Working group on radioprotection

Requirements for medical physicists in Nuclear Medicine and Radiology

Guidelines and recommendations for application of the radioprotection ordinance Article 74

Final version; June 2011





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Two additional documents are also available as extension of this document: **Supplement 1** : "Tasks and duties of <u>manufacturers</u>" **Supplement 2**: "Tasks and duties of <u>technologists</u>"

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Chapter 1: Introduction and scope of the document

Rationale

This document is intended as a general framework and basic guidelines or recommendations for application of the Radiation Protection Ordinance and its Article 74 regarding the support of medical physicists. It is not intended as a strict set of rules for the application of the law since it does not have the legal credential to be applied as such. The goal of this document is also to better define the scope of tasks, duties and responsibilities that should be performed by certified medical physicists in supporting radiology and imaging facilities using radiation intensive imaging devices mentioned in the law, namely, nuclear medicine scanners, CT scanners and fluoroscopy suites. This document can be considered as a starting point for application of Article 74. However, after gaining first experiences the scope and the frequencies of defined tasks and duties of medical physicists must most probably be revised.

This document is the result of collaborative work between representatives of the different societies mentioned on the cover of the document. It is intended as a general framework to be used by different institutions to better define their needs and plans for assigning specific tasks to certified medical physicists in compliance with Art. 74 of the Radiation Protection Ordinance. While the multidisciplinary group that contributed to this document did not reach full consensus on specific recommendations for the extent of duties and tasks that should be assigned to medical physicists, it has agreed to publish the recommendations of the FOPH as is. This document has not yet received the formal agreement of the different scientific societies involved and is therefore subject to further amendments and revisions in the future.

Scope

The scope of the document is to focus on the tasks and duties of medical physicist in medical imaging departments that use the following imaging modalities listed in the law:

- 1) Fluoroscopy used in diagnostic and interventional procedures (IR)
- 2) Computed tomography (CT) scanners
- 3) Nuclear medicine (NM) cameras and scanners (SPECT and PET)

Hybrid devices combining modalities such as SPECT-CT and PET-CT will simply be treated as two imaging devices and the recommendations apply for each device separately. No additional duties are required since hybrid devices are not mentioned in the law and should not be different from the radioprotection point of view from each device taken separately.

The current legal practices and requirements on quality control are summarized in Appendix A and serve as a base for defining the complementary tasks and duties assigned to certified medical physicists hired by the imaging centers as employees or consultants.

In nuclear medicine some of the periodical QC procedures as well as radioprotection tasks are performed by technologists. In recent years, as in radio oncology, some of the tasks and duties have been delegated from medical physicists (if there are any) to technologists. In radiology technical radiation protection tasks are performed by technologists, whereas QC procedures are done by the manufacturer only. Support of medical physicists is practically absent. In cardiology, urology and other related medical field with intense use of x-rays, technologists become rare and a lack of expertise is observed. No medical physics support is currently present in these areas.

According to the Swiss legislation, only qualified persons shall be permitted to carry out activities that may involve an ionizing radiation hazard. The license holder or the persons in charge of an enterprise are responsible for ensuring compliance with the radiological protection regulations. For this purpose, they are required to appoint an appropriate number of experts and to provide them with the necessary powers and resources. A delegation of some tasks and duties to another person can be applied as long as the delegated person has the qualified expertise. The responsibility for applying ionizing radiation to human lies in all cases by the license holder.

Concerning Article 74, the license holder is responsible for its correct implementation. This implies an adequate staffing with medical physicists. The medical physicist, on the other hand, takes the responsibility for the performance of the tasks and duties as defined in this report. The principal responsibilities of medical physicists are the following:

- 1. Measurements of appropriate patient / occupational / public safety related dosimetric monitoring quantities during the QC.
- 2. Improving patient protection by optimization of practices, procedures and acquisition protocols.
- 3. Improving protection of the medical staff by giving advice on machine operation and personal protective equipment, including protective garments, fixed and mobile shielding.
- 4. Establishing an effective education system in radioprotection for healthcare professionals.

