapy practice;
- Specific conditions in the authorization;
- Previous reviews and inspections performed;
- Safety concerns in previous appraisals.

SECURITY OF SOURCES

- Provisions to keep an inventory of all sources in the radiotherapy department;
- Clear assignment of responsibilities for keeping and updating the inventory;
- Tracking in a logbook of all movements of sources (responsibility for keeping the logbook assigned to a named individual);
- Means to prevent unauthorized access to sources.

RADIATION PROTECTION AND SAFETY PROGRAMME

- Radiation protection and safety programme in place and endorsed by the licensee;
- Radiation protection committee or equivalent mechanism in place;
- Members of the committee (usually including the chief nuclear medicine physician, a medical physicist, a radiotherapy technologist, the RPO, a staff member responsible for coordinating maintenance and an administrator (representing the hospital management)) chosen for decision making and provision of resources;
- Clear definition of responsibilities in the nuclear medicine department;
- Understanding of these responsibilities by the responsible staff and acknowledgment by them of these responsibilities;
- Provisions to ensure that only qualified staff assume the above responsibilities;
- Programme for education, training and continuing professional development.

RULES AND PROCEDURES

- Purchase of radiation sources and nuclear medicine equipment (preparation of technical specifications before purchase and decisions made about which staff should be involved and those who should be responsible for providing internal clearance);
- Receipt, storage and disposal of radioactive sources;
- Safe handling of radiation sources (preparation, dispensing and administration of radiopharmaceuticals such as $^{99}\text{Mo}/^{99\text{m}}\text{Tc}$ generators and other radiopharmaceuticals);
- Individual exposure monitoring (see occupational protection), including both external and internal exposure;
- Workplace monitoring (see occupational protection);
- Leak testing;
- Communication of safety critical issues;
- Movements of radiation sources and patients with sources inside the hospital.

PROTECTION FROM OCCUPATIONAL EXPOSURE

- Provisions to inform workers about their obligations and responsibilities for their own protection and the protection of others against radiation, as well as for the safety of sources.

Conditions of service

- Provisions to encourage pregnant workers to notify pregnancy and to adapt their working conditions so as to ensure that the embryo or foetus is afforded the same broad level of protection as required for members of the public, without exclusion of the female staff member from work.

Classification of areas

- Classification as controlled areas of source storage and preparation rooms, examination rooms and patient wards for therapy patients.

Local rules and supervision

- Procedures to ensure adequate levels of protection and safety of staff;
- Provisions to ensure that these procedures, protective measures and safety provisions are known by those staff members to whom they apply and by other persons who may be affected by them;
- Supervision to ensure observance of the procedures;
- Provision for investigation levels.

Personal protective equipment

- Availability of a shielded workplace for handling radionuclides;
- Availability of devices such as remote handling tools.

Cooperation between the employer and the licensee

- Provisions to exchange information with other employers and use specific exposure restrictions if workers are involved in other work using radiation.

Individual monitoring and exposure assessment

- Arrangements for provision of individual monitoring by an accredited and authorized service;
- Identification of staff members requiring individual monitoring;
- Establishment of monitoring period, frequency of readings, recording of accumulated doses, and rules for returning and changing dosimeters;
- Arrangements to ensure that doses recorded are made available to workers;
- Rules for estimating a worker's dose if a personal dosimeter is lost or damaged;
- Provision for assessing internal exposure.

Monitoring of the workplace

- Provisions for keeping the workplace under supervision and for monitoring external radiation and contamination at a frequency that enables assessment in controlled areas and in supervised areas.

Health surveillance

- Arrangements for health surveillance according to the rules of the regulatory body;
- Availability for counselling of pregnant women.

Records

- Ready availability of exposure and health surveillance records.

PROTECTION FROM MEDICAL EXPOSURES

Responsibilities

- Assignment of the overall responsibility for patient protection and safety to a medical practitioner (for example, the department head, nuclear medicine physician or chief medical officer);
- Assignment of the responsibility for advising on imaging and quality assurance to a qualified expert in nuclear medicine physics; the type of expert (for example, a qualified expert in nuclear medicine physics or a hospital physicist) is to be specified;

- Documentation of education and training of all staff;
- Inclusion in the training of lessons learned from accidents and their prevention.

Justification of medical exposures

- Procedure in place for the prescription and administration of medical exposures to ensure that these are justified;
- Provision to justify research involving application of radiation to humans.

Optimization: design and testing

- Acceptance testing carried out according to international (such as IEC) or equivalent national standards for radiotherapy equipment.

Optimization: operational considerations

- Provision for optimization [1] to ensure that the exposure of patients is the minimum required to achieve the intended diagnostic objective, taking into account relevant information from previous examinations, in order to avoid unnecessary additional examinations, and the relevant guidance levels for medical exposures.

Optimization: calibration

- Provisions for ensuring that unsealed sources for nuclear medicine procedures are calibrated in terms of the activity of the radiopharmaceutical to be administered, the activity being determined and recorded at the time of administration;
- Provisions to calibrate the activity meter.

