Chapter 3: Radiation Protection

Set of 103 slides based on the chapter authored by S.T. Carlsson and J.C. Le Heron of the IAEA publication (ISBN 978–92–0–143810–2):
Nuclear Medicine Physics: A Handbook for Teachers and Students

Objective: To familiarize with radiation protection aspects in nuclear medicine.

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CHAPTER 3 TABLE OF CONTENTS

3.1 INTRODUCTION

- Medical radiation exposure: 95% of total human-made radiation exposure
- **Nuclear Medicine:**

  35 million examinations / year worldwide

- Rapid increase of diagnostic examination due to hybrid imaging (SPECT-CT and PET-CT), joining traditional nuclear medicine procedures and X ray technology

⇨ a **Radiation Protection** system is needed:

to take advantage of the benefit from the use of radiation

while

- preventing the occurrence of deterministic effects
- limiting the occurrence of stochastic effects to acceptable levels

3.1 INTRODUCTION

The Radiation Protection system has evolved over many years until the formulation of a shared approach:

ICRP System of Radiological Protection

as espoused by the International Commission on Radiological Protection (ICRP)

A number of ICRP Publications are available on different topics (www.icrp.org).

3.2 BASIC PRINCIPLES OF RADIATION PROTECTION

3.2.1 The ICRP system of radiological protection

Types of Exposure Situations

- **Planned exposure situations**
- **Emergency exposure situations**
- **Existing exposure situations**

The use of radiation in Nuclear Medicine is a **planned exposure situation**.

Misadministration, spills or other incidents/accidents can give rise to potential exposure, which however falls under the planned exposure situation as their occurrence is considered in the granting of the exposure authorization.

3.2 BASIC PRINCIPLES OF RADIATION PROTECTION

3.2.1 The ICRP system of radiological protection

Categories of Exposure

- **Medical exposure:** patients undergoing exposure for medical diagnosis or treatment; individuals helping in the support and comfort of patients, and by volunteers in a programme of biomedical research
- **Occupational exposure:** workers exposed in the course of their work
- **Public exposure:** exposure incurred by members of the public from all exposure situations, but excluding any occupational and medical exposure

In a **Nuclear Medicine facility** all these exposures occur:

patients, staff occupied in performing nuclear medicine procedures, people present in the nuclear medicine facility (staff or member of the public), carers and comforters of patients, volunteers in research projects

Categories of Exposure

An individual person may be subject to one or more of these categories of exposure.

For radiation protection purposes such exposures are dealt with **separately**.

3.2 BASIC PRINCIPLES OF RADIATION PROTECTION

3.2.1 The ICRP system of radiological protection

ICRP Principles of Radiation Protection

- **Justification**

  "Any decision that alters the radiation exposure situation should do more good than harm"

- **Optimization**

  "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"

- **Limitation of the 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"

3.2 BASIC PRINCIPLES OF RADIATION PROTECTION

3.2.1 The ICRP system of radiological protection

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In a **Nuclear Medicine facility** **occupational** and **public** exposures are subject to all the three principles

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3.2 BASIC PRINCIPLES OF RADIATION PROTECTION

3.2.1 The ICRP system of radiological protection

ICRP Principles of Radiation Protection

- **Justification**

  "Any decision that alters the radiation exposure situation should do more good than harm"

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- **Limitation of the 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"

In a **Nuclear Medicine facility** **medical** exposure is subject to the first two principles only

3.2 BASIC PRINCIPLES OF RADIATION PROTECTION

3.2.1 The ICRP system of radiological protection

ICRP recommended Dose Limits

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 cm^2 area of skin regardless of the area exposed.

3.2 BASIC PRINCIPLES OF RADIATION PROTECTION

3.2.2 Safety standards

UNSCEAR (United Nations Scientific Committee on the Effects of Atomic Radiation)

compiles, assesses and disseminates information on the health effects of radiation and on levels of radiation exposure due to different sources

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ICRP

provides recommendations for protection, taking into account the scientific information provided by UNSCEAR

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based on ICRP recommendations, defines the **Basic Safety Standards = BSS**

Not only scientific considerations are taken into account, but also judgement about the relative importance of different kind of risks and the balancing of risks and benefits

International consensus has been achieved on BSS, with the approval of IAEA member states and relevant international organizations

3.2 BASIC PRINCIPLES OF RADIATION PROTECTION

3.2.2 Safety standards

International BSS (General Safety Requirements 3):

"Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards"

- issued in 2014
- superseding the previous BSS, published as IAEA Safety Series No.115 (1996)
- jointly sponsored by the IAEA, European Commission, Food and Agriculture Organization of the UN, International Labour Organization, OECD Nuclear Energy Agency, Pan American Health Organization, United Nations Environmental Program, World Health Organization

AIM:

to establish basic requirements for protection against exposure to ionizing radiation and for the safety of radiation sources that may deliver such exposure

1. Mean tissue or organ dose, D_T

$$D_T = \frac{\varepsilon_T}{m_T}$$

ε_T → Total energy imparted by radiation to that tissue or organ

m_T → Mass of the tissue or organ T

SI (International System of Units) unit :

$$[\,D_T\,] = \frac{1 \text{ Joule}}{1 \text{ kilogram}} = 1 \text{ Gray (Gy)}$$

2. Equivalent dose, H_T

For the same D_T to an organ or tissue:

different types of ionizing radiation → different damage to the organ or tissue

To account for this fact, the Equivalent dose H_T is introduced:

$$H_T = \sum_R w_R \cdot D_{T,R}$$

- $D_{T,R}$ → Mean tissue or organ dose delivered by type R radiation
- w_R → Weighting factor specific for type R radiation
- $\sum_R$ → In case of a mixed radiation field, the sum is performed over the different types of radiation delivering dose to the tissue or organ

2. Equivalent dose, H_T

Radiation R	W_R (ICRP Publication N° 103)
photons	1
electrons, muons	1
protons	2
alpha particles	20
neutrons	function depending on neutron energy, E_n:

$$w_R = \begin{cases} 2{,}5 + 18{,}2\, e^{-[\ln(E_n)]^2/6}, & E_n < 1\,MeV \\ 5{,}0 + 17{,}0\, e^{-[\ln(2E_n)]^2/6}, & 1\,MeV \le E_n \le 50\,MeV \\ 2{,}5 + 3{,}25\, e^{-[\ln(0{,}04E_n)]^2/6}, & E_n > 50\,MeV \end{cases}$$

2. Equivalent dose, H_T

SI (International System of Units) unit :

$$[H_T] = \frac{1 \text{ Joule}}{1 \text{ kilogram}} = 1 \text{ sievert (Sv)}$$

3. Effective dose, *E*

For the same H_T :

different organ or tissue → different probability of stochastic effect

To account for this fact, the Effective dose *E* is introduced:

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

H_T → Equivalent dose in organ or tissue T

w_T → Tissue weighting factor:

the relative contribution of an organ or tissue T to the total detriment due to stochastic effects resulting from a uniform irradiation of the whole body

Sum is performed over all the organ or tissues irradiated and considered to be sensitive to the induction of stochastic effects.

