21.5.2003

IAEA Post Graduate Educational Course on Radiation Protection and Safety of Radiation Sources
Greek Atomic Energy Commission, Athens 2003

Justification and Optimization in Nuclear Medicine (Radiation Protection of the patient)

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OBJECTIVE

To become familiar with the BSS detailed requirement for medical exposure in nuclear medicine: responsibilities, justification, optimization, guidance level, dose constraints accidental exposure and medical records



Content

- Responsibilities
- Justification
- Optimization of examination
- Guidance levels of activity
- Dose constraints
- Examination of children, pregnant women and lactating women
- Records
- Local rules



Medical Exposure Protection of the Patient



Introduction

MEDICAL EXPOSURE (definition)

"Exposure incurred
➢by patients as part of their own medical or dental diagnosis or treatment;
➢ by persons, other than those occupationally exposed, knowingly while voluntarily helping in
➢by volunteers in a programme of biomedical research involving their exposure."

Protection of the patient



Protection of comforters and visitors



Protection from what?

- Unnecessary examination or treatment (justification)
- Unnecessary exposure (optimization)
- Inadequate examinations, which can lead to incorrect or incomplete diagnosis (optimization)

MEDICAL EXPOSURE (BSS)

- Responsibilities
- Justification of medical exposure
- Optimization of protection for medical exposure
- Guidance levels
- Dose constraints
- Maximum activity for patients in therapy on discharge from hospital
- Investigation of accidental medical exposures
- Records

safety series

Medical Exposure
Protection of the Patient

Responsibilities

RESPONSIBILITES (BSS)

II.1. Registrants and licensees shall ensure that:

(a) no patient be administered a diagnostic or therapeutic medical exposure unless the exposure is prescribed by a medical practitioner;
(b) medical practitioners be assigned the primary task and obligation of ensuring overall patient protection and safety in the prescription of, and during the delivery of, medical exposure;
(c) medical and paramedical personnel be available as needed, and either be health professionals or have appropriate training adequately to discharge assigned tasks in the conduct of the diagnostic or therapeutic procedure that the medical practitioner prescribes;

RESPONSIBILITES (BSS) cont.

(d) for therapeutic uses of radiation (including teletherapy and brachytherapy), the calibration, dosimetry and quality assurance requirements of the Standards be conducted by or under the supervision of a qualified expert in radiotherapy physics;
(e) the exposure of individuals incurred knowingly while voluntarily helping (other than in their occupation) in the care, support or comfort of patients undergoing medical diagnosis or treatment be constrained as specified in Schedule II; and
(f) training criteria be specified or be subject to approval, as appropriate, by the Regulatory Authority in consultation with relevant professional bodies.

RESPONSIBILITES (BSS) cont.

II.2. Registrants and licensees should ensure that for diagnostic uses of radiation the imaging and quality assurance requirements of the Standards be fulfilled with the advice of a qualified expert in either radiodiagnostic physics or nuclear medicine physics, as appropriate.

II.3. Medical practitioners shall promptly inform the registrant or licensee of any deficiencies or needs regarding compliance with the Standards with respect to protection and safety of patients and shall take such actions as may be appropriate to ensure the protection and safety of patients.

How to apply this in nuclear medicine?

FACTORS AFFECTING MEDICAL EXPOSURE

Request
Examination or treatment
Biomedical research

Patient identification and information	Administration of radiopharmaceutical	Examination	Treatment
Child? Lactating woman? Pregnant woman?	Safe preparation of prescribed radio-pharmaceutical and activity Dose constraints	Method Quality of equip-ment Correct use of equipment	Dose constraints to comforters and visitors

Accidental medical exposure

Who is responsible?

RESPONSIBILITY STRUCTURE

Licensee/Hospital management
Optimization of medical exposure through organization and resources

Nuclear Medicine Department
Justification & Optimization of medical exposure through well educated personnel with clearly defined responsibilities

NM specialist
Qualified expert
NM technologist
Nurse
Engineer
Radiopharmacist

Referring physician
Justification of medical exposure

Referring physician

- Prescribe and justify diagnostic procedures and therapy in writing in co-operation with the nuclear medicine specialist



Administrative manager

- Appoint the necessary personnel and ensure the individuals have the necessary education to perform their duties.
- Establish a radiation protection programme and provide the necessary resources.
- Assign clear responsibilities for personnel.
- Appoint a Radiation Protection Officer.
- Establish a comprehensive QA programme.
- Support education and training of personnel.

Nuclear medicine staff

Individuals with key positions, i.e., responsibilities for protection and safety and those who could substantially affect protection and safety by virtue of tasks involving operation or manipulation of sources, or equipment which could lead to an accidental exposure should have documented evidence of education and training. The objective is to ensure that only qualified personnel fill such positions. In nuclear medicine, these individuals are:

- Nuclear medicine physicians
- Qualified experts in nuclear medicine physics (medical physicists)
- Other health professionals in nuclear medicine (radiopharmacists, nuclear medicine technologists, nurses,...)
- Radiation Protection Officer

Personal authorization

To obtain the personal authorization, the nuclear medicine staff should comply with the following requirements:

- university degree or equivalent relevant to the profession by the competent education authorities as required in the country;
- accreditation to exercise the profession granted by the competent authorities or institutions as required in the country;
- course on radiation protection for which the contents, the methodology and the teaching institution are approved by the Regulatory Authority. This course may be integrated in the curricula of the professional education; and
- on the job training supervised by professionals with authorization by the Regulatory Authority.