Optimization: clinical dosimetry

- Provision to determine representative absorbed doses to patients in diagnosis or treatment with unsealed sources.

Optimization: quality assurance

- Establishment of a quality assurance programme;
- Method to write new procedures and for changing and documenting the changes;

- Provisions for the programme to be based on an accepted and proven protocol;
- Provisions to ensure that all tasks of the programme are assigned to trained persons;
- Establishment of a maintenance strategy, arrangements and procedures.

Investigation of accidental medical exposures

- Provisions in place to investigate and report:
 - Any therapeutic treatment delivered to the wrong patient, the wrong tissue, using the wrong pharmaceutical, 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 that intended or resulting in doses repeatedly and substantially exceeding the established guidance levels;
 - Any equipment failure, accident, error, mishap or other unusual occurrence with the potential for causing a patient exposure significantly different from that intended.
- Provisions to estimate the doses received and indicate and implement corrective measures.

PROTECTION OF THE PUBLIC FROM EXPOSURE

- Consideration given to the public in the shielding design;
- Provisions in place for control of access for the public and visitors;
- Pathways designed to minimize interference of the public with console control space and examination rooms, to avoid potential exposure;
- Procedures for segregating and disposing of radioactive waste.

EMERGENCY PREPAREDNESS AND RESPONSE

- Preparation of a list of predictable incidents and accidents as well as measures to deal with them;
- Designation of persons responsible for taking actions, with complete relevant contact information, including telephone numbers;

- Responsibilities of individuals (for example, the nuclear medicine specialist, the qualified expert in nuclear medicine physics and nuclear medicine technologists) in an emergency defined in procedures;
- Set of concise instructions posted in a visible area;
- Availability of or quick access to persons responsible for carrying out emergency response actions;
- Availability of equipment and tools necessary to carry out the procedures;
- Training and periodic rehearsals carried out;
- Recording and reporting systems in place;
- Immediate measures taken to avoid unnecessary radiation doses to patients, staff and the public (such as removal of patients from teletherapy units, removal of implants, return of sources to the shielded position in remote control brachytherapy and teletherapy);
- Measures taken to prevent access of persons to the affected area during the time that the sources are exposed and before normal conditions are restored.

Appendix II

QUALITY ASSURANCE PROGRAMME FOR IN VIVO PRACTICES

Only an integrated quality assurance approach to nuclear medicine, taking into account medical, physical and radiation safety aspects, can help to achieve an adequate image quality at the lowest reasonable exposure of patients. Coordinated with the radiation protection programme, the quality assurance programme ensures good medical practice and radiation protection of the staff, patients and the public. Experience has shown that the frequency of accidental exposures during in vivo applications is directly related to the absence or inadequacy of an established quality assurance programme in the department concerned. A quality assurance committee should be responsible for systematically reviewing and auditing the entire quality assurance 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, for example radiology, radiotherapy and nuclear medicine, representatives from these departments can be integrated into a single quality assurance committee. For small establishments such as stand-alone nuclear medicine clinics, the radiation protection and quality assurance committees may be combined.

II.1. GENERAL COMPONENTS OF A QUALITY ASSURANCE PROGRAMME

The components meriting special attention in a quality assurance programme are listed in Table 3.

An analysis of the general outcome of the nuclear medicine service should include doses to staff and patients, the satisfaction of patients and referring physicians, workload indicators, records and a clinical audit.

II.2. QUALITY CONTROL OF RADIOPHARMACEUTICALS

Radiopharmaceuticals should comply with both radiation and pharmaceutical standards in order to ensure their safe and efficacious use. The in vivo behaviour of a radiopharmaceutical is dependent upon its quality, which demands high standards of radionuclide, radiochemical and chemical purity

TABLE 3. GENERAL COMPONENTS OF A QUALITY ASSURANCE PROGRAMME

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

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.

II.2.1. 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 radionuclide purity are laid down in the European Pharmacopoeia [14], the British Pharmacopoeia [15] and the United States Pharmacopoeia [16]. The reason for seeking radionuclide purity in a radiopharmaceutical is primarily to avoid unnecessary radiation doses to the patient, to avoid degradation of image quality and to limit errors in measurements in vivo. It should be noted that measured radionuclide 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 affect 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 radionuclide impurities in radiopharmaceuticals.

It is the duty of manufacturers to examine their 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–progeny generator system is used, a check should be made on each eluate to ensure that any breakthrough of the parent into the eluate at the time of patient administration is below the limit as specified in the pharmacopoeia. 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, for example, by the time of administration to patients, can be determined by calculation.

II.2.2. 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 (for example sodium, pertechnetate (^{99m}Tc) or 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.

II.2.3. Chemical purity and content

Chemical purity refers to the proportion of the preparation that 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 for reconstitution by the addition of sodium pertechnetate (^{99m}Tc) is the oxidation of stannous ions to stannic ions. It is important that the stannous ion content 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 component(s) of the radiopharmaceutical or cold kit shall be within the specified mass limit(s). The chemical content may be determined by quantitative chemical analysis.