3. Effective dose, *E*

Tissue	W_T (ICRP Publication N° 103)	$\Sigma\, W_T$
red marrow, colon, lung, stomach, breast, remaining tissues	0.12	0.72
gonads	0.08	0.08
bladder, esophagus, liver, thyroid	0.04	0.16
bone surface, brain, salivary glands, skin	0.01	0.04

4. Committed dose quantities

In case of internal exposure due to radionuclide intake, H_T and E depend not only on the physical properties of the radiation but also on the biological turnover and retention of the radionuclide = the radionuclide metabolism inside the body.

The dose is continuosly delivered troughout the period in which the radionuclide remains in the body.

To account for this fact, the Committed dose quantities are introduced, representing the total dose quantities received over time:

Committed equivalent dose, $H_T(\tau)$

Committed effective dose, $E(\tau)$

4. Committed dose quantities

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

- $\dot{H}_T(t)$: Equivalent dose rate in organ or tissue T
- t_0: Time of intake
- τ: Integration time = 50 years for workers and adult members of the public; 70 years for children (longer life expectancy)

$$E(\tau) = \sum_T w_T \cdot H_T(\tau)$$

5. Operational quantities

H_T, E, $H_T(\tau)$ and $E(\tau)$ are NOT directly measurable

The International Commission on Radiation Unit and Measurements (ICRU) has defined OPERATIONAL QUANTITIES for radiation protection purposes:

Ambient monitoring:	Ambient dose equivalent, $H^*(10)$
	Directional dose equivalent, $H'(0.07, \Omega)$
Personal monitoring:	Personal dose equivalent, $H_p(d)$

5. Operational quantities

Definitions/1

ICRU sphere

30 cm diameter sphere made of tissue equivalent material

(76.2% oxygen, 11.1% carbon, 10.1% hydrogen, 2.6% nitrongen; 1 g/cm^3 density)

For the purposes of RADIATION MONITORING, it adequately approximates the HUMAN BODY in terms of radiation attenuation and scattering.

For this reason it is used to define the Operational quantities

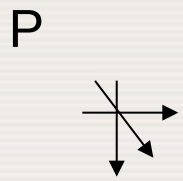
$H^*(10)$, $H'(0.07, \Omega)$, $H_p(d)$

5. Operational quantities

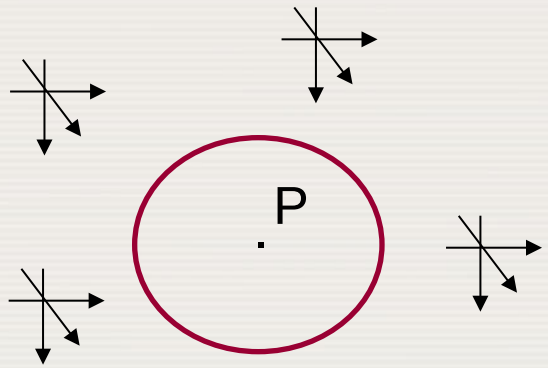
Definitions/2

Expanded radiation field

Hypothetical field which has – at all points of a sufficiently large volume – the same spectral and angular fluence as the actual field at the point of interest.



Actual field



Expanded field

5. Operational quantities

Definitions/2

Expanded radiation field

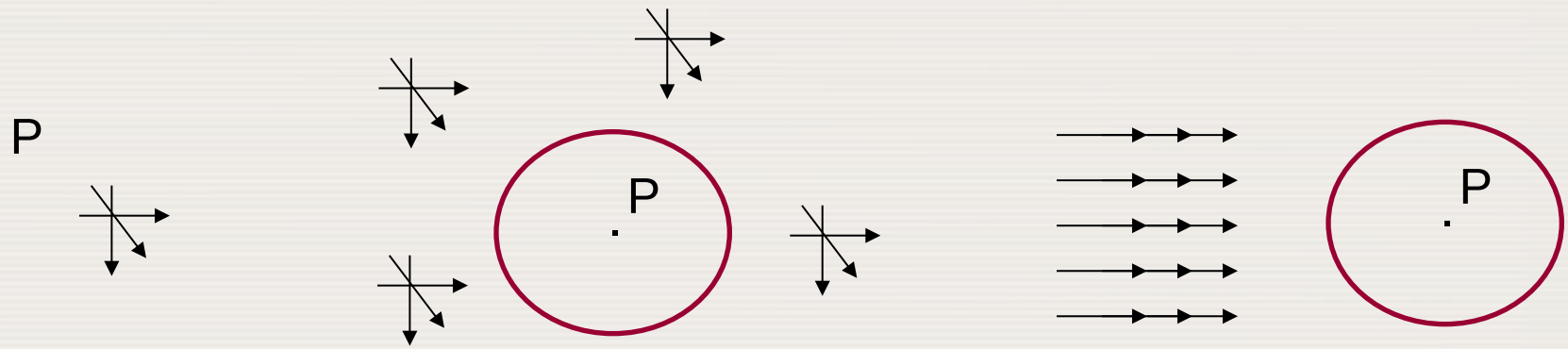
The expanded radiation field ensures that the whole ICRU sphere is exposed to a homogeneous radiation field with the same fluence, energy distribution and direction distribution as the real radiation field at the point of interest.

5. Operational quantities

Definitions/3

Expanded and aligned radiation field

An expanded field in which the angular distribution of the radiation field is assumed to be unidirectional.



