DNV·GL

CLINICAL RADIOCHEMIST

APPROVED VERSION

REVISION NO. 9

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1 INTRODUCTION

1.1 Purpose & Scope

This competence standard was developed to capture the fundamental competencies of Clinical Radiochemists. The standard focuses on the activities related to the development and production of non-registered radiopharmaceuticals.

In order to fill the gap in the quality assurance chain of the manufacture and applicaton of radiopharmaceuticals in nuclear medicine, the clinical radiochemist has an important specific knowledge in the process of the manufacture of radiopharmaceuticals. He carries certain responsibilities for the quality management of radiopharmaceutical production, within the overall responsibilities of the QP.

The standard can be used:

- as a reference for global competence and training requirements
- as a reference document for e.g. certification of personnel
- as a guide to educators, who are to develop courses according to the requirements of the standard and needs of the industry.
- as a reference to familiarise people

1.2 Professional profile

The Clinical Radiochemist is the focal point for design & development of non-registered radiopharmaceuticals as an answer to clinical questions/challenges.
He (where ever there is 'he' written, one could also read 'she') is the expert with respect to radiochemistry and laboratory operations within the process of radiopharmaceutical productions
He supports patient care, research and education.

The clinical radiochemist is a team player and he is an equal partner to other specialists, providing advise to physicians, pharmacologists, pharmacists, biologists, and physicists . He bears a responsibility in GMP-production, related to design, quality control and reliability of production processes and may act as Head of Production or Head of Quality Control.

In order to meet the competencies required, the Clinical Radiochemist possesses competencies in the following areas:

- radiochemistry, (in)organic chemistry, analytic chemistry, nuclear physics
- process technology (automation of synthesis processes)
- quality control, quality assessment, GMP, GCP
- health and safety (radioactivity, chemical hazards, ergonomics, etc)
- medical physics related to measuring of radioactivity
- molecular biology, clinical applications of medical imaging

The required level of competence is determined by the Table of Competence.

The Clinical Radiochemist is up to date on current technology and processes, monitors future developments related to his field of expertise and is able to transfer knowledge & skills related to clinical radiochemistry to various target groups.

He participates in organisations and networks and promotes the field of radiochemistry and radiopharmacy in a stimulating manner.
The Clinical Radiochemist is a trustworthy and responsible professional, working in a professional and ethical manner (efficient, verifiable) in accordance with prevailing rules, regulations, values and scientific integrity, considering professional interest above personal gain.

1.3 Portfolio requirements initial certification

As part of competence development and demonstrating actuality of competence the Clinical Radiochemist is expected to maintain expertise through post-education and recognised accreditation and to build up and maintain a portfolio containing:

1.	**Evidence of compliance with educational requirements:** (mandatory)
a.	*Academic education in pharmaceutical sciences, (in)organic chemistry, preferably radio-chemistry, at least master level.*
b.	*Certificate of GMP course*
c.	*Diploma Radiation safety*
2.	**expertise in tracer development and manufacture** (**one** of the following should be handed over to prove expertise)
a.	*PhD or MSc thesis related to tracer development*
b.	*invited lectures*
c.	*publication as first or last author related to tracer development*
d.	*contributions to scientific meetings*
e.	*scientific publications related to multidisciplinary research*

1.4 Portfolio requirements re-certification

1.	**Evidence of compliance with educational requirements:** **(mandatory)**
a.	*Evidence of retraining in advanced GMP*
b.	*Evidence of retraining in Radiation safety - for the Netherlands level 3*
2.	**Continuous Professional Development (CPD)** (mandatory)
a.	*Proof of personal education / development, including clincical radiochemistry related congress/workshops/courses certificate (CME accreditation etc)* *Half a day of a congress/workshops/courses equals 1 point* *invited lectures equals 3 points* *contributions to scientific meetings equals 2 points* *publication as (co-)author related to tracer development or multidisciplinary research equals 2 points* *in total 15 points are required in a period of 3 years*

1.5 Classification

Classification of the required professional behaviour specifies the level on which the person should be able to function. Classification of the required professional behaviour is a hierarchical arrangement, in four (4) levels, of what a person has to master from simple to complex requirements based on Bloom's taxonomy (i.e. Bloom, B. S. et al.(1956) Taxonomy of Educational Objectives – The Cognitive Domain). For every next level, it is a prerequisite that the preceding level is mastered.
The required professional behaviour is expressed by means of a verb.

Level 1: Knowledge (K)
To remember or to reproduce on basis of appropriate, previously learned information.

Level 2: Understanding (U)
To give meaning to new situations and or new material by recollection and using necessary present information. To give evidence of insight in certain activities. Called comprehension by Bloom.

Level 3: Application (A)
To use previously acquired information in new and concrete situations to solve problems that have single or best answers.

Level 4: Integration (I)
To separate information into their component parts, to examine such information to develop divergent conclusions by identifying motives or causes, making inferences, and or finding evidence to support generalizations. To creatively apply prior knowledge and skills to produce a new or original whole. To judge the value of material based on personal values or opinions, resulting in an end product, with a given purpose, without real right or wrong answers. Called analysis, synthesis and evaluation by Bloom.