II.2.4. pH

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

II.2.5. Specific activity

Specific activity is defined as the activity per unit mass (for example MBq/mg) of a particular radionuclide taking into account the bound and unbound forms of that nuclide. 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, for example in the labelling of an iodo compound by exchange with ^{123}I or ^{131}I .

II.2.6. Pharmaceutical aspects

All preparations intended for parenteral administration should 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 $^{99\text{m}}\text{Tc}$ preparations, cannot be tested prior to administration, emphasis is placed on quality control of the process and procedures. Thus, all operating procedures should be documented and strictly observed, and accurate records should 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 the chemical form of the preparation;
- The total activity present;
- The reference time for the activity measurement;
- The results of a 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, a batch or lot number;
- In the case of solutions, the total volume of the solution;
- Any other specified parameter, for example the presence or absence of an antimicrobial agent or preservative.

The documentation for a radiopharmacy should cover pharmaceutical, physical and safety aspects. It should include records of the 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, calibration of radiation monitors and staff radiation doses.

II.3. QUALITY CONTROL OF EQUIPMENT

The quality control of an instrument begins with its selection. The user should decide what functionality and performance are required and these requirements should 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 should 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 also the results of these tests, duly recorded, will 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 in Table 4. More detailed information can be found in Ref. [8]. 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 be used for the quality control of the film processor in order to ensure optimum transfer of the image information to the display medium.

TABLE 4. TESTS AND CHECKS FOR QUALITY CONTROL OF NUCLEAR MEDICINE INSTRUMENTS

Instrument	Acceptance and reference tests	Operational checks
Radionuclide activity meter	Precision	Reproducibility
	Accuracy	
	Linearity of activity response	Background
	Geometrical response	
	Background	
Sample counting system	Scaler and/or timer function	Analyser peak setting
	Energy calibration	
	Energy resolution	
	Sensitivity	
	Counting precision	Background
	Linearity of energy response	
	Background	
	Linearity of activity response	
	Geometrical response	
	Preset analyser facilities	
Gamma camera, including SPECT system and computer system	PHA ^a window settings	PHA window settings
	Energy resolution	
	Linearity of energy response	Uniformity
	Intrinsic uniformity	
	System uniformity	
	Intrinsic linearity	Sensitivity
	Intrinsic spatial resolution	
	System spatial resolution	
	Count rate performance	
	Sensitivity	
	Whole body uniformity	
	Whole body resolution	Background
	Head shielding leakage	
	Pixel size	Position of centre of rotation
	Computer timing	
	Position of centre of rotation	
Tomographic uniformity	Collimator setting	
Tomographic spatial resolution		
Total SPECT performance		

^a PHA, pulse height analysis.

TABLE 4. TESTS AND CHECKS FOR QUALITY CONTROL OF NUCLEAR MEDICINE INSTRUMENTS (cont.)

Instrument	Acceptance and reference tests	Operational checks
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 random counts Scanner cross-calibration Drifts in coincidence timing Drifts in energy thresholds Mechanical movement of detector rings Removable septa positioning Laser alignment Attenuation correction accuracy Dead time correction accuracy Scatter correction accuracy Random coincidence correction accuracy	Calibration check Normalization Blank scan Scanner cross-calibration

Appendix III

TRAINING PROGRAMME FOR RADIATION PROTECTION: IMPLEMENTATION OF THE BSS IN NUCLEAR MEDICINE

Personnel need to be instructed in radiation protection before assuming their 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.

Tables 5–16 provide lists of broad topics related to radiation protection, safety assurance 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 should 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: RADIATION PHYSICS

Objectives: To become familiar with the basics of radiation physics, dosimetric quantities and units up to performing related calculations, and with different types of radiation detectors and their characteristics, operating principles and limitations.

TABLE 5. TRAINING PROGRAMME FOR RADIATION PHYSICS

Module	Contents
1.1. Atomic structure	Basic atomic structure
1.2. Interactions of electrons with matter	Bremsstrahlung production Characteristic X ray production Primary and secondary ionization Elastic scattering of electrons
1.3. Interactions of photons with matter	Types of interaction Photoelectric effect Compton scattering Photon attenuation Half-value thickness Beam attenuation and half-value thickness
1.4. Interaction of neutrons with matter	Relevance to cyclotrons producing ^8F , ^{13}N , etc.
1.5. Radiation quantities and units	Electronic structure: Quantities and units Exposure and exposure rate Absorbed dose and kerma ^a Mean absorbed dose in a tissue Equivalent dose H Effective dose Tissue weighting factors
1.6. Radiation detectors and dosimeters	Basic principles in detection of ionizing radiation (gas filled detectors, scintillation detectors and semiconductor detectors) Personnel dosimetry systems, for example thermoluminescence dosimetry types of monitoring instrument Operating principles and limitations Workplace monitoring

^a Kerma: kinetic energy released per unit mass.