Nuclear Medicine Specialist

- Ensure overall patient protection and safety;
- provide consultation and clinical evaluation of patients
- ensure that the exposure of patients be the minimum required to achieve the intended objective;
- take into account relevant information from previous examinations in order to avoid unnecessary additional examinations;
- take into account the relevant guidance levels for medical exposure;
- determine dose prescription for therapy in consultation with the medical physicist; and
- provide evaluation of any radiation incident and accident from medical point of view.

MEDICAL PHYSICIST

- Participate in continuing review of the nuclear medicine practice's resources (including budget, equipment, and staffing), operations, and policies and procedures;
- Develop requirements and specifications for the purchase of appropriate equipment assuring radiation safety;
- Plan in conjunction with the nuclear medicine physician the facilities for nuclear medicine practice;
- Carry out acceptance testing;
- Establish dose calculation procedures in nuclear medicine therapy;
- Establish and implement QA procedures in nuclear medicine;
- Supervise equipment maintenance;
- Investigate and evaluate incidents and accidents.



Nuclear medicine technologist

- Patient identification;
- Patient information;
- Information to accompanying persons and staff nursing a patient after a nuclear medicine examination or therapy;
- Verifying that the female patient is non-pregnant;
- Assure that a mother in lactation is given information about discontinuation of nursing;
- Make the calculation of administered activity to a child according to the local rules;
- Verify the administered radiopharmaceutical and its activity;
- Perform regular quality control of activity meter and other relevant equipment;
- Perform regular workplace monitoring;
- Correct handling of the equipment and safety accessories;
- Inform the RPO in the case of accident or incident;
- Inform the Nuclear Medicine Physician in the case of misadministrations;
- Participate in education and training of new personnel.



Medical Exposure
Protection of the Patient



Justification

JUSTIFICATION (BSS)

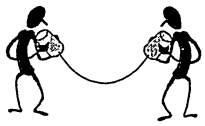
"II.4. Medical exposures should be justified by weighing the diagnostic or therapeutic benefits they produce against the radiation detriment they might cause, taking into account the benefits and risks of available alternative techniques that do not involve medical exposure.

II.5. In justifying each type of diagnostic examination by radiography, fluoroscopy or nuclear medicine, relevant guidelines will be taken into account, such as those established by the WHO. "

JUSTIFICATION

Although Nuclear Medicine is a justified diagnostic tool a case-by-case justification shall be applied.

This is the responsibility of the referring physician in co-operation with the nuclear medicine specialist and other specialists in diagnostic imaging, taking relevant guidelines into account.



JUSTIFICATION (BSS)

"II.6. Any radiological examination for occupational, legal or health insurance purposes undertaken without reference to clinical indications is deemed to be not justified unless it is expected to provide useful information on the health of the individual examined or unless the specific type of examination is justified by those requesting it in consultation with relevant professional bodies."

JUSTIFICATION (BSS)

II.8. The exposure of humans for medical research is deemed to be not justified unless it is:

(a) in accordance with the provisions of the Helsinki Declaration [16] and follows the guidelines for its application prepared by Council for International Organizations of Medical Sciences (CIOMS) [17] and WHO [18]; and

(b) subject to the advice of an Ethical Review Committee (or any other institutional body assigned similar functions by national authorities) and to applicable national and local regulations.

Medical Exposure Protection of the Patient

Optimization of examination

Optimization of medical exposure in Nuclear Medicine

BSS II.17. Registrants and licensees shall ensure that:

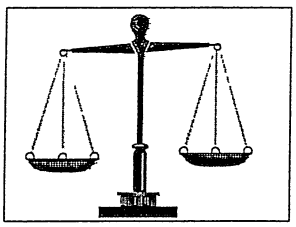
(a) the medical practitioners who prescribe or conduct diagnostic applications of radionuclides:

(i) ensure that the exposure of patients be the minimum required to achieve the intended diagnostic objective;

(ii) take into account relevant information from previous examinations in order to avoid unnecessary additional examinations; and

(iii) take into account the relevant guidance levels for medical exposure;

OPTIMIZATION OF PATIENT EXAMINATION



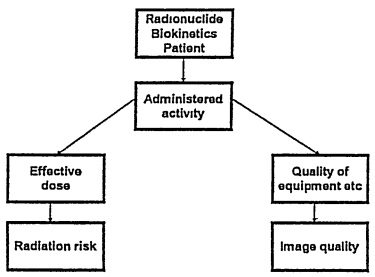
Diagnostic objective Medical exposure

Optimization (BSS II.17 cont)

(b) the medical practitioner, the technologist or other imaging staff, as appropriate, endeavour to achieve the minimum patient exposure consistent with acceptable image quality by:

(i) appropriate selection of the best available radiopharmaceutical and its activity, noting the special requirements for children and for patients with impairment of organ function;

OPTIMIZATION OF MEDICAL EXPOSURE



RADIOPHARMACEUTICAL

Considering that, according to the BSS, the activities listed below also require authorization, regulatory authorities may require the licensee of a nuclear medicine practice to contract any of the following services only to enterprises authorized by the Regulatory Authority:

- production, import, distribution, sale or transfer of radioactive sources
- personal monitoring
- installation, maintenance of nuclear medicine equipment
- disposal of radioactive sources

Use only radiopharmaceuticals from an authorized manufacturer!

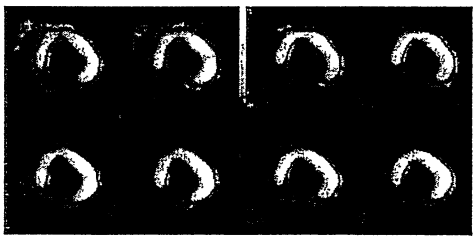
Radiopharmaceutical

If more than one radiopharmaceutical can be used for a procedure consideration should be given to physical, chemical and biological properties.

