

CHAPTER 3

RADIATION PROTECTION

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3.1. INTRODUCTION

Medical exposure is the largest human-made source of radiation exposure, accounting for more than 95% of radiation exposure. Furthermore, the use of radiation in medicine continues to increase worldwide — more machines are accessible to more people, the continual development of new technologies and new techniques adds to the range of procedures available in the practice of medicine, and the role of imaging is becoming increasingly important in day to day clinical practice. The introduction of hybrid imaging technologies, such as positron emission tomography/computed tomography (PET/CT) and single photon emission computed tomography (SPECT)/CT, means that the boundaries between traditional nuclear medicine procedures and X ray technologies are becoming blurred. Worldwide, the total number of nuclear medicine examinations is estimated to be about 35 million per year.

In Chapter 2, basic radiation biology and radiation effects were described, demonstrating the need for a system of radiation protection. Such a system allows the many beneficial uses of radiation to be utilized, but at the same time ensures detrimental radiation effects are either prevented or minimized. This can be achieved by having the objectives of preventing the occurrence of deterministic effects and of limiting the probability of the stochastic effects to a level that is considered acceptable. In a nuclear medicine facility, consideration needs to be given to the patient, the staff involved in performing the nuclear medicine procedures, members of the public and other staff that may be in the nuclear medicine facility, carers and comforters of patients undergoing procedures,

and persons who may be undergoing a nuclear medicine procedure as part of a biomedical research project.

This chapter discusses how the objectives stated above are achieved through a system of radiation protection, and how such a system should be applied practically in a hospital in general and in nuclear medicine specifically.

3.2. BASIC PRINCIPLES OF RADIATION PROTECTION

The means for achieving the objectives of radiation protection have evolved over many years to the point where, for some time, there has been a reasonably consistent approach throughout the world — namely the ‘system of radiological protection’, as espoused by the International Commission on Radiological Protection (ICRP). The following will briefly describe this system, specifically as it applies to nuclear medicine.

3.2.1. The International Commission on Radiological Protection system of radiological protection

The principles of radiation protection and safety upon which the IAEA safety standards are based are those developed by the ICRP. The detailed formulation of these principles can be found in ICRP publications and they cannot easily be paraphrased without losing their essence. However, a brief, although simplified, summary of the principles is given in this section.

The ICRP recommends a system of radiological protection to cover all possible exposure situations. There are many terms associated with the system and some of these will now be introduced.

The ICRP in its Publication 103 [3.1] divides all possible situations of where exposure can occur into three types — planned exposure situations, emergency exposure situations and existing exposure situations. For the practice of nuclear medicine, only the first situation is relevant. The use of radiation in nuclear medicine is a planned exposure situation — it needs to be under regulatory control, with an appropriate authorization in place from the regulatory body before operation can commence. Misadministration, spills and other such incidents or accidents can give rise to what is called potential exposure, but these remain part of the planned exposure situation as their occurrence is considered in the granting of an authorization. It should be noted that the ICRP has used the term ‘practice’ to describe a planned exposure situation such as the operation of a nuclear medicine facility.

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The ICRP then puts exposure of individuals into three categories — medical exposure, occupational exposure and public exposure:

- Medical exposure refers primarily to exposure incurred by patients for the purpose of medical diagnosis or treatment. It also refers to exposures incurred by individuals helping in the support and comfort of patients undergoing diagnosis or treatment, and by volunteers in a programme of biomedical research involving their exposure.
- Occupational exposure is the exposure of workers incurred in the course of their work.
- Public exposure is exposure incurred by members of the public from all exposure situations, but excluding any occupational or medical exposure.

All three need to be considered in the nuclear medicine facility.

An individual person may be subject to one or more of these categories of exposure, and for radiation protection purposes such exposures are dealt with separately.

The ICRP system has three fundamental principles of radiological protection, namely:

- The principle of justification: Any decision that alters the radiation exposure situations should do more good than harm.
- The principle of optimization of protection: The likelihood of incurring exposures, the number of people exposed and the magnitude of their individual doses should all be kept as low as reasonably achievable (ALARA), taking into account economic and societal factors.
- The principle of limitation of doses: The total dose to any individual from regulated sources in planned exposure situations other than medical exposure of patients should not exceed the appropriate limits recommended by the ICRP. Recommended dose limits are given in Table 3.1.

In a nuclear medicine facility, occupational and public exposures are subject to all three principles, whereas medical exposure is subject to the first two only. More detail on the application of the ICRP system for radiological protection as it applies to a nuclear medicine facility is given in the remainder of this chapter.

TABLE 3.1. RECOMMENDED DOSE LIMITS IN PLANNED EXPOSURE SITUATIONS^a

Type of limit	Occupational	Public
Effective dose	20 mSv per year, averaged over defined periods of 5 years ^b	1 mSv in a year ^c
Annual equivalent dose in:		
Lens of the eye ^d	20 mSv	15 mSv
Skin ^{e, f}	500 mSv	50 mSv
Hands and feet	500 mSv	—

^a Limits on effective dose are for the sum of the relevant effective doses from external exposure in the specified time period and the committed effective dose from intakes of radionuclides in the same period. For adults, the committed effective dose is computed for a 50 year period after intake, whereas for children it is computed for the period up to reaching 70 years of age.

^b With the further provision that the effective dose should not exceed 50 mSv in any single year. Additional restrictions apply to the occupational exposure of pregnant women.

^c In special circumstances, a higher value of effective dose could be allowed in a single year, provided that the average over 5 years does not exceed 1 mSv/a.

^d In 2011, the ICRP recommended that the occupational dose limit be lowered from the previous 150 mSv/a to 20 mSv/a, averaged over 5 years, and with no more than 50 mSv in any single year.

^e The limitation on effective dose provides sufficient protection for the skin against stochastic effects.

^f Averaged over a 1 cm² area of skin regardless of the area exposed.

3.2.2. Safety standards

Safety standards are based on knowledge of radiation effects and on the principles of protection described above. In this respect, the development of safety standards by the IAEA follows a well established approach. The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), a body set up by the United Nations in 1955, compiles, assesses and disseminates information on the health effects of radiation and on levels of radiation exposure due to different sources; this information was taken into account in developing the standards. Following a decision made in 1960, the IAEA safety standards are based on the recommendations of the ICRP, which also take account of the scientific information provided by UNSCEAR.

Purely scientific considerations, however, are only part of the basis for decisions on protection and safety, and the safety standards implicitly encourage

decision makers to make value judgements about the relative importance of different kinds of risks and about the balancing of risks and benefits. General acceptance of risk is a matter of consensus and, therefore, international safety standards should provide a desirable international consensus for the purpose of protection.

For these reasons, international consensus is integral to the IAEA safety standards, which are prepared with the wide participation of and approval by its Member States and relevant international organizations. The current version of what is commonly called the Basic Safety Standards (BSS) is entitled Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards (2014) [3.2]. The BSS are jointly sponsored by the European Commission, the Food and Agriculture Organization of the United Nations, the IAEA, the International Labour Organization, the OECD Nuclear Energy Agency, the Pan American Health Organization (PAHO), the United Nations Environment Programme and the World Health Organization (WHO).

The BSS comprises five sections: Introduction, General requirements for protection and safety, Planned exposure situations, Emergency exposure situations and Existing exposure situations, as well as four schedules. The purpose of the BSS is to establish basic requirements for protection against exposure to ionizing radiation and for the safety of radiation sources that may deliver such exposure. The requirements of the BSS underpin the implementation of radiation protection in a nuclear medicine facility, supplemented by the relevant IAEA Safety Guides and Safety Reports.

3.2.3. Radiation protection quantities and units

The basic dosimetry quantity for use in radiation protection is the mean organ or tissue dose D_T given by:

$$D_T = \varepsilon_T / m_T \tag{3.1}$$

where

m_T is the mass of the organ or tissue T;

and ε_T is the total energy imparted by radiation to that tissue or organ.

The International System of Units (SI) unit of mean organ dose is joules per kilogram (J/kg) which is termed gray (Gy).

Owing to the fact that different types of ionizing radiation will have different effectiveness in damaging human tissue at the same dose, and the fact

that the probability of stochastic effects will depend on the tissue irradiated, it is necessary to introduce quantities to account for these factors. Those quantities are equivalent dose and effective dose. Since they are not directly measurable, the International Commission on Radiation Units and Measurements (ICRU) has defined a set of operational quantities for radiation protection purposes (area monitoring and personal monitoring): the ambient dose equivalent, directional dose equivalent and personal dose equivalent.

Regarding internal exposure from radionuclides, the equivalent dose and the effective dose are not only dependent on the physical properties of the radiation but also on the biological turnover and retention of the radionuclide. This is taken into account in the committed dose quantities (equivalent and effective).

3.2.3.1. Equivalent dose

It is a well known fact in radiobiology that densely ionizing radiation such as α particles and neutrons will cause greater harm to a tissue or organ than γ rays and electrons at the same mean absorbed dose. This is because the dense ionization events will result in a higher probability of irreversible damage to the chromosomes and a lower chance of tissue repair. To account for this, the organ dose is multiplied with a radiation weighting factor in order to get a quantity that more closely reflects the biological effect on the irradiated tissue or organ. This quantity is called the equivalent dose and is defined as:

$$H_T = w_R D_{T,R} \quad (3.2)$$

where

$D_{T,R}$ is the mean tissue or organ dose delivered by type R radiation;

and w_R is the radiation weighting factor.

