CHAPTER 20

MANAGEMENT OF THERAPY PATIENTS

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20.1. INTRODUCTION

The basic principles of radiation protection and their implementation as they apply to nuclear medicine are covered in general in Chapter 3. This chapter will look at the specific case of nuclear medicine used for therapy. In addition to the standards discussed in Chapter 3, specific guidance on the release of patients after radionuclide therapy can be found in the IAEA's Safety Reports Series No. 63 [20.1].

When the patient is kept in hospital following radionuclide therapy, the people at risk of exposure include hospital staff whose duties may or may not directly involve the use of radiation. This can be a significant problem. However, it is generally felt that it can be effectively managed with well trained staff and appropriate facilities. On the other hand, once the patient has been released, the groups at risk include members of the patient's family, including children, and carers; they may also include neighbours, visitors to the household, co-workers, those encountered in public places, on public transport or at public events, and finally, the general public. It is generally felt that these risks can be effectively mitigated by the radiation protection officer (RPO) with patient-specific radiation safety precaution instructions.

20.2. OCCUPATIONAL EXPOSURE

20.2.1. Protective equipment and tools

Protective clothing should be used in radionuclide therapy areas where there is a likelihood of contamination. The clothing serves both to protect the body of the wearer and to help to prevent the transfer of contamination to other areas. Protective clothing should be removed prior to going to other areas such as staff rooms. The protective clothing may include laboratory gowns, waterproof

gloves, overshoes, and caps and masks for aseptic work. When β emitters are handled, the gloves should be thick enough to protect against external β radiation (perhaps double gloves should be utilized, when appropriate).

In radionuclide therapy nuclear medicine, most of the occupational exposures come from ^{131}I, which emits 356 keV photons. The attenuation by a lead apron at this energy is minimal (less than a factor of two) and is unlikely to result in significant dose reductions and may not justify the additional weight and discomfort of wearing such protective equipment. Typically, thicker permanent or mobile lead shielding may be more effectively applied for those situations which warrant its use. The RPO should determine the need and types of shielding required for each situation.

20.2.2. Individual monitoring

Individual monitoring, as discussed in Chapter 3, needs to be considered during the management of radionuclide therapy patients. In addition to general advice (see Chapter 3) on persons most likely to require individual monitoring in nuclear medicine, consideration needs to be given to nursing or other staff who spend time with therapy patients.

20.3. RELEASE OF THE PATIENT

Protection of the patient in therapeutic nuclear medicine is afforded through the application of the principles of justification and optimization — the principle of dose limitation is not applied to patient exposures. A discussion of these principles is given in Chapter 3. However, a patient that has undergone a therapeutic nuclear medicine procedure is a source of radiation that can lead to the exposure of other persons that come into the proximity of the patient. External irradiation of the persons close to the patient is related to the radionuclide used, its emissions, half-life and biokinetics, which can be important with some radionuclides. Excretion results in the possibility of contamination of the patient's environment and of inadvertent ingestion by other persons.

The system of radiation protection handles, in different ways, people that may be exposed by therapeutic nuclear medicine patients. If the person is in close proximity because their occupation requires it, then they are subject to the system of radiation protection for occupationally exposed persons. If the person, other than occupationally, is knowingly and voluntarily providing care, comfort and support to the patient, then their exposure is considered part of medical exposure, and they are subject to dose constraints as discussed in Chapter 3. If the person is simply a member of the public, including persons whose work in the nuclear

medicine facility does not involve working with radiation, then their exposure is part of public exposure and that is discussed in the next section.

While precautions for the public are rarely required after diagnostic nuclear medicine procedures, some therapeutic nuclear medicine procedures, particularly those involving ^{131}I, can result in significant exposure to other people, especially those involved in the care and support of patients. Hence, members of the public caring for such patients in hospital or at home require individual consideration.

20.3.1. The decision to release the patient

Patients do not need to be hospitalized automatically after all radionuclide therapies. Relevant national dose limits must be met and the principle of optimization of protection must be applied, including the use of relevant dose constraints. The decision to hospitalize or release a patient should be determined on an individual basis. In addition to residual activity in the patient, the decision should take many other factors into account. Hospitalization will reduce exposure to the public and relatives, but will increase exposure to hospital staff. Hospitalization often involves a significant psychological burden as well as monetary and other costs that should be analysed and justified.

Medical practitioners shall determine whether the patient is willing and is physically and mentally able to comply with appropriate radiation safety precautions in the medical facility, should medical confinement be necessary, or at home after release. For some patients, hospitalization during and following treatment may be necessary and appropriate. The medical practitioners can determine that such patients may need to remain hospitalized beyond the period of time dictated by other dose constraint or clinical criteria. For example, incontinent patients or ostomy patients may require extended hospitalization to ensure safe collection and disposal of radioactively contaminated body wastes. Where the social system and infrastructure is such that there may be contamination risks from discharged patients, it may be necessary to hospitalize the patient or extend the normal hospitalization time, to avoid risk to the environment or other persons [20.1].

The decision to hospitalize or release a patient after therapy should be made on an individual basis considering several factors including residual activity in the patient, the patient's wishes, family considerations (particularly the presence of children), environmental factors, and existing guidance and regulations. The nuclear medicine physician has the responsibility to ensure that no patient who has undergone a therapeutic procedure with unsealed sources is discharged from the nuclear medicine facility until it has been established by either a medical physicist or by the facility's RPO that the activity of radioactive substances in the body is such that the doses that may be received by members of the public

and family members would meet national criteria, including compliance with relevant dose limits and the application of relevant dose constraints. Iodine-131 typically results in the largest dose to medical staff, the public, caregivers and relatives. Other radionuclides used in therapy are usually simple β emitters (e.g. ^{32}P, ^{89}Sr and ^{90}Y) that pose much less risk.

