ENSREG WG2 survey on the management of radioactive waste from medical applications of ionising radiation

Analysis of answers to a questionnaire conducted in ENSREG WG2 in 2021-22

Final Report

Background

Radioactive waste from non-power uses of nuclear and radiation technology may result from e.g. industrial, research, educational, medical, agricultural and environmental applications. Sources of such waste can include laboratory and university research activities, industrial applications involving both sealed and unsealed sources, and applications in nuclear medicine as well as radioactive waste generated from operation and decommissioning of production facilities associated with such activities.

The operational waste from this broad spectrum of applications and activities may result in waste streams with widely different physical (e.g. volume, chemical form, mixed waste) and radiological (e.g. activity, half-life, concentration) characteristics. In accordance with national provisions, the radioactive waste may follow different processes of treatment, transfer, storage, including storage with a view to decay and clearance, and disposal.

Depending on national circumstances, the volumes, masses and radiological characteristics of radioactive waste in various waste streams may vary according to origin. Operational waste from industrial, research, educational, medical, agricultural and environmental applications may in general be expected to be characterised by moderate volumes compared to radioactive waste resulting from decommissioning of production facilities such as research reactors, cyclotron facilities and particle therapy facilities.

In 2019, the Council of the EU adopted conclusions on waste management in non-energy uses of nuclear technologies, following a workshop co-organised by the European Commission and the Finnish Presidency of the Council.

In this context an ENSREG position on best practices in national management systems for radioactive waste generated from non-power use of nuclear and radiation technology has been envisaged.

In February 2021, the European Commission published a Strategic Agenda for Medical Ionising Radiation Applications (SAMIRA), as a deliverable of Europe's Beating Cancer Action Plan beginning of 2021. SAMIRA is a comprehensive plan of action to support a safe, high quality and reliable use of radiological and nuclear technologies in healthcare that paves the way for future coordinated EU action in this field.

Objectives and scope

ENSREG decided to launch a review study of regulatory requirements and management practices for radioactive waste generated from non-power use of nuclear and radiation technology applied in MS. Taking into consideration the SAMIRA action plan, the review was focussed on approaches in regulation and management of radioactive waste arising from medical applications. In this framework, the study examined how radioactive waste generated by the medical sector is managed in various MS, and how the outcomes can aid in identifying the potential for enhancing the safety of management of radioactive waste in the medical sector.

The ENSREG WG2 was tasked with the coordination and conduct of the study. To perform the above-mentioned review a specific questionnaire (below) with regard to the management of medical waste was developed.

The following report presents the results of MS responses to this questionnaire.

Questionnaire

The questionnaire is comprised of three (**A-C**) sections with 13 questions in total. In this section of the report, each question is presented along with examples or other information provided to the respondents to clarify the question.

A. Description of the legal and organisational framework with regard to radioactive waste arising from nuclear medicine application

A.1 Please explain how management of radioactive waste arising from nuclear medicine application is included in the national provisions for management of radioactive waste, as described in the national programme (Council directive 2011/70/Euratom).

(Example of the expected answer: The management of radioactive waste arising from nuclear medicine applications constitutes a separate management route/is fully integrated in the management route for radioactive waste generated from nuclear power production/ other).

A.2 Please specify the legal framework for the management of radioactive waste arising from nuclear medicine applications.

(*Example of the expected answer: The management of radioactive waste arising from nuclear medicine applications is regulated though Act X, decree Y, regulation Z.)*

A.3 Are these provisions part of the legal framework for nuclear energy production or other (non-energy) nuclear activities?

(*Example of the expected answer: In MS, the provisions for management of radioactive waste arising from nuclear medicine applications are part of the legal framework for all nuclear/non-nuclear activities/specific requirements, as specified in ….)*

A.4 Are there specific legal provisions for management of radioactive waste from decommissioning following termination of an application (e.g. decommissioning of research reactors, cyclotrons, particle therapy facilities, etc.
(*Example of the expected answer: Management of radioactive waste from decommissioning following termination of an application is regulated by the same/specific/case-by-case provisions…*)

A.4 What are the legal provisions to ensure financing of the costs associated with management of radioactive waste arising from nuclear medicine application?