For X rays, γ rays and electrons, $w_R = 1$; for α particles, $w_R = 20$. The SI unit of equivalent dose is joules per kilogram (J/kg), which is termed sievert (Sv). In a situation of exposure from different types of radiation, the total equivalent dose is the sum of the equivalent dose from each type of radiation.

3.2.3.2. *Effective dose*

The relationship between the probability of stochastic effects and equivalent dose is found to depend on the organ or tissue irradiated. To account for this, tissue weighting factors w_T are introduced. They should represent the relative contribution of an organ or tissue T to the total detriment due to the stochastic effects resulting from a uniform irradiation of the whole body. The total tissue weighted equivalent dose is called effective dose and is defined as:

$$E = \sum w_T H_T \tag{3.3}$$

where H_T is the equivalent dose in organ or tissue T.

The sum is performed over all organs and tissues of the human body considered to be sensitive to the induction of stochastic effects. Recommended tissue weighting factors are found in ICRP Publication 103 [3.1]. Despite depending on the sex and age of the person, for the purposes of radiation protection, the values for tissue weighting factors are taken as constants and are applicable to the average population.

The use of effective dose has many advantages in practical radiation protection. Very different exposure situations (e.g. internal and external exposure by different types of radiation) can be combined and result in a single value, the effective dose.

3.2.3.3. *Committed dose*

When radionuclides are taken into the body, the resulting dose is received throughout the period of time during which they remain in the body. The total dose delivered during this period of time is referred to as the committed dose and is calculated as a specified time integral of the rate of receipt of the dose. The committed equivalent dose is defined as:

$$H_T(\tau) = \int_{t_0}^{t_0+\tau} \dot{H}_T(t) dt \tag{3.4}$$

where

t_0 is the time of intake;

and τ is the integration time.

For workers and adult members of the general public, τ is taken to be 50 years while for children 70 years is regarded as appropriate.

The committed effective dose is given by:

$$E(\tau) = \sum_T w_T H_T(\tau) \quad (3.5)$$

3.2.3.4. Operational quantities

For all types of external radiation, the operational quantities for area monitoring are defined on the basis of a dose equivalent value at a point in the ICRU sphere. It is a sphere of tissue-equivalent material (30 cm in diameter with a density of 1 g/cm³ and a mass composition of: 76.2% oxygen, 11.1% carbon, 10.1% hydrogen and 2.6% nitrogen). For radiation monitoring, it adequately approximates the human body in regards to the scattering and attenuation of the radiation fields under consideration.

The operational quantities for area monitoring defined in the ICRU sphere should retain their character of a point quantity. This is achieved by introducing the terms ‘expanded’ and ‘aligned’ radiation field in the definition of these quantities. An expanded radiation field is a hypothetical field in which the spectral and the angular fluence have the same values at all points of a sufficiently large volume equal to the values in the actual field at the point of interest. The expansion of the radiation field ensures that the whole ICRU sphere is thought to be exposed to a homogeneous radiation field with the same fluence, energy distribution and direction distribution as at the point of interest of the real radiation field. If all radiation is aligned in the expanded radiation field so that it is opposed to a radius vector Ω specified for the ICRU sphere, the aligned and expanded radiation field is obtained. In this hypothetical field, the ICRU sphere is homogeneously irradiated from one direction, and the fluence of the field is the integral of the angular differential fluence at the point of interest in the real radiation field over all directions. In the expanded and aligned radiation field, the value of the dose equivalent at any point in the ICRU sphere is independent of the direction distribution of the radiation in the real radiation field.

For area monitoring, the operational quantity for penetrating radiation is the ambient dose equivalent, $H^*(10)$:

- The ambient dose equivalent at a point in a radiation field is the dose equivalent that would be produced by the corresponding expanded and aligned field in the ICRU sphere at a depth of 10 mm on the radius vector opposing the direction of the aligned field.

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For area monitoring, the operational quantity for low-penetrating radiation is the directional dose equivalent $H'(0.07, \Omega)$:

- The directional dose equivalent at a point in a radiation field is the dose equivalent that would be produced by the corresponding expanded field in the ICRU sphere at a depth of 0.07 mm in a specified direction Ω .

The personal dose equivalent $H_p(d)$ is defined as:

- The equivalent dose at a depth d in soft tissue below a specified point on the body.

The relevant depth is $d = 10$ mm for penetrating radiations (photon energies above 15 keV), while depths $d = 0.07$ mm and $d = 3$ mm are used for weakly penetrating radiations (photon energies below 15 keV) in skin and the lens of the eye, respectively.

3.3. IMPLEMENTATION OF RADIATION PROTECTION IN A NUCLEAR MEDICINE FACILITY

3.3.1. General aspects

Implementation of radiation protection in a nuclear medicine facility must fit in with, and be complementary to, the systems for implementing medical practice in the facility. Radiation protection must not be seen as something imposed from 'outside' and separate to the real business of providing medical services and patient care. Most countries have their own radiation protection legislation and regulatory framework, typically requiring any facility or person wishing to provide or perform nuclear medicine procedures to have an appropriate authorization from the radiation protection regulatory body. The requirements to be fulfilled in order to be granted such an authorization will vary from country to country, but in general, compliance with the requirements of the BSS would be expected.

To achieve a high standard of radiation protection, the most important thing is to establish a safety based attitude in every individual, such that protection and accident prevention are regarded as a natural part of daily duties. This objective is basically achieved by education and training, and encouraging a questioning and learning attitude, but also by a positive and cooperative attitude from the national authorities and the employer in supporting radiation protection with sufficient resources, both in terms of personnel and money. A feeling of responsibility

can only be achieved if the people involved regard the rules and regulations as necessary, and are a support to and not a hindrance in their daily work. Every individual should also know their responsibilities through formal assignment of duties.

3.3.2. Responsibilities

3.3.2.1. Licensee and employer

The licensee of a nuclear medicine facility, through the authorization issued by the regulatory body, has the prime responsibility for applying the relevant national regulations and meeting the conditions of the licence. The licensee may appoint other people to carry out actions and tasks related to these responsibilities, but the licensee retains overall responsibility. In particular, the nuclear medicine physician, the medical physicist, the nuclear medicine technologist, the radiopharmacist and the radiation protection officer (RPO) all have key roles and responsibilities in implementing radiation protection in a nuclear medicine facility, and these are discussed in more detail below.

The BSS need to be consulted for details on all of the requirements for radiation protection that are assigned to licensees. Employers are also assigned many responsibilities, in cooperation with the licensee, for occupational radiation protection. Key responsibilities for the licensee include ensuring that the necessary personnel (nuclear medicine physicians, medical physicists, nuclear medicine technologists, radiopharmacists and an RPO) are appointed, and that the individuals have the necessary education, training and competence to perform their respective duties. Clear responsibilities for personnel must be assigned; a radiation protection programme (RPP) must be established and the necessary resources provided; a comprehensive quality assurance (QA) programme must be established; and education and training of personnel supported.

3.3.2.2. Nuclear medicine specialist

The general medical and health care of the patient is, of course, the responsibility of the individual physician treating the patient. However, when the patient presents in the nuclear medicine facility, the nuclear medicine specialist has the particular responsibility for the overall radiation protection of the patient. This means responsibility for the justification of a given nuclear medicine procedure for the patient, in conjunction with the referring medical practitioner, and responsibility for ensuring the optimization of protection in the performance of the examination or treatment.

3.3.2.3. Nuclear medicine technologist

The technologist has a key position, and their skill and care to a large extent determine the optimization of the patient's exposure.

3.3.2.4. Radiation protection officer

It is highly recommended that the licensee appoint a person to oversee and implement radiation protection matters in the hospital. This person is called an RPO or radiation safety officer. The RPO should have a good theoretical and practical knowledge of the properties and hazards of ionizing radiation, as well as protection. In addition, the RPO should possess necessary knowledge of all the appropriate legislation and codes of practice relating to the uses of ionizing radiation in the relevant medical area, e.g. nuclear medicine. The RPO, unless also a qualified medical physicist in nuclear medicine, has no responsibilities for radiation protection in medical exposure.

3.3.2.5. Medical physicist

The medical physicist is a person who by education and training is competent to practise independently in one or more of the subfields in medical physics. For instance, a medical physicist in nuclear medicine should have a comprehensive knowledge of the imaging equipment used, including performance specifications, physical limitations of the equipment, calibration, quality control and image quality. The medical physicist should also be qualified in handling radiation protection matters associated with nuclear medicine, and has particular responsibilities for radiation protection in medical exposure, including the requirements pertaining to imaging (for diagnostic procedures), calibration, dosimetry and QA. Whenever possible, a medical physicist should serve as the RPO (see above). Other important tasks for the medical physicist are to be responsible for QA and for the local continuing education in radiation protection of the nuclear medicine staff and other health professionals.