The modes of exposure to other people are: external exposure, internal exposure due to contamination, and environmental pathways. The dose to adults from patients is mainly due to external exposure. Internal contamination of family members is most likely in the first seven days after treatment. In most circumstances, the risks from internal contamination of others are less significant than those from external exposure [20.1]. In general, contamination of adults is less important than external exposure. However, contamination of infants and children with saliva from a patient could result in significant doses to the child's thyroid [20.2]. Therefore, it is important to avoid contamination (particularly from saliva) of infants, young children and pregnant women owing to the sensitivity of fetal and paediatric thyroids to cancer induction [20.1, 20.3]. Written instructions to the patient concerning contact with other persons and relevant precautions for radiation protection must be provided as necessary (see Section 20.3.2).

The day to day management of hospitalization and release of patients should be the responsibility of the licensee. In applying dose constraints, registrants and licensees should have a system to measure or estimate the activity in patients prior to discharge and assess the dose likely to be received by members of the household and members of the public. The result should be recorded. A method to estimate the acceptable activity of radiopharmaceuticals for patients on discharge from hospitals is to calculate the time integral of the ambient dose equivalent rate and compare it with the constraints for patient comforters, or for other persons who may spend time close to the patient. For this calculation, either a simple conservative approach based on the physical half-life of the radionuclide or a more realistic one, based on patient-specific effective half-life, can be used. The assumptions made in these calculations with regard to time (occupancy factors) and distance should be consistent with the instructions given to patients and comforters at the time the patient is discharged from hospital. In the calculation of the effective half-life, the behaviour of ^{131}I can be modelled using two components for the biological half-life: the extra-thyroidal (i.e. existing outside the thyroid) iodine and thyroidal iodine following uptake by thyroid tissue. The assumptions used often err on the side of caution; it is sometimes felt that they significantly overestimate the potential doses to carers and the public. Examples of such calculations are found in the literature [20.4, 20.5]. Further guidance on radiation protection following radionuclide therapy can be found in Ref. [20.1] (especially in annex II).

When deciding on the appropriate discharge activity for a particular patient, the licensee should take into account the transport and the living conditions of the patient, such as the extent to which the patient can be isolated from other family members and the requirement to dispose safely of the patient's contaminated excreta. Special consideration shall be given to the case of incontinent patients. In some cases, such as for the elderly or children, it may be necessary to discuss the precautions to be taken with other family members.

Additional guidance on specific release considerations depending on various radionuclide therapies can be found in annex V of Ref. [20.1].

20.3.2. Specific instructions for releasing the radioactive patient

Current recommendations regarding release of patients after therapy with unsealed radionuclides vary widely around the world. However, the decision to release a patient is based on the assumption that the risk can be controlled when the patient returns to their home. This is generally achieved by combining an appropriate release criterion with well tailored instructions and information for the patient that will allow them to deal effectively with the potential risk [20.1].

When required, the patient or legal guardian shall be provided with written (and perhaps a verbal explanation of) instructions with a view to the restriction of doses to persons in contact with the patient as far as reasonably achievable, and information on the risks of ionizing radiation. It is important to develop effective communication methods. The IAEA gives example information/leaflet information in Safety Reports Series No. 63 [20.1]. Specific instructions should include items such as instructions to patients concerning the spread of contamination, minimization of exposure to family members, cessation of breast-feeding, and conception after therapy. The amount of time that each precaution should be implemented should be determined based on an estimate of the activity in patients prior to discharge and an assessment of the dose likely to be received by carers and comforters or members of the public under various precaution formulations as compared to the appropriate dose constraints. Procedures for advising carers and comforters should be in place in consultation with the RPO. Registrants and licensees should ensure that carers and comforters of patients during the course of treatment with radionuclides (e.g. ^{131}I for hyperthyroidism and thyroid carcinoma; ^{89}Sr, ^{186}Re for pain palliation) receive sufficient written instructions on relevant radiation protection precautions (e.g. time and proximity to the patient). Example methodologies for evaluating precaution time requirements have been published [20.5, 20.6].

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

administrations. The IAEA's Safety Reports Series No. 40 [20.7] recommends cessation of breast-feeding for a patient given 5550 MBq (150 mCi) of ^{131}I-NaI. Following treatment with a therapeutic activity of a radionuclide, female patients should also be advised to avoid pregnancy for an appropriate period. The International Commission on Radiological Protection (ICRP) suggests that women should not become pregnant for some time after radionuclide therapy (e.g. 6 months for radioiodine, the most common radionuclide used) [20.2]. Various shorter or longer times for this and other radionuclides are given in ICRP Publication 94 [20.8] and Ref. [20.7] which identifies periods of 3, 4 and 24 months for ^{32}P, ^{131}I and ^{89}Sr treatments, respectively. Some practitioners use a 6–12 month gap for ^{131}I, with a view to providing further confidence in this regard. Table 13 of Ref. [20.1] gives additional information on precaution times for female avoidance of conception for specific radionuclide therapies [20.1].

The administration of therapeutic doses of relatively long lived radionuclides in ionic chemical forms to males is also a possible source of concern because of the appearance of larger quantities of these radionuclides in ejaculate and in sperm. It is widely recommended in practice, on the basis of prudence, that male patients take steps to avoid fathering children during the months immediately following therapy [20.1]. However, there is no strong evidence base to support this view. Some have suggested that it may be prudent to advise sexually active males who have been treated with ^{131}I (iodide), ^{32}P (phosphate) or ^{89}Sr (strontium chloride) to avoid fathering children for a period of 4 months after treatment, a period suggested as it is longer than the life of a sperm cell [20.9].