(Example of the expected answer: Act X specifies "polluter pays principle, assigning responsibility for ensuring financing of radioactive waste management, including disposal, to license holder, through internal allocation of funds/payment to state fund/other).

A.5 Please describe the roles and responsibilities, as applicable, related to radioactive waste management of medical waste with respect to:

- **Licensees**
- **Regulatory authority(ies)**
- **Organisation(s) responsible for radioactive waste management**

B. Characteristics of radioactive waste arising from nuclear medicine application. Specifics of the managements of this type of waste

B.1 Do you have specific radioactive waste management steps for radioactive waste arising from nuclear medicine application? Yes/No

If yes, please describe these steps.

B.2 Do you have specific categories for the medical radioactive waste in your waste classification system? Yes/ No

- If yes, describe these categories.
- If no, describe under which waste categories this waste is classified

B.3 Do you specify in the national inventory the radioactive waste radioactive waste arising from nuclear medicine application? Yes/No

- If yes, please explain the information recorded in the inventory of radioactive waste arising from nuclear medicine application

B.4 How are the waste streams from decommissioning following termination of a medical application managed in your country? For each of these waste streams please describe existing radioactive waste management solution(s) including disposal if available.

- Please specify if the following is applied
    - Decay storage
    - Free release
    - Conditional release

  If yes, specify the conditions for application of the above.

C. Particular issues and difficulties with regard to the management of radioactive waste arising from nuclear medicine application

C.1 Do you have waste streams i.e. for which you have currently no waste management solution? Yes/No

- If yes, please specify why and describe these type of the waste streams.

C.2 In case problematic medical waste streams exist in your country, what is the specific difficulty and how are the current solutions applied for its safe management and storage?

C.3 Do you any difficulties/challenges with regard to the operational management of the radioactive medical waste? Yes/No

- If yes, please, specify what they are.

C.4 Do you any difficulties/challenges with regard to the legislation aspect of the management of the radioactive medical waste? Yes/No

- If yes, please, specify what they are.

Summary of responses

In total 27 MS (12 MS with no nuclear power stations ("non-nuclear" countries) and 15 MS with nuclear power stations ("nuclear" countries)) responded to the questionnaire.

Section A of the questionnaire is related to the legal and organisational framework with regard to radioactive waste arising from nuclear medicine application in participating MS.

Question A1 seeks to compare how the management of radioactive waste arising from the nuclear medicine applications is included in the national provisions for management of radioactive waste. The responses to this question show that the management of radioactive waste arising from nuclear medicine applications is fully integrated in the national provisions for management of radioactive waste and are as such included in the national programme. Several MS (Belgium, Cyprus, Finland, Greece, Italy, Latvia, Lithuania, Luxembourg, Portugal, Netherlands) make specific reference to the use of decay storage as part of the management provisions for this type of radioactive waste. Two MS (Estonia, Romania) report that radioactive waste arising from nuclear medicine application is included in the national provisions for management of radioactive waste, but is managed according to distinct regulatory and management provisions. In "nuclear countries", the management system for radioactive waste originating from non-nuclear activities is at some stage in the management chain integrated in the management system for radioactive waste originating from nuclear activities.

Question A2 asks each respondent to specify the legal framework for the management of radioactive waste arising from nuclear medicine applications. Overall, the survey showed that "nuclear" and "non-nuclear" countries all have legal provisions and systems for management of radioactive waste arising from nuclear medicine applications.

Question A3 asks each participating country whether the above mentioned provisions are part of the legal framework for nuclear energy production or other (non-energy) nuclear activities. The analyses of the survey showed that the responses to these questions were divided as expected, i.e. these responses seem to reflect some general differences between "nuclear" and "non-nuclear" countries. For example, in four MS (Estonia, Latvia, Lithuania and Poland), all "non-nuclear" countries, the provisions for management of radioactive waste arising from nuclear medicine applications are part of the legal framework for all non-nuclear activities. For the "nuclear" countries, these provisions are part of the legal framework for nuclear energy.