3.3.2.6. Other personnel

Other personnel that may have responsibilities in radiation protection in nuclear medicine include radiopharmacists and other staff that may have been trained to perform special tasks, such as contamination tests or some quality control tests.

3.3.3. Radiation protection programme

The BSS require a licensee (and employer where appropriate) to develop, implement and document a protection and safety programme commensurate with the nature and extent of the risks of the practice to ensure compliance with radiation protection standards. Such a programme is often called an RPP and each nuclear medicine facility should have one. The RPP for a nuclear medicine facility is quite complex as it needs to cover all relevant aspects of protection of the worker, the patient and the general public. The details of such an RPP can be found in Ref. [3.3].

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

3.3.4. Radiation protection committee

An effective way to supervise compliance with the RPP is the formation of a committee for radiation protection. Since a representative of the management is usually a member of the radiation protection committee, communication with the representative may be the most appropriate. The members of the radiation protection committee should include an administrator representing the management, the chief nuclear medicine physician, a medical physicist, the RPO, a nuclear medicine technologist, possibly a nurse for patients undergoing therapy with radiopharmaceuticals, and a maintenance engineer.

3.3.5. Education and training

According to the BSS, provision must be made to ensure that all personnel on whom protection and safety depend are appropriately trained and qualified so that they understand their responsibilities and perform their duties with appropriate judgement and according to defined procedures. Such personnel clearly include the nuclear medicine physician (or other medical specialist wishing to perform nuclear medicine procedures), nuclear medicine technologist, medical physicist, radiopharmacist and the RPO. However, there are additional staff that may also need appropriate training, such as nurses working with radioactive patients and maintenance staff. Details about appropriate levels of training are given in Ref. [3.3].

3.4. FACILITY DESIGN

It is an important task for the medical physicist to be actively involved in the planning and design of the nuclear medicine facility. Factors that are to be considered are:

- Safety of sources;
- Optimization of protection for staff and the general public;
- Preventing uncontrolled spread of contamination;
- Maintaining low background where most needed;
- Fulfilment of national requirements regarding pharmaceutical work.

3.4.1. Location and general layout

The location of the nuclear medicine facility within the hospital or clinic is not critical, but a few factors need to be considered. It should be readily accessible, especially for outpatients, who constitute the majority of the patients. The facility should also be located away from radiotherapy sources and other strong sources of ionizing radiation such as a cyclotron, which can interfere with the measuring equipment. Isolation wards for patients treated with radionuclides should be located outside of the nuclear medicine facility.

The general layout of the nuclear medicine facility should take into account a possible separation of the work areas and the patient areas. It is also essential to reduce uncontrolled spread of contamination. This will be achieved by locating rooms for preparation of radiopharmaceuticals as far away as possible from rooms for measurements and patient waiting areas. Another important factor is to reduce the transport of unsealed sources within the facility. The general layout is from a low activity area close to the entrance to high activity areas at the opposite end. More details regarding floor planning and additional topics can be found in the IAEA's Nuclear Medicine Resources Manual [3.4]. It should be borne in mind that the design of facilities is an important tool in the optimization of protection of workers and the general public. This is further discussed in Section 3.6.2.

3.4.2. General building requirements

The design of the facility should take into consideration the type of work to be performed and the radionuclides (and their activity) intended to be used. The ICRP's concept of categorization of hazard can be used in order to determine the special needs concerning ventilation and plumbing, and the materials used in walls, floors and work-benches. The different rooms in the facility will be categorized as low, medium or high hazard areas.

Of special concern in a nuclear medicine facility is the risk of contamination, and if contamination occurs, the ability to contain it and clean it up. Therefore, the floors and work-benches should generally be finished in an impermeable material which is washable and resistant to chemical change, with all joints sealed. The floor cover should be curved to the wall. The walls should also be easily cleaned. Chairs and beds used in high hazard areas should be easily decontaminated. However, some attention has to be given to the comfort of the patients, for instance in the waiting areas.

Rooms in which unsealed sources, especially 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 glove box. It should be noted that this might also be necessary in the examination room depending on the radiopharmaceutical used in ventilation scintigraphy. Details regarding fume hoods, etc. are given in Chapter 9.

If the regulatory body allows the release of aqueous waste to the sewer, a dedicated sink needs to be used, and this needs to be easily decontaminated. Local rules for the discharge shall be available.

A separate bathroom for the exclusive use by injected patients is recommended. A sign requesting patients to always sit down, flush the toilet well and wash their hands should be displayed to lower the risk of contamination of the floor and to ensure adequate dilution of excreted radioactive materials. The bathroom should include a sink as a normal hygiene measure and should be finished in materials that are easily decontaminated. Local rules should be available for cleaning the toilet. The patient toilet facilities should not be used by hospital staff as it is likely that the floor, toilet seat and taps will frequently be contaminated.

Drain-pipes from the nuclear medicine facility should go as directly as possible to the main building sewer. It should be noted that some countries require that drain-pipes from a nuclear medicine facility and especially from isolation wards for patients undergoing radionuclide therapy end up in a delay tank.

3.4.3. Source security and storage

The licensee needs to establish a security system to prevent theft, loss, unauthorized use or damage to sources. It should be included in all steps from ordering and delivery of the sources to disposal of spent sources. Only authorized personnel are permitted to order radionuclides. Routines for delivery and unpacking shipments should be available, as well as routines for safe handling and storage of sources. Records of all sources should be kept. The user is always responsible for the security of sources and, in principle, it should be possible to identify where an individual source is located or how it has been used, even

if it has left the facility in a patient. The regulatory body should promptly be informed in cases of lost or stolen sources.

When a radioactive source is not in use, it should always be stored. In a nuclear medicine facility, the sources are generally stored in the room where preparation of radiopharmaceuticals is undertaken. Storage of sources is further discussed in Chapter 9.

It is necessary to consider the possible consequences of an accidental fire and to take steps to minimize the risk of this. Careful selection of non-flammable construction materials when building the storage facility will greatly reduce this hazard. The storage facility should not be used to hold any highly flammable or highly reactive materials. Liaison with the local firefighting authority is necessary and their advice should be sought regarding provision of firefighting equipment in the vicinity of the radioactive waste store.

3.4.4. Structural shielding

Structural shielding should be considered in a busy facility where large activities are handled and where many patients are waiting and examined. In a PET/CT facility, structural shielding is always necessary and the final design will generally be determined by the PET application because of the high activities used and because of the high energy of the annihilation radiation. Careful calculations should be performed to ensure the need and construction of the barrier. Such calculations should include not only walls but also the floor and ceiling, and must be made by a qualified medical physicist. Radiation surveys should always be performed to ensure the correctness of the calculations.

The correct design of protective barriers is of the utmost importance not only from a protection but also from an economic point of view. If the basic calculations are wrong, it will become very expensive to correct the mistakes later when the whole construction is completed. It is, therefore, very important that a qualified expert, such as a medical physicist, be consulted in the planning stage.

3.4.5. Classification of workplaces

With regard to occupational exposure, the BSS require the classification of workplaces as controlled areas or as supervised areas.

In a controlled area, individuals follow specific protective measures to control radiation exposures. It will be necessary to designate an area as controlled if it is difficult to predict doses to individual workers or if individual doses may be subject to wide variations. The controlled area must be delineated and

it is convenient to use existing structural boundaries, which should already be considered at the planning stage of a facility.

A supervised area is any area for which occupational exposure conditions are predictable and stable. They are kept under review even though specific additional protective measures and safety provisions are not normally needed.

In a nuclear medicine facility, the rooms for preparation, storage (including radioactive waste) and injection of the radiopharmaceuticals will be controlled areas. Owing to the potential risk of contamination, the imaging rooms and waiting areas for injected patients might also be classified as controlled areas. The area housing a patient to whom therapeutic amounts of activity have been given will also be a controlled area. In the case of pure β emitters, such as ^{90}Y , ^{89}Sr or ^{32}P , which are not excreted from the body, the area may not need to be classified as a controlled area.

3.4.6. Workplace monitoring

Workplace monitoring means checking the facility for the presence of radiation or radioactive contamination. The two basic types of workplace monitoring are exposure monitoring and contamination monitoring. Exposure monitoring (sometimes called ‘area monitoring’ or ‘radiation surveying’) consists of measuring radiation levels (in microsieverts per hour) at various points using an exposure meter or survey meter. Contamination monitoring is the search for extraneous radioactive material deposited on surfaces.

Routine workplace monitoring should be performed at predefined places in the facility as defined by the RPO. It is an advantage if one member of staff is appointed to take the measurements. The staff member should be well trained in handling the instrument. The results should be recorded and investigated if they exceed the investigation levels predefined by the RPO.

More details regarding workplace monitoring are given in Chapters 9 and 20.

3.4.7. Radioactive waste

The radioactive waste in a nuclear medicine facility comprises many different types of waste. It may be of high activity, such as a technetium generator, or of low activity, such as from biomedical procedures or research. In addition, it may have a long or short half-life and it may be in a solid, liquid or gaseous form. Radioactive waste needs to be safely managed because it is potentially hazardous to human health and the environment. Through good practices in the use of radionuclides, the amount of waste can be significantly reduced but not eliminated. It is important that safe waste management, in full compliance with

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all relevant regulations, is considered and planned for at the early stages of any projects involving radioactive materials. It is the responsibility of the licensee to provide safe management of the radioactive waste. It should be supervised by the RPO and local rules should be available.