Actual field Expanded field Expanded and aligned field

5. Operational quantities

Definitions/3

Expanded and aligned radiation field

In the expanded and aligned radiation field, the ICRU sphere is homogeneously irradiated from one direction, by a fluence obtained as the integral over all directions of the differential angular fluence of the real radiation field at the point of interest.

Under these conditions, the dose equivalent at any point in the ICRU sphere does not depend on the angular distribution of the radiation direction in the real radiation field.

5. Operational quantities

Area monitoring for penetrating radiation:

***H**(10)** = ambient dose equivalent at a point in a radiation field

= the dose equivalent that would be produced by the corresponding expanded and aligned field in the ICRU sphere at a 10 mm depth on the radius vector opposed to the direction of the radiation field

Area monitoring for low penetrating radiation:

***H*'(0.07, Ω)** = directional dose equivalent at a point in a radiation field

= the dose equivalent that would be produced by the corresponding expanded field in the ICRU sphere at a 0.07 mm depth along a specified direction Ω

5. Operational quantities

Personal monitoring:

$H_p(d)$ = personal dose equivalent

= the equivalent dose at a depth d in soft tissue below a specified point on the body

d = 10 mm for penetrating radiation (photons energy > 15 keV)

d = 3 mm for low penetrating radiation in the lens of the eye

d = 0.07 mm for low penetrating radiation in skin

3.3 RADIATION PROTECTION IN A NUCLEAR MEDICINE FACILITY

3.3.1 General aspects

- Radiation protection must be totally integrated in the clinical practice (delivery of medical service and patient care)
- Each country addresses radiation protection with a dedicated legislation and regulatory framework. Specific authorization is typically required to the radiation protection regulatory body for each facility or person wishing to perform nuclear medicine procedures
- High standard of radiation protection is typically achieved by encouraging a safety-based attitude in each individual, through
  - education and training
  - development of a questioning and learning attitude
  - cooperation of national authorities and employer in supporting radiation protection with adequate resources (personnel and money)
- Every individual must be aware of their own responsibilites. Formal assignment of duties improves self-consciousness.

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3.3 RADIATION PROTECTION IN A NUCLEAR MEDICINE FACILITY

3.3.2 Responsibilities

Licensee and Employers

- Applies the relevant national regulations and meets the licence conditions
- May appoint other people to carry out actions and tasks related to these responsibilities, but the licensee retains overall responsibility
- Consults the BSS for the details regarding all the radiation protection requirements
- Ensures that the necessary personnel is appointed (nuclear medicine physicians and technologists, medical physicists, radiopharmacists and a radiation protection officer, RPO)
- Ensures and supports that all individuals have the necessary education, training and competence for their respective duties
- Assigns clear responsibilities, establishes a radiation protection programme and provides the necessary resources to adopt it
- Establishes a comprehensive Quality Assurance programme
- Employers are assigned many responsibilities, in cooperation with the Licensee, regarding occupational radiation protection

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Nuclear medicine specialist

Is responsible for the overall radiation protection of the patient (besides his/her general medical and health care)

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Justification of a given nuclear medicine procedure, in conjunction with the referring medical practitioner

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Optimization of protection during the examination/treatment

Nuclear medicine technologist

Has a key role in the optimization of the patient's exposure

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His skills and care are decisive

Radiation protection officer (RPO)

- Oversees and implements radiation protection matters in the hospital
- Unless also a qualified medical physicist in nuclear medicine, has no responsibilities for radiation protection in medical exposure
- Required skills:

  good theoretical and practical knowledge of ionizing radiation properties, hazards and protection

  knowledge of all the legislation and codes of practice related to the uses of ionizing radiation in the nuclear medicine field

Medical physicist

- Has a comprehensive knowledge of the imaging equipment (performance, physical limitations, calibration, quality control, image quality) and the basis of internal dosimetry
- Is responsible for the radiation protection during medical exposure, including all the issues pertaining to imaging, calibration, dosimetry and quality assurance
- Is responsible for the Quality Assurance and the local continuing education in radiation protection of the nuclear medicine staff and other health professionals
- Whenever possible, a medical physicist should also serve as a RPO

Other personnel

Radiopharmacists or other staff that may have been trained to perform specific tasks, such as contamination tests or some quality control tests.

3.3 RADIATION PROTECTION IN A NUCLEAR MEDICINE FACILITY

3.3.3 Radiation protection programme

RPP = Radiation Protection Programme

- Developed by the Licensee (and Employer when appropriate) as requested in the BSS for each nuclear medicine facility
- Represents a **protection and safety programme** commensurate with the nature and extent of the risk of the practice, ensuring compliance with radiation protection standards
- Deals with the protection of the workers, the patient and the general public
- The Licensee provides for its implementation, and facilitates the cooperation between all the relevant parties

Radiation Protection Committee

- Supervision of compliance with RPP
- Should include:

  an administrator representing the management

  the chief nuclear medicine physician

  a medical physicist

  the RPO

  a nuclear medicine technologist

  a nurse attending the patient undergoing therapy with radiopharmaceuticals

  a mainteinance engineer

3.3 RADIATION PROTECTION IN A NUCLEAR MEDICINE FACILITY

3.3.5 Education and training

Personnel to be trained:

- nuclear medicine physicians (or other medical specialists performing nuclear medicine procedures)
- medical physicists
- nuclear medicine technologists
- radiopharmacists
- RPO
- nurses attending the patient undergoing therapy with radiopharmaceuticals
- mainteinance staff

Aim:

- to understand personal responsibilities
- to perform their duty with appropriate judgement and according to defined procedures

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3.4 FACILITY DESIGN

Milestones

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

3.4 FACILITY DESIGN

3.4.1 Location and general layout

Location of the nuclear medicine facility:

- Readily accessible, especially for outpatients
- Far away from radiotherapy sources or other strong sources of ionizing radiation (e.g. cyclotron) which could interfere with the measuring equipment
- Separated from the isolation wards for patients treated with radiopharmaceuticals

Layout of the nuclear medicine facility:

- Separation between work areas and patient areas
- Rooms for radiopharmaceutical preparation far away from measurement rooms and patient waiting rooms
- Low activity areas close to the entrance, high activity areas to the opposite side
- Transport of unsealed sources within the facility as short as possible
- Uncontrolled spread of contamination reduced to the lowest level achievable

ICRP categorization of hazards

According to the type of work to be performed and the radionuclides (and their activity) to be used, the ICRP provides criteria to categorize the different rooms of the facility as LOW, MEDIUM or HIGH hazard areas

According to the hazard level, indications are provided regarding the needs of ventilation, plumbing, and the materials to be used for walls, floors and work-benches.