Patients travelling after radioiodine therapy rarely present a hazard to other passengers if travel times are limited to a few hours. Travel for 1–2 h immediately post-treatment in a private automobile large enough for the patient to maintain a distance of 1 m or greater from the other vehicle occupant(s) is generally permissible. A case by case analysis is necessary to determine the actual travel restrictions for each patient, especially for longer trips and for travel by public transport.

Current international security measures, such as those in place at airports and border crossing points, can include extremely sensitive radiation detectors. It is quite possible that patients treated with γ emitting radionuclides could trigger these alarms, particularly in the period immediately following discharge. Environmental or other radiation detection devices are able to detect patients who have had radioiodine therapy and some diagnostic procedures for several weeks after treatment [20.10, 20.11]. Triggering of an alarm does not mean that a patient is emitting dangerous levels of radiation — the detectors are designed to detect levels of radioactivity far below those of concern to human health. The security authorities are well aware of this possibility, and if a patient is likely to travel soon after discharge, the hospital or the patient's doctor should provide a

written statement of the therapy and radionuclide used, for the patient to carry. The IAEA gives an example of a credit card-style card that might be given to a patient at the time of discharge (see Fig. 20.1) [20.1]. Personnel operating such detectors should be specifically trained to identify and deal with nuclear medicine patients. Records of the specifics of therapy with unsealed radionuclides should be maintained at the hospital and given to the patient along with written precautionary instructions [20.2].

FIG. 20.1. Example of a credit card-style card that might be given to a patient at the time of discharge: (a) front side; (b) rear side [20.1].

20.4. PUBLIC EXPOSURE

The registrant or licensee is responsible for controlling public exposure resulting from a nuclear medicine practice [20.6]. The presence of members of the public in and near the nuclear medicine facility shall be considered when designing the shielding and flow of persons in the facility. Exposure to members of the general public from released patients also occurs, but this exposure is almost always very small. The unintentional exposure of members of the public in waiting rooms and on public transport is usually not high enough to require special restrictions on nuclear medicine patients, except for those being treated with radioiodine [20.3] who should receive patient-specific instructions for limiting public exposure [20.8, 20.12]. In addition, exposure of those immediately involved with the patient and the general population can occur through environmental pathways including sewerage, discharges to water, incinerated sludge or cremation of bodies. From the point of view of the individual doses involved, this is of relatively minor significance [20.1].

20.4.1. Visitors to patients

Arrangements should be made to control access of visitors (with special emphasis on controlling access of pregnant visitors or children) to patients undergoing radionuclide therapy and to provide adequate information and instruction to these persons before they enter the patient's room, so as to ensure appropriate protection. Registrants and licensees should also take measures for restricting public exposure to contamination in areas accessible to the public.

20.4.2. Radioactive waste

Registrants and licensees are responsible for ensuring that the optimization process for measures to control the discharge of radioactive substances from a source to the environment is subject to dose constraints established or approved by the regulatory body [20.13–20.15]. Chapter 3 gives specific recommendations for managing radioactive waste within the hospital facility.

For diagnostic patients, there is no need for collection of excreta and ordinary toilets can be used. For therapy patients, there are very different policies in different countries, but, in principle, the clearance criteria should follow a dilution and decay methodology. Much of the activity initially administered is eventually discharged to sewers. Storing a patient's urine after therapy appears to have minimal benefit as radionuclides released into modern sewage systems are likely to result in doses to sewer workers and the public that are well below public dose limits [20.8]. Once a patient has been released from hospital, the

excreted radioactivity levels are low enough to be discharged through the toilet in their home without exceeding public dose limits. The guidelines given to patients will protect their family, carers and neighbours, provided the patient follows these guidelines.

20.5. RADIONUCLIDE THERAPY TREATMENT ROOMS AND WARDS

The following aims should be considered in the design of radionuclide therapy treatment rooms and wards: optimizing the exposure to external radiation and contamination, maintaining low radiation background levels to avoid interference with imaging equipment, meeting pharmaceutical requirements, and ensuring safety and security of sources (locking and control of access).

Typically, rooms for high activity patients should have separate toilet and washing facilities. The design of safe and comfortable accommodation for visitors is important. Floors and other surfaces should be covered with smooth, continuous and non-absorbent surfaces that can be easily cleaned and decontaminated. Secure areas should be provided with bins for the temporary storage of linen and waste contaminated with radioactive substances.

20.5.1. Shielding for control of external dose

Radiation sources used in radiopharmaceutical therapy have the potential to contribute significant doses to medical personnel and others who may spend time within or adjacent to rooms that contain radiation sources. Meaningful dose reduction and contamination control can be achieved through the use of appropriate facility and room design. Shielding should be designed using source related source constraints for staff and the public. The shielding should be designed using the principles of optimization of protection and taking into consideration the classification of the areas within it, the type of work to be done and the radionuclides (and their activity) intended to be used. It is convenient to shield the source, where possible, rather than the room or the person. Structural shielding is, in general, not necessary for most of the areas of a nuclear medicine department. However, the need for wall shielding should be assessed in the design of a therapy ward to protect other patients and staff, and in the design of rooms housing sensitive instruments (e.g. well counters and gamma cameras) to keep a low background.

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

Placing radiopharmaceutical therapy patients in unshielded hospital rooms may expose persons in adjacent areas to levels that might cause dose constraints to be exceeded. Vacating adjacent rooms or areas or installing shielding (e.g. permanent poured concrete, solid concrete block, steel plates, lead sheets or portable shielding devices) may be necessary to ensure dose constraints are maintained in adjacent areas. Table 20.1 gives typical shielding effectiveness values for ^{131}I. Exposure rate or dose rate measurements should be taken after each radionuclide therapy administration, or worst case scenario evaluations documented to confirm that these are below levels that could cause a dose constraint to be exceeded.