Containers to allow segregation of different types of radioactive waste should be available in areas where the waste is generated. The containers must be suitable for the purpose (volume, shielding, being leakproof, etc.). Each type of waste should be kept in separate containers that are properly labelled to supply information about the radionuclide, physical form, activity and external dose rate.

A room for interim storage of radioactive waste should be available. The room should be locked, properly marked and, if necessary, ventilated. Flammable waste should be placed separately. It is essential that all waste be properly packed in order to avoid leakage during storage. Biological waste should be refrigerated or put in a freezer. Records should be kept, so that the origin of the waste can be identified.

The final disposal of the radioactive waste produced in the nuclear medicine facility includes several options: storage for decay and disposal as cleared waste into the sewage system (aqueous waste), through incineration or transfer to a landfill site (solid waste), or transfer of sources to the vendor or to a special waste disposal facility outside of the hospital.

For many of the wastes generated in hospitals, storage for decay is a useful option because the radionuclides generally have short half-lives. This can be done in the hospital and may include some treatment of the wastes to ensure safe storage. Other types of waste containing radionuclides with longer half-lives must be transferred to a special waste treatment, storage and disposal facility outside of the hospital. One option is to return the source to the vendor. This is an attractive option for radionuclide generators and might also be useful for sealed sources used in a quality control programme. The option of returning the source should be provided for in the purchase process.

For diagnostic patients there is generally no need for collection of excreta. Ordinary toilets can be used. For therapy patients, there are different policies in different countries, either to use separate toilets equipped with delay tanks or an active treatment system, or to allow the excreta to be released directly into the sewage system. This is further discussed in Chapter 20.

3.5. OCCUPATIONAL EXPOSURE

Detailed requirements for protection against occupational exposure are given in Section 3 of the BSS, and recommendations on how to meet these requirements are given in IAEA Safety Guides [3.5–3.7]. All of these safety

standards are applicable to nuclear medicine practice, and in addition Ref. [3.3] provides further specific advice. A summary of the most relevant issues for nuclear medicine is given in this section.

3.5.1. Sources of exposure

Exposure of workers may arise from unsealed sources either through external irradiation of the body or through entry of radioactive substances into the body. The main precautions required in dealing with external irradiation depend on the physical characteristics of the emitted radiation and the activity as reflected by the specific dose rate constant as well as the half-life of the radionuclide. When a radionuclide enters the body, the internal exposure will depend on factors such as the physical and chemical properties of the radionuclide, the activity and the biokinetics.

Every type of work performed in a nuclear medicine facility will make a contribution to the external exposure of the worker: unpacking radioactive material, activity measurements, storage of sources, preparation of radiopharmaceuticals, administration of radiopharmaceuticals, patient handling and examination, care of the radioactive patient and handling of radioactive waste. Generally, the yearly effective dose to staff working full time in nuclear medicine with optimized protection should be well below 5 mSv.

Among the different tasks involved, the highest effective dose is received from the patient at injection and imaging. The dose rate close to the patient can be quite high, for instance, 300 $\mu\text{Sv/h}$ at 0.5 m from a patient who has received 350 MBq of ^{18}F .

High equivalent dose to the fingers can be received in preparation and administration of radiopharmaceuticals, even if proper shielding is used. Injecting eight patients per day with 400 MBq of $^{99\text{m}}\text{Tc}$ per patient has been reported to give a mean and maximum equivalent dose to the fingers of 80 and 330 mSv/a, respectively, even if syringe shields are used. Without shielding, the maximum equivalent dose will be about 2500 mSv/a.

Higher risk of internal exposure due to contamination is associated with radioactive spills, animal experiments, emergency surgery of a therapy patient and autopsy of a therapy patient. However, traces of the radionuclides used in a nuclear facility can be found almost everywhere, especially on door handles, taps, some specific equipment and in the patient's toilet. Some procedures, such as ventilation scans, might also cause contamination of both personnel and equipment. Whole body measurements of workers have revealed an equilibrium internal contamination of up to 10 kBq of $^{99\text{m}}\text{Tc}$, which will result in an effective dose of ~ 0.05 mSv/a. Although this is a small fraction of the external exposure, every precaution must be taken to avoid contamination of the facility.

Of special concern is contamination of the skin, since this can result in extremely high local equivalent doses. For instance, 1 kBq of ^{18}F will result in an initial equivalent dose rate to the skin of 0.8 mSv/h. The activity on the hands after elution, preparation and administration of $^{99\text{m}}\text{Tc}$ radiopharmaceuticals has been reported to be 0.02–200 kBq, which results in an initial skin dose of 0.005–50 mSv/h.

3.5.2. Justification, optimization and dose limitation

Nuclear medicine workers have no personal benefit from exposure. Therefore, justification of occupational exposure must be included in justification of the nuclear medicine practice itself. The risks in radiation work should not be greater than for any other similar work. The upper limit of a tolerable risk for the individual is determined by the dose limits (see Table 3.1). However, through optimized protection, the incurred effective dose should be further reduced. Besides facility and equipment design, shielding of sources, handling of sources as well as personal protective equipment are important in the optimization of occupational radiation protection. Optimization is also achieved through education and training, resulting in awareness and involvement in radiation protection.

From the examples above, it should be clear that the dose limits for workers can be exceeded if the necessary protective precautions are not taken. Radiation protection measures must be applied in each step of the work with radiopharmaceuticals in the nuclear medicine facility, including work with the patient.

The principal parties responsible for occupational exposure are licensees and employers, and they should ensure that the exposure is limited and that protection is optimized. The worker also has responsibilities and must follow the rules and procedures as well as using the devices for monitoring and the protective equipment and tools provided, and in all aspects cooperate with the employer in order to improve the protection standard in the workplace.

3.5.3. Conditions for pregnant workers and young persons

It is generally accepted that the unborn child should be afforded the same protection level as a member of the general public, meaning that a dose limit of 1 mSv should be applied once pregnancy is declared. Good operational procedures should ensure that the radiation doses received by staff working in nuclear medicine facilities are well below any occupational dose limits. Therefore, there is generally no need for a pregnant member of staff to change her duties based on the expected dose to the embryo or fetus. However, removal of pregnant

women from work in laboratories where large quantities of radionuclides are prepared and administered, and from nursing teams responsible for patients who have been treated with radionuclides should be considered. These staff members could receive a dose to the embryo or fetus comparable with the public dose limit over the period of the pregnancy. Since all doses should be reduced whenever possible, some supervisors will consider it prudent to reassign pregnant staff to non-radiation duties if this is possible. Many nuclear medicine facility managers would also accept requests from women to be reassigned to other duties for reasons beyond radiation protection. Previous personal monitoring results can help guide any decisions, noting that the dose to the fetus from external radiation is not likely to exceed 25% of the personal dosimeter measurement.

According to the BSS, no person under the age of 16 years is to be subjected to occupational exposure, and no person under the age of 18 years is to be allowed to work in a controlled area unless supervised and then only for the purpose of training.

3.5.4. Protective clothing

Suitable personal protective clothing should be provided for the use of all persons employed in work in controlled areas. The protective clothes should be adequate to prevent any contamination of the body of the worker for whom it is provided and should include gloves, laboratory coats, safety glasses and shoes or overshoes, as well as caps and masks for aseptic work.

A question frequently asked is whether lead aprons are useful for nuclear medicine work. Wearing a lead apron at all times will reduce the effective dose by a factor of about two. It is, therefore, a matter of judgement whether this dose reduction compensates for the effort of wearing an apron. In some hospitals, lead aprons are used in the case of prolonged injections and high activity.

3.5.5. Safe working procedures

The safety of the work in nuclear medicine is based on facility design as well as on the use of protective clothing and the use of protective equipment and tools as discussed above. These measures together with working procedures aimed to minimize external exposure, risk of contamination and spread of contamination, will optimize protection of workers. Work with unsealed sources should always be supported by written local rules.

In order to minimize the risk of contamination in handling radiopharmaceuticals, clean operation conditions and good laboratory practice should be adopted, and protective clothing used. The work area should be kept tidy and free from articles not required for work. It should be monitored

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periodically and be cleaned often enough to ensure minimal contamination. 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.

All manipulation for preparation, dispensing and administration of radioactive materials should be carried out in such a way that the spread of contamination is minimized. That includes preparing and dispensing radiopharmaceuticals over a drip tray covered with absorbing paper as well as using absorbing compresses at administrations. Any spills of radioactive material should be immediately covered with absorbent material to prevent the spread of material. If the spill cannot be cleaned up immediately, it must be marked to warn other personnel of its location. Decontamination of the area must begin as soon as possible.

When wearing gloves which may be contaminated, unnecessary contact with all other objects should be avoided. Gloves should be removed and disposed of in the radioactive waste bin as soon as work with radioactive substances is finished.

After finishing work with the potential for contamination, the protective clothing should be removed and placed in an appropriate container. Hands should be washed and monitored.