3.4 FACILITY DESIGN

3.4.2 General building requirements

Risk of contamination

Aiming to avoid the spread of contamination and to facilitate the cleaning in case of contamination:

- The floors and work-benches should be finished with an impermeable material, washable, resistant to chemical damage and with all joints sealed
- The floor cover should be curved to the wall
- The wall should also be easy to clean
- The chairs and beds in high hazard areas should be easy to decontaminate (still paying attention to the comfort of the patients)

3.4 FACILITY DESIGN

3.4.2 General building requirements

Unsealed aerosol/gas sources

- To be produced and handled in rooms with an appropriate ventilation system including:

  fume hood

  laminar air flow cabinet / glove box

- The ventilation system may also be needed in the examination room, depending on the radiopharmaceutical used to perform ventilation scintigraphy (see Chapter 9)

3.4 FACILITY DESIGN

3.4.2 General building requirements

Waste release to the sewer – if allowed by the regulatory body

- Aqueous waste: dedicated sink
  easy to decontaminate
- Injected patients: separate bathroom, exclusive use for patients
  warn patients to sit down, flush the toilet, wash hands
  materials easy to decontaminate
- Drain-pipes from the nuclear medicine facility should go as directly as possible to the main building sewer or, if required by the regulatory body, directed to a delay tank (especially from isolation wards for patients undergoing radionuclide therapy)

3.4 FACILITY DESIGN

3.4.3 Source security and storage

For a safe handling of the sources:

- Security system to prevent theft, loss, unauthorized use or damage
- Only authorized personnel can order radionuclides
- Routines for delivery, unpacking, safe handling and storage
- It should be possible to trace any source, even if it leaves the facility in a patient
- The regulatory body must be promptly informed in case of stolen or lost source
- If the source is not in use, it must be stored
- Consider the possible consequences of an accidental fire and take steps to minimize the risk (e.g. not hold highly flammable or reactive materials in the facility, activate a liaison with the local firefighting authority)

3.4 FACILITY DESIGN

3.4.4 Structural shielding

Calculation of the barriers:

- Fundamental in case of busy facilities where high activities are handled and many patients are waiting and examined (e.g: PET/CT facility)
- Accurate barrier calculation, including walls, floor, ceiling, made by a qualified medical physicist or qualified expert when designing the facility (at planning stage)
- Radiation survey routinely performed to ensure the correctness of the calculation and the shielding efficacy
- Incorrect barriers are dangerous and correcting them later can be very expensive

3.4 FACILITY DESIGN

3.4.5 Classification of workplaces

The **BSS** requires classification into

controlled areas

- delineated, possibly with structural boundaries designed ad hoc when planning the facility
- individuals follow protective measures to control radiation exposures
- an area must be designated as controlled if it is difficult to predict doses to individual workers or if individual doses may be subject to wide variations

supervised areas

- occupational exposure conditions are predictable and stable
- kept under review
- additional protective measures and safety provisions are not normally needed

3.4 FACILITY DESIGN

3.4.5 Classification of workplaces

In a Nuclear Medicine facility

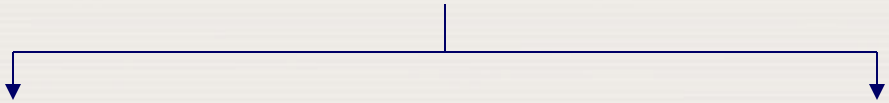
- rooms for preparation, storage (including radioactive waste) and injection of the radiopharmaceuticals
- imaging rooms and waiting areas for injected patients (due to the potential risk of contamination)
- areas housing patients undergoing therapy with radiopharmaceuticals

controlled areas

3.4 FACILITY DESIGN

3.4.6 Workplace monitoring

To check the presence of radiation or radioactive contamination



exposure monitoring

measuring radiation levels (μSv/h) at different points with an exposure meter or survey meter

contamination monitoring

search for extraneous radioactive material deposited on surfaces

- The RPO indicates the places where routine monitoring should be performed and defines the investigation levels
- A member of the staff – well trained in handling the instrument - should be appointed for this task
- The results must be recorded and investigated in case the investigation levels are exceeded

3.4 FACILITY DESIGN

3.4.7 Radioactive waste

Features of radioactive waste

- activity: high (e.g. Technetium generator) / low (e.g.biomedical procedures, research)
- half-life: long / short
- form: solid / liquid / gaseous

The licensee is responsible for a **safe management** of the radioactive waste

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- making adequate plans since the early stages of any project involving radioactive materials
- in full compliance with all relevant regulations
- asking for the supervision of the RPO

3.4 FACILITY DESIGN

3.4.7 Radioactive waste

Good practices

- Containers for different types of radioactive waste available in the areas where the waste is generated
- Label each container indicating the radionuclide, physical form, activity and external dose rate.
- Pack properly to avoid material leakage during storage.
- Keep record of origin of the waste.
- Biological waste should be refrigerated or put in a freezer
- Availability of a room for ad interim storage of radioactive materials (locked, properly indicated and, if necessary, ventilated)

3.4 FACILITY DESIGN

3.4.7 Radioactive waste

Final disposal of the radioactive waste

Storage inside the hospital facility

After decay to acceptable levels (ruled by the regulatory body) the source is disposed as cleared waste in the sewage (aqueous waste), incinerated or transferred to a landfill site (solid waste)

Frequently adopted since the radionuclides generally have short half-lives

Return the source to the vendor

Attractive option for radionuclide generators and sealed sources used for the quality control programme

This option should be provided for in the purchase process

Transfer the source to a disposal facility outside the hospital

More frequent in case of long half-life radionuclides

3.5 OCCUPATIONAL EXPOSURE

References and guidelines

- Section 3 of the BSS
- IAEA Safety Guides
- IAEA, Applying Radiation Safety Standards in Nuclear Medicine, Safety Reports Series No. 40, IAEA, Vienna (2005)