This document focuses on the needs and requirements in routine clinical practice mostly represented by radiology practices where standardized protocols are applied routinely with very limited changes for different diagnostic tasks. That means that the document addresses primarily to the majority of private radiology institutes and regional hospitals where medical physicist support has not been organized so far. It is preferable to establish a contract with an external medical physicist on a regular basis.

This situation differs significantly from academic centers and large medical institutions where, in addition to the above mentioned routine clinical practices, innovative protocols are constantly being developed by multidisciplinary teams involving physicists, computer and imaging scientists, technologists and physicians. In such centers, the medical physicists are part of the team and have well defined responsibilities in development but also in application of imaging protocols in clinical practice.

In chapter 2 of this document, tasks and duties are listed that need to be performed by medical physicists hired by each center, and these duties are clearly separated by imaging modality. For each task, the frequency and extent are estimated. Only with these numbers it is possible to estimate the medico-economic impact over the current cost of diagnostic procedures. There is no doubt that this will be the major item that each center will have to negotiate with local authority (for public institutions) and with payers and insurance companies (for private institutions)

Incentives

The regulation should create motivating incentives for high-quality radiation protection. There is probably no doubt that currently - without a compulsory implication of medical physicists - the quality of radiation protection in Switzerland varies a lot between different institutions; some maintain a high level of quality, and some have major deficits, with a large spread in between. Motivation, in many instances could work as a better stimulus for improving radiation protection than a legal order with a periodic, planned interaction of specialists. It is envisioned that institutions that perform well within the range of accepted dose will require less support and coaching from medical physicists than institutions that regularly exceed the range of admitted dose.

The current level of quality of radiation protection in an institution will be assessed by the medical physicist and discussed with the radiologist or nuclear medicine professional. Based on the result the extent of time of medical physicist support will be jointly defined by the medical physicist and the physician. The reduction in time and extent of medical physicist support for institutions with a high quality level of radiation protection should be based on quantitative objective criteria, which are yet to be defined.

Additional documents

A detailed list of tasks and periodical controls performed by industry and technologist are listed in two separate documents, supplement 1 : "Tasks and duties of <u>manufacturers</u>" and supplement 2: "Tasks and duties of <u>technologists</u>", that can be obtained separately from this main document.

Supplement 1 is compiled by FASMED representatives of industry. It is reflecting the support of the industry for a continuous optimization in the appliance of radiation intensive medical equipment. The industry constantly improves and implements procedures to minimize dose. This includes training and education support. In times where costs should decrease and efficiency should increase there is a strong recommendation and commitment from the industry to avoid repetition of tasks and duties by different parties. This especially applies to repeated measurements or re-checking when commissioning a system. With respect to an efficient workflow, activities such as the adjustment of an imaging system or the verification of the performance parameters should take place at the same time by all parties.

Chapter 2: Tasks and duties that require support of medical physicists

This chapter reviews the areas where additional support from certified medical physicists is needed to insure best utilization of imaging devices while optimizing the balance between patient dose, medical staff dose and image quality.

It is important to separate additional need for physicists' support in research protocols in academic institutions, which fall beyond the routine applications and usually are managed under strict research protocols. Also, many research projects use standard protocols, and CT just serves to objectively assess the temporal changes.

t has to be clearly stated that medical physicists are hired by the license holder on a contractual basis and working as independent professionals. The tasks and duties of medical physicists are aiming uniquely at complying with Article 74 of the Radiation Protection Ordinance in order to improve the radiation protection of patients and medical staff. There is no direct or indirect dependency of medical physicists to the FOPH and they will report results only to the license holder.

However, it is a fact that with today's advances in imaging technology the differentiation between different categories of users will have only a minor impact on the amount of support required from medical physicists in the domains of CT and nuclear medicine.

In large centers the medical physicist is a team member and he will also be involved in following processes:

- Equipment procurement and acceptance testing and establishment of routine quality control;
- Close work with the medical staff to provide technical advice relevant to the execution of the studies;
- Teaching of other professionals particularly in the fields of radiation safety and instrument principles.

