The Radiation Protection

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Salus populi suprema lex esto.
—Health of the people should be the supreme law—Marcus Tullius Cicero

4.1 Basic Factors in Radiation Protection

One delicate issue in nuclear endocrinology is radiation protection. There are a multitude of documents, legislations and rules, recommendations, and approvals that endocrinologists should obtain from the national authorities before starting to work with nuclear products and to treat patients with radiopharmaceuticals.

Depending on the national legislation, there are different restrictions in the usage of radiopharmaceuticals. There are countries or states where the use of radiopharmaceuticals is allowed only for inpatients, while other countries permit treatments of the outpatients, restricted only by an established national dose limit.

In any of these conditions, endocrinologists should know the basic requirements of safety both for medical staff and for patient and his family. In this section of the book, there are provided several general rules available in direct relation with the basic principles of radiation protection, recognized worldwide.

All medical activities using ionizing radiation must be held under strict regulation respecting the legal requirements: the International Commission on Radiological Protection (ICRP) recommendations; European Union directives regarding medical exposure and basic safety standards; National Council on Radiation Protection and Measurements, legislation, and national codes of practice; and local hospital radiation protection arrangements, reporting, and record-keeping regulations.

The issues related to radiation protection are strictly dependent on the type of radiation; different rays need various modalities of protection to be efficient in relation with humans.

Radiation effects are deterministic and stochastic, also being influenced by the sensitivity of different types of cells to radiation.

Schematic Fig. 4.1 presents three different materials in relation with radiation protection.

Considering the above example, we conclude that the attenuation of the radiation through a given medium might be summarized as follows: the thicker the absorbing material is, the greater is the attenuation, and the greater the atomic number of the material is, the greater is the attenuation. An important characteristic for attenuation is the half-value layer (HVL). HVL can be defined as the thickness of an absorbing material that reduces the radiation beam intensity to half of its original value.

The main factors affecting radiation doses in nuclear medicine are:

1. The radionuclide used (the dose depends on the energy, type, and number of emissions). Gamma emitters provide imaging information but give local and long-range dose to other organs. Beta emitters do not give imaging information and give much higher local doses.

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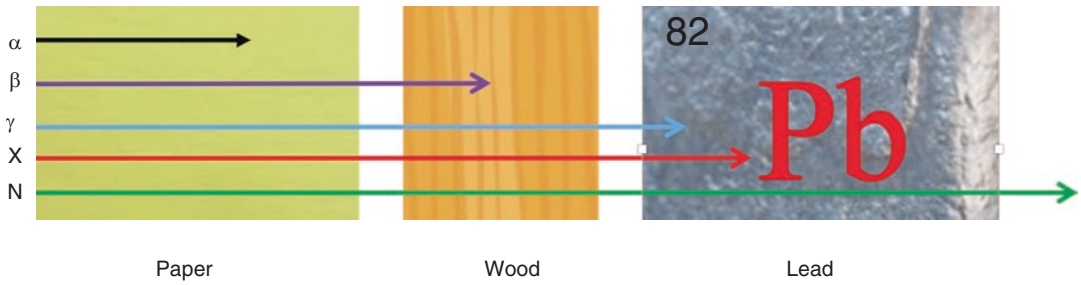

Fig. 4.1 Different materials in relation with radiation protection and ionizing radiations. α—alpha rays are stopped by a piece of paper of 2 mm; β—beta rays pass the paper, but are stopped by wood; γ—gamma rays pass through paper and wood, but are stopped by lead; X-rays pass the paper, wood and are stopped by lead; N-neutrons need special precaution

2. The physical half-life of the radionuclide (the dose increases when half-life increases). The half-life should be long enough to complete the study but short enough for the radiation to effectively disappear after the study.
3. The administered activity for the procedures (the dose increases when the activity increases). The activity should be kept to a minimum level but high enough to obtain the required diagnosis information.
4. The target and critical organs. Although usually one organ is targeted, other organs also receive a radiation dose.
5. Physiological factors. For example, in case of investigations involving isotopes of iodine, the radiation dose targeted to the thyroid may be decreased, by blocking it with stable iodine. In general, the radiation dose will be reduced, if there is fast excretion.