Example: Leucocytes labelled with

In-111	Tc-99m
0.36 mSv/MBq	0.011 mSv/MBq
20 MBq → 7.2 mSv	200 MBq → 2.2 mSv
$T_{1/2}$ = 2.8 days	$T_{1/2}$ = 6 hours

RADIOPHARMACEUTICAL



Tl-201 25 mSv Tc-99m 8 mSv

Optimization of image quality

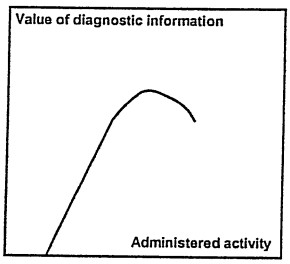
Image quality depends on:

- Administered activity
- Technical factors
  - equipment used
  - acquisition protocol
  - image processing & evaluation
  - noise
  - spatial resolution
  - scatter
- Patient factors
  - size
  - age
  - disease
  - movement

OPTIMIZATION OF ADMINISTERED ACTIVITY

In general, doses should be maintained as low as reasonable achievable but high enough to obtain the desired diagnostic information. This means that exposures above clinically acceptable maximum doses must be avoided as well as doses below clinically acceptable minimum doses

Optimization of Administered activity



There is a threshold below which no useful information can be expected

Above this threshold the diagnostic quality increases steeply with the administered activity

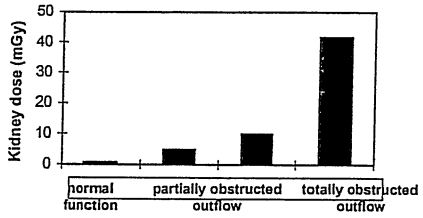
Once an acceptable level has been reached further increase of activity will not improve the result

(ICRP 52)

.....noting the special requirements for patients with impairment of

ORGAN FUNCTION

KIDNEY FUNCTION
(100 MBq Tc99m-DTPA)



Optimization (BSS II.17 cont)

(ii) use of methods for blocking the uptake in organs not under study and for accelerated excretion when applicable;



- Blocking agents for thyroid
- Hydration and frequent voiding of the urinary bladder
- Laxatives
- Catheterisation to empty the bladder???
- Cholecystokinin (fatty meal) for gallbladder emptying

Tc-99m-MAG_3, Two different first voiding times, girl 7 years

	Time between injection and first void		
Organ	30 min	2 hours	2h/30min
Bladder wall (mGy/MBq)	0.07	0.15	2.1
Gall bladder wall	0.099	0.01	1.0
Kidneys	0.0078	0.0081	1.0
Liver	0.0018	0.002	1.1
Red marrow	0.0018	0.0022	1.2
Ovaries	0.005	0.0086	1.7
Testes	0.0045	0.0082	1.8
Effective dose (mSv/MBq)	0.0062	0.011	1.8

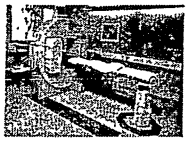
(Eleonor Westergren)

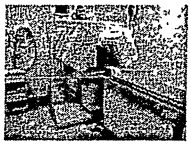
Optimization (BSS II.17 cont)

(iii) appropriate image acquisition and processing;

Equipment used:
- Single head/dual head camera
- Collimator used





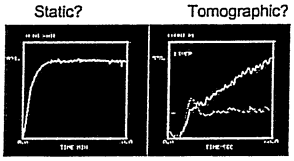


AQUISITION PROTOCOLS





Static? Tomographic?



Dynamic?

ACQUISITION PROTOCOL

Static imaging	- matrix size - number of counts - projections, zoom
Dynamic imaging	- matrix size - time/frame - number of groups
Tomographic imaging	- 180° or 360° - matrix size - number of angles - time/angle

IMAGE PROCESSING & EVALUATION

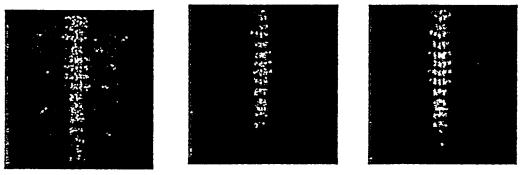
Static	- smoothing - image filtering - quantification - applications programme
Dynamic	- regions of interest (ROI) - time-activity curves - application programme
Tomographic	- attenuation correction - reconstruction method - image filtering - slices displayed - application programme

NOISE



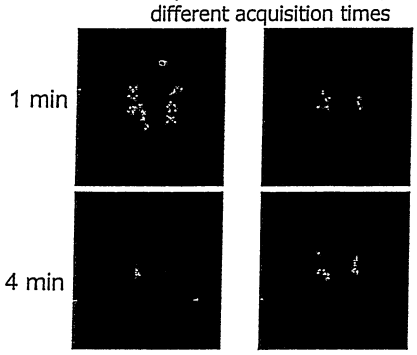
1000000 counts 100000 counts

Phantom, different number of counts



50 k 250 k 1000 k

Thyroid scintigraphy, different acquisition times



Spatial resolution

- Describes how a point source is reproduced
  - small details are not seen
  - uptakes seem to be lower
- Improved spatial resolution can be achieved by changing to a collimator with higher resolution but:
  - lower sensitivity requires more administered activity or longer acquisition times

Appropriate image acquisition

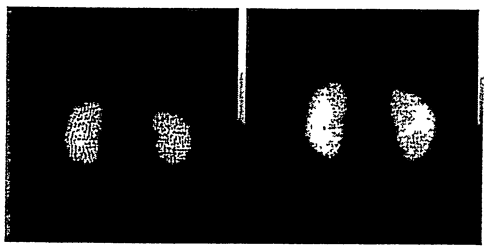


Close 15 cm Wrong setting of energy window

PATIENT FACTORS

Size	increased scatter spatial resolution
Age & Disease	radiopharmaceutical distribution movement artifacts