PART 2: BIOLOGICAL EFFECTS OF IONIZING RADIATION

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

TABLE 6. TRAINING PROGRAMME FOR BIOLOGICAL EFFECTS OF IONIZING RADIATION

Module	Contents
2.1. Biological effects of ionizing radiation	Basic concepts in radiobiology Deterministic and stochastic effects Radiosensitivity Factors affecting radiosensitivity Dose–effect response curve
2.2. Epidemiological studies and risk assessment	Whole body response: acute radiation syndrome (bone marrow syndrome, gastrointestinal syndrome and central nervous syndrome) Effects of antenatal exposure Delayed effects of radiation Risks, weighting factors and types of epidemiological study (e.g. retrospective or prospective) Confounding factors and definition of risk Risk perception, risk estimates and risk models Historical overview of exposed populations (in the medical field) The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR)

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

Objectives: To become aware of the ICRP’s conceptual framework, the BSS requirements and Safety Guide RS-G-1.5 [28] on radiation protection in the medical field.

TABLE 7. TRAINING PROGRAMME FOR INTERNATIONAL FRAMEWORK AND REGULATORY REQUIREMENTS FOR RADIATION PROTECTION

Module	Contents
3.1. Principles of radiation protection	The ICRP Concept and aims of radiation protection Framework of radiation protection System of radiation protection: Justification Dose limitation Optimization limitation
3.2. The BSS	Preamble and principal requirements Detailed requirements; occupational, medical and public exposures, potential exposures, emergency exposure situations and chronic exposure
3.3. Regulatory control	Establishment of a regulatory body System of notification, authorization, inspection and enforcement Guidance for implementation of the BSS in nuclear medicine

PART 4: SAFETY OF SOURCES AND DESIGN OF FACILITIES

Objectives: 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, for example those given in various pharmacopoeias [14–16]. 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 acquire basic information about shielding calculations.

TABLE 8. TRAINING PROGRAMME FOR SAFETY OF SOURCES AND DESIGN OF FACILITIES

Module	Contents
4.1. Introduction	Principles of safety of sources and security of sources The concepts of defence in depth and categorization of hazards
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
4.5. Security of sources	Records and storage of sources

PART 5: OCCUPATIONAL PROTECTION – PROTECTION OF WORKERS

Objectives: To become familiar with the BSS detailed requirements and Safety Guide RS-G-1.1 [23].

TABLE 9. TRAINING PROGRAMME FOR OCCUPATIONAL PROTECTION

Module	Contents
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	Definitions 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 exposures Radioactive patients Typical dose rates from patients and sources
5.4. Personal protective equipment in nuclear medicine 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 decontamination 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	Definitions of the procedures and applications that need to be converted into local rules An example of local rules
5.7. Health surveillance	Design of a health surveillance programme for radiation workers
5.8. Records	Type and contents of records to be kept for workers ILO code of practice regarding records to be kept

PART 6: MEDICAL EXPOSURES

Objectives: To become familiar with the detailed BSS requirements and Safety Guide RS-G-1.5 [28]: responsibilities, justification, optimization, guidance level, dose constraints, requirements for discharge of therapy patients, investigation of accidental exposures and medical records.

TABLE 10. TRAINING PROGRAMME FOR MEDICAL EXPOSURES

Module	Contents
6.1. Responsibilities	Definition of the responsibilities of the referring physician, the nuclear medicine specialist, the medical physicist and the nuclear medicine technologist in accordance with the BSS and other IAEA publications
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 of reference levels of activity Investigation of accidental exposures
6.4. Medical records	BSS requirements for medical records to be kept

PART 7: OPTIMIZATION OF PROTECTION IN MEDICAL EXPOSURE –
DIAGNOSTIC PROCEDURES

Objectives: To be able to apply the principles of radiation protection including design, operational considerations, calibration, clinical dosimetry and quality control to diagnostic procedures using these major types of equipment: activity meters, monitoring equipment, probes, scanners, gamma cameras, SPECT systems including the coincidence option, and PET.

TABLE 11. TRAINING PROGRAMME FOR PROTECTION DURING
DIAGNOSTIC PROCEDURES

Module	Contents
7.1. Activity meters 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 doses absorbed by patients (see also Section 5.3.4) Internal dosimetry: MIRD ^a and ICRP concepts on internal dosimetry

^a MIRD: Medical Internal Radiation Dose Committee of the Society of Nuclear Medicine (Reston, Virginia, United States of America).

PART 8: OPTIMIZATION OF PROTECTION IN MEDICAL EXPOSURE – THERAPEUTIC PROCEDURES

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

TABLE 12. TRAINING PROGRAMME FOR PROTECTION DURING THERAPEUTIC PROCEDURES

Module	Contents
8.1. Radionuclide therapy	Operational considerations, calibration, clinical dosimetry and quality control Instructions to patients concerning spread of contamination Minimization of exposure to family members Conception after therapy Requirements for discharge

PART 9: RADIOACTIVE WASTE

Objectives: 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.

TABLE 13. TRAINING PROGRAMME FOR RADIOACTIVE WASTE

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

PART 10: QUALITY ASSURANCE

Objectives: To become familiar with the concepts of quality assurance and radiation protection in nuclear medicine and the procedures for reviewing and assessing the overall effectiveness of radiation protection.