Question A4 asks whether any specific legal provisions for management of radioactive waste from decommissioning following termination of an application (e.g. decommissioning of research reactors, cyclotrons, particle therapy facilities, etc.) are applied in any of the MS.

The analysis of the survey shows that no special provisions specific to the management of radioactive waste from decommissioning following termination of an application are reported by the participating countries.

Question A5 of the survey seeks to identify what legal provisions to ensure financing of the costs associated with management of radioactive waste arising from nuclear medicine application are implied in each of the MS.

The analysis of the questionnaire highlights in all responses, that the owner of radioactive waste holds responsibility for the management of radioactive waste, including the associated costs, as part of the "polluter pays" principle. However, it has to be underlined that, in Slovakia this is not required by law, but is included in the Slovakia National policy and National program for the management of spent fuel and radioactive waste. Two MS (Czech Republic and Slovenia) refer to requirements for securing of funds at the waste producer through internal allocation of funds. Five MS (Belgium, Bulgaria, Croatia, Hungary, Spain) report on a radioactive waste management fund receiving fee and funding from licensees and/or the state. Five MS (Austria, Germany, Hungary, Netherlands, Portugal) and Switzerland report that funding for radioactive waste management organizations may (in part or completely) be covered by the state.

Question A6 of the survey asks every participating MS to describe the roles and responsibilities, as applicable, related to radioactive waste management of medical waste with respect to: licensees, regulatory authority(ies) and organisation(s) responsible for radioactive waste management, respectively.

All responses to the survey show that licensees (radioactive waste producers) are responsible for management of radioactive waste from production until final disposal, or until transfer to a radioactive waste management organization.

With regard to the regulatory authorities, all responses show that the regulatory authorities are charged with performing inspections and assessing compliance with regulatory requirements for radioactive waste management, including disposal. In Finland, interim storage of radioactive waste (pending disposal) is managed by the Regulatory authority. Operation and regulation of the interim storage facility is done by two separate departments of the authority.

The analyses of the questionnaire show that 19 MS (Austria, Belgium, Bulgaria, Croatia, Denmark, Estonia, France, Germany, Greece, Hungary, Italy, Latvia, Netherlands, Poland, Portugal, Romania, Spain, Sweden) and Switzerland report on one or more organizations responsible for radioactive waste management (WMO). The WMO´s may be private entities or government undertakings, tasked with responsibilities to receive, treat and store radioactive waste, and in some cases, to dispose of it or to develop disposal facilities.

Section B of the survey focuses on the characteristics of radioactive waste arising from nuclear medicine application and specifics of the managements of this type of waste.

Question B1 addresses specific radioactive waste management steps for radioactive waste arising from nuclear medicine application in participating MS.

The MS have indicated that no specific/unique waste management steps for medical radioactive waste exists, meaning that medical radioactive waste is managed in the same manner as other types of radioactive waste as specified in legislation.

Question B2 asks the participants to describe whether there are any specific categories for the radioactive waste arising from medical applications (if applicable).

The analysis of the questionnaire shows that MS divide radioactive waste arising from medical applications in a number of different categories that are generally based on the radioactivity content of the waste and its half-life.

Some MS refer to classification of radioactive waste arising from medical applications as “very short” or “short lived” or “exempt” radioactive waste as shown in the example below:

- Category I: very short-lived radionuclides with a T1/2 < 6 h;
- Category II: short-lived radionuclides with a T1/2 of 6 h - 3 days;
- Category III: long-lived radionuclides with a T1/2 > 3 days.

Additionally, MS describe that typically the following information is recorded for radioactive waste arising from medical applications;

- Radionuclide
- Decay type and half-life of the radionuclide;
- Activity (Bq);
- Physical properties (solid, liquid, gas);
- Chemical properties;
- Biological hazards;
- Environmental impact considerations

The analysis of the questionnaire shows that the applied categorization of the medical radioactive waste reflects operational safety concerns and requirements in every Member State together with the specified further management steps in line with risks associated with management of the particular type of waste.

