

AUTHORISATION AND COMPETENCE REGARDING MEDICAL EXPOSURE

PURPOSE

The purpose of this internal procedure is to offer a further elaboration of the *Radiation Protection Act* (Dutch: '*Besluit basisveiligheidsnormen stralingsbescherming*' or *Bbs*) in terms of medical radiological procedures, in accordance with the provisions stated in the *Individual Healthcare Professions Act*, or *BIG Act* (Dutch: '*Wet op de Beroepen in de individuele gezondheidszorg*' or *Wet BIG*).

INTRODUCTION

The purpose of the *BIG Act* is to promote and monitor the quality in healthcare and protect the care recipient against incompetent and negligent practices.

The *BIG Act* contains a system of registration and title protection. For professions listed under section 3, the right is given to use a protected professional title by enlisting in a registry, which is administered by the Minister of Health, Welfare and Sports (Dutch: '*Volksgesondheid, Welzijn en Sport*' or *VWS*). For professions listed under section 34, the right is given to use a protected academic title through designation by Order in Council ('*Algemene Maatregel van Bestuur*' or *AMvB*). Education requirements and area of competence are defined of all the professions regulated by the *BIG Act*. These can be found in the education requirements act ('*Besluit opleidingseisen*') in the *AMvB*.

Physicians and dentists have an independent authorisation, based on the *BIG Act*, section 3. If they are competent, they are permitted to make an assessment and perform a reserved practice on their own authority. Under certain circumstances they are allowed (as mandator) to order a non-independent, authorised person (mandatary; section 34) to perform a reserved practice. This practice, however, has to lie within the area of competence described in the *BIG Act*.

Reserved practices are medical procedures that carry unacceptable risks for the patient's health if someone incompetent performs them. For these so-called reserved practices an authorisation regulation applies, which can be found in the *BIG Act*. Among these reserved practices are practices in the area of individual healthcare, using radioactive substances or devices that emit ionising radiation.

These practices may exclusively be performed by, or under the authority of, physicians and dentists. Also, an additional requirement is set for the level of expertise of the physicians and dentists as well as the mandataries (see conditions and responsibilities), with regards to the subject of radiation safety. The corresponding section 34 professions that by order, but without supervision or intervention, are permitted to perform these reserved practices are radiodiagnostic and radiotherapeutic technicians.

INVOLVED PROFESSIONAL GROUPS

Within the institutions participating in the Complex License Randwyck, the following professional groups are involved in (reserved) practices using radioactive substances or devices that emit ionising radiation:

1. physicians independently performing medical radiological procedures;
2. physicians ordering to perform medical radiological procedures;
3. employees performing medical radiological procedures by order.

Below the conditions and responsibilities that are attached to performing, ordering to perform, or by order performing medical radiological procedures, are presented.

CONDITIONS AND RESPONSIBILITIES OF PERFORMING MEDICAL RADIOLOGICAL (RESERVED) PROCEDURES

Within the *BIG Act* as well as the *Bbs* and related legislation, conditions are stated when performing practices with radioactive substances or devices that emit ionising radiation.

The conditions and corresponding responsibilities for each appointed professional group are:

Ad 1: Physicians independently performing medical radiological procedures

Conditions / legal framework / internal policy

- the physician is registered in the BIG register (*authorised*);
- the physician has the competence to properly perform medical radiological procedures (*competent*);
- the physician has the required radiation safety expertise (*expert*);
- the physician assesses the justification of medical radiological procedures, where necessary in consultation with the requesting or referring physician;
- the physician conforms to the internal policy of the department at which he works, which possibly sets additional conditions to performing medical radiological procedures (see table at end of document).

Responsibilities

- the physician ensures that his level of expertise regarding radiation safety (which education and when achieved) is registered in the established internal register of the management of the institute;
- the physician ensures, if not or insufficiently authorised, competent and/or expert, that the procedures are performed by or under the responsibility of a physician who is.