TABLE 14. TRAINING PROGRAMME FOR QUALITY ASSURANCE

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

PART 11: POTENTIAL EXPOSURE AND EMERGENCY PREPAREDNESS

Objectives: To be 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.

TABLE 15. TRAINING PROGRAMME FOR POTENTIAL EXPOSURE AND EMERGENCY PREPAREDNESS

Module	Contents
11.1. 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
11.2. Accident prevention	Examples of accidents and incidents Discussion of the actions that should be taken Lessons learned

PART 12: PROTECTION OF THE GENERAL PUBLIC

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

TABLE 16. TRAINING PROGRAMME FOR PROTECTION OF THE GENERAL PUBLIC

Module	Contents
12.1. Dose limits	Dose limits for the general public
12.2. Design considerations	Safe storage and prevention of spread of contamination
12.3. Radioactive patients	Release of patients from hospital Visiting restrictions Restricted contact with children and pregnant women
12.4. Special problems	Handling of radioactive cadavers
12.5. Transportation	Information about the international rules on safe transportation Principles of internal transportation

Appendix IV

CESSATION OF BREAST FEEDING

Recommendations for cessation of breast feeding following administration of the various classes of radiopharmaceutical are given in Tables 17–19.

TABLE 17. RECOMMENDATIONS FOR CESSATION OF BREAST FEEDING FOR CLASS A RADIOPHARMACEUTICALS

Radiopharmaceutical	Administered activity, MBq (mCi)	Need for counselling	Advice
Ga-67 citrate	185 (5.0)	Yes	Cessation
Tc-99m DTPA ^a	740 (20)	No	
Tc-99m MAA ^b	148 (4)	Yes	Cessation for 12 h
Tc-99m pertechnetate	185 (5)	Yes	Cessation for 4 h
I-131 NaI	5550 (150)	Yes	Cessation

^a DTPA, diethylene-triamine-penta-acetic acid.

^b MAA, macro-aggregated albumin.

TABLE 18. RECOMMENDATIONS FOR CESSATION OF BREAST FEEDING FOR CLASS B RADIOPHARMACEUTICALS

Radiopharmaceutical	Administered activity, MBq (mCi)	Need for counselling	Advice
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	

TABLE 18. RECOMMENDATIONS FOR CESSATION OF BREAST FEEDING FOR CLASS B RADIOPHARMACEUTICALS (cont.)

Radiopharmaceutical	Administered activity, MBq (mCi)	Need for counselling	Advice
Tc-99m RBCs in vivo labelling	740 (20)	Yes	Cessation for 12 h
Tc-99m RBCs in vitro labelling	740 (20)	No	
Tc-99m sulphur colloid	444 (12)	No	
In-111 WBCs	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	Cessation for 48 h
I-125 OIH	0.37 (0.01)	No	
I-131 OIH	11.1 (0.3)	No	
Tl-201	111 (3)	Yes	Cessation for 96 h
Tc-99m DTPA aerosol	37 (1)	No	

Note: The abbreviations used in this table are as follows:

- EDTA, ethylene-diamine-tetra-acetic acid;
- DISIDA, di-isopropyl-iminodiacetic acid;
- HAM, human albumin microsphere;
- MIBI, methoxy-isobutyl-isonitrile;
- MDP, methylene diphosphonate;
- PYP, pyrophosphate;
- RBCs, red blood cells;
- WBCs, white blood cells;
- OIH, ortho-iodo-hippurate;
- MIBG, meta-iodo-benzyl-guanidine;
- DTPA, diethylene-triamine-penta-acetic acid.

TABLE 19. RECOMMENDATIONS FOR CESSATION OF BREAST FEEDING FOR CLASS C RADIOPHARMACEUTICALS

Radiopharmaceutical	Administered activity, MBq (mCi)	Need for counselling	Advice
Tc-99m WBCs ^a	185 (5)	Yes	Cessation for 48 h
Tc-99m MAG3 ^b	370 (10)	No	
Xe-133 gas		No	

^a WBCs, white blood cells.

^b MAG3, mercapto-acetyl-triglycine.

Appendix V

AVOIDANCE OF PREGNANCY FOLLOWING THERAPY

The periods for which it is recommended to avoid pregnancy are given in Table 20.

TABLE 20. RECOMMENDED TIMES FOR AVOIDING PREGNANCY FOLLOWING RADIONUCLIDE THERAPY

(pregnancy should be avoided for the period indicated in column four even when the activity administered was smaller than that shown in column three)

Nuclide and form	Disease	Maximum activity (MBq)	Pregnancy avoidance period (months)
Au-198 colloid	Cancer	10 000	2
I-131 iodide	Thyrotoxicosis	800	4
I-131 iodide	Thyroid cancer	5 000	4
I-131 MIBG ^a	Phaeochromocytoma	5 000	4
P-32 phosphate	Polycythemia	200	3
Sr-89 chloride	Bone metastases	150	24
Y-90 colloid	Arthritic joints	400	0
Y-90 colloid	Cancer	4 000	1
Er-169 colloid	Arthritic joints	400	0

^a MIBG, meta-iodo-benzyl-guanidine.