IMAGE QUALITY PATIENT MOVEMENT



Movement Corrected

STAFF & PROCEDURES

- Well trained staff with access to manuals and other documentation.
- Quality control program.
- Regular maintenance of equipment

Medical Exposure
Protection of the Patient



Guidance levels of activity

GUIDANCE LEVELS (BSS)

2.27. Guidance levels for medical exposure shall be established for use by medical practitioners. The guidance levels are intended:

(a) to be a reasonable indication of doses for average sized patients;
(b) to be established by relevant professional bodies in consultation with the Regulatory Authority following the detailed requirements of Appendix II and the guidance levels given in Schedule III;
(c) to provide guidance on what is achievable with current good practice rather than on what should be considered optimum performance;
(d) to be applied with flexibility to allow higher exposures if these are indicated by sound clinical judgment; and
(e) to be revised as technology and techniques improve.

GUIDANCE LEVELS

II.24. Registrants and licensees should ensure that guidance levels for medical exposure be determined as specified in the Standards, revised as technology improves and used as guidance by medical practitioners, in order that:

(a) corrective actions be taken as necessary if doses or activities fall substantially below the guidance levels and the exposures do not provide useful diagnostic information and do not yield the expected medical benefit to patients;
(b) reviews be considered if doses or activities exceed the guidance levels as an input to ensuring optimized protection of patients and maintaining appropriate levels of good practice; and
(c) for diagnostic radiology, including computed tomography examinations, and for nuclear medicine examinations, the guidance levels be derived from the data from wide scale quality surveys which include entrance surface doses and cross-sectional dimensions of the beams delivered by individual facilities and activities of radiopharmaceuticals administered to patients for the most frequent examinations in diagnostic radiology and nuclear medicine respectively.

GUIDANCE LEVELS

II.25. In the absence of wide scale surveys, performance of diagnostic radiography and fluoroscopy equipment and of nuclear medicine equipment should be assessed on the basis of comparison with the guidance levels specified in Schedule III, Tables III-I to III-V. These levels should not be regarded as a guide for ensuring optimum performance in all cases, as they are appropriate only for typical adult patients and, therefore, in applying the values in practice, account should be taken of body size and age.

Guidance levels of activity

Examination	Radionuclide	Chemical form	Guidance level (MBq)	Effective dose (mSv)
Bone scan	Tc-99m	phosphonate	600	4.8
Brain scan	Tc-99m	pertechnetate	500	2.7
CBF	Tc-99m	HMPAO	500	5.5
Thyroid imaging	Tc-99m	pertechnetate	200	2.6
Thyroid imaging	I-123	iodide	20	3.4
Parathyroid	Tl-201	chloride	90	18
Lung perfusion	Tc-99m	MAA	100	1.2
Lung ventilation	Tc-99m	aerosol	90	0.6
Lung ventilation	Kr-81m	gas	6000	0.2
Lung ventilation	Xe-133	gas	400	0.4
Liver & spleen	Tc-99m	colloid	80	0.6
Myocardium	Tl-201	chloride	100	23
Myocardium	Tc-99m	isonitriles	600	4.2
Kidneys	Tc-99m	DMSA	160	2.5
Kidneys	Tc-99m	DTPA	350	2.2
Kidneys	I-123	hippuran	20	0.3
Tumours	Ga-67	citrate	300	36
Tumour	I-123	MIBG	400	7.2
Tumour	I-131	MIBG	20	4

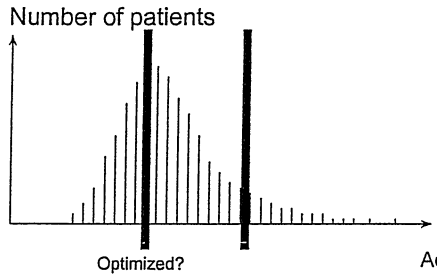
Guidance levels

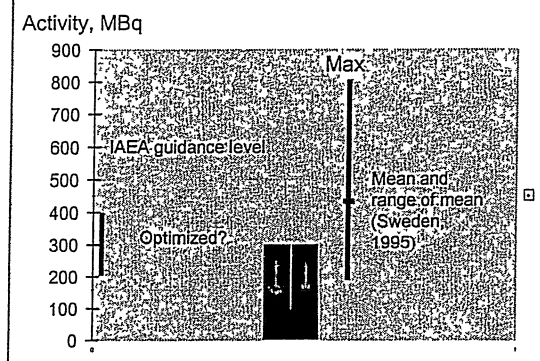
How to establish

1. Elimination of outliers
2. State-of-the practice (good practice)
3. State-of-the art (optimal practice)

Distribution of administered activities

Log-normal distributions





Bone scintigraphy

Medical Exposure Protection of the Patient

Dose constraints

Dose constraints (BSS II.26.)

The Ethical Review Committee or other institutional body assigned similar functions on the subject by national authorities shall specify dose constraints to be applied on a case by case basis in the optimization of protection for persons exposed for medical research purposes if such medical exposure does not produce direct benefit to the exposed individual.

BIOMEDICAL RESEARCH

ICRP and WHO categorization of risk

Level of Risk:	Trivial	Minor to Intermediate		Moderate
Risk Category:	I	I A.	I.	III
Total detriment	$< 10^{-6}$ or less	$\sim 10^{-5}$	$\sim 10^{-4}$	$\sim 10^{-3}$ or more
Range of effective doses (adults), mSv	< 0.1	0.1 - 1	1 - 10	> 10*
Anticipated level of benefit to Society	Minor	Intermediate to moderate		Substantial

* To be kept below deterministic thresholds except for therapeutic experiments

Dose constraints (BSS II.27.)