Ad 2: Physicians ordering to perform medical radiological practices

Conditions / legal framework / internal policy

- the physician, insofar it is reasonably necessary, gives directions to the mandatary, and ensures that supervision and intervention is guaranteed;
- the physician has to be able to reasonably assume that the mandatary has the competence to properly perform the medical radiological procedures; for this the physician may reasonably assume that the mandatary is competent if he has been educated in accordance with *section 34* of the *BIG Act*; in the setting of the Complex License Randwyck this applies to radiodiagnostic and radiotherapeutic technicians;
- the physician has to be able to reasonably assume that the mandatary has the required expertise in the field of radiation safety.

Responsibilities

- the physician at any time stays medically responsible for the medical radiological practices which are performed by others by his order.

Ad 3: Employees performing medical radiological procedures by order

Conditions / legal framework / internal policy

- the medical radiological procedures may be performed by order if the mandator is independently authorised to perform these practices, i.e. that he is:
 - registered in the BIG register,
 - competent to properly perform the medical radiological procedures,
 - has the required radiation safety expertise;
- the mandatary has the competence and expertise which is required to properly execute the order; this is the case for the radiodiagnostic and radiotherapeutic technicians.

Responsibilities

- the mandatary checks if an order is given by a physician who is registered in the BIG register; in case of doubt he reports this to the radiation protection officer ('toezichthoudend medewerker stralingsbescherming' or TMS) or coordinating expert ('coördinerend deskundige' or CD) of the institute, or to the employer;
- the mandatary follows the (possible) directions of the mandator;
- the mandatary ensures that directions are asked where necessary, and ascertains that supervision is present and possible intervention is guaranteed.

MANDATORY (LOCAL) PROCEDURES

To ensure proper application of legal provisions, additional procedures and/or protocols are to be established at the departments, concerning at least the following aspects:

Ordering to perform a medical radiological procedure

The physician or dentist makes the assessment to perform a medical radiological procedure. He can either perform this reserved practice himself, or order another professional to do so. Assignment of orders has to be established within the institute in an additional local procedure or protocol, in such a way that the conditions stated in this procedure, 'Authorization and competence regarding medical exposure', are met.

Directions, supervision and intervention

When a physician or dentist gives an order to perform a medical radiological procedure, he has to be able to offer directions, if this is reasonably necessary.

Furthermore, supervision and intervention need to be ensured if either the mandator or mandatory requires this. Supervision and intervention are defined as:

- the possibility to monitor the procedure and
- the capability to take action.

The level of supervision and intervention by the physician is determined by the possible complications and the complexity of the medical radiological procedure. This implies that the mandatory has to request directions, or a stricter form of supervision and intervention, if exceptional circumstances call for it.

EXPERTISE REQUIREMENTS MEDICAL SPECIALISTS AND RADIOTHERAPEUTIC AND RADIODIAGNOSTIC TECHNICIANS

Table 1 below shows the legal requirements for radiation safety expertise which, in accordance with the *Nuclear Energy Act ('Kernenergiewet')*, are an additional requirement in addition to the provisions in the *BIG Act*.

Table 1: *Stralingshygiënische deskundigheidseisen volgens Kernenergiewet (als aanvulling op bepalingen in Wet BIG)*

Specialism	Radiation safety expertise ¹
Radiation-oncologist	Radiation safety for radiation-oncologists
Nuclear Radiologist	Radiation safety for nuclear radiologists
Radiologist	Radiation safety for radiologists
Medical specialist (other)	Radiation safety for medical specialists that use X-ray devices
Dentist/dental surgeon	Radiation protection officer for dentistry
Dentist/dental surgeon (CBCT)	Radiation protection officer for dentistry and CBCT
Radiotherapeutic technician (X-ray)	Radiation protection officer for accelerators C
Radiotherapeutic technician (open source)	Radiation protection for accelerators C / radiation protection officer dispersible radioactive materials C
Radiodiagnostic technician (X-ray)	Radiation protection officer – medical practices
Radiodiagnostic technician (open source)	Radiation protection officer – medical practices / radiation safety officer dispersible radioactive materials C

Further information about Table 1:

Several job profiles can be described for the technicians working within the institutes that participate in the complex license Randwyck. For instance, radiodiagnostic technicians may solely be involved with the use of X-ray devices, while their colleagues also may be in contact with radioactive sources in dispersible form. The same situation may be at hand in the radiotherapeutic field.