3.5 OCCUPATIONAL EXPOSURE

3.5.1 Sources of Exposure

Main sources of exposure from an unsealed source

External irradiation of the body

The main precautions depend on the physical properties of the radiation emitted

→ specific dose rate constant of the radionuclide + physical half-life

Intake of a radioactive source

The main precautions depend on

- physical properties of the radiation emitted
- physical and chemical properties of the radionuclide
- activity
- patient specific biokinetics (metabolism)

3.5 OCCUPATIONAL EXPOSURE

3.5.1 Sources of Exposure

External exposure

- Every type of work in a Nuclear Medicine facility can contribute to external exposure:

  unpacking radioactive material, activity measurements, storage of sources, preparation/administration of radiopharmaceuticals, patient handling and examination, care of radioactive patients, handling of radioactive waste

- With optimized protection, the yearly effective dose for a full-time staff should be well below 5 mSv
- The highest contribution is given by patient injection and imaging
- High equivalent dose to the fingers can be received during preparation and administration of radiopharmaceuticals, even with proper shielding

3.5 OCCUPATIONAL EXPOSURE

3.5.1 Sources of Exposure

Internal exposure

- Main risk from radioactive spills, animal experiments, emergency surgery or autopsy of a therapy patient
- Lower risk from traces of radioactivity found almost everywhere in a Nuclear Medicine facility (door handles, taps, equipment, patients' toilet)
- Whole body measurements of workers revealed an equilibrium internal contamination of up to 10 kBq of ^{99m}Tc, which will result in an effective dose of about 0.05 mSv/year
- Special concern for contamination of the skin, which can lead to high local equivalent doses

3.5 OCCUPATIONAL EXPOSURE

3.5.2 Justification, Optimization and Dose Limitation

Justification

- The worker has no personal benefit from the professional exposure
- Occupational exposure justification is included in the justification of the Nuclear Medicine practice itself

Dose limitation

- The risk in radiation work should not be greater than for any other similar work
- The upper limit of a tolerable risk is reflected by the dose limits (3.2.1)

Optimization

Reduce exposure well below the dose limits

facility and equipment design, source shielding, personal protective equipment, education and training

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Responsibilities

Licensees and Employers

ensure that the exposure is limited and that protecion is optimized

Workers

follow rules and procedures

use the devices for monitoring

use the protective equipment provided

cooperate with the employer to improve the protection standard

3.5 OCCUPATIONAL EXPOSURE

3.5.3 Conditions for pregnant workers and young people

Pregnant workers

- Unborn child is regarded as a member of the general public: 1 mSv dose limit should be applied once the pregnancy is declared
- Good operational procedures can maintain exposure well below the limits → it may not be necessary for a pregnant member of the staff to change her duties
- However, it is considered prudent to reassign pregnant staff to non-radiation duties whenever possible

Young people

- No person under 16 is to be subject to occupational exposure
- No person under 18 is to be allowed to work in a controlled area unless supervised and only for the purpose of training

3.5 OCCUPATIONAL EXPOSURE

3.5.4 Protective clothing

To prevent contamination:

- Gloves
- Laboratory coats
- Safety glasses
- Shoes / Overshoes
- Caps and masks for aseptic work

Lead aprons:

- If worn at all times, it reduces the effective dose by a factor of about 2
- It is a matter of judgement whether such dose reduction justifies the effort of wearing it
- At some facilities it is used in case of prolonged injection of high activities

3.5 OCCUPATIONAL EXPOSURE

3.5.5 Safe working procedures

Fundamentals for SAFE working conditions:

1. Facility design

planned and optimized in terms of safety

3. Working procedures

clearly defined, known and followed by all the operators

2. Protective clothing and equipment

systematically and properly used by all the operators

4. Written local rules

especially when dealing with unsealed sources

3.5 OCCUPATIONAL EXPOSURE

3.5.5 Safe working procedures

To minimize the risk of CONTAMINATION:

- Keep tidy the work areas, free from articles not required for work
- Periodical monitoring and cleaning in order to ensure minimal contamination
- No food, drink, cosmetics, cutlery, crockery, handkerchieves or smoking materials in areas where unsealed sources are manipulated
- Prepare radiopharmaceuticals over a drip tray covered with absorbing paper
- Immediately cover with absorbent material any spill of radioactive material to prevent the spread
- If the spill cannot be cleaned promptly, it must be marked to warn other personnel, and decontamination must be done as soon as possible
- When wearing gloves which may be contaminated, avoid unnecessary contact with other objects
- When finishing work, the protective clothes should be removed and placed in appropriate containers. Hands should be washed and monitored

3.5 OCCUPATIONAL EXPOSURE

3.5.5 Safe working procedures

Three RULES to minimize the risk of EXTERNAL EXPOSURE:

Time

The time of exposure should be kept as short as possible, without compromising the quality of work and the use of protective measures

Shielding

Use shielding devices whenever possible

- properly designed vials, shielded syringes
- work behind properly designed lead glass shield or similar type of protective barrier

Distance

The distance from any source should be kept as high as possible

- during manipulation: use of forceps or tongs
- transfer radioactive waste in a separate room as soon as possible
- injected patients: maximize the distance and spend as little time as possible in close proximity

3.5 OCCUPATIONAL EXPOSURE

3.5.6 Personal monitoring

The **licensee** and the **employer** have the joint responsibility to ENSURE that **appropriate personal monitoring** is provided to the staff

- the RPO specifies which workers need to be routinely monitored, the type of monitoring device and the body position where the monitor should be worn
- some countries may have specific regulatory requirements on this issue
- the regulatory body specifies the monitoring period and the time frame for reporting monitoring results

3.5 OCCUPATIONAL EXPOSURE

3.5.6 Personal monitoring

Who needs to be monitored?

- All those who work routinely with the radiopharmaceuticals or with the administered patients
- The staff dealing with excreta from radionuclide therapy
- Those who come into occasional contact with nuclear medicine patients are not normally included

Who provides the devices for monitoring?