APPENDIX VI

GUIDANCE LEVELS FOR DIAGNOSTIC PROCEDURES

Table III-V from the BSS [1] is reproduced here. It should be noted that these values correspond to the time at which the BSS were written, i.e. the early 1990s. Since then, nuclear medicine has evolved and new procedures have emerged. Some of the radiopharmaceuticals listed may have been replaced or their activities may no longer be up to date. Examples of new radiopharmaceuticals are immuno-scintigraphy (monoclonal antibodies (MoAbs) or Fab fragments) and receptor scintigraphy in neurology (β -CIT and iodobenzamide (IBZM)) and oncology (somatostatine-receptor analogues) procedures, as well as PET procedures.

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

Test	Radionuclide	Chemical form ^a	Maximum usual activity per test ^b (MBq)
<i>Bone</i>			
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 ^c	400
<i>Brain</i>			
Brain imaging (static)	^{99m} Tc	TcO ₄ ⁻	500
	^{99m} Tc	Diethylene-triamine-penta-acetic acid (DTPA) or glucoheptonate	500
Brain imaging (SPECT)	^{99m} Tc	TcO ₄ ⁻	800
	^{99m} Tc	DTPA, gluconate and glucoheptonate	800

For footnotes see end of table.

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

Test	Radionuclide	Chemical form ^a	Maximum usual activity per test ^b (MBq)
Cerebral blood flow	^{99m} Tc	Exametazime	500
	¹³³ Xe	In isotonic sodium chloride solution	400
	^{99m} Tc	Hexamethyl propylene amine oxime (HM-PAO)	500
Cisternography	¹¹¹ In	DTPA	40
<i>Lacrimonal</i>			
Lacrimal drainage	^{99m} Tc	TcO ₄ ⁻	4
	^{99m} Tc	Labelled colloid	4
<i>Thyroid</i>			
Thyroid imaging	^{99m} Tc	TcO ₄ ⁻	200
	¹²³ I	I ⁻	20
Thyroid metastases (after ablation)	¹³¹ I	I ⁻	400
Parathyroid imaging	²⁰¹ Tl ^d	Tl ⁺ chloride ^d	80
<i>Lungs</i>			
Lung ventilation imaging	^{81m} Kr	Gas	6000
	^{99m} Tc	DTPA aerosol	80
Lung ventilation study	¹³³ Xe	Gas	400
	¹²⁷ Xe	Gas	200
Lung perfusion imaging	^{81m} Kr	Aqueous solution	6000
	^{99m} Tc	Human albumin (macroaggregates or microspheres)	100
Lung perfusion imaging (with venography)	^{99m} Tc	Human albumin (macroaggregates or microspheres)	160
Lung perfusion studies	¹³³ Xe	Isotonic solution	200
	¹²⁷ Xe	Isotonic chloride solution	200
Lung imaging (SPECT)	^{99m} Tc	Macroaggregated albumin (MAA)	200

For footnotes see end of table.

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

Test	Radionuclide	Chemical form ^a	Maximum usual activity per test ^b (MBq)
<i>Liver and spleen</i>			
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 blood cells	100
Liver imaging (SPECT)	^{99m} Tc	Labelled colloid	200
<i>Cardiovascular</i>			
First pass blood flow studies	^{99m} Tc	TcO ₄ ⁻	800
	^{99m} Tc	DTPA	800
	^{99m} Tc	Macroaggregated globulin 3	400
Blood pool imaging	^{99m} Tc	Human albumin complex	40
Cardiac and vascular imaging/probe studies	^{99m} Tc	Human albumin complex	800
	^{99m} Tc	Labelled normal red blood cells	800
Myocardial imaging/probe studies	^{99m} Tc	Phosphonate and phosphate compounds	600
Myocardial imaging	^{99m} Tc	Isonitriles	300
	²⁰¹ Tl	Tl ⁺ chloride	100
Myocardial imaging (SPECT)	^{99m} Tc	Phosphonate and phosphate compounds	800
	^{99m} Tc	Isonitriles	600
<i>Stomach, gastrointestinal tract</i>			
Stomach/salivary gland imaging	^{99m} Tc	TcO ₄ ⁻	40
Meckel's diverticulum imaging	^{99m} Tc	TcO ₄ ⁻	400

For footnotes see end of table.

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

Test	Radionuclide	Chemical form ^a	Maximum usual activity per test ^b (MBq)
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
	^{113m} In	Non-absorbable compounds	12
<i>Kidney, urinary system and adrenals</i>			
Renal imaging	^{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
Adrenal imaging	⁷⁵ Se ^e	Selenorcholesterol	8
<i>Miscellaneous</i>			
Tumour or abscess imaging	⁶⁷ Ga	Citrate	300
	²⁰¹ Tl	Chloride	100
Tumour imaging	^{99m} Tc	Dimercaptosuccinic acid	400
Neuroectodermal tumour imaging	¹²³ I	Meta-iodo-benzyl guanidine	400
	¹³¹ I	Meta-iodo-benzyl guanidine	20

For footnotes see end of table.

