A New Profession: Clinical Radiochemist

Towards excellence in nuclear medicine

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Abstract

Elsinga PH, Läppchen T, Laverman P, Windhorst AD, Wolterbeek B. A New Profession: Clinical Radiochemist. In this opinion paper, we describe our motivations to support the development of the new specialisation "Clinical Radiochemist". This ambitious development falls under the umbrella of the Dutch Society of Clinical Radiochemistry (NKRV).
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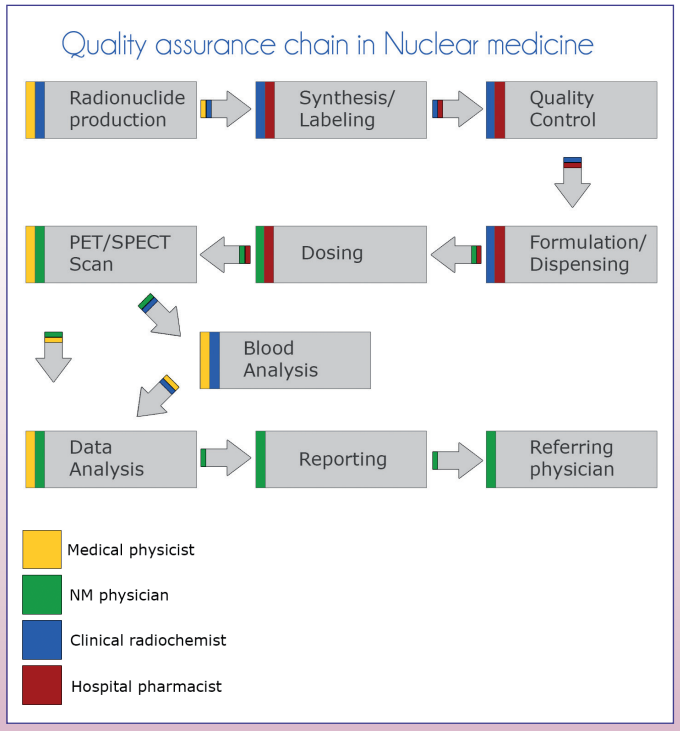
'Nuclear Medicine and Molecular Imaging' requires cooperation of a multidisciplinary team of professionals who have complementary expertise resulting in synergy in research, patient care and education. Most disciplines within nuclear medicine are well organised in the Netherlands. Expert organisations of nuclear medicine physicians, medical physicists and hospital pharmacists conserved their responsibilities and concomitant education in Dutch legislation. Several procedures in relation to professional competences including responsibilities and Quality Assurance have been documented. Examples are education requirements, evaluations, audits, examination and continuing education. Currently, there is no legal status for the radiochemist in the field of nuclear medicine.
It is expected that the need for highly trained radiochemists will increase in the near future since molecular imaging is expanding and the diversity in radiopharmaceuticals and their application will further increase. To optimally ensure high standards in the disciplines related to production and development of radiopharmaceuticals, there is an urgent need to launch the specialisation of the Clinical Radiochemist. The profession of Clinical Radiochemist should combine three core competences in the field of radiochemistry: science, patient care and education.

Establishment of an education program for Clinical Radiochemists will boost the quality of tracer development. Availability of novel radiopharmaceuticals is one of the driving forces to further develop molecular imaging and nuclear medicine in particular.

The Hospital Pharmacist is legally responsible for the quality of the production process. The implementation and production of radiopharmaceuticals for clinical use is performed in close collaboration with the Clinical Radiochemist. The combined expertise and shared responsibilities should have a positive effect on the total quality management of radiopharmaceuticals in nuclear medicine. The Clinical Radiochemist has expertise of the production process whereas the Hospital Pharmacist is trained to ensure a safe product for the patient. Synergy between Hospital Pharmacist and Clinical Radiochemist will ensure optimal quality of the production process from development to clinical use.



To realise these goals, the Dutch Society of Clinical Radiochemistry (NKRV) will introduce the specialisation Clinical Radiochemist in combination with the required education program. The NKRV has developed a competence standard with an installed Certification Committee, in collaboration with Det Norske Veritas (DNV), a company specialised in certifications. This competence standard was developed to attain the fundamental competencies of the Clinical Radiochemist. The standard focuses on activities related to the development and production of non-registered radiopharmaceuticals.

The competence 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 on the aspects related to Clinical Radiochemist

The competence standard includes the following definitions: "The Clinical Radiochemist is primarily responsible for design & development of non-registered radiopharmaceuticals as an answer to clinical questions and challenges. The Clinical Radiochemist is the expert with respect to radiochemistry and laboratory operations within the process of radiopharmaceutical productions. He or she supports patient care, research and education.

The clinical radiochemist is a team player and is an equal partner of other specialists, providing advice to physicians, pharmacologists, pharmacists, biologists and physicists. He or she 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 required competencies, the Clinical Radiochemist possesses competences 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 radioactivity
- clinical applications of medical imaging
- molecular biology

The Clinical Radiochemist is aware of state-of-the-art 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, such as the several disciplines within nuclear medicine or Regulatory bodies. The Clinical Radiochemist 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.

In 2014, the first certificates for Clinical Radiochemists will be issued. This will be a major step forward in improving the quality chain in nuclear medicine and will boost efforts to improve the development of new radiopharmaceuticals for clinical use."