TABLE 20.1. TYPICAL SHIELDING EFFECTIVENESS VALUES FOR ^{131}I

Material	Half-value layer	Tenth-value layer
Lead [20.16]	3.0 mm	11 mm
Concrete [20.17]	5.5 cm	18 cm

For permanent shielding evaluations, the design effective dose rate P (in millisieverts per year or millisieverts per week) in a given occupied area is derived by selecting a source related dose constraint, with the condition that the individual effective doses from all relevant sources will be well below the prescribed effective dose constraints for persons occupying the area to be shielded. Table 20.2 gives typical values for design effective dose in occupied areas adjacent to a radionuclide therapy room [20.18]. A critical review of conservative assumptions should be performed, so as to achieve a balanced decision and avoid accumulation of over-conservative measures that may go far beyond optimization.

It is preferable that patient treatment rooms be for individual patients and adjacent to each other. If this is not possible, appropriate shielding between one patient and another is required. When required, shielding should be provided for nurses and visitors of radionuclide therapy patients, for which movable shields may be used within patient rooms. When required, prior to each treatment, movable shields should be placed close to the patient's bed in such a way that exposure of the nurses caring for the patient is minimized. This is achieved by anticipating the nurse's tasks, positions and movements throughout the room.

TABLE 20.2. TYPICAL VALUES FOR DESIGN EFFECTIVE DOSE *P* IN OCCUPIED AREAS ADJACENT TO A RADIOTHERAPY TREATMENT ROOM

	Annual effective dose (mSv/a)	Weekly effective dose (mSv/week)
Occupational worker	10	0.2
Member of the public	0.5	0.01

20.5.2. Designing for control of contamination

Floors and other surfaces should be covered with smooth, continuous and non-absorbent surfaces that can be easily cleaned and decontaminated. The floors should be finished in an impermeable material which is washable and resistant to chemical change, curved to the walls, with all joints sealed and glued to the floor. The walls should be finished in a smooth and washable surface, for example, painted with washable, non-porous paint.

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

The design of safe and comfortable accommodation for visitors is important. Shielding should be designed using source related dose constraints for staff and the public. Secure areas should be provided with bins for the temporary storage of linen and waste contaminated with radioactive substances.

20.6. OPERATING PROCEDURES

General advice on operating procedures in a nuclear medicine facility is given in Chapter 3. Management of radionuclide therapy patients should be planned and performed in a way that minimizes the spread of contamination in air and on surfaces. Work with unsealed sources should be restricted to a minimum number of locations.

20.6.1. Transport of therapy doses

Specific radiation safety considerations for the radiopharmacy are addressed in Chapter 9. Radiopharmaceuticals need to be transported within the facility in shielded, spill-proof containers if warranted by the type of radionuclide and amount of activity. The shielding should be such that external doses are maintained as low as reasonably achievable (ALARA). The facility RPO should be consulted in designing or evaluating the appropriateness of shielding and transport methods.

20.6.2. Administration of therapeutic radiopharmaceuticals

Administration is normally by the oral route, intravenous injection (systemic) or instillation of colloidal suspensions into closed body cavities (intracavitary). Shielded syringes should be utilized during the intravenous administration of radiopharmaceuticals as necessary to ensure that extremity doses are maintained below occupational dose constraints. Absorbent materials or pads should be placed underneath an injection or infusion site. The facility RPO should be consulted to determine the necessity of other protective equipment (e.g. shoe covers, step-off-pads, etc.) for particular radiopharmaceutical therapies.

For oral administrations of therapeutic radiopharmaceuticals, the radioactive material should be placed in a shielded, spill-proof container. Care should be taken to minimize the chance for splashing liquid or for dropping capsules. Appropriate long-handled tools should be utilized when handling unshielded radioactive materials. For intravenous administrations by bolus injections, when dose rates warrant, the syringe should be placed within a syringe shield (plastic for β emitting radionuclides to minimize bremsstrahlung, high Z materials for photon-emitting radionuclides) with a transparent window to allow for visualization of the material in the syringe. For intravenous administrations by slower drip or infusions, the activity container should be placed within a suitable shield. For high energy photons, a significant thickness of lead or other high Z material may need to be evaluated. In addition, consideration should be given for shielding pumps and lines.

Procedures for administering a therapeutic radiopharmaceutical shall include considerations to ensure as complete a delivery as possible of the prescribed therapeutic activity. Any retention of material in syringes, tubing, filters or other equipment utilized for administration should be analysed. Where appropriate, equipment should be flushed or rinsed with isotonic saline (or another physiological buffer) for parenteral administration or water for oral administrations. All materials utilized in administrations shall be considered as medical and radioactive waste, and should be labelled with the radionuclide, a

radiation precaution sticker, and stored and or disposed of in a manner consistent with local regulations.

20.6.3. Error prevention

Care should be exercised in avoiding administration of a therapeutic radiopharmaceutical to the wrong patient. In addition, prior to administration, the following should be verified:

— The dose on the radiopharmaceutical label matches the prescription;
— Identification of the patient by two independent means;
— Identity of the radionuclide;
— Identity of the radiopharmaceutical;
— Total activity;
— Date and time of administration;
— Patients have been given information about their own safety.

The therapeutic radiopharmaceutical, activity, the date and time of administration, and verification of the initial and residual assay should be entered in some form in the patient's medical record.