In order to minimize external exposure, the three fundamental measures of protection should be applied: time, distance and shielding. As far as possible, the time of exposure should be as short as possible. Of course, this is important in work where high exposure rates can be expected, such as in the preparation of radiopharmaceuticals. However, limiting exposure time should not compromise the quality of work or the use of other protective measures.

Direct handling of vials, syringes or other sources which produce a significant radiation field is not recommended. Forceps or tongs should be used to reduce the radiation exposure by increasing the distance between the source and the hands. Properly designed vial and syringe shields must be used wherever practicable. In cases where unshielded sources are handled or the exposure time is prolonged, the work should be performed behind a properly designed lead glass shield or similar type of protective barrier.

Radioactive waste should not be stored in the work area but transferred to a separate radioactive waste storage room as soon as possible.

A patient undergoing a nuclear medicine imaging study is a source of radiation exposure and contamination. Contact with these patients by nursing staff presents little hazard, as the radiation dose rate is quite low, and accumulated dose to any single individual would not be significant. However, for nuclear medicine staff that spend a great deal of time in the immediate vicinity of

these patients, the accumulated radiation dose can be significant. These workers should, whenever possible, maximize their distance from the patient and spend as little time as possible in close proximity to the patient.

In summary, the following protective approaches can reduce external exposure significantly:

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

3.5.6. Personal monitoring

The licensee and employer have the joint responsibility to ensure that appropriate personal monitoring is provided to staff. This normally means that the RPO would specify which workers need to be monitored routinely, the type of monitoring device to be used and the body position where the monitor should be worn, bearing in mind that some countries may have specific regulatory requirements on these issues. Further, the regulatory body is likely to have specified the monitoring period and the time frame for reporting monitoring results.

Staff to be monitored in a nuclear medicine facility should include all those who work routinely with radionuclides or with the patients who have received administrations of radiopharmaceuticals. This will include nursing staff who either work routinely in nuclear medicine or nurse patients who have received radionuclide therapy and staff dealing with excreta from radionuclide therapy. Monitoring would not normally be extended to those that come into occasional contact with nuclear medicine patients.

There are several types of external personal dosimetry systems and the system to use is dependent on national or local conditions. In many countries, the service is centralized to the regulatory body or provided through third party personal dosimetry providers. Occasionally, some large hospitals have their own personal dosimetry service. In all cases, the dosimetry provider must be approved by the regulatory body.

Finger monitoring should be carried out occasionally on staff that regularly prepare and administer radioactive substances to patients, and also when setting up an operation which requires the routine handling of large quantities of radionuclides. After handling unsealed radionuclides, the hands should be monitored. It may, therefore, be convenient to mount a suitable contamination

monitor near the sink where hands are washed. Care should be taken to ensure that the monitor itself does not become contaminated. In high background areas, it will be necessary to shield the detector, and it may be convenient to have a foot or elbow operated switch to activate the monitor.

Monitoring for internal contamination is rarely necessary in nuclear medicine on radiation protection grounds but it may be useful in providing reassurance to staff. The circumstances in which internal monitoring becomes advisable are those where staff use significant quantities of ^{131}I for thyroid therapy. They should be included in a programme of thyroid uptake measurements.

In other circumstances where it is necessary to assess the intake of γ emitting radionuclides (e.g. after a serious incident), the use of a whole body counter may be appropriate. Such equipment should be available at national referral centres. The possible use of an uncollimated gamma camera should also be considered.

Sometimes, a more detailed monitoring survey may be indicated if staff doses have increased (or it is anticipated that they may do so in the future) as a result of either the introduction of new examinations or procedures, or a change in the nuclear medicine facility's equipment. The RPO should decide who should be monitored and at which monitoring sites.

Individual monitoring results must be analysed and records must be kept. It is vital that the individual monitoring results are regularly assessed and the cause of unusually high dosimeter readings should be investigated by the RPO, with ensuing corrective actions where appropriate. The administrative arrangements, the scope and nature of the individual monitoring records, and the length of time for which records have to be kept may differ among countries.

3.5.7. Monitoring of the workplace

The BSS require licensees to develop programmes for monitoring the workplace. Such programmes are described in Section 3.4.6 and in Chapters 9 and 20.

3.5.8. Health surveillance

According to the BSS, the licensee needs to make arrangements for appropriate health surveillance in accordance with the rules established by the national regulatory body. The primary purpose of health surveillance is to assess the initial and continuing fitness of employees for their intended tasks. The health surveillance programme 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 would special investigations involving biological dosimetry and further extended diagnosis and medical treatment be necessary.

Counselling should be available to workers 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.

3.5.9. Local rules and supervision

According to the BSS, employers and licensees must, in consultation with the workers or through their representatives:

- Establish written local rules and procedures necessary to ensure adequate levels of protection and safety for workers and other persons;
- 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;
- Make the local rules and procedures, the protective measures and safety provisions known to those workers to whom they apply and to other persons who may be affected by them;
- 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.

These local rules should include all working procedures involving unsealed sources in the facility such as:

- Ordering radionuclides;
- Unpacking and checking the shipment;
- Storage of radionuclides;
- General rules for work in controlled and supervised areas;
- Preparation of radiopharmaceuticals;
- Personal and workplace monitoring;
- In-house transport of radionuclides;
- Management of radioactive waste;
- Administration of radiopharmaceuticals to the patients;
- Protection issues in patient examinations and treatments;
- Routine cleaning of facilities;
- Decontamination procedures;
- Care of radioactive patients.

It is the responsibility of the licensee of the nuclear medicine facility to ensure that local rules are established, maintained and continually reviewed. The RPO would have significant involvement in this process.

3.6. PUBLIC EXPOSURE

3.6.1. Justification, optimization and dose limitation

According to the BSS, public exposure is exposure incurred by members of the public from radiation sources, excluding any occupational or medical exposure.

The three ICRP principles described in Section 3.2.1 apply to public exposure arising from the practice of nuclear medicine. Just as for occupational exposure, the justification of public exposure is based on the justification of the practice of nuclear medicine. The exposure of the general public is ultimately restricted by the application of dose limits (see Table 3.1), but in the first instance the application of the principle of optimization of protection ensures that public doses will be ALARA.

The licensee is responsible for controlling public exposure arising from a nuclear medicine facility. The presence of members of the public in or near the nuclear medicine facility needs to be considered when designing the shielding and flow of persons in the facility.

The sources of exposure of the general public are primarily the same as for workers. Hence, the use of structural shielding and the control of sources, waste and contamination are fundamental to controlling exposure of the public. There are, however, some additional situations that need special consideration. These include the release of patients examined or treated with radiopharmaceuticals.

3.6.2. Design considerations

The general layout of the nuclear medicine facility should take into account the protection of members of the public. The areas for storage and preparation of radiopharmaceuticals must be well separated from public areas such as waiting rooms. The movement of radionuclides must be minimized. For example, the room for preparation and dispensing of radiopharmaceuticals and the room for administration should be adjacent and connected by a pass through. Areas where significant activities of radionuclides are present must be appropriately shielded. Access must be restricted so that members of the public are not allowed into controlled areas. Radioactive waste must be stored in a secure location away from areas accessible to the public. Since a patient still waiting for administration of the radiopharmaceutical is regarded as a member of the public, separate waiting

rooms and toilets for injected and not injected patients should be considered in order to minimize both external exposure and the spread of contamination.

3.6.3. Exposure from patients

Every precaution must be taken to ensure that the doses received by individuals who come close to a patient or who spend some time in neighbouring rooms remain below the dose limit for the public and below any applicable dose constraint. For almost all diagnostic procedures, the maximum dose that could be received by another person due to external exposure from the patient is a fraction of the annual public dose limit and it should not normally be necessary to issue any special radiation protection advice to the patient. One exception is restrictions on breast-feeding a baby, which will be further discussed in Section 3.7.2.4. Another exception is an intensive use of positron emitters which may require structural shielding based on the exposure of the public as discussed above (Section 3.4.4). For patients who have undergone radionuclide therapy, specific advice should be given regarding restrictions on their contact with other people. This is discussed separately in Chapter 20.

3.6.4. Transport of sources

One possible source of exposure of the general public is transport of sources. It is performed both inside and outside the nuclear medicine facility. Inside the facility, the transport includes distribution of the radioactive sources from the storage area to where it will be used. Such transport should be limited as far as possible by the facility design. The transport that takes place should be performed according to optimized radiation protection conditions as given by local rules.

The transport of radioactive sources to and from the nuclear medicine facility should follow the internationally accepted IAEA Regulations for the Safe Transport of Radioactive Material [3.8]. These Regulations include basic rules for the transport itself and regulations about the shape and labelling of packages.

In general, the package is built in several parts. It should be mechanically safe and reduce the effect of potential fire and water damage. The package should be labelled with a sign. There are three different labels: I–White, II–Yellow and III–Yellow. In all cases, the radionuclide and its activity should be specified. The label gives some indication of the dose rate D at the surface of the package:

- Category I–White $D \leq 0.005$ mSv/h
- Category II–Yellow $0.005 < D \leq 0.5$ mSv/h
- Category III–Yellow $0.5 < D \leq 2$ mSv/h

A more exact figure of the radiation around the package is given by the transport index which is the maximum dose rate (mSv/h) at a distance 1 m from the surface of the package multiplied by a hundred.