General outline of the tasks requiring the support of medical physicists

2.1 CT

For CT a selection of basic tasks and duties to be performed by the medical physicist is listed here (the list is not exhaustive). QA tasks relating to patient dose should be performed in collaboration with the manufacturer and should not just repeat or double check measurements already performed during acceptance testing or during status and periodical tests.

- QA relating to patient dose:
 - Reliability of the displayed dose indicators (CTDI, DLP)
 - \circ $\,$ Verification of the X-ray beam collimation
 - o Behavior of the X-ray tube modulation
 - Level of image quality produced for a given dose level
 - Homogeneous image quality for various CT systems of different manufacturers any
 - Adequacy of the imaging protocols with DRLs
 - Adaptation of protocols as a function of weight and age of the patient
 - Measurements concerning constructional radioprotection
 - Dose assessment for FOPH or ethical committees
 - Participation to a clinical study when a dose problematic exist
- Patient dose estimation and verification:
 - Phantom measurements
 - Dose modeling
 - Analyzing individual patient dose protocols and comparison to DRLs
- Patient dose optimization:
 - Discussion with the physician and technologist on the benefits and possibilities of optimization; general discussion when a change in practice is introduced (e.g. change of reconstructed slice thickness, test of a low dose protocol, ...)
 - Individual patient dose adaptation
 - Protocol optimization
- Support and coaching of technologists and physicians so both professional groups:
 - o are able to use the unit according to the manufacturer's recommendation
 - o know how to adapt for patient age and weight
 - are able to verify if adapted protocols remain within the state of the practice (technical parameters)
 - know the advantages and inconvenience of using tube current modulation
 - understand the risk of changing parameters on image quality (maximum mAs setting, pitch, kV, ...)
 - understand and know how to judge the dose indicators (CTDI, DLP, E%, and overranging problem)
 - know the DRL and know how to adapt the protocols to reach them
 - can establish a link between the clinical need (image quality) and the parameters that could be proposed
 - know and are able to explain the advantages and risks associated to the procedure (informed consent of the patient that might be obtained by delegation)
 - know how to scan safely pregnant women and young patients
 - know the efficacy of the radiation protection devices that might be placed on the patients
 - o are aware of the latest developments in radioprotection (continuous education)

The time required to perform these duties is presented in the table in chapter 2.4. These duties have to be done on site during the working hours with the team of technologists and physicians.

2.2 Fluoroscopy

For fluoroscopy, given the wide range of possible applications and potential variations in the radiation dose applied to the patient, it was felt that there should be two different categories.

The definition of categories A and B can be summarized as follows:

Category A*	Category B
Potentially high radiation dose	Potentially low radiation dose
procedure	procedure
More than 5% of cases result in a	All other units
cumulative dose exceeding 3 Gy	
or a DAP exceeding 300 Gy.cm ²	
Average fluoroscopy time > 5 min.	Average fluoroscopy time 2-5 min.
High-quality images	No high-quality images

*) this classification is proposed by NCRP 168 report (2010) where for category A there is a strong recommendation to involve medical physicists. This should include all units where interventional radiology or cardiology is performed.

2.2.1 Category A

For fluoroscopy units of Category A when the medical physicist is a team member, she/he should be directly involved in the procurement of the equipment as well as of radiation protection devices that might be needed. A selection of fundamental duties to be performed by the medical physicist is presented in the following list (the list is not exhaustive). QA tasks relating to patient dose should be performed in collaboration with the manufacturer and should not just repeat or double check measurements already performed during acceptance testing or during status and periodical tests.