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

Test	Radionuclide	Chemical form ^a	Maximum usual activity per test ^b (MBq)
Lymph node imaging	^{99m} Tc	Labelled colloid	80
Abscess imaging	^{99m} Tc	Exametazime labelled white cells	400
	¹¹¹ In	Labelled white cells	20
Thrombus imaging	¹¹¹ In	Labelled platelets	20

Note: The first two footnotes appear in the BSS [1], while the last three provide updated information.

- ^a In some countries, some of the compounds are considered obsolete.
- ^b In some countries, the typical values are lower than those indicated in this table.
- ^c Currently bone marrow imaging should be performed with antigranulocyte antibodies rather than with labelled colloids [37].
- ^d Currently also performed with perfusion tracers such as sestamibi or tetrofosmine [37].
- ^e Currently replaced by ¹²³I/¹³¹I.

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

Appendix VII

EXAMPLES OF ACCIDENTAL EXPOSURES IN NUCLEAR MEDICINE

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

A therapeutic dose of 370 MBq of ^{131}I 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 ^{131}I 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 cross-check 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 ^{131}I , the nurses discovered the error and informed the physician and the RPO. As a remedy, a dose of 1000 mg of potassium iodide was administered immediately, and three subsequent doses of 1000 mg each, given at four hour intervals. The estimated radiation dose to the patient's thyroid was between 1.2 and 1.4 Gy.

Exercise on identifying lessons and preventive actions from this event:

- (a) Do I have written procedures in my nuclear medicine department for unambiguous identification of therapy patients (for example, by means of a photograph)?
- (b) Would computer programs for bed assignments provide a clear warning in case of conflicting information?
- (c) Would conflicting information on patients be investigated until complete clarification?
- (d) Would communication procedures between physicians and nurses prevent misidentification of patients?
- (e) Are radionuclide therapy patients segregated from other patients by being in different rooms?

Event No. 2: ^{131}I treatment of wrong patient

A therapy dose of 333 MBq of ^{131}I was given inadvertently to the wrong patient (patient A instead of patient B). Patient A was to receive 740 MBq of $^{99\text{m}}\text{Tc}$ for a diagnostic bone scan; the $^{99\text{m}}\text{Tc}$ was administered and the patient was seated in the waiting room. Patient B, who was scheduled to receive an ^{131}I 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 ^{131}I and called patient B; however, patient A responded. The technologist explained the ^{131}I 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 ^{131}I trapped in the thyroid and to block further uptake. The dose to patient A's thyroid was estimated at 8.2 Gy.

Exercise on identifying lessons and preventive actions from this event:

- (a) Do I have written procedures in my nuclear medicine department for unambiguous identification of therapy patients (for example, by means of a photograph)?
- (b) Would the procedure be effective, even if the wrong patient were to respond?

Event No. 3: Wrong dose of ^{131}I

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

The hospital received from the distributor the patient's prescribed amount of ^{131}I in one vial, together with a second vial containing 5180 MBq of ^{131}I . 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 their contents correctly labelled.

When the physician was ready to administer the ^{131}I , 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 ^{131}I . 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 ^{131}I and could not find the second vial. The resulting investigation determined that the vial had been used the previous day.

Exercise on identifying lessons and preventive actions from this event:

- (a) Do I have written procedures in my nuclear medicine department for receipt, storage, preparation and dispensing of radiopharmaceuticals?
- (b) Do these procedures include verification of the activity to be administered to each patient against the prescription?
- (c) Do these procedures include double, independent, checks of the activity to be administered?
- (d) Do these procedures include communication between physician and technologists with regard to the administration of radiopharmaceuticals?

Event No. 4: Radiopharmacy error

A patient was referred for treatment of Graves' disease with 555 MBq of ^{131}I . The radiopharmacist assumed that the dose 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 with an activity meter, he failed to take note of the dose of 555 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%.

Exercise on identifying lessons and preventive actions from this event:

- (a) Do I have written procedures in my nuclear medicine department for the dispensing of radiopharmaceuticals?
- (b) Do these procedures include verification of the activity to be administered to each patient against the prescription?
- (c) Do these procedures include double, independent, checks of the activity to be administered?
- (d) Do these procedures include communication between physician and technologists with regard to the administration of radiopharmaceuticals?

Event No. 5: Confusion regarding activity of ^{131}I

A patient was prescribed 370 MBq of ^{131}I 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 an activity meter. However, because the technologist was expecting a reading of 370 MBq, he misread 444 MBq as 370 MBq. The administration of 444 MBq resulted in an overdose of 20%.

Exercise on identifying lessons and preventive actions from this event:

- (a) Do I have written procedures in my nuclear medicine department for receipt, verification and dispensing of radiopharmaceuticals?
- (b) Do these procedures include provisions for maintaining alertness in the process, such as proper reading of the activity with the activity meter?
- (c) Do these procedures include double, independent, checks of the activity to be administered?