There are three basic requirements in daily medical practice with ionizing radiation:

1. No practice shall be adopted unless its introduction produces a positive relevant benefit (*justification*).
2. All exposures shall be kept as low as reasonable achievable—ALARA principle (*optimization*).
3. The patient doses should not exceed those prescribed by the International Commission on Radiological Protection (*ICRP dose limits*).

All over the world, the national authorities have published and implemented regulations, which represent the basic legal patterns in order to be able to work with radiation. In Europe, the European Atomic Energy Community (EURATOM) has specific legislation regarding the basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation. This standard, 96/29/EURATOM, was implemented on May 13, 1996, and renewed by 2013/59/EURATOM.

The directive applies to all practices, which involve a risk from ionizing radiation, either from an artificial source or from a natural source, where natural radionuclides are processed because of their radioactive, fissile, or fertile properties. Prior authorization is required for the disposal, recycling, or reuse of radioactive substances or materials containing radioactive substances resulting from any practice, which is compulsory, reported, or authorized, unless the clearance levels established by the competent national authorities are complied with.

Before they are adopted or approved for the first time, member states must ensure that all new classes or types of practices involving exposure to ionizing radiation are justified regarding their economic, social, or other benefits outweighing any adverse effects they may have on health. Persons under the age of 18 may not be assigned to any work, which would make them exposed workers.

The effective dose for exposed workers is limited to 100 mSv during a period of 5 consecutive years and must not exceed 50 mSv/year.

As soon as a pregnant woman or nursing mother informs an undertaking of her situation, she may not be assigned to work involving a significant risk of bodily radioactive contamination.

Regarding the medical exposure directive, EURATOM has established the effective dose limits, which must be complied with by the authorized personnel (occupational dose limits) and by the general public (public dose limits).

The effective dose limit for the occupational personnel (workers with ionizing radiation) is 20 mSv/year/averaged during defined periods of 5 years (Table 4.1).

Areas where there is a risk of exposure must be designated as controlled or supervised areas; designation depends on the extent of likely exposure.

Controlled and supervised areas must include: monitoring and recording of the activities, doses and dose rates, lay down working instructions, indication of area types, nature of the sources, and correct signs for hazardous risks.

Controlled areas must be delineated and must have controlled access.

The effective dose limit for the general public is 1 mSv in a year (Table 4.2).

Justification and optimization of the ionizing medical procedures underline that the ionizing radiation exams must outweigh radiation risk. The results may be sufficiently consistent to improve the management of the patient. Any errors should be avoided in any part of the procedure starting from patient selection to the interpretation of final results. The misadministration leads to an increased radiation dose not only to the patient but also to the staff.

Table 4.1 The effective dose limits for authorized personnel

The annual dose limits (mSv)	
Whole body	20
Lens	150
Skin (cm^2)	500
Hands and feet	500

Table 4.2 The effective dose limits for general public

Annual dose limits (mSv)	
Whole body	1
Lens	15
Skin (cm^2)	50
Hands and feet	50

4.2 Staff Protection in Nuclear Medicine Units

For staff protection, there are several rules that must be respected: adequate dose monitoring, continuous education and training, implementation of local hospital rules, informing the supervisor as soon as a pregnancy is confirmed, employer must undertake risk assessment, reassignment of staff if required, restriction of tasks if required (e.g., injection), remember principles of time and distance and shielding, and escort staff for nuclear medicine patients must not be pregnant.

Radiation protection measures for handling radiopharmaceuticals:

- Wear dedicated single-use coat.
- Remove coat when leaving the area.
- Wear gloves when handling radioactive materials or containers that may have been contaminated.
- Wash and monitor hands frequently.
- Do not eat, drink, or smoke in an area where radioactive materials are used.
- Remove gloves when leaving the area.
- Work in a suitable contained workstation.
- Use different gloves to touch instrument switches.
- Prepare all materials required before starting to handle radioactive materials so that there is no need to open recipients, etc.
- Routine quality control of equipment.

Practical information for pregnant and breastfeeding staff:

- Unborn child should be protected as a member of the public.
- Radiation dose should be limited to 1 mSv after declaration of pregnancy.
- Breastfeeding staff: in case of breastfeeding, work must not involve significant risk of bodily contamination (e.g., iodine therapy).