For this reason, several levels of radiation safety expertise may be required, to ensure that technicians have sufficient knowledge and skills in the field they are involved in.

¹ In accordance with the education requirements for the respective courses, as included in the 'Rbs'.

EXECUTION OF MEDICAL-RADIOLOGICAL PROCEDURES WITHIN THE INSTITUTES OF THE COMPLEX LICENSE RANDWYCK

Table 2: Execution of medical-radiological procedures within the institutes of the Complex License Randwyck

Medical radiological procedure as part of:	Application	Type of source	Mandator/executor	Mandatory	Additional conditions
Medical diagnostics ²	Diagnostics conventional radiology	X-ray equipment	Radiologist	Radiodiagnostic technician	
	Diagnostics OMS surgery	X-ray equipment	Dentist	Dental assistant	Dentist educated at level 4 for use of CBCT
	Cardiologic intervention	X-ray equipment	Cardiologist		
	Hybrid procedures	X-ray equipment	Cardiologist, Radiologist, Surgeon		
	Simulation as part of radiotherapy	X-ray equipment (possibly PET-CT)	Radiotherapist-oncologist	Radiotherapeutic technician	
	Diagnostics nuclear medicine	Open radioactive substances	Nuclear physician	Radiodiagnostic technician	
Medical therapy	Nuclear medicine	Open radioactive substances	Nuclear physician		By way of exception execution by radiodiagnostic technician in presence of medical specialist with radiation safety expertise level 3
	Brachytherapy	Sealed source/HDR	Radiotherapist-oncologist	Radiotherapeutic technician	
	Brachytherapy	Sealed source	Urologist, Radiotherapist-oncologist		Execution in presence of clinical physicist; radiotherapeutic technician assists
	Radiotherapy	Linear accelerator	Radiotherapist-oncologist	Radiotherapeutic technician	

² The medical diagnostic procedures listed here are not complete, but exemplary for the situations applicable within the Complex License Randwyck. All situations, in which medical diagnostics are performed using sources of ionising radiation, have been discussed with and assessed by the CD and/or SBE beforehand, in agreement with the medical committee(s).

LIST OF ABBREVIATIONS

Dutch		English	
AMvB	Algemene Maatregel van Bestuur	-	-
Bbs	Besluit basisveiligheidsnormen stralingsbescherming	-	-
CBCT	cone beam computed tomography	-	cone beam computed tomography
CD	coördinerend deskundige	-	coordinating expert
CT	computed tomography	-	computed tomography
HDR-brachytherapie	high-dose-rate brachytherapie	HDR brachytherapy	high-dose-rate brachytherapy
MBB	medisch beeldvormings- en bestralingsdeskundige (radiotherapeutisch/-diagnostisch laborant)	-	radiodiagnostic/-therapeutic technician
MKA-chirurgie	mond-, kaak- en aangezichts chirurgie	OMS surgery	oral and maxillofacial surgery
PET	positron emission tomography	-	positron emission tomography
SBE	stralingsbeschermingseenheid	RPU	radiation protection unit
TMS	toezichthoudend medewerker stralingsbescherming	RPO	radiation protection officer
TMS-MT	toezichthoudend medewerker stralingsbescherming – medische toepassingen	-	radiation protection officer – medical practices
TMS-VRS C	toezichthoudend medewerker stralingsbescherming – verspreidbare radioactieve stoffen niveau C	-	radiation protection officer – dispersible radioactive materials level C
VWS	Ministerie van Volksgezondheid, Welzijn en Sport	-	Ministry of Health, Welfare and Sport
Wet BIG	Wet op de Beroepen in de individuele gezondheidszorg	BIG Act	Individual Healthcare Professions Act

REFERENCES

- Besluit basisveiligheidsnormen stralingsbescherming: <https://wetten.overheid.nl/BWBR0040179/2018-07-01>
- Wet op de Beroepen in de individuele gezondheidszorg: <https://wetten.overheid.nl/BWBR0006251/2020-03-19>