- External personal dosimetry systems are sometimes centrally provided by the regulatory body
- Third party personal dosimetry providers – approved by the regulatory body – may be contracted
- Large hospitals may have their own personal dosimetry service

3.5 OCCUPATIONAL EXPOSURE

3.5.6 Personal monitoring

Specific indications for personal monitoring

Fingers

- Occasionally on staff which regularly prepares and administers radiopharmaceuticals
- When performing operations with the handling of large quantities of radionuclides
- Hands monitoring after handling unsealed materials, by a contamination monitor mounted near the sink. In high background areas it may be necessary to shield the detector

Internal contamination

- Rarely necessary on radiation protection grounds
- May be useful to provide reassurance to the staff
- Advisable in case of use of significant quantities of ^{131}I for thyroid therapy (programme of thyroid uptake measurement)
- Monitor after a serious incident: whole body counter (should be available at national referral centers). Otherwise, uncollimated gamma camera

3.5 OCCUPATIONAL EXPOSURE

3.5.6 Personal monitoring

Specific indications for personal monitoring

Further monitoring

- May be indicated if staff dose has increased or it is anticipated that they may do so in the immediate future
  - introduction of new examinations/procedures
  - change in the nuclear medicine facility's equipment
- The RPO decides who should be monitored and at which monitoring site

Record of results

- Regular assessment and record of individual results
- The RPO promptly investigates the causes of unusually high dose readings
- The RPO indicates corrective actions, when needed
- Countries have different rules regarding the nature of the record and the time period for which the data must be preserved

3.5 OCCUPATIONAL EXPOSURE

3.5.8 Health surveillance

The **licensee** makes arrangements for an appropriate health surveillance

- following the rules of the national regulatory body
- aiming to assess the initial and continuing fitness of each employee for his/her intended task
- basing on the general principles of occupational health

3.5 OCCUPATIONAL EXPOSURE

3.5.8 Health surveillance

Specifically for **Nuclear Medicine**

- No specific surveillance is necessary for Nuclear Medicine staff
- In case of overexposed workers (> dose limits):

  special investigation with biological dosimetry, diagnostic examinations and – if necessary – medical treatment

- Counseling available to workers who have or may have substantially exceeded the dose limits, or workers worried about their radiation exposure

3.5 OCCUPATIONAL EXPOSURE

3.5.9 Local rules

The **licensee** and the **employers**, according to BSS and after consulting the workers representatives

- establish written rules and procedures to assure adequate levels of protection
- include in the rules the values of investigation and authorized levels, and the actions to be adopted when exceeded
- make the involved people aware of the rules, the procedures and the safety provisions
- ensure supervision of any occupational exposure, and that the rules are observed
- the rules must be established, maintained and continually reviewed, with an active participation of the RPO

3.6 PUBLIC EXPOSURE

3.6.1 Justification, optimization and dose limitation

Public exposure

- Defined by BSS as the exposure to radiation sources incurred by members of the public, excluding any medical or occupational exposure
- The licensee is responsible for controlling public exposure arising from a nuclear medicine facility.
- Public exposure IN or NEAR the nuclear medicine facility needs to be considered when designing the shielding and people flow in the facility
- The public sources of exposure are primarily the same as for workers, with a notable exception: the release out of the facility of patients diagnosed or treated with radiopharmaceuticals

3.6 PUBLIC EXPOSURE

3.6.1 Justification, optimization and dose limitation

Justification

As for workers, public exposure justification is included in the justification of the Nuclear Medicine practice itself

Dose limitation

The exposure of the general public is ultimately restricted by the application of the dose limits

Optimization

The principle of optimization ensures that public doses will be ALARA = As Low As Reasonaly Achiavable

3.6 PUBLIC EXPOSURE

3.6.2 Design considerations

The facility layout should be meant for protecting the public:

- Areas for radionuclide storage and preparation well separated from public areas
- Minimize the movement of the radionuclides

  e.g: a pass trough connecting the room for pharmaceutical preparation and the room for administration
- Shielding of areas containing significant amount of activity
- Restricted access so that members of the public are not allowed to enter the controlled areas
- Radioactive waste stored far away from areas accessible to the public
- Separate waiting rooms and toilets for injected and non-injected patients

3.6 PUBLIC EXPOSURE

3.6.3 Exposure from patients

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;
- 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
- is not normally necessary to issue any special radiation protection advise to the patient
- exceptions:
  - restrictions on breast-feeding a baby (see 3.7.2.4)
  - intensive use of positron emitters which may require structural shielding based on the exposure of the public (see 3.4.4)

For patients who have undergone **radionuclide therapy**:

- advise regarding restrictions on their contact with other people (Chapter 20)

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3.6 PUBLIC EXPOSURE

3.6.4 Transport of sources

Transport of the sources

INSIDE the facility

- From the storage areas to the site where it will be used
- Limited as far as possible by the facility design
- Local rules to further optimize radiation protection conditions

OUTSIDE the facility

- IAEA Regulations for the Safe Transport of Radioactive materials should be followed
- Mechanically safe package reducing the effect of potential fire and water damage
- Package labelling indicating the radionuclide and the activity

  Category I (white): $D \leq 0.005$ mSv/h

  Category II (yellow): $0.005 < D < 0.5$ mSv/h

  Category III (yellow): $0.5 < D < 2$ mSv/h
- Transport Index = 100 · maximum dose rate @ 1m from the package surface

3.7 MEDICAL EXPOSURE

3.7.1 Justification of medical exposure

Justification according to the **BSS**:

"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."

- Three levels of justification (according to the ICRP):

Level 1: General justification of the Nuclear Medicine practice:

accepted for granted, doing more good than harm)

Level 2: Generic justification of new technologies and techniques:

carried out by the health authority in conjunction with appropriate professional bodies

Level 3: Individual justification of the procedure for a given individual:

- the final responsibility belongs to the Nuclear Medicine specialist, who makes a decision on the appropriateness of the examination and the techniques to be used;
- relevant national and international guidelines need to be taken into account

- In case of biomedical research projects, exposer is considered to be justified if the project has been approved by an ethics committee

3.7 MEDICAL EXPOSURE

3.7.2 Optimization of protection

Optimization of procedures which have been justified:

Diagnostic procedures

- Minimum patient exposure needed to achieve the clinical purpose of the procedure
- Respect of relevant norms regarding acceptable image quality established by professional bodies
- Respect of Diagnostic Reference Levels (DRLs)

