EUROPEAN RADIOECOLOGY ALLIANCE

ALLIANCE Webinar / 2nd June 2022 – 9:30-16:30

Assessing impact of production, use and disposal of radiopharmaceuticals on members of public and the environment

Abstract

Ongoing developments in the medical field have resulted in an expansion of the use of radioactive isotopes for diagnostic and therapeutic purposes (radiopharmaceuticals). This has led to a demand for an increasing range of radionuclides (e.g. ^{177}Lu and the α-emitting isotopes ^{223}Ra and ^{227}Th). Increasing production and use of radiopharmaceuticals lead to additional radionuclide releases into the environment. From the regulatory perspective (e.g. during approval of radiopharmaceuticals by the European Medicines Agency or marketing authorisation at national level) the impact on members of the public has to be assessed and compliance with dose limits has to be demonstrated.

During normal operation of production facilities and as a result of routine clinical application, medical radionuclides reach the environment as authorized releases with air and authorized discharges with water. The need for production and medical facilities to monitor and assess the impact of their releases may not be equally mandatory in all European countries. In some countries, facilities may be exempted from regulatory control of activities released if dose limits are not exceeded (e.g. in Belgium releases and expected dose to public is reported by FANC). Also, there are requirements to prove that such radionuclides do not significantly affect the quality of drinking water or have only a negligible impact on people and the environment in other ways.

Incidental releases from either radiopharmaceutical or medical radionuclide production plants have occurred in Europe (e.g. Masson et al., 2018). In the future, new medical radioisotopes and production routes (such as ^{225}Ac production from ^{226}Ra targets) may potentially be involved.

After the application of radiopharmaceuticals, radionuclides leave the patient's body via excretion. In hospitals, the radioactive excretions during inpatient treatment are usually collected in dedicated sewage tankers and discharged in a controlled way. Outpatient treatment, on the other hand, results in radionuclides leaving the patient's body and entering the municipal sewage system. Additional releases may occur if patients die during or shortly after the medical therapy and their bodies are cremated.

Information on the production of radionuclides and radiopharmaceuticals, the type of medical application and the activities involved as well as the remaining radioactive residues need to be known for selecting sound modelling approaches, for using robust parameters as well as for adopting an adequate mathematical representation.

Overall, impact assessments for authorized and accidental releases during radionuclide production, as well as for diagnostic and therapeutic applications are not abundant, and few data are available for validating assessment models. There is growing interest of international organisations such as the EU and the OSPAR commission in this topic, and in several member states there is a growing demand for a more transparent assessment of releases of medical radioisotopes.

The main challenges in hazard characterisation from radioecological perspective of radionuclides used for medical purposes may be missing data, for example terrestrial and freshwater transfer parameter values (CR, K_d, $T_{B1/2}$), sludge/treated water partition in Waste Water Treatment Plants for radionuclides uncommon in current databases (e.g. ^{225}Ac), either because they are part of new medical applications or because of the different physico-chemical form for medical purposes compared to applications in industry and science.

Exposure pathways that may need to be considered are the transfer of radionuclides to land (through sewage sludge incineration, application of sewage sludge in agricultural fields or use of irrigation waters downstream of the wastewater treatment plant) as well as airborne emissions from radioisotope production facilities.

Issues related to generation of large amounts of radioactive waste due to medical radionuclide production include, for example, the irradiated uranium targets for Mo-99 production. The presence of nominal levels (detection limits) of long-lived impurities in radiopharmaceuticals may complicate the clearance procedure of waste following radiopharmaceuticals' application.

At the beginning of the webinar, the state of the art of application of medical radionuclides for purpose of diagnostic and therapy will be presented together with possible future developments.

A discussion on the role of radioecology, use of radioecological models and challenges of assessing the environmental impact of medical radionuclides will conclude the webinar.

Purpose of webinar: The webinar aims at gathering information including insight experiences from regulators, producers of radiopharmaceuticals and experts in the field of nuclear medicine necessary to carry out dose assessments for members of public and non-human-biota.

References:

(Masson et al., 2018) Potential source Apportionment and Metereological conditions Involved in Airborne I-131 Detections in January/February 2017 in Europe. Environ. Sci. Technology 2018 Aug. 7, 52(15): 8488-8500.

ORGANISER: BfS (lead), SCK CEN and CIEMAT

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