Pregnancy is a strong contraindication to unsealed radionuclide therapy, unless the therapy is life-saving. This advice is all the more valid for radioiodine therapy and for other radionuclides with the potential to impart radiation doses to the fetus in the range of a few millisieverts. Therefore, where treatment is likely or anticipated, the patient should be advised to take appropriate contraceptive measures in the time prior to therapy [20.1]. Some radiopharmaceuticals, including ^{131}I as iodide and ^{32}P as phosphate, rapidly cross the placenta, so that the possibility of pregnancy should be carefully excluded before administration. Before any procedure using ionizing radiation, it is important to determine whether a female patient is pregnant. The feasibility and performance of medical exposures during pregnancy require specific consideration owing to the radiation sensitivity of the developing embryo/fetus [20.3]. Some procedures and some radiopharmaceuticals (e.g. radioiodides) can pose increased risks to the embryo/fetus. The ICRP has given detailed guidance in Publications 84 [20.19] and 105 [20.2]. Radiation risks after prenatal radiation exposure are discussed in detail in ICRP Publication 90 [20.20].

20.6.4. Exposure rates and postings

Values of ambient dose equivalent from the patient should be determined. This information will assist in deriving appropriate arrangements for

entry by visitors and staff. Following the administration of the therapeutic radiopharmaceutical to the patient, anterior exposure rates at the surface of and 1 m from the patient should be measured at the level of the patient's umbilicus (or other location as appropriate for the type of nuclear medicine administered), using a calibrated radiation monitor (e.g. a portable ionization chamber). Typically, these initial measurements are to be taken within 1 h of administration of the radiopharmaceutical therapy.

Rooms with radiotherapy patients should be controlled areas. A sign such as that recommended by the International Organization for Standardization (ISO) [20.21] should be posted on doors to the patient's room and radioactive material storage areas as an indicator of radiation (see Fig. 20.2).

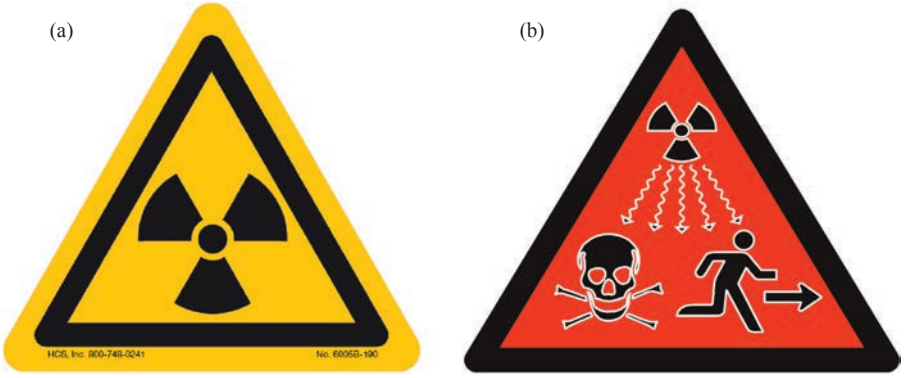

FIG. 20.2. (a) International Organization for Standardization (ISO) radiation symbol; (b) New IAEA/ISO radiation warning symbol.

It should be noted, however, that the ISO radiation symbol is not intended to be a warning signal of danger but only of the existence of radioactive material. A new symbol has been launched by the IAEA and the ISO to help reduce needless deaths and serious injuries from accidental exposure to large radioactive sources [20.22]. It will serve as a supplementary warning to the trefoil, which has no intuitive meaning and little recognition beyond those educated in its significance. The new symbol is intended for IAEA category 1, 2 and 3 sources [20.23] defined as dangerous sources capable of death or serious injury, including food irradiators, teletherapy machines for cancer treatment and industrial radiography units. The symbol is to be placed on the device housing the source, as a warning not to dismantle the device or to get any closer. It will not be visible under normal use, only if someone attempts to disassemble the device. For radionuclide therapy applications, the new symbol will not be located on building access doors, transport packages or containers. Rather, the

ISO radiation symbol should be utilized to notify individuals of the existence of radioactive material.

Facilities may also consider placing a 'radioactive precautions' wristband on the patient's wrist if the patient is to remain in medical confinement. In addition, for those patients remaining in medical confinement, the patient should be resurveyed each day at the point of maximal uptake of the radiopharmaceutical. The exposure rate or dose rate measured can then be used in determining the activity remaining in the patient as well as developing appropriate release instructions for the patient (see Section 20.3).

20.6.5. Patient care in the treating facility

Medical practitioners should exercise their clinical duties consistent with patient safety and good quality medical care. Unless otherwise specified by the facility RPO, nurses, physicians and other health care personnel are to perform all routine duties, including those requiring direct patient contact, in a normal manner. However, medical practitioners should avoid lingering near the patient unnecessarily and should spend as little time as necessary in close proximity to radioactive materials or patients treated with radiopharmaceuticals and remain at distances appropriate for the exposure rate or dose rate measurements from such materials and patients. When necessary, portable shielding should be used to reduce radiation levels to medical practitioners.

Ward nurses should be informed when a patient may pose a radioactive hazard, and advice and training should be provided. The training should include radiation protection and specific local rules, in particular, for situations where there is a risk of significant contamination from, for example, urine, faeces or vomiting. Appropriate training should also be given to night staff. In the case of high activity patients, only essential nursing should be carried out. Other nursing should be postponed for as long as possible after administration, to take full advantage of the reduction of activity by decay and excretion. In addition, there should be minimum handling of contaminated bed linen, clothing, towels, crockery, etc. during the initial period and the instructions on how long these precautions should be maintained should be documented.

The nursing staff should be familiar with the implications of the procedure, the time and date of administration, and any relevant instructions to visitors. Values of ambient dose equivalent at suitable distances should be determined. This information will assist in deriving appropriate arrangements for entry by visitors and staff. These arrangements should be made in writing in the local rules.