Registrants and licensees shall constrain any dose to individuals incurred knowingly while voluntarily helping (other than in their occupation) in the care, support or comfort of patients undergoing medical diagnosis or treatment and to visitors to patients who have received therapeutic amounts of radionuclides or are being treated with brachytherapy sources

Dose limitation for comforters and visitors of patients (BSS Schedule II.9)

..The dose shall be constrained so that it is unlikely that his or her dose will exceed 5 mSv during the period of a patient's diagnostic examination or treatment. The dose to children visiting patients who have ingested radioactive materials should be similarly constrained to less than 1 mSv

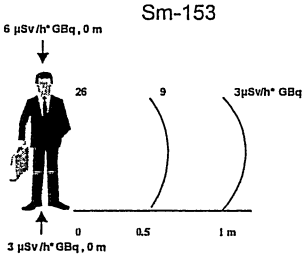


The radioactive patient

Examination	Dose rate nGy/h & MBq					
	0 h post inj			2 h post inj		
	0 m	0.3 m	1.0 m	0 m	0.3 m	1.0 m
Bone (MDP)	27	13	4	13	7	2
Liver (colloid)	27	13	4	20	10	3
Heart (RBC)	27	13	4	20	10	3
Myocardium (Thallium)	36	18	6	36	18	6

The Radioactive Patient

Sm-153

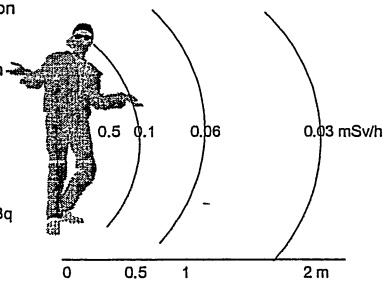


Actvity concentration in urine: 0.3 MBq/ml*GBq

THE RADIOACTIVE PATIENT

Contamination

saliva
perspiration
breath
urine



MAXIMUM ACTIVITY FOR PATIENTS IN THERAPY ON DISCHARGE FROM HOSPITAL

II.28. In order to restrict the exposure of any members of the household of a patient who has undergone a therapeutic procedure with sealed or unsealed radionuclides and members of the public, such a patient shall not be discharged from hospital before the activity of radioactive substances in the body falls below the level specified in Schedule III, Table III-VI. Written instructions to the patient concerning contact with other persons and relevant precautions for radiation protection shall be provided as necessary.

GUIDANCE LEVEL

Radionuclide	Activity (MBq)
Iodine - 131	1100 (a)

(a) In some countries a level of 400 MBq in used as an example of good practice.

INSTRUCTIONS TO OUT-PATIENT (Iodine-131)

- No eating and drinking during the first hour after treatment.
- During the following two days You should drink more than usual.
- Use only a WC and flush 2-3 times. Keep the toilet and the floor clean.
- Wash Your hands frequently and take a shower every day.
- Avoid close contact to members of the family, children and pregnant women according to the table attached
- Avoid solid waste

Contact the Nuclear medicine department is case of problems or questions. Phone: 052292788

RESTRICTIONS

Patient with iodine-131

Activity (MBq)	Public travel allowed per day 1:st w (h)	2:nd w (h)	Off work (d)	Sleep apart from partner pregn. (d)	no (d)	Restricted close contact with children <2 y (d)	2-5 y (d)	5-11 y (d)
200	3,5	24	0	15	1	15	11	5
400	1,5	14	3	20	8	21	16	11
600	1	9	6	24	11	25	20	14
800	0,5	7	8	26	13	27	22	16

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VISITORS WARNING CARD

The patient you are about to visit has received a therapeutic dose of radioactive iodine. It is in your own best interest to protect yourself as much as possible from receiving more radiation than is necessary. To assist you in meeting that end we offer the following recommendations:

- Visitors are discouraged for a 48 hour period after the patient receives the treatment.
- Pregnant women and children under the age of 18 are not permitted to visit.
- You should keep your visit short (<30 min).
- Keep a reasonable distance (e.g. 2 m) away from the patient.
- Do not kiss the patient.
- Do not eat, drink or smoke in the patient's room
- Do not touch the toilet or sink in the patient's room

If you have any questions, please ask the nursing staff.

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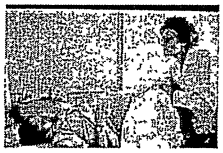
Medical Exposure Protection of the Patient

Examination of children, pregnant women and lactating women

Optimization (BSS II.17 cont)

(c) administration of radionuclides for diagnostic or radiotherapeutic procedures to women pregnant or likely to be pregnant be avoided unless there are strong clinical indications;

(d) for mothers in lactation, discontinuation of nursing be recommended until the radiopharmaceutical is no longer secreted in an amount estimated to give an unacceptable effective dose to the nursling;



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Radiation risks Embryo and fetus

Threshold dose deterministic effects	50-100 mSv
Mental retardation	40 % /Sv
Cancer and leukemia	
before 10 years of age	2 % /Sv
lifetime	15 % /Sv
Hereditary effects	1 % /Sv

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Irradiation of fetus results from:

- **Placental transfer**
  - distribution of activity in fetal organs
    - not much data available
    - I-131 as iodide Tc-99m pertechnetate
- **External radiation from activity present in the mothers organs and tissues**
  - radiopharmaceuticals eliminated via the kidneys

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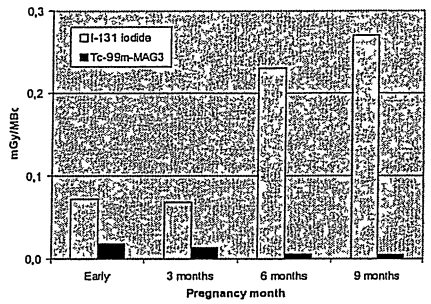
Absorbed dose to the fetus