Question B3 of the questionnaire reflects whether the radioactive waste arising from nuclear medicine application is specified in the national inventory.

The analysis of the survey showed although radioactive waste arising from medical applications is included in national inventories, most of MS do not specify the origin of radioactive waste arising from nuclear medicine in the national inventory. 5 MS (France, Netherlands, Switzerland, Cyprus and Italy) do provide specification in the national inventory about the medical radioactive waste.

Question B4 of the survey asks the participants to list the waste streams from decommissioning following termination of a medical application managed in the MS country. Further, the MS are asked to describe existing radioactive waste management solution(s) including disposal if available for each of these waste streams.

The analysis of the answers of the participants shows that the MS (both “nuclear” and “non-nuclear”) manage waste streams deriving from decommissioning of medical application in the same manner as waste streams deriving from other routes. The abovementioned question has been considered to be “not applicable” for two MS: Cyprus and Poland.

The analysis of the questionnaire shows that some of the MS manage decommissioning waste according to the provisions for management of unsealed sources, without specification of the waste origin (decommissioning).

The third Section C of the questionnaire aims to identify particular issues and difficulties with regard to the management of radioactive waste arising from nuclear medicine application in the MS.

Question C1 asks participants to give a list of the waste streams that can be considered problematic with regard to the pre-disposal and/or disposal management.

The majority of the countries declare no particular problems with regard to the waste management solution for waste streams arising from non-nuclear applications. In general, pre-disposal management arrangements exist in all MS, even if disposal solutions for all waste streams are not fully specified. However, some MS report on the need to address particular waste streams with a view to fully integrate all management steps in the national framework for waste management. Waste streams that require further specification of pre-disposal management fall into three groups: waste streams arising from historical activities and/or from the decommissioning activities (past or/and present) and waste streams arising from the use of current and new technologies. Below a tabular overview of some radioactive waste streams which MS have identified to require further specification of pre-disposal management is presented.

Historical activities	Disused radioactive sources. Sealed neutron sources declared as waste. (Cyprus, Sweden) Radium needles for brachytherapy (Italy, Belgium) Laboratory materials, activated metals and some fissile material containing waste (Netherlands)
Decommissioning activities	High activity sealed sources (Italy) Activated waste from linear and non-linear accelerators (France)
Current and new technology activities	Waste streams (in particular Ra-223) that contain Ac-227 impurities (Estonia) Radioactive waste containing C-14 and H-3 (Sweden) Liquid radioactive waste (treatment problems for the purposes of conditioning and volume reduction) (Italy)

Question C2 asks participants to describe particular issues to be further specified in the pre-disposal management and how the current waste management solutions are applied.

Below a summary table with regard to the identified management issues is given

Origin of waste stream	Group of waste stream	Description of the management issue
Historical activities	Disused radioactive sources (Technetium 99^m generators)	No pre-disposal management and disposal solution defined
	Sealed neutron sources	No disposal solution defined.
	Radium needles for brachytherapy	No disposal solution defined
	Laboratory materials, activated metals and some fissile material containing waste	Pre-disposal management solution has been developed for some of the streams and is currently being implemented or already in use.
Decomissioning activities	High activity sealed sources declared as radioactive waste	No pre-disposal management and disposal solution defined
	Activated waste from linear and non-linear accelerators	No pre-disposal solution defined.
Current and new technologies activities	Radioactive waste containing C-14 and H-3	No pre-disposal solution (treatment) defined
	Liquid radioactive waste	No pre-disposal solution (conditioning and volume reduction) defined.

The majority of the answers related to the management of the identified waste streams arising from the historical or/and decommissioning activities identify two main issues:

- Absence of suitable treatment methods – pre-disposal management solutions
- Absence of the final solution for this type of waste – disposal solutions

The analysis of the survey showed that for the problematic waste streams arising from the current or/and new technologies the main issue is related to the absence of pre-disposal management solutions, i.e. suitable treatment methods for these particular waste streams.