20.6.6. Contamination control procedures

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

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

Particular attention and measures to limit spread of contamination are required in the case of incontinent patients and, in cases of oral administration, if there are reasons for believing that the patient may vomit. Contaminated bedding and clothing should be changed promptly and retained for monitoring. Crockery and cutlery may become contaminated. Local rules should specify washing up and segregation procedures, except for disposable crockery and cutlery.

Where possible, a radionuclide therapy patient that requires medical confinement should be placed in a private hospital room with a private toilet and sink. The use of disposable plastic-backed absorbent pads or plastic sheeting taped in place in the areas most likely to be contaminated, such as the floor around the toilet and sink, may be appropriate for a facility. In all cases, consideration of the ALARA principle should be maintained. Removal of loose contaminated items from the patient's room should be done on a daily basis.

In the event of a large volume spill of blood, urine or vomitus, medical practitioners or staff should cover the spill with an absorbent material and immediately contact the facility radiation safety service for appropriate cleanup assistance and specific instructions. After such a spillage, the following actions should be taken:

(a) The RPO should immediately be informed and directly supervise the cleanup;
(b) Absorbent pads should be thrown over the spill to prevent further spread of contamination;
(c) All people not involved in the spill should leave the area immediately;
(d) All people involved in the spill should be monitored for contamination when leaving the room;
(e) If clothing is contaminated, it should be removed and placed in a plastic bag labelled 'radioactive';

(f) If contamination of skin occurs, the area should be washed immediately;
(g) If contamination of an eye occurs, it should be flushed with large quantities of water.

Upon discharge and release of the patient, all remaining waste and contaminated items should be removed and segregated into bags for disposable items and launderable items. All radioactively contaminated waste items should be labelled with the radionuclide and a radiation precaution sticker, and be stored and or disposed of in a manner consistent with local regulations. The patient's room should be surveyed and checked for removable contamination utilizing appropriate survey equipment (e.g. a Geiger–Müller counter or scintillation survey meter). Where necessary, wipe tests should be performed. Facility procedures should address applicable criteria for removable radioactive contamination. Contamination monitoring is required for:

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

20.7. CHANGES IN MEDICAL STATUS

If the medical condition of a patient deteriorates such that intensive nursing care becomes necessary, urgent medical care is a priority and should not be delayed. However, the advice of the RPO should be sought immediately. In the event of a deterioration in the patient's medical condition, frequent or continual monitoring of the patient may be necessary (e.g. septic shock, pulmonary oedema, stroke or myocardial infarction). In some cases, the patient may need to be transferred to intensive, special care or cardiac care units. It is possible that patients in these units are in close proximity to each other with little or no shielding available. As such, radionuclide therapy patients may present a radiation hazard to other patients or medical practitioners. The nuclear medicine physician and the RPO shall be notified of the transfer to a special unit as soon as possible or prior to the transfer. The RPO shall determine whether portable shielding is necessary to reduce doses to other patients or medical practitioners,

whether specific personnel monitoring is necessary, and whether specific radiation precautions are necessary to keep radiation exposures ALARA.

20.7.1. Emergency medical procedures

Life-saving efforts shall take precedence over consideration of radiation exposures received by medical personnel. This is particularly important for therapy patients containing large amounts of radioactivity. Medical personnel should, therefore, proceed with emergency care (e.g. when a patient has suffered a stroke), while taking precautions against the spread of contamination and minimizing external exposure. The staff should avoid direct contact with the patient's mouth, and all members of the emergency team should wear protective gloves. Medical staff should be informed and trained on how to deal with radioactive patients. Rehearsals of the procedures should be held periodically.

The only exceptional, life-saving situations are those medical emergencies involving immediate care of patients in the case of strokes or similar situations, when large amounts of radioactive material have been incorporated (of the order of 2 GBq of ^{131}I) [20.7].

20.7.2. The radioactive patient in the operating theatre

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

— The operating room staff should be notified;
— Operating procedures should be modified under the supervision of the RPO to minimize exposure and the spread of contamination;
— Protective equipment may be used as long as efficiency and speed are not affected;
— Rotation of personnel may be necessary if the surgical procedure is lengthy;
— The RPO should monitor all individuals involved;
— Doses to members of staff should be measured as required.

The RPO should consider whether personnel monitoring is required. The number of persons in the operating theatre should be minimized, and operating personnel should only remain in the operating room for the minimum amount of time consistent with surgical objectives. If it is estimated that the circulating blood or the area of the body to be treated surgically contains a significant quantity of the radiopharmaceutical, the RPO and the surgeon should discuss the procedures to be performed to keep radiation exposure to surgical personnel

ALARA. The spread of radioactive contamination can be minimized through the use of typical primary precautions used in the operating theatre. Radioactive material can be kept off of surgeons through the use of gloves (the use of double gloves may be appropriate). If an injury to surgical staff such as a cut or puncture occurs, radioactive contamination of the skin or wound may occur. The RPO should be consulted to evaluate contamination and any possible radiation hazard, including the possibility of internal intakes. Any specimens sent for pathological examination should be monitored for contamination. Tools and other equipment from the surgery should be monitored for radioactive contamination, decontaminated as necessary, and stored for radioactive decay or treated as radioactive waste in accordance with local regulations.

20.7.3. Radioactive patients on dialysis

The care of patients receiving radiopharmaceutical therapy and who are on dialysis may require additional consideration. In general, for systemic treatments, these patients will not biologically clear radioactive materials as quickly as typical patients since the clearance is highly dependent on the schedule of the dialysis session. It may be necessary to reduce or otherwise adjust the activity required for a therapy. The decision as to the activity required for such patients should be based on either a trace trial administration of activity and the observed elimination rate, or a careful review of the available literature for similar patient administrations. Typically, the largest amount of radioactivity will be eliminated during the first dialysis session following radiopharmaceutical therapy.