Examination	Activity (MBq)	Dose to fetus (mSv)
Bone (Tc99m)	600	4
Brain (CBF)	500	4
Lung (Tc99m-MAA)	160	0.4
Kidneys (MAG3)	100	2
Tumour or abscess (Ga-67 citrate)	300	28
Heart (Tc99m-MIBI)	300	5
Heart (Tl-201)	100	10
Thyroid (Tc99m)	100	1
Thyroid (I-131)	100	7
Kidney clearance (Cr-51-EDTA)	4	0.02

(Data from Russell, Stabin et al Radiation dose to the embryo/fetus from radiopharmaceuticals Draft, 1997

Absorbed dose to the fetus



(Data from Russell, Stabin et al Radiation dose to the embryo/fetus from radiopharmaceuticals Draft, 1997

Risk of childhood cancer from mother's diagnostic procedure in NM

- The risk to an embryo or fetus from absorbing 1 mSv of radiation dose - an increased risk of developing childhood cancer of 6 in 100,000 (3 of which would be fatal)
- Natural risk of complications of pregnancy or of birth anomalies is approximately 4,000 in 100,000
- Natural risk of the incidence of childhood cancer – 150 in 100,000
- Fetal doses from diagnostic procedures in NM – max. tens of mSv (^{67}Ga, ^{131}I)

IF YOU THINK THAT YOU MIGHT BE PREGNANT , NOTIFY STAFF BEFORE TREATMENT



If an examination of a pregnant woman is judged to be necessary

- Choice of radiopharmaceutical
- Is it possible to reduce the administered activity?
- Prolonged acquisition times?
- For radiopharmaceuticals eliminated via the kidneys:
  - Partially filled urinary bladder at the time of administration
  - Hydration and frequent voiding

PREGNANCY / THERAPY

A pregnant woman should not be treated with a radioactive substance unless the therapy is required to save her life; in that event the potential absorbed dose to the fetus should be estimated.

Radiopharmaceutical	All activities up to (MBq)	Avoid pregnancy (months)
Au-198 colloid	10000	2
I-131 iodide	5000	6
I-131 MIBG	5000	6
P-32 phosphate	200	3
Sr-89 chloride	150	24
Y-90 colloids	400	0

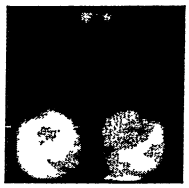
Optimization (BSS II.17 cont)

(c) administration of radionuclides for diagnostic or radiotherapeutic procedures to women pregnant or likely to be pregnant be avoided unless there are strong clinical indications;

(d) for mothers in lactation, discontinuation of nursing be recommended until the radiopharmaceutical is no longer secreted in an amount estimated to give an unacceptable effective dose to the nursling;

Irradiation of breastfed child results from:

- Activity in milk
- External radiation from the mother
- Possible contamination





Recommendations for cessation of breast feeding

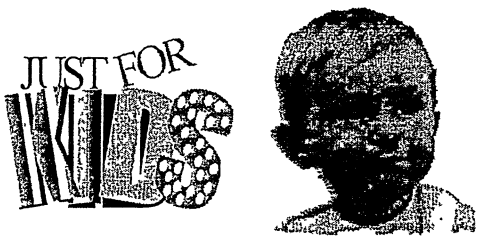
Radiopharmaceutical	Administered activity (MBq)	Counseling?	Advice
Tc-99m DTPA	740	no	
Tc-99m MAA	148	yes	12 hr
Tc-99m Pertechnetate	185	yes	4 hr
Tc-99m DISIDA	300	no	
Tc-99m glucoheptonate	740	no	
Tc-99m HAM	300	no	
Tc-99m MIBI	1110	no	
Tc-99m MDP	740	no	
Tc-99m PYP	740	no	
Tc-99m RBC's in vivo labelling	740	yes	12 hr
Tc-99m RBC's in vitro labelling	740	no	
Tc-99m Sulphur Colloid	444	no	
Tc-99m DTPA Aerosol	37	no	
Tc-99m WBC's	185	yes	48 hr
Tc-99m MAG3	370	no	

Recommendations for cessation of breast feeding

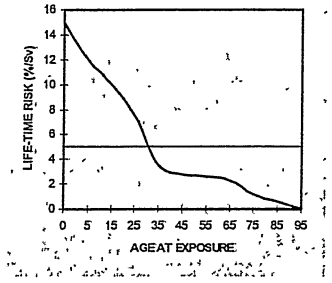
Radiopharmaceutical	Administered activity (MBq)	Counseling?	Advice
Ga-67 Citrate	185	yes	Cessation
I-131 NaI	5550	yes	Cessation
Cr-51 EDTA	1.85	no	
In-111 WBC's	20	no	
I-123 NaI	15	yes	Cessation
I-123 OIH	74	no	
I-123 mIBG	370	yes	48 hr
I-125 OIH	0.37	no	
I-131 OIH	11.1	no	
Tl-201	111	yes	96 hr
Xe-133 gas		no	

IF YOU ARE BREAST-FEEDING, PLEASE NOTIFY THE STAFF





RADIATION RISKS



Optimization (BSS II.17 cont)

(e) administration of radionuclides to children for diagnostic procedures be carried out only if there is a strong clinical indication, and the amount of activity administered be reduced according to body weight, body surface area or other appropriate criteria.