4.3 General Measures to Reduce the Irradiation of Patient

- Examination must be clinically justified.
- Refer to previous results.
- Choose the most appropriate technique.
- Consider the usage of alternative techniques.
- Choose the radiopharmaceuticals appropriately.
- Prepare the patient adequately, e.g., instructions on diet, drug, etc.
- Administered activity should be minimum consistent with obtaining required diagnostic information.
- Ensure about the accuracy of the injected doses.
- Consider a layout of the waiting area.
- Increased fluid intake and frequent voiding.
- For children, pregnant women, and breastfeeding mothers, take additional measures.
- Use of appropriate equipment.
- Continuous training of the staff.
- Particular attention to justification and optimization for children examinations.
- When I-123, I-125, and I-131 are administered as iodine or iodine-labeled compounds such as albumin or fibrinogen, a substantial part of the effective dose equivalent stems from thyroid gland irradiation. Use thyroid's blocking protocol to reduce dose for non-thyroid imaging studies, e.g., I-123 MIBG studies.

Blocking protocol:

- Blocking typically begins 1–2 days before the test and continues for 7 days afterward.
- Oral dose of 100 mg KI (or 140 mg KIO_3) or Lugol's solution reduces uptake to less than 1%.
- The most important side effect may be hyperthyroidism (particular problem in elderly or those with cardiovascular disease). The clinician should take additional specific measures.

4.4 Physical Factors in Radiation Protection

In nuclear medicine, radiation protection uses three fundamental principles of physical factors:

4.4.1 Time

Due to the particularities of radiopharmaceuticals used in nuclear endocrinology, for patients submitted to diagnostic or treatment procedures with radionuclides, the principle of time is one of the simplest and most important to reduce the radiation exposure both for the medical staff, patient, and for the patient's family.

Keeping in mind that the less time is spent with the patient after the dose is administrated, the less is the exposure; therefore, all procedures, treatments, examinations, information, and discussion should be carried out *before* the administration of the radioactive dose. The contact with the patient, especially in the first several hours after the dose administration, must be limited as much as possible to strict situations or emergency events.

- Minimize the time spent close to the radioactive sources.
- The examination of the patient and the discussion with the patient should take place before the radiopharmaceutical is injected or orally administrated.
- Remove contaminated items to a safe, shielded place as soon as possible.

Key Point
Time (t) and exposure (absorbed dose—Gy) are directly proportional:

$$\uparrow t \rightarrow \uparrow \text{Gy}$$

The time that may be spent near a source of radiation (including the patient who has been treated or injected with radiopharmaceuticals) is calculated according to the following formula (Eq. 4.1):

$$\text{Stay time}(\text{h}) = \frac{\text{Dose limit}(mSv)}{\text{Dose rate}(mSv/\text{h})} \quad (4.1)$$

4.4.2 Distance

The next important factor that influences the dose rates in radiation protection is distance.

- Makes use of the inverse square law, by maximizing distance away from sources. For example, by doubling the distance from a point source, one reduces the dose rate by a factor of 4.
- Use handling tools to lift sources thereby to minimize the dose.
- Because of this particularity of inverse proportionality, the distance is even more important than the time in radiation protection.
- At an appropriate distance, the time spent with the patient may be increased significantly, by a factor of 4.

Key Point
Distance (D) and exposure (absorbed dose—Gy) are inverse square proportional:

$$\uparrow D \rightarrow \downarrow \text{Gy}^2$$

Example:
After the treatment with 33 mCi (1.2 GBq) of I-131 of a patient with thyroid carcinoma, the radiation exposure at 1 m (D_1) is 0.07 mSv/h (7 mrem/h)—E_1.
If the distance is increased at 2 m (D_2), the final dose rate (E_2) is inexistent, being almost 0 (Eqs. 4.2 and 4.3):
D_1—1 m
E_1—0.07 mSv/h
D_2—2 m
E_2—?

$$\text{Dose rate}(E_2) = \frac{\text{Dose rate}(E_1) \times \text{Distance}(D_1)}{\text{Distance}(D_2)^2} \quad (4.2)$$

$$E_2 = \frac{0.07 \frac{mSv}{\text{h}} \times 1 \text{ m}}{(2)^2 \text{ m}} = 0.0175 \ mSv/\text{h} \sim 0. \quad (4.3)$$

4.4.3 Shielding

If reducing the time or increasing the distance may not be possible, one can choose shielding materials to reduce the external radiation hazard. The proper material to be used depends on the type of radiation and its energy.