2 COMPETENCE REQUIREMENTS

Each competence requirement is either a task or is derived from a task that needs to be performed.
The competence requirement is stated in objective format to clearly define what has to be done to satisfy the requirements of the competence.
At the same time it facilitates the derivation of assessment criteria and the assessments to measure individual competencies.

Each competence requirement is allocated a level of cognition that can be used to determine the type of assessment required to measure competence. The competence requirements for this operation require both theoretical knowledge, intellectual and physical skills.

The total levels of competences should meet a required basic knowledge to be able to operate as clinical radiochemist.

Competence Requirements

Column 1 shows the ID for the competence
Column 2 defines the expected competence
Column 3 defines the level of cognition (Knowledge, Understanding, Application or Integration)

1	2	3
1	**Development of radiopharmaceutical processes**	
1.1	Is able to design a laboratory, considering all aspects incl. GMP, in cooperation with the hospital pharmacist	A

Competence Requirements

Column 1 shows the ID for the competence
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1.2	Defines criteria, together with stakeholders for the radiopharmaceutical to be developed or implemented	A
1.3	Provides input for a development plan in cooperation with other specialists	A
1.4	Is able to design and develop high quality, robust manufacturing to meet product specifications as agreed with the pharmacist	A
1.5	Defines requirements for the production of radiopharmaceuticals	U
1.6	Designs QC protocols	U
1.7	Develops new QC methods	A
1.8	Defines criteria for qualifying / validating a location, equipment and necessary resources documented in a validation master plan	A
1.9	Develops new validation protocols	U
2	**Implementation of radiopharmaceutical processes**	
2.1	Selects a radiopharmaceutical based on a literature survey, to solve a clinical problem	A
2.2	Supports development and implementation of and acts in accordance with the Quality Management System	U
2.3	Knows principles of Good Clinical Practice (GCP) guidelines	K
2.4	Adapts manufacturing processes to meet GMP requirements.	A
2.5	Determines appropriateness of rooms/areas, persons and equipment	U
2.6	Describes and validates a radiochemical manufacturing process from bench to routine production	A
2.7	Is able to perform QC implementation and validation	A
2.8	Implements new techniques and developments in the production process	A
2.9	Is aware of the possibilities and limitations of automation technologies available for the development of a new process	A
2.10	Translates manual or semi-automated R&D processes to fully automated, GMP compliant processes considering the limitations and possibilities of automation equipment	A
3	**Execution of processes**	
3.1	Ensures compliance of the processes with Good Manufacturing Practice (GMP) guidelines related to clinical application of (radio)pharmaceuticals	A
3.2	Provides support input to validation processes by responsible person	A
3.4	Is able to effectively transfer expertise to radiochemical / radiopharmaceutical laboratory	A
3.5	Validates new production and QC methods	A
4	**Quality assurance of a radiopharmaceutical process**	
4.1	Performs validations according to applicable protocols	U
4.2	Demonstrates continuous improvement techniques during process reviews	A
4.3	Has knowledge of quality risk management	U
4.4	Performs QC follow up like trending, audit, improvement	U
4.5	Performs follow-up and trouble-shooting of productions	A
4.6	Assures the quality of radionuclide precursors	A
5	**Scientific skills**	
5.1	Describes and publishes findings related to newly developed techniques	A
5.2	Understands the criteria for the development of new radiopharmaceuticals	U
5.3	Understands research processes aimed at developing a specific radiopharmaceutical	U
5.4	Reads and understands scientific reports and presentations	A
5.5	Develops learning programs for different target groups, with objectives for specific learning programmes	A

Competence Requirements		
Column 1 shows the ID for the competence Column 2 defines the expected competence Column 3 defines the level of cognition (Knowledge, Understanding, Application or Integration)		
5.6	Delivers a learning program in a structured way	U
5.7	Assesses result of the learning program	A
5.8	Contributes to the preclinical or clinical evaluation of the effectiveness of radiopharmaceuticals	K
5.9	Has knowledge of relevant legislation	U
5.10	Has basic knowledge of Nuclear Medicine	K
5.11	Has basic knowledge of translational medicine.	K
5.12	Knows about the creation and impact of clinical trials	U
6	**Continuing education**	
6.1	Attends (International) conferences, lectures etc.	U
6.2	Follows new developments for R&D, production and QC	A
7	**Attitude and Communication**	
7.1	Manages radiochemical and radiopharmaceutical staff	U
7.2	Shows project management skills	U
7.3	Gives presentations / provide information related to the area of expertise	U
7.4	Communicates effectively (hospital pharmacists, clinical staff, production staff and other parties involved	A
7.5	Consults with other professionals related to the development of a radiopharmaceutical	A
7.6	Has management skills.. Diploma of e.g. management course. Also simulation or interview to determine the attitude and communicative skills.	U

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