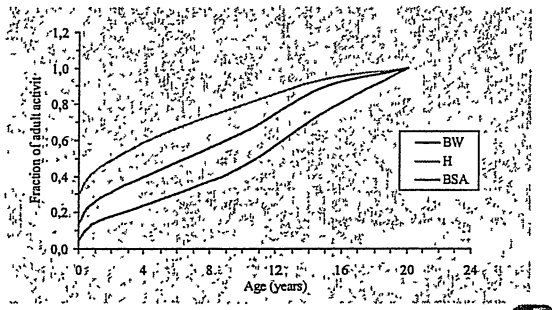


Activity to children

The amount of activity administered to an adult can for children be reduced by one of the following methods:

- body weight/70 kg
- body surface area/1.73 m^2
- height/174 cm

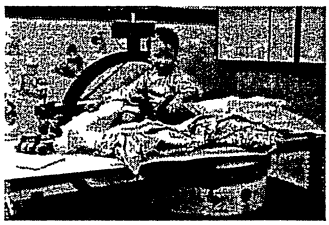
Fraction of the adult activity



.....noting the special requirements for

CHILDREN

Local rules for administered activities to children should be available. Recommendations from international professional organizations should be followed.



Medical Exposure Protection of the Patient

Records

RECORDS (BSS)

II.31. Registrants and licensees shall keep for a period specified by the Regulatory Authority and make available, as required, the following records:

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

.....

(d) the exposure of volunteers in medical research.

II.32. Registrants and licensees shall keep and make available, as required, the results of the calibrations and periodic checks of the relevant physical and clinical parameters selected during treatments.

CALIBRATION OF SOURCES BSS (II:19 b)

Registrants and licensees shall ensure that:

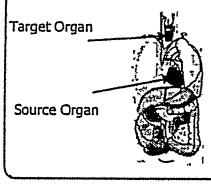
•unsealed sources for nuclear medicine procedures be calibrated in terms of activity of the radio-pharmaceutical to be administered, the activity being determined and recorded at the time of administration;

DOCUMENTATION

II.20. Registrants and licensees shall ensure that the following items be determined and documented:

.....

(d) in diagnosis or treatment with unsealed sources, representative absorbed doses to patients; and





RECORDS AND DOCUMENTS MEDICAL EXPOSURE

•Administered radiopharmaceutical and activity (each patient)
•Route of administration (each patient)
•Incident and accident investigation reports
•Absorbed doses to patients
•Calibration certificate (activity meter)
•Quality control of equipment (gammacamera & activity meter)
•Maintenance and repair work
•Audits and reviews of radiation safety programme
•Training provided:
initial
refresher



Medical Exposure Protection of the Patient

Local Rules

LOCAL RULES MEDICAL EXPOSURE

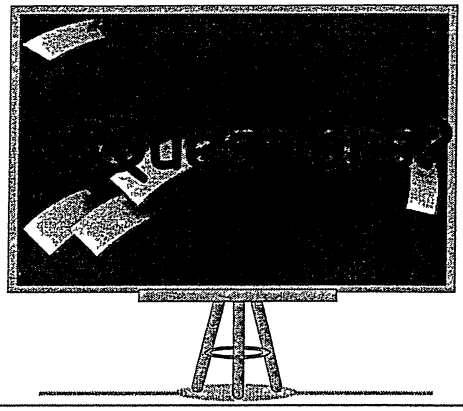
Activity to adults in nuclear medicine examinations
Activity to children in nuclear medicine examinations
Rules for pregnant women
Rules for lactating women
Preparation and dispensation of radiopharmaceuticals
Procedure manual, activity meter
Patient identification and information
Administration of radiopharmaceuticals
Procedure manual, gammacamera examinations
Procedures in case of misadministrations
Procedures in case of accidents
Records



LOCAL RULES

Department of Nuclear Medicine
Radiation Protection Manual
PROTECTION OF THE PATIENT

Activity to Adults	Children & Young people
Pregnant women	Lactating women
Radiopharmaceuticals	Activity measurement
Misadministration	Examination



DISCUSSION

- **Increase the activity for elderly patients and patients with pain to reduce the examination time?**
- **Increase the activity for all patients in order to increase the throughput of patients?**
- **Increase the activity for paediatric patients in order to avoid sedation or general anaesthesia?**
- **Increase the activity to cancer patients who are nevertheless going to receive radiotherapy?**





DISCUSSION

A patient is referred to a bone scan. It is obvious from the information on the request that this is the wrong type of examination to get the right diagnosis. The examination is done anyway. Who is responsible for this non justified exposure?

DISCUSSION

Discuss how to handle the problem when it is necessary to to examine or treat a woman who is pregnant.

Where to Get More Information

- Other sessions
  - Part 7 Optimization of protection in Nuclear Medicine Examinations
  - Part 8 Optimization of protection in Nuclear Medicine therapy
  - Part 11 Potential exposure and accidental medical exposure
- Further readings
  - IAEA Basic Safety Standards
  - IAEA Safety Guide on Radiological Protection for Medical Exposure
  - IAEA Model regulations on radiation safety in nuclear medicine (in preparation)
  - WHO. Manual on Radiation Protection in Hospitals and General Practices. Volume 4: Nuclear Medicine
  - ICRP publication 84
- Practical session
  - Simulated inspection

LOCAL RULES 1

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ADULTS

Examination	Radiopharmaceutical	Activity (MBq)
Bone scan	Tc99m DPD	400
Thyroid	Tc99m-pertechnetate	100
Kidney	Tc99m-MAG3	75

Note. For not listed examinations consult the nuclear medicine specialist

LOCAL RULES 2

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CHILDREN & YOUNG PEOPLE

Examination	Radiopharmaceutical	Activity (MBq) Age 0-14	Age 15-18
Bone scan	Tc99m DPD		
Thyroid	Tc99m-pertechnetate		
Kidney	Tc99m-MAG3		

Note For not listed examinations consult the nuclear medicine specialist

LOCAL RULES 3

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PROTECTION OF THE PATIENT

PREGNANT WOMEN

•If a female patient is pregnant or think that she might be, the responsible physician shall always make a decision whether the examination shall be done or shall be postponed either until after delivery or to the latter half of the pregnancy, carefully considering the use of other diagnostic methods.