- QA relating to patient dose:
 - Reliability of the displayed dose indicators (DAP)
 - Verification of the X-ray beam collimation
 - Level of image quality produced for a given dose level in all imaging mode
 - Effect of the setting of the unit on the behavior of the system
 - What to do to increase image contrast, lower patient dose
- Patient dose estimation and verification:
 - Measurement of entrance skin dose rates as a function of the mode (scopy and imaging), thickness of absorber, magnification, frame rate
 - Dose modeling
 - Analyzing individual patient dose protocols and comparison to DRLs
- Staff dose estimation and verification:
 - Measurement of ambient equivalent dose rates at the position of the staff as a function of the mode (scopy and imaging), thickness of absorber, magnification, frame rate
 - Dose modeling
 - Evaluation of how the staff is protected/monitored
- Patient dose optimization:
 - Discussion with the physician and technologist on the benefits and possibilities of optimization; general discussion when a change in practice is introduced
 - Individual patient dose adaptation
 - Protocol optimization
 - Establishing local reference levels in collaboration with the technologists or the staff that use the unit
- Staff dose optimization:
 - Discussion with the physician and technologist on the benefits and possibilities of optimization; general discussion when a change in practice is introduced
 - Optimization of the use of shielding devices
- Support and coaching of technologists and physicians so both professional groups:
 - understand and know how to judge the dose indicators (DAP, cumulative dose)
 - are able to interpret the dose delivered for different types of examination and complexity
 - o can estimate the deterministic and stochastic risks associated with a procedure
 - have a strategy to follow the patient when a particularly high dose has been delivered
 - know how to work in a optimal way and are able to modify their practice to decrease staff and patient exposure
 - develop and provide technical advices relevant to the radiation protection of the patient and the staff
 - o are able to assess the current situation using technical publications
 - establish a routine quality control that the staff might perform
 - o are aware of the latest developments in radioprotection (continuous education)

The time required to perform these duties is presented in the table in chapter 2.4. These duties have to be done on site during the working hours with the team of technologists and physicians. Particular attention should be paid to the units where no technologist is involved, such as in cardiology.

2.2.2 Category B

The setting of these units and the way they are used should be analyzed by a medical physicist who should also check if the staff satisfies the FOPH requirements (dosemeters, presence and use of radiation protection devices). However, following minimal duties should be performed:

- Patient dose estimation, verification, and optimization
- Staff dose estimation, verification, and optimization
- Support and coaching of technologists and physicians

The time required to perform these duties is presented in the table in chapter 2.4.

2.3 Nuclear Medicine

For nuclear medicine units a selection of fundamental duties to be performed by the medical physicist is presented in the following list (the list is not exhaustive). QA tasks relating to patient dose should be performed in collaboration with the manufacturer and should not just repeat or double check measurements already performed during acceptance testing or during status and periodical tests.

- QA relating to patient dose of a gamma camera system:
 - Level of image quality produced for a given activity
 - Correlation between algorithms and image quality
 - o Adequacy of the imaging protocols with DRLs
 - o Multiple window spatial registration
 - Intrinsic count rate performance in air
 - Intrinsic uniformity and spatial resolution at 75k counts per sec.
 - Collimator hole alignment
 - For SPECT
 - Spatial resolution in air + with scatter
 - Detector to Detector sensitivity
- QA relating to patient dose of a PET system:
 - \circ $\;$ Level of image quality produced for a given activity
 - \circ $\,$ Correlation between algorithms and image quality $\,$
 - \circ $\,$ Adequacy of the imaging protocols with DRLs $\,$
 - Count rate performance
 - Spatial resolution
 - Image quality, accuracy of attenuation and scatter corrections
 - Recovery factors
 - o Scatter fraction, count losses and random measurement
 - o Sensitivity
 - Accuracy: corrections for count losses and random
- Patient dose estimation and verification:
 - Phantom measurements
 - Dose modeling
 - Analyzing individual patient dose protocols and comparison to DRLs
- Staff dose estimation and verification:
 - o Measurements
 - o Dose modeling
 - o Evaluation of how the staff is protected/monitored
- Patient dose optimization:
 - Discussion with the physician and technologist on the benefits and possibilities of optimization; general discussion when a change in practice is introduced
 - o Individual patient dose adaptation
 - Protocol optimization
 - \circ $\;$ Establishing local reference levels in collaboration with the staff
- Staff dose optimization:
 - Discussion with the physician and technologist on the benefits and possibilities of optimization; general discussion when a change in practice is introduced
 - o Optimization of radioprotection issues
- Support and coaching of technologists and physicians so both professional groups:

- \circ $\,$ are able to use the unit according to the manufacturer's recommendation $\,$
- are able to verify if adapted protocols remain within the state of the practice (technical parameters)
- \circ $\,$ know the DRL and know how to adapt the protocols to reach them
- o are able to establish their local DRL
- can establish a link between the clinical need (image quality) and the parameters that could be proposed
- o know how to adapt for patient age and weight
- know the advantages and inconvenience of using different times for SPECT and PET and number of angles for SPECT for the different available algorithms
- know and are able to explain the advantages and risks associated to the procedure (inform consent of the patient that might be obtained by delegation)
- o know how to scan safely pregnant women and young patients
- \circ $\,$ know how to use the process and devices for measuring radiation
- \circ $\;$ know the principles of the dosimetry in nuclear medicine
- o are aware of the latest developments in radioprotection (continuous education)

The CT associated with a PET or SPECT should be treated as a normal CT unit.

The time required to perform these duties is presented in the table in chapter 2.4. These duties have to be done on site during the working hours with the team of technologists and physicians.

2.4 Overview of recommended contractual hiring times of medical physicists

In the following table below the recommended hiring times of medical physicists in days per year are listed for each of the modalities concerned in Article 74 of the Radiation Protection Ordinance. The numbers listed here represent the current recommendations of FOPH.

Modality	QA relating to patient dose	Verification and optimization of patient and staff dose	Training and coaching of technologists and physicians *	Sum per year
СТ	0.5	1	1.5	3
Fluoroscopy Cat. A	0.5	1.4	1.5	3.4
Fluoroscopy Cat. B	0.125	0.125	0.75	1
Gamma camera	0.5	0.5	1.5	2.5
PET	0.5	0.75	1.5	2.75
SPECT/CT	1	1.5	3	5.5
PET/CT	1	1.75	3	5.75

* Time needed for the preparation of the support and coaching (evaluation, presentation, concept, etc.) is included. If there are several identical modalities operated in a hospital or private institute the overall time allocated for training and coaching could be lower than the sum of time for each modality. On the other hand, if there is more than one team to be trained the time recommended in the table for training and coaching should be adapted in order to ensure that all involved medical staff (physicians, technologists) receives their appropriate formation.

A more detailed overview specifying how much time is allocated for which tasks and duties of medical physicists are presented in Appendix B.

APPENDIX A: Current practice in quality control and instrument monitoring

This appendix reviews the legal requirements as well as the common practices of acceptance testing of new imaging equipment as well as periodic quality control tests and maintenance procedures performed by the technologist or manufacturer.

Legal background

The legal scope of the specific requirements can be extracted from the X-ray Ordinance and directives as published by the FOPH on quality assurance (QA). These directives must be reviewed to identify areas where additional controls by medical physicists are needed. The following documents must be reviewed and used as a basis for defining the tasks and duties of medical physicists:

- Radiation Protection Ordinance [RPO] specifying general requirements
- X-ray Ordinance [XO] specifying requirements in X-ray applications
- Directive FOPH R-06-06 specifying diagnostic reference levels (DRLs) in CT
- Directive FOPH R-06-05 specifying diagnostic reference levels (DRLs) in interventional radiology and cardiology
- Directive FOPH L-08-01 specifying diagnostic reference levels (DRLs) in nuclear medicine
- Directive FOPH R-08-08 specifying QA periodicities and test parameters for CT
- Directive FOPH R-08-06 specifying QA periodicities for digital radiography and/or fluoroscopy
- Directive FOPH R-08-10 specifying QA periodicities for interventional radiology and cardiology
- Directive FOPH L-09-04 specifying QA periodicities and test parameters for nuclear medicine

Legal requirements for acceptance and quality control tests

Acceptance testing and performance tests at installation

According to the XO art. 19, this is the responsibility of the manufacturer or provider of the unit.

- Computed tomography scanners (CT) : test parameters are defined in directive R-08-08
- Interventional radiology/cardiology: test parameters are defined in XO annex 13
- Nuclear medicine: test parameters are defined in L-09-04

Status test (after major change or periodically)

According to the XO art. 21, this is the responsibility of the licensee who may delegate this task to technical experts.