The RPO should assess the radiation exposures likely to be received by medical practitioners during the sessions. In such cases, no significant contamination of dialysis machines has been reported [20.1]. The materials, tubing, filters and waste containers used during the sessions should be checked by radiation safety staff to evaluate whether these need to be considered low level radioactive waste and managed in accordance with facility and local regulations (see Section 20.4.2). There may be slight contamination of disposable items such as liners and waste bags, which may require storage for some time, in the case of ^{131}I. In most cases, however, no special precautions will be required and the dialysis and radiation safety staff will advise patients on how to deal with disposables.

20.7.4. Re-admission of patients to the treating institution

If a patient who still contains a therapeutic amount of radioactive material is re-admitted to the treating institution, the RPO shall be notified as soon as possible after re-admission. Patient medical charts should include information on

dates of cessation of radiation precautions (perhaps in electronic chart systems which could provide useful triggers for the needed precautions in the event of re-admission). The RPO shall monitor the patient and specify any required precautions to be followed by medical practitioners. Where required, radiation precaution tags should be placed on the patient, the patient's room and chart.

20.7.5. Transfer to another health care facility

Some patients may need to be transferred to another health care facility (i.e. another hospital, skilled nursing facility, nursing home or hospice, etc.) following therapy treatments. In such a case, care must be taken that, in addition to practical measures and advice to ensure safety of other staff, any legal requirements relevant to the second institution are also complied with [20.1]. Patients transferred to another health care facility should meet the criteria for unrestricted clearance. However, the possibility for the generation of low level radioactive waste should be examined by the RPO of the treating facility and any issues should be discussed with the facility accepting the patient transfer. In the rare event that a patient being transferred to another health care facility does not meet the criteria for unrestricted clearance, the RPO shall ensure that the facility accepting the patient transfer has an appropriate registration or licence that would allow acceptance of the patient with therapeutic amounts of radioactive materials on board. The RPO should provide radiation safety information and precautions, if any, for the patient and for the receiving health care facility.

20.8. DEATH OF THE PATIENT

Therapeutic amounts of radioactive materials are typically not administered to critically ill patients unless there are circumstances where the palliative use of radioactive materials in terminal patients will significantly improve the quality of life of the patient. However, should the patient die in the period immediately following therapy, special consideration may need to be given to the treatment of the corpse. To facilitate this, the patient should be given a small card with details of their treatment and contact details for a radiation protection specialist/medical physicist associated with the department responsible for the therapy (see Fig. 20.1). Additional specific guidance for the death of a radionuclide therapy patient has been developed by the IAEA [20.1].

Areas of concern arise with respect to embalming, burial or cremation of the corpse and the conduct of autopsy examinations. National regulations, some quite dated, are available for some or all of these in many countries, but there is a lack of international recommendations. Practice tends to be guided by an untidy

mixture of custom, professional guidance and national regulation [20.1]. Recent reports have emphasized the need to be sensitive to the wishes of the deceased and their family when decisions about the disposal of the corpse are being made. This may be particularly important if the possibility of retaining some organs for radiation protection reasons is being considered [20.1].

The authorities in many countries now place limits on the radioactivity that may be present in the corpse before autopsy, embalming, burial or cremation. No special precautions are required for direct burial or cremation, without embalming, provided the activity involved is not in excess of national limits. No special precautions are required for embalming if activities do not exceed the levels mentioned in table 14 of Ref. [20.1] for autopsy. If the activities are greater, then a corpse should not normally be embalmed, but if embalming is required an RPO should be consulted.

20.8.1. Death of the patient following radionuclide therapy

In cases where the death occurs in a hospital, access to the room occupied by the deceased should be controlled until the room has been decontaminated and surveyed. Radioactive bodies should be identified as potential hazards by a specified form of identifier. Identification of the possibility that a body may contain radioactive substances relies on information provided in the patient records, the information card (Fig. 20.1) or information gleaned from relatives or others. A body bag may need to be used to contain leakage of radioactive substances. To minimize external radiation risk, the corpse may need to be retained in a controlled area.

In the event that a patient dies within the treating health care facility while still containing a therapeutic quantity of radioactive material, the treating medical practitioner and the RPO shall be notified immediately. Depending on the number of days that have elapsed between radiopharmaceutical treatment and death, the radiation hazard may have been reduced considerably, and precautions minimized. In the rare event that large quantities of radiopharmaceuticals are still within the body, the RPO shall identify specific radiation precautions as necessary, depending on the type of radionuclide and measured exposure rates or dose rates. Nursing staff should be provided with instructions informing them that the normal procedure of pressing down on the abdomen of a corpse must not be performed due to the radiation and/or contamination levels that may result [20.1]. The RPO shall notify the morgue prior to the arrival of the body, and the RPO should discuss radiation safety precautions with morgue personnel, as required.

In most cases, if the patient has already been released from the treating facility, no special precautions are generally necessary for handling the body.

20.8.2. Organ donation

If organ donation is being considered, the RPO shall determine necessary precautions for operating theatre personnel who will harvest the organ(s). Unless the organ is directly involved in the treatment regime, it is unlikely that the donated organ will contain an amount of radioactive material to cause significant damage to the organ or deliver a radiation dose to the recipient sufficient to nullify the donation. However, the nuclear medicine physician and RPO should be prepared to estimate such quantities and doses.