Therapeutic procedures

The radionuclide and administered activity are selected so that

- the radiopharmaceutical is primarily localized in the organ(s) of interest
- the activity in the rest of the body is kept as low as reasonably achievable

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3.7 MEDICAL EXPOSURE

3.7.2.1 Administered activity and radiopharmaceuticals

Diagnostic procedures

- Nuclear Medicine specialist
- Medical physicist

→ Determine the optimum activity for the type of examination and the individual patient, taking DRLs into account

↓

depending on:

- patient body build and weight
- patient's metabolic characteristics and clinical conditions
- type of equipment used
- type of study (static, dynamic, tomographic, …)
- examination time

3.7 MEDICAL EXPOSURE

3.7.2.1 Administered activity and radiopharmaceuticals

Diagnostic procedures – Administered activity:

Low activity

Below the threshold, no useful information can be expected

Poor quality images could lead to serious diagnostic errors or require exam repetition, with unjustified irradiation

Minimum activity threshold

Above the threshold:

–activity, ↑ diagnostic quality

Activity corresponding to an acceptable quality

Once acceptable quality has been reached, a further increase of the administered activity increases the absorbed dose without adding any diagnostic information

High activity

3.7 MEDICAL EXPOSURE

3.7.2.1 Administered activity and radiopharmaceuticals

Diagnostic procedures – Choice of the radiopharmaceutical:

If more than one radiopharmaceutical can be used for a procedure, consideration must be given to:

- physical, chemical, biological properties
- availability of the pharmaceutical
- shelf life
- instrumentation and relative costs
- choice of approved manufacturers and distributors, following national and international requirements

→ The final value of the administered activity must be determined and recorded, to allow the calculation of the organ absorbed doses and the effective dose

3.7 MEDICAL EXPOSURE

3.7.2.2 Optimization of protection in procedures

Patient undergoing a **diagnostic** procedure → to be kept fully informed and motivated

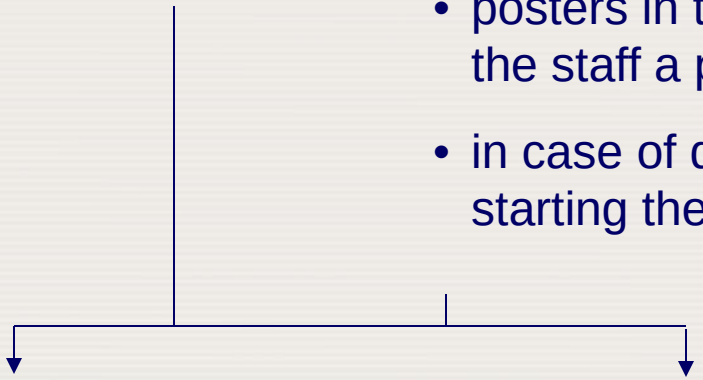
- Before administration: interview about possible pregnancy, small children at home, breast-feeding or other relevant questions which may have implications on the procedure
- Check the request to confirm that the right examination, radiopharmaceutical and activity are going to be dispensed
- It may be necessary to immobilize / sedate children in order to complete successfully the examination
- Old patients with pain: increasing the administered activity to reduce examination time may be considered
- Ensure that the equipment work within the conditions established by technical specifications

3.7 MEDICAL EXPOSURE

3.7.2.3 Pregnant women

Possible pregnancy?

- interview the patient before performing the procedure
- posters in the waiting room inviting the patient to notify the staff a possible or verified status of pregnancy
- in case of doubt, pregnancy test is performed before starting the procedure



NO

the examination or treatment can be performed as planned

YES

- as a basic rule, nuclear medicine procedures should be avoided unless there are strong clinical indications
- carefully consider other methods of diagnosis / to postpone the examination until after delivery
- if the procedure is unavoidable, the process of optimization must include the embryo/fetus

3.7 MEDICAL EXPOSURE

3.7.2.3 Pregnant women

Protection of the embryo / fetus

Diagnostic procedures

- reduce the administered activity and acquire the images for longer time (still caring the quality of the results)
- after examination, encourage frequent voiding to minimize the irradiation from the bladder
- inject the patient with partially filled bladder rather than empty
- low dose CT protocols in case of PET-CT or SPECT-CT scans, reducing the scanning area to a minimum

Therapeutic procedures

- not administer therapy, unless life-saving
- after therapy, advise patients to avoid pregnancy for an appropriate period
- when suspecting high fetal doses (>10mSv) require careful determination to the medical physicist and inform the patient about the possible risk (even in case of inadvertent exposure of patients who later are found to have been pregnant at the time of exposure)
- fetal dose < 100 mGy does not justify pregnancy termination for radiation risk
- at higher doses, individual circumstances have to be taken into account

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3.7 MEDICAL EXPOSURE

3.7.2.4 Lactating women

Nuclear Medicine procedure to a lactating woman → possible activity uptake in the breast tissue → possibly activity moving into the breast milk → **Possible RISK for the baby / 2**

possible RISK for the baby / 1

- the mother is a source of external exposure and contamination of the baby during feeding or cuddling
- the dose depends on the time the baby is held, the distance from mother's body and the personal hygiene

- the dose depends on the radiopharmaceutical, the amount of milk, the time between pharmaceutical administration to the mother and the feeding of the child

Restrictions on breast-feeding and advice to the mother are necessary to minimize the exposure of the baby under acceptable levels

(< 0.3 mSv per episode)

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3.7 MEDICAL EXPOSURE

3.7.2.4 Lactating women

Nuclear Medicine procedure to a lactating woman ?

- in any case, BEFORE the procedure, the possibility to delay the examination / treatment until the suspension of breat-feeding should be considered
- it is responsibility of the Nuclear Medicine specialist and the Medical Physicist to establish local rules on breast-feeding and close contact between mother and child after examination / treatment
- the rules should be based on recommendations given by national and international authorities, as well as professional organizations

3.7 MEDICAL EXPOSURE

3.7.2.5 Children

Optimization during children examination = **Optimize the administered activity**

Method: scaling the adult administered activity according to the body weight

How?

Simply reducing the activity in proportion to the body weight may result in inadequate image quality

Reduction in proportion to the body surface area should yield the same count density as for adults, but the effective dose is higher

General rule:

activities less than 10% of the normal adult activity should not be administered

3.7 MEDICAL EXPOSURE

3.7.2.5 Children

Optimization during child examination with

Hybrid protocols **=** **Optimize also the CT protocol**

How?