Event No. 6: Dose to ineligible patient

A patient was administered 180 MBq of ^{131}I for a whole body scan. The scan indicated an unusually high breast uptake of ^{131}I , after which it was

discovered that the patient was a nursing mother. Before administering the dose, both the physician and the nuclear medicine technologist had failed to confirm that the patient was not breast feeding. 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.

Exercise on identifying lessons and preventive actions from this event:

- (a) Do I have written procedures in my nuclear medicine department for asking female patients whether they are breast feeding?
- (b) Do I have provisions to prevent situations of staff shortage, and to ensure that staff maintain alertness and do not relax compliance with the procedures?

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

A therapy dose of 7400 MBq of ^{131}I was administered to an 87 year old patient in an effort to relieve oesophageal 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 the staff involved. Monitoring of personnel showed that the highest reading was 0.3 mGy for one of the nurses.

Exercise on identifying lessons and preventive actions from this event:

- (a) Do I have in my nuclear medicine department contingency procedures for emergency situations involving radionuclide therapy patients?
- (b) Do these procedures include training exercises simulating emergencies involving all staff potentially involved?
- (c) Are radioactive patients treated with radionuclide therapy clearly identified?

Event No. 8: Administration of wrong dose of ^{131}I

A patient was to be administered 259 MBq of ^{131}I . The isotope was in the form of two capsules, of 130 MBq each, which were labelled correctly and contained in a vial. 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.

Exercise on identifying lessons and preventive actions from this event:

- (a) Do I have written procedures in my nuclear medicine department to check the vial label to ascertain the activity of each vial against the prescription?
- (b) Do these procedures include measurement of the vials before administering the dose?
- (c) Do these procedures include double, independent, checks of the activity contained in the vials against the prescription?

Appendix VIII

SUMMARY OF TYPICAL CAUSES OF AND CONTRIBUTING FACTORS TO ACCIDENTAL EXPOSURES IN NUCLEAR MEDICINE

The following types of error can be made:

- Communication errors, faulty transmission of information, misunderstanding of prescriptions and protocols, or use of obsolete protocols;
- Errors in the identification of the patient;
- Use of 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 physicians, medical physicists or nuclear medicine technologists;
- No reassessment of staffing requirements after purchasing new equipment, hiring new technologists or increasing workload;
- Inadequate quality assurance 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 users;
- Misunderstanding of displays or software messages;
- Inattention;
- Inconsistent use of different quantities and units.

In most 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 quality assurance.

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DEFINITIONS

The definitions given below may not necessarily conform to definitions adopted elsewhere for international usage.

absorbed dose. The fundamental dosimetric quantity D , defined as:

$$D = \frac{d\bar{\epsilon}}{dm}$$

where $d\bar{\epsilon}$ 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 ($\text{J}\cdot\text{kg}^{-1}$), 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.

authorization. The granting by a regulatory body or other governmental body of written permission for an operator to perform specified activities.

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, the 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:

$$E = \sum_T w_T H_T$$

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:

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

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 the joule per kilogram ($\text{J}\cdot\text{kg}^{-1}$), 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 a 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 body] 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, paediatrics, nursing, medical physics,

radiation and nuclear medical technology, radiopharmacy or occupational health).

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

kerma. The quantity K defined as:

$$K = \frac{dE_{\text{tr}}}{dm}$$

where dE_{tr} is the sum of the initial kinetic energies of all charged ionizing particles liberated by uncharged ionizing particles in a material of mass dm . The SI unit of kerma is the joule per kilogram ($\text{J}\cdot\text{kg}^{-1}$), termed the gray (Gy).

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 having implications for protection or safety.

licence. A legal document issued by the regulatory body granting authorization to perform specified activities related to a facility or activity.

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 protection and safety purposes, 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. 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 body by a legal person to notify an intention to carry out a practice or other use of a source.

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 BSS.

potential exposure. Exposure that is not expected to be delivered with certainty but that may result from an accident involving 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 additional 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.

protection and safety. The protection of people against exposure to ionizing radiation or radioactive materials and the safety of radiation sources, including the means for achieving this, and 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 emergencies or situations of chronic exposure.

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. (The BSS require that for diagnostic uses of radiation the imaging and quality assurance requirements of the BSS be fulfilled with the advice of a qualified expert 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 BSS.

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 BSS.

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

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

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.

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.

safety assessment. Assessment of all aspects of the siting, design and operation of an authorized facility that are relevant to protection and safety.

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.

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.

source. Anything that may cause radiation exposure, such as by emitting ionizing radiation or by 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 fission. 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 international safety 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.

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.)

unsealed source. A source that does not meet the definition of a sealed 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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This report is intended to be of assistance to both regulators and users of radiation sources in nuclear medicine in applying the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS). Regulators will find it useful for reviewing applications for authorization and for inspection. Users of radiation in nuclear medicine may follow the guidance provided in order to comply with the BSS requirements or the equivalent national requirements.

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