20.8.3. Precautions during autopsy

The dose constraints applying to pathology staff responsible for the conduct of autopsy examinations will be either those for the general public or those for radiation workers, depending on the training and classification of the staff concerned. However, it is almost inevitable that some members of the pathology staff will be classified as members of the public from a radiation protection point of view. These constraints and the radiation safety procedures to be applied in practice should be determined in close consultation with the RPO from the department in which the therapy was administered. Where the possibility that the corpse may be radioactive arises, a proposed autopsy should be suspended until the situation is clarified to the greatest extent possible and a risk assessment has been undertaken by the RPO. This should establish the type, nature and location of the radioactive material used and when the therapy occurred. Any reporting or notifications required by law and/or good practice should also be undertaken. Additional points to consider for autopsies of radioactive bodies are noted in annex IV of Ref. [20.1].

Although it is rare that the body of a patient will be sent for autopsy shortly after administration of a therapeutic radiopharmaceutical, if death occurs within 24–48 h post-administration, a considerable amount of activity may be present in blood and urine. In these cases, the RPO or radiation safety staff should supervise the autopsy. Any residual activity in tissue samples should be evaluated prior to releasing the samples to the pathology laboratory. If death occurred more than 48 h post-administration, there will typically be little, if any, activity in the blood or urine. In these cases, activity may only be present in residual treated areas or metastatic disease sites. The staff dose may be reduced by deferring the autopsy where necessary and practical. Finally, Singleton et al. [20.24] conclude that:

> “provided that appropriate precautions are implemented, determined through consultation with a qualified expert in radiation protection and by

completion of risk assessment, the radioactive autopsy can be undertaken safely and in compliance with relevant legislative requirements."

Unsealed radioactive substances may be present in a particular body cavity or organ, or they may have concentrated after systemic administration (e.g. ^{131}I in the thyroid gland). Drainage of the cavity or excision of the organ will reduce exposure if undertaken at the start of the autopsy. In addition, care should be given with respect to organs with significant activity. In cases where the patient had received a dose of β emitting colloid or spheres (e.g. ^{32}P chromic phosphate into a body cavity or ^{90}Y microspheres into the liver), significant activity may be present in the cavity fluid or in the embolized organ. Beta radiation sources may provide a significant dose to the hands because they will be in close contact with body tissues and fluids [20.5]. Autopsy and pathology staff should wear standard protective clothing (i.e. gloves, lab coats, eye protection, etc.) and personnel monitoring should be considered. For β emitters, double surgical gloves may be helpful in reducing skin exposures. An intake of airborne material inadvertently released during cutting or movement of radioactive tissue or organs can be prevented by wearing eye protection and a face mask.

20.8.4. Preparation for burial and visitation

Funeral directors will need to be advised of any necessary precautions, and notification of the relevant national competent authorities may be required. It is essential that funeral directors and ministers of religion do not overreact to the risks associated with the radioactive corpse. Careful communication is needed to ensure that adequate controls are implemented without compromising dignity. Situations where the wishes of the next of kin have to be significantly disrupted should be rare [20.1].

In cases where the body will be prepared for burial without autopsy or embalming, if the RPO believes that the potential dose likely to be received by the personnel preparing the body will not exceed the appropriate dose constraint, burial can proceed. In rare cases where dose constraints may be exceeded, the RPO should provide radiation precaution information (e.g. restricting the time spent near the body). In cases where the body will be prepared for burial by embalming, the RPO should notify the morgue or funeral home that the body contains therapeutic quantities of radioactive material and should provide them with precautions to minimize radiation exposure and radioactive contamination. Embalming is conducted by injecting an embalming fluid into the body and flushing body fluids into the drain. Embalming staff should wear standard protective clothing (i.e. gloves, lab coats, eye protection, etc.) and personnel

monitoring should be considered. Careful cleaning of equipment in the usual manner will remove radioactive contamination [20.5].

In most cases, no precautions will be necessary during visitation. If the possibility exists that there are measurable dose rates at 30 cm from the body, the family and funeral home should be given appropriate precautions, as necessary to provide assurance that dose constraints are met.

20.8.5. Cremation

A proportion of the activity retained will appear in cremated remains and may be sufficient, particularly in the case of long lived radionuclides, to require controls to be specified. The main concern is in respect to the scattering of ashes, although contact dose rates with the container may have to be considered if cremation takes place shortly after administration [20.1].

Assuming that the body has been prepared in accordance with the recommendations in the preceding sections, no additional handling precautions are necessary in transporting the body to the crematorium. The crematorium personnel should be informed by the treating facility or family that the body might contain radioactive material. Crematorium personnel may contact the treating facility if they need additional guidance on handling the body. Such guidance should include methods to minimize radiation exposure, contamination of the retort and especially methods to minimize radioactive ash particles. Crematorium employees may receive external exposure from the radioactive body or from contamination of the crematorium or internal exposure from inhalation of radioactive particles while handling the ashes [20.25]. Bodies that contain γ emitting radionuclides may result in some external exposure to employees of the crematorium. No precautions are necessary as long as there is minimal time required to handle the body at the crematorium (a likely assumption). Cremation of non-volatile radionuclides might result in contamination of the retort. As the most significant hazard from this contamination is inhalation of ash particles during cleaning of the retort, it is appropriate for workers who clean the retort to wear dust masks and protective garments.

The most likely hazard to the general population in the vicinity of the crematorium is the inhalation of radioactive material emitted with the stack gases. Each crematorium should maintain records of the type and activity in bodies cremated, when known.

The potential for effective doses from cremation of bodies containing ^{131}I should be evaluated and some have suggested that if a crematorium were to handle bodies that contain ^{131}I and do not exceed 100 GBq in a single year, the effective dose to individuals in the surrounding population would not likely exceed 0.1 mSv [20.5]. It, therefore, appears that no specific radiation hazard

would exist even if a crematorium were to handle several bodies per year containing ^{131}I.

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