• If there is uncertainty concerning pregnancy, either because the period is known to be overdue or for other reasons, the woman shall be treated as pregnant until otherwise proved.

• The administered activity shall be in proportion to body weight using 70% of the normal adult activity for the required examination

LOCAL RULES 4

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LACTATING WOMEN

No counseling of breastfeeding for the following radiopharmaceuticals:
^{51}Cr-EDTA, ^{99m}Tc-DMSA, ^{99m}Tc-DTPA, ^{99m}Tc-MDP, ^{99m}Tc-glycoheptonate ^{99m}Tc-HMPAO, ^{99m}Tc-MIBI, ^{99m}Tc-colloids, ^{99m}Tc-MAG3(<100MBq), ^{201}Tl-chloride (<80MBq) and ^{111}In-leucocytes (<20MBq).

For other radiopharmaceuticals, see attached table
For not listed radiopharmaceuticals, consult the nuclear medicine specialist

LOCAL RULES 4:1

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PROTECTION OF THE PATIENT

LACTATING WOMEN

Counseling of breastfeeding

Radiopharmaceutical	Advice
^{99m}Tc-pertechnetate	4h
^{99m}Tc-MAA	12h
^{201}Tl-chloride	96h
^{67}Ga-citrate	Cessation
. . .	.

LOCAL RULES 5

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PROTECTION OF THE PATIENT

RADIOPHARMACEUTICALS

Preparation | Dispensing

Injection

LOCAL RULES 5:1

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PREPARATION OF RADIOPHARMACEUTICALS

Name:	DPD (CIS bio)
Composition	13 mg 3,3-diphosphono-1,2-propanedicarboxylic acid, tetrasodium salt (DPD) 0 23 mg tin(II)oxide
Usage:	Bone scintigraphy
Preparation:	Use a transparent vial shield. Put the kit vial in the shield. Dispense 5 ml pertechnetate (3000 MBq) in a shielded syringe. Add the solution to the vial containing the freeze dried kit Remove an equal volume of gas to equalize the pressure. Shake the vial gently for 10 s. Store the preparation for 5 min. Temporarily remove the vial from the shield and measure the activity. Use a forceps when moving the vial. Put a label on the shield The label shall contain: Name of radiopharmaceutical, activity and activity concentration as well as date and time. Check the label against the vial. Same radiopharmaceutical? Record the preparation and sign. The preparation can be used for 5 patient examinations within 6 h from time of preparation.
Storage:	Kit in fridge Radiopharmaceutical in the shielded container and protected from light

LOCAL RULES 5:2

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PROTECTION OF THE PATIENT

DISPENSING RADIOPHARMACEUTICALS

1. Check the label on the vial shield. Is it the required radiopharmaceutical?
2. Calculate the volume to dispense from the decay corrected activity concentration and the requested activity for the intended examination.
3. Dispense the calculated volume using a shielded syringe.
4. Temporarily remove the syringe shield and measure the activity.
5. Write a label and put it on the syringe shield. The label shall contain patient name and id number, radiopharmaceutical, activity, date and time. The label shall be signed.

LOCAL RULES 5:3

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PROTECTION OF THE PATIENT

IDENTIFICATION OF PATIENT
INJECTION OF RADIOPHARMACEUTICALS

1. Ask the patient about name and birthdate or identification number.
2. Ask a female patient about pregnancy.
3. Ask a female patient if she is breastfeeding a child.
4. If necessary, inform the patient about any restrictions according to the local rules.
5. Read the request
6. Check the label on the syringe shield.
7. Is it the correct radiopharmaceutical and activity for the requested examination?
8. Inject according to the local rules for intravenous injections
9. The radiopharmaceutical and the injected activity.shall be recorded

LOCAL RULES 6

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PROTECTION OF THE PATIENT

ACTIVITY MEASUREMENT

The activity of the radiopharmaceutical shall always be measured after preparation and before and after injection.

1. Select the isotope
2. Check the background reading and make a background adjustment
3. Put the syringe or the vial in the holder using a forceps
4. Put the holder into the chamber
5. Read the activity
6. Remove the holder and put the syringe or vial back into the shield

LOCAL RULES 7

Department of Nuclear Medicine
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PROTECTION OF THE PATIENT

MISADMINISTRATION

The following are defined as misadministrations: Administration to the wrong patient, administration of the wrong radiopharmaceutical, administration of wrong activity (>15% from prescribed activity in therapy and >75% in diagnostic examinations) and wrong route of administration.

In case of misadministration:

1. Inform the nuclear medicine specialist
2. Inform the patient and the referring physician
3. Inform the medical physicist (phone .....), who shall calculate and report the patient dose
4. The responsible technician shall write a report about the event and try to explain the causes.
5. The nuclear medicine specialist shall send the report to the Head of the Department who shall decide if the event shall be reported to the authorities.
6. All members of the staff shall be informed

LOCAL RULES 8

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Study name:	**Bone scan**
Preparation of patient:	**Empty bladder**
Radiopharmaceutical:	**Tc99m-DPD**
Route of administration:	**iv injection**
Activity:	**400 MBq**
Start of measurement:	**3h post injection**
Type of examination:	**Whole body scan**
Views:	**AP, PA**
Scanning speed:	**10 cm/min**
Collimator:	**LEHR**
Window setting:	**140+/-20% keV**
Positioning of patient:	**Supine**
Presentation of result:	**Images in BW on film.**