3.7. MEDICAL EXPOSURE

The detailed requirements given in Section 3 of the BSS are applicable to medical exposure in nuclear medicine facilities. Furthermore, Ref. [3.9] describes strategies to involve organizations outside the regulatory framework, such as professional bodies (nuclear medicine physicians, medical physicists, nuclear medicine technologists, radiopharmacists), 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 QA and for reporting accidental medical exposure. Reference [3.3] provides further specific advice. A summary of the most relevant issues for nuclear medicine is given in this section.

3.7.1. Justification of medical exposure

The BSS state that:

“Medical exposures shall be justified by weighing the expected diagnostic or therapeutic benefits...that they yield against the radiation detriment that they might cause, with account taken of the benefits and the risks of available alternative techniques that do not involve medical exposure.”

The principle of justification of medical exposure should not only be applied to nuclear medicine practice in general but also on a case by case basis, meaning that any examination should be based upon a correct assessment of the indications for the examination, the actual clinical situation, the expected diagnostic and therapeutic yields, and the way in which the results are likely to influence the diagnosis and the medical care of the patient. The nuclear medicine specialist has the ultimate responsibility for the control of all aspects of the conduct and extent of nuclear medicine examinations, including the justification of the given procedure for a patient. The nuclear medicine specialist should advise and make decisions on the appropriateness of examinations and determine the techniques to be used. In justifying a given diagnostic nuclear medicine procedure, relevant international or national guidelines should be taken into account.

Any nuclear medicine procedure that occurs as part of a biomedical research project (typically as a tool to quantify changes in a given parameter

under investigation) is considered justified if the project has been approved by an ethics committee.

3.7.2. Optimization of protection

The principle of optimization of protection is applied to nuclear medicine procedures that have been justified, and can be summarized as follows. For diagnostic nuclear medicine procedures, the patient exposure should be the minimum necessary to achieve the clinical purpose of the procedure, taking into account relevant norms of acceptable image quality established by appropriate professional bodies and relevant diagnostic reference levels (DRLs).

For therapeutic nuclear medicine procedures, the appropriate radiopharmaceutical and activity are selected and administered so that the activity is primarily localized in the organ(s) of interest, while the activity in the rest of the body is kept ALARA.

The implementation of optimization of protection for patients in nuclear medicine is quite complex and includes equipment design, choice of radiopharmaceutical and activity, procedure considerations, DRLs, calibration, clinical dosimetry and QA, as well as special considerations for children, pregnant women and lactating women. This is further discussed in the following sections.

3.7.2.1. Administered activity and radiopharmaceuticals

For diagnostic procedures, it is necessary for the nuclear medicine specialist in cooperation with the medical physicist to determine the optimum activity to administer in a certain type of examination, taking the relevant DRL (see below) into account. For any given procedure used on an individual patient, the optimum activity will depend on the body build and weight of the patient, the patient's metabolic characteristics and clinical condition, the type of equipment used, the type of study (static, dynamic, tomographic) and the examination time.

For a given type of imaging equipment, the diagnostic value of the information obtained from an examination will vary with the amount of administered activity. There is a threshold of administered activity below which no useful information can be expected. Above this level, the diagnostic quality will increase steeply with increasing activity. Once an acceptable image quality has been reached, a further increase of the administered activity will only increase the absorbed dose and not the value of the diagnostic information.

It should also be noted that limiting the administered activity below the optimum, even for well intentioned reasons, will usually lead to a poor quality of the result which may cause serious diagnostic errors. It is very important to

avoid failure to obtain the required diagnostic information; failure would result in unnecessary (and, therefore, unjustified) irradiation and may also necessitate repetition of the test.

If more than one radiopharmaceutical can be used for a procedure, consideration should be given to the physical, chemical and biological properties for each radiopharmaceutical, so as to minimize the absorbed dose and other risks to the patient while at the same time providing the desired diagnostic information. Other factors affecting the choice include availability, shelf life, instrumentation and relative cost. It is also important that the radiopharmaceuticals used are received from approved manufacturers and distributors, and are produced according to national and international requirements. This is a requirement also for in-house production of radiopharmaceuticals for PET studies.

The activity administered to a patient should always be determined and recorded. Knowing the administered activity makes it possible to estimate the absorbed dose to different organs as well as the effective dose to the patient. Substantial reduction in absorbed dose from radiopharmaceuticals can be achieved by simple measures such as hydration of the patient, use of thyroid blocking agents and laxatives.

3.7.2.2. Optimization of protection in procedures

The nuclear medicine procedure starts with the request for an examination or treatment. The request should be written and contain basic information about the patient's condition. This information should help the nuclear medicine specialist to decide about the most appropriate method to use and to decide how urgent the examination is. The patient should then be scheduled for the examination or treatment and be informed about when and where it will take place. Some basic information about the procedure should also be given, especially if it requires some preparation of the patient, such as fasting. These initial measures require an efficient and reliable administrative system. In parallel to these routines, the nuclear medicine facility has to ensure that the radiopharmaceutical to be used is available at the time of the scheduled procedure.

When the patient appears in the nuclear medicine facility, they should be correctly identified using the normal hospital or clinic routines. The patient should be informed about the procedure and have the opportunity to ask questions about it. A fully informed and motivated patient is the basis for a successful examination or treatment. Before the administration of the radiopharmaceutical, the patient should be interviewed about possible pregnancy, small children at home, breast-feeding and other relevant questions which might have implications for the procedure. Before administration, the technologist or doctor should check the request and ensure that the right examination or treatment is scheduled

and that the right radiopharmaceutical and the right activity are dispensed. If everything is in order, the administration can proceed. The administered activity should always be recorded for each patient.

While most adults can maintain a required position without restraint or sedation during nuclear medicine examinations, it may be necessary to immobilize or sedate children, so that the examination can be completed successfully. Increasing the administered activity to reduce the examination time is an alternative that can be used in elderly patients with pain.

Optimization of protection in an examination means that equipment should be operated within the conditions established in the technical specifications, thus ensuring that it will operate satisfactorily at all times, in terms of both the tasks to be accomplished and radiation safety. More details are given in Chapters 8 and 15. Particular procedural considerations for children, pregnant women and lactating women are given in the following subsections.

Optimization of protection in radionuclide therapy means that a correctly calculated and measured activity should be administered to the patient in order to achieve the prescribed absorbed dose in the organ(s) of interest, while the radioactivity in the rest of the body is kept as low as reasonably achievable. Optimization also means using routines to avoid accidental exposures of the patient, the staff and members of the general public. Radionuclide therapy is further discussed in Chapter 20.

The availability of a written manual of all procedures carried out by the facility is highly desirable. The manual should regularly be revised as part of a QA programme.

3.7.2.3. Pregnant women

Special consideration should be given to pregnant women exposed to ionizing radiation due to the larger probability of inducing radiation effects in individuals exposed in utero compared to exposed adults. As a basic rule, it is recommended that diagnostic and therapeutic nuclear medicine procedures of women likely to be pregnant be avoided unless there are strong clinical indications.

In order to avoid unintentional irradiation of the unborn child, a female of childbearing age should be evaluated regarding possible pregnancy or a missed period. This should be done when interviewing and informing the woman prior to the examination or treatment. It is also common to place a poster in the waiting area requesting a woman to notify the staff if she is or thinks she is pregnant. If the patient is found not to be pregnant without any doubt, the examination or treatment can be performed as planned. If pregnancy is confirmed, careful consideration should be given to other methods of diagnosis or to the

postponement of the examination until after delivery. If, after consultation between the referring physician and the nuclear medicine specialist, these options are not feasible, then the examination should be performed, but the process of optimization of protection needs to also consider protection of the embryo/fetus.

In order to reduce the fetal dose, it may sometimes be possible to reduce the administered activity and acquire images for longer times, but great care must be taken not to compromise the quality of the result. After the administration of radiopharmaceuticals, frequent voiding should be ensured to minimize exposure from the bladder. This contribution to the fetal dose can be further reduced by administering the radiopharmaceutical when the bladder is partially filled, rather than immediately after voiding.

Of special concern is also the use of CT in PET/CT or SPECT/CT examinations. Routine diagnostic CT examinations of the pelvic region with and without contrast injection can lead to a dose of 50 mSv to the uterus which is assumed to be equivalent to the fetal dose in early pregnancy. It is important to use low dose CT protocols and to reduce the scanning area to a minimum when PET/CT or SPECT/CT scanning is indicated in a pregnant patient.

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. More details are given in Ref. [3.3].

If the fetal dose is suspected to be high (e.g. >10 mSv), it should be carefully determined by a qualified medical physicist and the pregnant woman should be informed about the possible risks. The same procedure should be applied in the case of an inadvertent exposure, which can be incurred by a woman who later was found to have been pregnant at the time of the exposure or in emergency situations.