- Computed tomography scanners (CT): test parameters are defined in directive R-08-08; periodicity is yearly (also for reproduction and documentation systems)
- Interventional radiology/cardiology: test parameters are defined in XO annex 13; periodicity is 3-yearly (yearly for reproduction and documentation systems)
- Nuclear medicine cameras and scanners (SPECT and PET): test parameters are defined in directive L-09-04; periodicity is biannual

Periodical tests performed for constancy and preventive maintenance tests

According to the XO art. 20, this is the responsibility of the licensee who may delegate this task to a third party.

- Computed tomography scanners (CT): test parameters are defined in directive R-08-08; periodicity is 3-monthly (weekly for reproduction and documentation systems)
- Interventional radiology/cardiology: test parameters are defined in XO annex 15; periodicity is yearly (weekly for reproduction and documentation systems)
- Nuclear medicine cameras and scanners (SPECT and PET): test parameters are defined in directive L-09-04; periodicity is daily, weekly, or biannual.

APPENDIX B: Detailed summary of time needed for specific tasks and duties of medical physicists

(The numbers listed here represent the current recommendations of FOPH)

CT

Торіс	Hours	Days
QA relating to patient dose	4	0.5
 QA measurements related to patient dose Phantom measurements, radiation measurements 		
Verification and optimization of patient dose	8	1
 Analysis of measured and collected doses Comparison of doses to DRLs Discussion with physicians on optimization methods Optimization of patient doses (protocols) 		
Training and coaching of technologists and physicians	12	1.5
 Education of medical staff (2.5 h per year) Education of physicians (2.5 h per year) Topics of the education/training/coaching: Dose determining factors Image quality Diagnostic reference levels DRLs Optimization of patient doses (protocols) Optimization of staff doses Continuous education Preparation of the education concept and the documentation 		

Fluoroscopy – Category A

Hours	Days
4	0.5
11	1.4
12	1.5
	4 11

- Preparation of the education concept and the documentation

Fluoroscopy – Category B

Торіс	Hours	Days
QA relating to patient dose	1	0.125
 QA measurements related to patient dose Phantom measurements, radiation measurements 		
Verification and optimization of patient and staff dose	1	0.125
 Analysis of patient dose measurements Discussion with physicians on optimization methods Optimization of patient doses (protocols) Analysis of staff dose measurements Discussion with physician/staff on optimization methods Optimization of staff doses 		
Training and coaching of staff and physicians	6	0.75
 Education of medical staff (1 h per year) Education of physicians (1 h per year) Topics of the education/training/coaching: Dose determining factors Optimization of patient doses (protocols) Optimization of staff doses Continuous education 		

- Preparation of the education concept and the documentation

Gamma camera

Торіс	Hours	Days
QA relating to patient dose	4	0.5
 QA measurements related to patient dose Phantom measurements, radiation measurements 		
Verification and optimization of patient and staff dose	4	0.5
 Analysis of patient dose measurements Comparison of doses to DRLs Discussion with physicians on optimization methods Optimization of patient doses (protocols) Analysis of staff dose measurements Discussion with physician/staff on optimization methods Optimization of staff doses 		
Training and coaching of technologists and physicians	12	1.5
 Education of medical staff (2.5 h per year) Education of physicians (2.5 h per year) Topics of the education/training/coaching: Dose determining factors Image quality Diagnostic reference levels DRLs Optimization of patient doses (protocols) Optimization of staff doses Continuous education Preparation of the education concept and the documentation 		

PET

Торіс	Hours	Days
QA relating to patient dose	4	0.5
 QA measurements related to patient dose Phantom measurements, radiation measurements 		
Verification and optimization of patient and staff dose	6	0.75
 Analysis of patient dose measurements Comparison of doses to DRLs Discussion with physicians on optimization methods Optimization of patient doses (protocols) Analysis of staff dose measurements Discussion with physician/staff on optimization methods Optimization of staff doses 		
Training and coaching of technologists and physicians	12	1.5
 Education of medical staff (2.5 h per year) Education of physicians (2.5 h per year) Topics of the education/training/coaching: Dose determining factors Image quality Diagnostic reference levels DRLs Optimization of patient doses (protocols) Optimization of staff doses Continuous education Preparation of the education concept and the documentation 		