The half-value layer (HVL) is the thickness of the shielding material required to reduce the intensity (I) to one-half of its original

intensity (I_0) and can be calculated from Eqs. 4.4 and 4.5:

$$\frac{I}{I_0} = e^{-\mu x^{1/2}} = 0.5 \quad (4.4)$$

μ is the linear attenuation coefficient.
$x^{1/2}$ is the half-value layer (HVL).

$$x^{1/2} = \text{HVL} = \frac{0.693}{\mu} \quad (4.5)$$

- Use quick release syringe shields at all stages when handling radiopharmaceuticals.
- Locate generators, sharps containers, etc., behind or within shields.
- Use enclosed vial shields for radiopharmaceuticals, liquid isotopes, and elution vials.
- Cover vial shields when they are not used.
- When working in the radiopharmacy, work behind protective shielding, contained workstation.

4.5 Special Recommendations for Patients Undergoing Nuclear Medicine Procedures

- Instruction sheet detailing activity administered and duration of restrictions required should accompany the patient.
- Nursing and clinical staff, in contact with the patient, should be informed that the patient is radioactive.
- Pregnant visitors or small children should not be allowed to visit the patient during the period of restrictions.

4.5.1 For Female Patients of Childbearing Age and Breastfeeding

Prescriber and practitioner should inquire whether she is pregnant or breastfeeding. In the case of a female breastfeeding in nuclear medicine, special attention must be accorded to justification and optimization of the exposure for mother and child; there are two standard rules that are used worldwide for application.

10 Days Rule

Examinations involving ionizing radiation are only carried out in the first 10 days of the menstrual cycle.

28 Days Rule

Women of childbearing age could undergo medical exposures during the first 4 weeks following last menstrual period (LMP). Practical implementation of LMP rule varies nationally.

Assess if patient is pregnant:

- A pregnancy test or the serological determination of beta HCG (human chorionic gonadotropin), as an early marker of pregnancy, might be used.
- If pregnancy cannot be ruled out, treat patient as pregnant.
- If pregnant, review justification for exam, and consider alternative techniques or deferring exam.
- If exam to proceed, optimize with respect to radiation protection of unborn child.
- Assess fetal dose before and after exam.

After radioisotope scan:

- If breastfeeding to be continued after procedure, express milk before scan and store for use in period immediately after scan.
- Express and discard milk immediately after scan.
- Period of interruption of breastfeeding may be required for certain radiopharmaceuticals; the time is dependent to the isotope. For example, for Tc-99m pertechnetate used for a thyroid scan, a maximum period of 24 h may be recommended.
- Minimize time holding child.
- For most diagnostic procedures, avoidance of pregnancy is not indicated.

In case of therapies with radioiodine:

- Patients should be advised in advance that pregnancy is a contraindication to I-131 therapy, and they should take measures to prevent pregnancy once treatment is planned. Pregnant women should never be treated; the therapy is postponed after delivery.

- Check of pregnancy:
  - Pregnancy tests within 72 h prior to treatment
  - Historical evidence of hysterectomy
  - No menses for a minimum of 2 years and >48 years old
  - Other incontrovertible evidence for absence of pregnancy
- Pregnancy should be delayed for at least 6 months after radioiodine therapy; a delay is based on the need to normalize thyroid levels for a successful pregnancy and healthy infant development and to ensure that additional radiation treatment is not imminent.
- There may be some treated patients who later discover that they were pregnant; such cases should be handled on a case-by-case basis, and a qualified medical physicist should estimate the absorbed radiation dose to the fetus. If a pregnant woman is treated, data must be provided to her obstetrician, and the patient must be counseled on possible pregnancy outcomes and treatment options.
- In meta-analysis study (Sawka et al. 2008a), no evidence was found that I-131 treatments impaired fertility. The latest 2017 American Thyroid Association guideline (Alexander et al. 2017) referring to the diagnosis and management of thyroid disease during pregnancy and the postpartum underlines that there are no relations between the I-131 therapy for ablation in thyroid cancer and any of the following conditions: an increased risk of infertility, pregnancy loss, stillbirths, neonatal mortality, congenital malformations, preterm births, low birth weight, death during the first year of life, or cancers in offspring.
- Radioiodine therapy for thyroid cancer in young men has been associated with transient testicular dysfunction; men should be advised to wait a period of at least 3 months (Sawka et al. 2008b).