Exposure of a pregnant patient at a time when the pregnancy was not known often leads to her apprehension because of concern about the possible effects on the fetus. It may lead to a discussion regarding termination of pregnancy due to the radiation risks. Many misunderstandings and lack of knowledge, also among physicians, have probably resulted in unnecessary termination of pregnancies. It is generally considered that for a fetal dose of less than 100 mGy, as in most diagnostic procedures, termination of pregnancy is not justified from the point of radiation risks. At higher doses, individual circumstances should be taken into account. This is an ethical issue and the national authorities should give guidance.

3.7.2.4. Lactating women

When nuclear medicine examinations are requested for women who are breast-feeding, they present a potential radiation hazard to the baby. This is due

to uptake of some radiopharmaceuticals in breast tissue followed by excretion into the breast milk. The dose to the baby depends on various factors such as the radiopharmaceutical, the amount of milk and the time between the administration of the radiopharmaceutical to the mother and the feeding of the child. The mother also represents a source of external exposure and contamination when feeding or cuddling the baby. The dose will depend on the time the child is held, the distance from the mother's body and personal hygiene. Some restrictions on breast-feeding and advice to the mother are necessary in order to minimize the exposure of the baby to an acceptable level. The baby is a member of the public and a typical constraint on the dose from a single source of exposure (in this case, per episode) is 0.3 mSv.

Before a nuclear medicine examination or therapy with radionuclides, the woman should be asked, orally or in writing, whether she is breast-feeding a child. A notice requesting the patient to inform the staff about breast-feeding should also be prominently displayed in the waiting area. If the answer is yes, consideration should be given as to whether the examination or treatment could reasonably be delayed until she has ceased breast-feeding. If not, advice about restriction of breast-feeding dependent on the diagnostic or therapeutic procedure should be given to the patient.

It is the responsibility of the nuclear medicine specialist in cooperation with the medical physicist to establish local rules regarding breast-feeding and close contact between the mother and the child after a nuclear medicine examination or treatment. The rules should be based on recommendations given by international and national authorities as well as professional organizations. Some guidance is found in Ref. [3.3].

3.7.2.5. Children

Optimization of protection for an examination of a child is basically an optimization of the administered activity. There are several approaches to the problem of how to calculate the administered activity for children. It should be the minimum consistent with obtaining a diagnostic result. As this is the same principle which is applied to adult doses, the normal activity administered to adults should be used as a guide, bearing in mind that the average adult body weight is 70 kg. For children or young persons, body weight should always be measured and the adult administered activity should then be scaled down. Opinions differ as to how the scaling should be achieved. Simply reducing the activity in proportion to body weight may, in some types of investigation, result in inadequate image quality. Another method is based on the principle of scaling in proportion to body surface area. This approach should give the same image count density as that for an adult patient, although the effective dose is higher. As

a general guide, activities less than 10% of the normal adult activity should not be administered.

In hybrid imaging, the CT protocol should be optimized by reducing the tube current–time product (mAs) and tube potential (kV) without compromising the diagnostic quality of the images. Careful selection of slice width and pitch as well as scanning area should also be done. It is important that individual protocols based on the size of the child are used. The principles behind such protocols should be worked out by the medical physicist and the responsible specialist.

Since the examination times in nuclear medicine examinations are quite long, there may be problems in keeping the child still during the examination. Even small body motions can severely interfere with the quality of the examination and make it useless. There are several methods of mechanical support to fasten the child. Drawing the child's attention to something else such as a television programme can also be useful for older children. Sometimes, even sedation or general anaesthesia may be necessary.

3.7.2.6. Calibration

The licensee of a nuclear medicine facility needs to ensure that a dose calibrator or activity meter is available for measuring activity in syringes or vials. The validity of measurements should be ensured by regular quality control of the instrument, including periodic reassessment of its calibration, traceable to secondary standards.

3.7.2.7. Clinical (patient) dosimetry

The licensee of a nuclear medicine facility should ensure that appropriate clinical dosimetry by a medical physicist is performed and documented. For diagnostic nuclear medicine, this should include representative typical patient doses for common procedures. For therapeutic nuclear medicine, this needs to be for each individual patient, and includes absorbed doses to relevant organs or tissues.

3.7.2.8. Diagnostic reference levels

Many investigations have shown a large spread of administered activities for a certain type of diagnostic nuclear medicine examination between different hospitals within a country, even if the equipment used is similar in performance. Even though no dose limits are applied to medical exposure, the process of optimization should result in about the same administered activity for the same type of examination and for the same size of patient.

The concept of a DRL provides a tool for the optimization of protection in medical exposure. In the case of nuclear medicine, the DRL is given as administered activity for a certain type of examination and for a normal sized patient. DRLs are aimed to assist in the optimization of protection by helping to avoid unnecessarily high activities to the patient or too low activities to provide useful diagnostic information. DRLs are normally set at the national level as a result of consultation between the health authority, relevant professional bodies and the radiation protection regulatory body.

3.7.2.9. Quality assurance for medical exposures

The BSS require the licensee of the nuclear medicine facility to have a comprehensive programme of QA for medical exposures. The programme needs to have the active participation of the medical physicists, nuclear medicine specialists, nuclear medicine technologists and radiopharmacists, and needs to take into account principles established by international organizations, such as the WHO and PAHO, and relevant professional bodies.

The programme of QA for medical exposures should be complementary to and part of the wider programme of QA for radiation protection — the latter also including occupational and public exposure. In turn, this programme needs to be part of and harmonized with the nuclear medicine facility's quality management system. Section 3.9 discusses the wider QA programme, while the remainder of this subsection deals with some aspects of the programme as it applies to medical exposures.

The programme of QA for medical exposures should include:

- Measurements by, or under the oversight of, a medical physicist of the physical parameters of medical radiological equipment at the time of acceptance and commissioning prior to clinical use on patients, periodically thereafter, and after any major maintenance that could affect patient protection;
- Implementation of corrective actions if measured values of the physical parameters are outside established tolerance limits;
- Verification of the appropriate physical and clinical factors used in patient diagnosis or treatment;
- Records of relevant procedures and results;
- Periodic checks of the appropriate calibration and conditions of operation of dosimetry and monitoring of equipment.

In addition, the licensee needs to ensure that there are regular and independent audits of the programme of QA for medical exposures, their

frequency depending on the complexity of the nuclear medicine procedures performed and the risks involved.

The above indicates, among other actions, the need for quality control tests on the equipment. More details regarding quality control of equipment used in diagnosis will be found in other chapters of this book.

3.7.3. Helping in the care, support or comfort of patients

Certain patients, such as children, the elderly or the infirm, may have difficulty during a nuclear medicine procedure. Occasionally, people knowingly and voluntarily (other than in their employment or occupation) may volunteer to help in the care, support or comfort of patients. In such circumstances, the dose to these persons (excluding children and infants) should be constrained so that it is unlikely that it will exceed 5 mSv during the period of a patient's diagnostic examination or treatment. The dose to children visiting patients who have ingested radioactive materials should be similarly constrained to less than 1 mSv. Special concern should be given to members of the family of a patient who has received radionuclide therapy. This is further discussed in Chapter 20.

Sometimes, a nurse escorting a patient to the nuclear medicine facility is asked to provide assistance during a procedure. Any resultant exposure should be regarded as occupational, and the nurse should have received education and training on this role.

3.7.4. Biomedical research

The exposure of humans for biomedical research is deemed not to be justified unless it is in accordance with the provisions of the Helsinki Declaration [3.10] and follows the guidelines for its application prepared by the Council for International Organizations of Medical Sciences [3.11]. It is also subject to the approval of an ethics committee.

The use of radioactive trace substances is common in biomedical research. Diagnostic nuclear medicine procedures may be part of a biomedical research project, typically as a means for quantifying changes in a given parameter under investigation or assessing the efficacy of a treatment under investigation. An exposure as part of biomedical research is treated on the same basis as a medical exposure and, therefore, is not subject to dose limits. However, in all investigations involving exposure of humans, a careful estimation of the radiation dose to the volunteer should be made. The associated risk should then be weighed against the benefit for the patient or society. Recommendations are given by the ICRP. The BSS require the use of dose constraints, on a case by case basis, in the process of optimization.

3.7.5. Local rules

The management of patients in the nuclear medicine facility should be supported by written local rules covering all procedures that may affect medical exposure. These local rules should be signed by the responsible person and known to every member of the staff and should include:

- Routines for patient identification and information;
- Prescribed radiopharmaceutical and activity for adults and children for different types of examination, including methods used to adjust the activity to the single patient and routes of administration;
- Management of patients that are pregnant or might be pregnant;
- Management of breast-feeding patients;
- Routines for safe preparation and administration of radiopharmaceuticals including activity measurements;
- Procedures in case of misadministration of the radiopharmaceutical;
- Detailed procedure manuals for every type of examination including handling of equipment.

3.8. POTENTIAL EXPOSURE

3.8.1. Safety assessment and accident prevention

Unintended and accidental exposure may occur due to equipment failure, human error or a combination of both. Although such events can be identified by a careful safety assessment, their details and the time of occurrence cannot be predicted. These exposures are called potential exposures. It is the responsibility of the licensee to take measures in order to prevent such events as far as possible and, in case they occur, mitigate their consequences.