- reduce the tube current · time product (mAs) and the tube potential (kV) without compromising the diagnostic quality of the images
- carefully select the slice width, the pitch and the scanning area
- use individual protocols based on child size (delineated by the medical physicist and the responsible specialist)

3.7 MEDICAL EXPOSURE

3.7.2.6 Calibration

Dose calibrator or activity meter

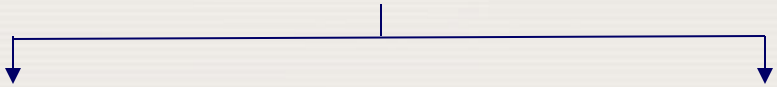
- available for measurement in syringe or vials
- regular quality control of the instrument
- Periodic reassessment of the calibration with secondary standards

3.7 MEDICAL EXPOSURE

3.7.2.7 Clinical patient dosimetry

It is responsibility of the licensee to ensure that

Appropriate clinical dosimetry is performed by a Medical Physicist and documented.



Diagnostic procedures

Evaluation of representative typical patient doses for common procedures

Therapeutic procedures

Individual evaluation for each patient, including absorbed doses to relevant organs or tissues

3.7 MEDICAL EXPOSURE

3.7.2.8 Diagnostic Reference Levels (DRLs)

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.

Instead,

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.

→ **DRL** = a tool to optimize the protection in medical exposure

= the activity to be delivered to a normal sized patient for a certain type of examination

The hospital procedures should indicate the administration of activities

not higher (unnecessary)

not excessively lower (not adequate to give an useful diagnostic information)

than the DRL (normally set at the national level).

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3.7 MEDICAL EXPOSURE

3.7.2.9 Quality assurance for medical exposures

Nuclear Medicine facility's quality management system

→ QA for radiation protection

→ **QA for medical exposure**

- required by the BSS
- responsibility of the licensee
- composed with the active participation of the medical physicist, nuclear medicine specialist, nuclear medicine technologist and radiopharmacist
- takes into account the principles established by international organizations and relevant professional bodies

3.7 MEDICAL EXPOSURE

3.7.2.9 Quality assurance for medical exposures

The QA for medical exposure 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.

\+ regular and independent **audits** of the QA programme

3.7 MEDICAL EXPOSURE

3.7.3 Helping in the care, support or comfort of patients

Who?

- People who knowingly and voluntarily help in the care, support and comfort of patients undergoing nuclear medicine procedures

OTHER THAN in their employment or occupation

→ **dose < 5 mSv** during the period of patient's examination or treatment (excluding children and infants)

- Children visiting patients who ingested radiopharmaceuticals

→ **dose < 1 mSv** during the period of the visit

3.7 MEDICAL EXPOSURE

3.7.4 Biomedical research

Justification

- only if in accordance with the provisions of the Helsinki Declaration
- only if following the guidelines prepared by the Council for International Organizations of Medical Sciences
- only if approved by an ethical committee

Dose limitation

An exposure as a part of biomedical research is treated on the same basis as a medical exposure → it is not subject to dose limitation

Optimization

- a careful evaluation of the radiation dose to the volunteer has to be made
- the associated risk has to be weighed against the benefit for the patient or the society
- recommendations on this topic are given by ICRP
- the BSS requires the use of dose constraints in the optimization process

3.7 MEDICAL EXPOSURE

3.7.5 Local rules

Written **local rules** should

cover all the procedures that may affect medical exposure

be known by every member of the staff

They 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

Equipment failure — Human error

↓

Possible unintended and accidental exposure

↓

The licensee has the RESPONSIBILITY to take measures in order to

- prevent such events as far as possible
- in case they occur, determine the dose and identify corrective actions to mitigate the consequences, implement corrective measures, prevent recurrence

How? According to the BSS:

- conduct a safety assessment at all stages of the design of the facility

  systematical review of possible events leading to unintended or accidental exposure

  list all procedures involving unsealed sources, asking what could go wrong

- presents a report to the regulatory body, if required

3.8 POTENTIAL EXPOSURE

3.8.2 Emergency plans

For the events identified by the safety assessment

Emergency procedures

- clear, concise and unambiguous
- posted in visible places

including:

- 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.

3.8 POTENTIAL EXPOSURE

3.8.3 Reporting and lesson learned

After an incident/accident

Under the licensee's responsibility:

comprehensive investigation of the events

production of a report including

- 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.

3.9 QUALITY ASSURANCE

3.9.1 General considerations

Quality Assurance = "all planned and systematic actions needed to provide confidence that a structure, system or component will perform satisfactorily in service"

up to the licensee (as required by the BSS)

- QA programme
- adequate assurance that the requirements related to protection and safety are satisfied
- providing quality control mechanisms
- providing procedures for reviewing and assessing the overall effectiveness of protection and safety measures
- QA for medical exposure (3.7.2.9) is a part of a wider programme covering all the aspects related to a Nuclear Medicine facility, which in turn is a part of the hospital QA programme

3.9 QUALITY ASSURANCE

3.9.1 General considerations

Quality Assurance in a Nuclear Medicine facility:

- QA committee: representative from management, nuclear medicine physician, medical physicist, nuclear medicine technologist, engineer
- cover the entire process from the initial decision to adopt a particular procedure to the interpretation and recording of the results
- ongoing auditing, both internal and external
- mainteinance of records
- continuous quality improvement based on the learning from the QA programme itself and from the new techniques developed by the nuclear medicine community
- collect feedback from experience and learning from accidents or near misses

3.9 QUALITY ASSURANCE

3.9.1 General considerations`

Quality Assurance in a Nuclear Medicine facility:

covering:

- 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.

3.9 QUALITY ASSURANCE

3.9.2 Audit

QA programme is reviewed through **Audits**

internal	external
staff from other work areas within the organization	independent organization

- scheduled on the basis of the status and importance of the activity
- conducted by people technically competent to evaluate the processes, but not having any direct responsibility on that activity
- following written procedures and checklists
- including medical, technical and procedural checks, aiming to enhance the effectiveness and efficiency of the QA programme

External audits are generally required for an accredited practice