Breastfeeding after radioiodine therapies:

- Women who are lactating or have recently stopped breastfeeding should not be treated with I-131.
- Breastfeeding must be stopped at least 6 weeks before administration of I-131 therapy, and a delay of 3 months will more reliably ensure that lactation-associated increase in breast sodium iodide symporter activity has returned to normal.
- If the I-131 treatment is urgent or there is concern regarding residual breast uptake, an I-123 scan will detect whether breast concentrations of radioactivity greater than normal (substantially above background) impose a delay in therapy.

4.5.2 Procedures in Case of Nuclear Events

During the preparation and administration of radiopharmaceuticals, or because of an unexpected intolerance in the patient's body, nuclear events, mainly incidents, may appear.

According to the International Atomic Energy Agency (IAEA), the events related to nuclear materials are divided in nuclear accidents and nuclear incidents. These events are classified on a scale of seven levels and are defined in direct relation with their impact on the safety of general population (INES, International Nuclear and Radiological Event Scale).

- Major accident—level 7
- Major release of radioactive material, with widespread health and environmental effects, requiring the implementation of planned and extended countermeasures.
- Serious accident—level 6
- Significant release of radioactive material likely to require implementation of planned countermeasures.
- Accident with wider consequences—level 5
- Limited release of radioactive material; requires implementation of some planned countermeasures; several deaths from radiation may occur.
- Accident with local consequences—level 4
- Minor release of radioactive material unlikely to result in implementation of planned countermeasures other than local food controls; at least one death from radiation occurs.

- Serious incident—level 3
- Exposure in excess of ten times the statutory annual limit for workers.
- Leads to nonlethal deterministic health effects (e.g., burns) from radiation.
- Severe contamination in an area not expected by design, with a low probability of significant public exposure.
- Incident—level 2
- Exposure of a member of the public exceeds 10 mSv.
- A worker is exposed in excess comparing with the statutory annual limits.
- Radiation level in an operating area exceeds 50 mSv/h.
- A significant contamination into an area not expected by design, to be affected.
- Anomaly—level 1
- Overexposure of a member of the public, in excess comparing to the statutory annual limit, occurs.
- Low activity lost or stolen radioactive source, device, or transport package.
- Levels 1, 2, and 3 are defined as nuclear incidents and may occur as possible events in the daily nuclear endocrinology practice.
- In this situation, it is mandatory to ensure the safety of individuals and to avoid the spread of radioactivity.

There are two categories of actions: decontamination of persons and decontamination of rooms.

4.5.2.1 Actions for Person Decontamination

- Urgent notification of the responsible with radiation protection.
- Avoid external contamination entering the body through damaged skin or ingestion.
- Remove contaminated clothing as soon as possible, taking care not to spread the contamination.
- Store contaminated clothing until contamination is reduced to an acceptable level.
- Clean affected areas; wash contaminated areas repeatedly with large quantities of soap and running water. Avoid contamination of the mouth or eyes. Irrigate eyes with sterile 0.9% saline solution.
- If the skin is broken or cut in the area of contamination, open the wound and irrigate immediately with tap water.

4.5.2.2 Actions for Room Decontamination

In case of a nuclear incident occurring in the department of nuclear medicine or in the clinical department of endocrinology, the following measures should be taken:

- *For minor spills*, put on gloves, cover the spill with paper towels to soak up the liquid, mark the area of contamination, then work inward from the marked boundary, and scrub the area with detergent; avoid spreading the contamination; label and store all contaminated cleaning equipment. Monitor the area and continue to clean until the activity is within acceptable limits. Monitor all the personnel involved in the cleaning process.
- *For major spills*, vacate the room, post signs, decontaminate the personnel, and then assemble cleaning equipment; put on overshoes, gloves, and plastic apron. Proceed as for minor spills but use forceps to handle cleaning equipment; enclose monitor in protective cover; when contamination is short-lived, consider covering the affected area and restricting access until activity is within acceptable limits. For long-lived contamination, try to remove the paint and to use organic solvents for plastics and steel for woodwork. Wear facemask during treatment and ensure adequate ventilation. If all measures fail, take the area out of service.

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