According to the BSS, the 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 needs to include, as appropriate, a systematic critical review of identification of possible events leading to unintended or accidental exposure. In practice, this means that all procedures in which unsealed sources are involved in the work should be listed and for every procedure it should be asked what can go wrong. Some examples are given in Table 3.2.

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TABLE 3.2. EXAMPLES OF WHAT CAN POTENTIALLY GO WRONG IN A NUCLEAR MEDICINE FACILITY

Procedure and involvement	What can go wrong?
<i>Patients involved</i>	
Request and scheduling	Wrong patient scheduled
Identification at arrival	Wrong patient identified
Information	Missed pregnancy or breast-feeding
Administration of radiopharmaceutical	Misadministration (wrong patient, wrong activity, wrong radiopharmaceutical)
Waiting	Contamination of waiting area (vomiting, incontinence)
Examination	Inconclusive due to contamination, equipment and/or software failure
<i>Workers involved</i>	
Ordering of sources	Unauthorized ordering
Receipt and unpacking of shipments	Damage to package, contamination
Storage of sources	Unshielded sources, high dose rates, loss of sources
Preparation and administration of radiopharmaceutical	High doses recorded, contamination of workers and facilities
Handling of radioactive waste	Contamination of workers and facilities
<i>General public involved</i>	
Storage of sources	Loss of sources
Handling of sources	Contamination of facility
Radioactive waste	Loss of sources, contamination of facilities
Radioactive patient	Escape of hospitalized patient, medical emergency, death of patient

Undertaking a safety assessment requires using one's imagination to try to define an event that could result in a potential exposure, even if the event has never occurred before. For instance, what should be done if a patient who just received 15 GBq of ^{131}I escapes from the isolation ward and the hospital and is seriously injured in a road accident?

If an unintended or accidental medical exposure occurs, the licensee is required to determine the patient doses involved, identify any corrective actions

needed to prevent recurrence and implement the corrective measures. There may be a requirement to report the event to the regulatory body.

A well established RPP is fundamental in accident prevention together with a high level of safety culture in the organization and among the people working in a nuclear medicine facility. The content of an RPP as well as the importance of well established working procedures in order to protect patients, workers and the general public have been discussed in the sections above. It should be stressed that documentation of the procedures used in the facility is also important in accident prevention. Other important factors are a well working QA programme and a programme for continuing education and training which includes not only the normal practices, but also accidental situations and lessons learned from accidents.

3.8.2. Emergency plans

According to the BSS, the licensee needs to prepare emergency procedures on the basis of events identified by the safety assessment. The procedures should be clear, concise and unambiguous, and need to be posted visibly in places where their need is anticipated. An emergency plan needs to, as a minimum, list and describe:

- Predictable incidents and accidents, and measures to deal with them;
- The persons responsible for taking actions, with full contact details;
- The responsibilities of individual personnel in emergency procedures (nuclear medicine physicians, medical physicists, nuclear medicine technologists, etc.);
- Equipment and tools necessary to carry out the emergency procedures;
- Training and periodic drills;
- The recording and reporting system;
- 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.

The most likely accident in a nuclear medicine facility is contamination of workers, patients, equipment and facilities. It can range from small to very large spillages of radioactivity, for example, serious damage to the technetium generator or spillage of several gigabecquerels of ^{131}I . The procedures of cleaning up a small amount of contamination should be known and practised by every technologist in the facility. The cleaning procedures in cases of more severe contamination should always be supervised by the RPO. Local rules should be

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established that define serious contamination based on radionuclide, activity and whether it is contamination of a person or equipment and facilities. It is recommended that the facility have an emergency kit readily available in case of contamination. Such a kit should contain:

- Protective clothing, e.g. overshoes, gloves;
- Decontamination materials for the affected areas, including absorbent materials for wiping up spills;
- Decontamination materials for persons;
- Warning notices;
- Portable monitoring equipment (in working order and regularly checked);
- Bags for waste, tape, labels, pencils.

Several severe accidents in medical exposures in nuclear medicine have been reported and are solely associated with radionuclide therapy and especially when using ^{131}I in treatment of thyroid diseases. Several incidents with misadministration of radiopharmaceuticals in diagnostic nuclear medicine have also been reported. These include examination of the wrong patient or administration of the wrong radiopharmaceutical or the wrong activity. The most common incident is to administer the wrong radiopharmaceutical. Even if this does not cause severe injury to the patient, it is a non-justified exposure with increased radiation risks. It will also lead to a delayed diagnosis, increased cost and increased workload because the examination will have to be repeated. Last but not least, it will cause reduced confidence in the practice of nuclear medicine.

Other accidents and incidents that also involve the general public include the possible death of a patient containing radionuclides. In diagnostic nuclear medicine, such an incident can generally be left without specific measures. However, in radionuclide therapy, emergency plans have to be available on how to handle the cadaver. Since this is a sensitive issue, depending on ethical and religious rules and traditions, advice should be available from the national authorities.

3.8.3. Reporting and lessons learned

In the event of an incident or accident, the licensee has the responsibility to ensure that a comprehensive investigation takes place and a report is produced that includes the following information:

- A description of the incident by all persons involved;

- Methods used to estimate the radiation dose received by those involved in the incident and implications of those methods for possible subsequent litigation;
- Methods used to analyse the incident and to derive risk estimates from the data;
- The subsequent medical consequences for those exposed;
- The particulars of any subsequent legal proceedings that may ensue;
- Conclusions drawn from the evaluation of the incident and recommendations on how to prevent a recurrence of such an accident.

In the case of a misadministration or an accident in radionuclide therapy, the responsible nuclear medicine specialist should be promptly informed. They should then inform the referring physician and the patient. The medical physicist should make dose calculations and the staff involved in the accident should independently describe their view of the accident. Conclusions regarding any deficits in the procedures should be drawn and necessary changes implemented. Finally, the licensee may need to submit the report to the regulatory body.

In order to avoid future accidents, it is important to learn from previous ones. The initiating event and the contributing factors can always be identified. This information provides material that should be used to prevent future accidents. This is achieved by informing all members of staff about the accident or incident, which means that it is very important to have an efficient reporting system and a programme for local education and training that also includes potential exposures.

3.9. QUALITY ASSURANCE

3.9.1. General considerations

The International Organization for Standardization defines QA as all planned and systematic actions needed to provide confidence that a structure, system or component will perform satisfactorily in service. Satisfactory performance in nuclear medicine implies the optimum quality of the entire process. Since an examination or therapy is justified only if the procedure benefits the patient, QA in the whole process of nuclear medicine is an important aspect of radiation protection.

The BSS require the licensee of the nuclear medicine facility to have established a QA programme that provides adequate assurance that the specified requirements relating to protection and safety are satisfied, and that provides

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 or clinics implement a quality management system for all of the medical care received in diagnosis and treatment, i.e. covering the overall nuclear medicine practice. The QA programme envisaged by the BSS should be part of the wider facility quality management system. In the hospital or clinic, it is common to include QA as part of the RPP or, conversely, to include the RPP as part of a more general QA programme for the hospital or clinic. Regardless of its organization, it is important that radiation protection is an integral part of a system of quality management. The remainder of this section considers aspects of QA applied to a nuclear medicine facility that are covered in the BSS. Specific details with respect to medical exposure are covered in Section 3.7.2.9.

An effective QA programme requires a strong commitment from the nuclear medicine facility's management to provide the necessary resources of time, personnel and budget. It is recommended that the nuclear medicine facility establish a group that actively works with QA issues. Such a QA committee should have a representative from management, a nuclear medicine physician, a medical physicist, a nuclear medicine technologist and an engineer as members. The QA committee should meet regularly and review the different components of the programme.

The QA programme should cover the entire process from the initial decision to adopt a particular procedure through to the interpretation and recording of results, and should include ongoing auditing, both internal and external, as a systematic control methodology. The maintenance of records is an important part of QA. One important aspect of any QA programme is continuous quality improvement. 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 QA programme and new techniques developed by the nuclear medicine community at large. Feedback from operational experience and lessons learned from accidents or near misses can help identify potential problems and correct deficiencies, and should, therefore, be used systematically, as part of the continuous quality improvement.

A QA programme should cover all aspects of diagnosis and therapy, including:

- 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.

Further details on the general components of a QA programme and the associated quality control tests are given in Ref. [3.3]. The WHO has also published guidelines on QA in nuclear medicine [3.12], 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. The IAEA has several other relevant publications on QA for various aspects of nuclear medicine (see the Bibliography for details).

3.9.2. Audit

The QA programme should be assessed on a regular basis either as an external or internal audit or review. Audits of activities within the QA programme should be scheduled on the basis of the status and importance of the activity. Management should establish a process for such assessments to identify and correct administrative and management problems that may prevent achievement of the objectives. Audits and reviews should be conducted by persons who are technically competent to evaluate the processes and procedures being assessed, but do not have any direct responsibility for those activities. These may be staff from other work areas within the organization (internal audit), or an independent assessment by other organizations (external audit). External audits are generally a requirement for an accredited practice.

The quality audit should be performed in accordance with written procedures and checklists. It should include medical, technical and procedural checks, with the objective to enhance the effectiveness and efficiency of the QA programme. Any major changes in the QA programme should initiate an audit. The result should be documented and necessary correction initiated and followed up.

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