Nevertheless, every MS declares that the safe storage of the abovementioned problematic waste streams is assured.

Question C3 asks the participants to identify difficulties/challenges with regard to the operational management of radioactive waste arising from nuclear medicine application (if applicable).

The analysis of the survey shows that the majority of the MS do not declare any particular difficulties and/or challenges with regard to the operation aspect of the management of the radioactive waste arising from nuclear medicine application.

Below, a list of the identified difficulties and challenges reported is presented.

MS	Identified difficulties and challenges
Belgium	• Limited storage space on sites • Lack of human resources • Prices of radioactive waste evacuation which leads to the undesirable accumulation of the radioactive waste on site of the dedicated installations
Cyprus	• Operational management of the alumina insides of the Technetium 99m generators
Denmark	• Possible time delays in update of pre-disposal management arrangements as required by updated licensing framework (waste suitable for incineration)
Estonia	• Release of radioactive waste arising from nuclear medicine application due to financial difficulties (Procurement of equipment is costly.)
France	• Implementation of regulatory provisions (convention, waste management plan, waste storage sharing…) • Level of awareness regarding operational management of the radioactive waste arising from nuclear medicine application in general
Italy	• Limited amount of authorized pre-disposal facilities (hot cells) for the treatment and dismantling of, e.g., HASS sources. • Limited storage capacity

Question C4 addresses difficulties/challenges with regard to the legislation aspect of the management of the radioactive medical waste that MS experiences at the moment.

The analysis of the survey shows that the majority of the MS report no difficulties with regard to the current legislation and its application. However, 4 MS (Croatia, Denmark, Italy and Latvia) have reported on challenges. Croatia identified no legislative provisions regarding radioactive waste generated in decommissioning following termination of a medical application. Denmark stated that licensed incineration facilities require time to submit updated documentation for safety as required by new legal provisions. This prompted delays in receiving radioactive waste suited for incineration. Italy pointed to the accumulation of the radioactive waste due to the absence of legislation allowing for incineration of this radioactive waste.

Summary and potential for future work

The analysis of the answers from MS to the questionnaire has shown that no particular overarching themes regarding the legal and organisational framework for management of radioactive waste arising from nuclear medicine applications have been identified. The responses have revealed that the management of radioactive waste arising from nuclear medicine applications is widely integrated into the general national provisions for management of radioactive waste. As such, the management of radioactive waste arising from nuclear medicine applications is considered an integrated part of national waste management policies and strategies (national programmes).

Consequently, MS manage this radioactive waste in the same manner as other types of radioactive waste. In line with that, radioactive waste arising from medical applications is included in national inventories, but most MS do not specify the origin of radioactive waste from nuclear medicine in the national inventory.

In general, MS report that pre-disposal management arrangements are in place for radioactive waste arising from nuclear medicine application, even if disposal solutions for some waste streams are not fully specified. Some MS report on specific challenges regarding availability of pre-disposal management solutions, and to some degree, disposal solutions for radioactive waste of historical origin, radioactive waste originating from decommissioning activities and from some current and novel applications in nuclear medicine. Reported challenges include limited storage capacity at the sites of radioactive waste generators, limited pre-defined management options for disused sealed radioactive sources and pre-disposal and disposal arrangements for Ra-223. Identified regulatory challenges include areas concerning the legislative framework for decommissioning and incineration activities.

While the reported challenges appear related to waste streams with different physical and radiological characteristics, and while not all MS report on such challenges, the resolution of identified issues may be promoted through exchange of experiences between MS.

Outcomes of this survey suggest that ENSREG WG2 continue to explore specific management aspects by promoting the sharing of the practical experiences regarding management of radioactive waste in the medical sector. A forum for exchange of experiences could be created, for instance, in the format of a dedicated/themed workshop focussed on how the safety of management of radioactive waste in the medical sector can be further enhanced in the framework of each MS national programme. As such, the outcome of the survey and workshop could facilitate and enhance the safety of management of radioactive waste in the medical sector across MS.