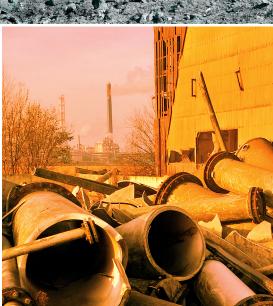






Application of the concepts of exemption and clearance to the regulation of naturally occurring radioactive material (NORM) across HERCA countries









HERCA WORKING GROUP ON NATURAL RADIATION SOURCES



Application of the concepts of exemption and clearance to the regulation of naturally occurring radioactive material (NORM) across HERCA countries

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This document is based on the national legislative frameworks as of May 2021. However, it will be periodically updated to reflect any changes in national legislations affecting to exemption or clearance of NORM. Please, notify any changes or comments by e-mail to *wgnat@herca.org*

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Foreword

HERCA as a voluntary association of the Radiation Protection Authorities (RPA) in Europe was created in 2007 with the aim of identifying common significant radiation protection issues and proposing harmonization and/or practical solutions towards a common approach of how to deal with them, whenever possible. The goal of HERCA is to contribute to a high level of radiation protection throughout Europe.

HERCA is also a forum for the RPA to share information and experience, in particular with regard to the practical transposition of European legislation and international recommendations. Positions and recommendations approved by the board of HERCA (HERCA Policies) are therefore expected to result in concrete actions, translated into regulations and applied within practices.

One of the current issues identified is the regulation of exposure to natural radiation sources. HERCA created, for this purpose, a new Working Group on Natural Radiation (WG NAT), focused on the practical implementation of the EU BSSD provisions related to natural radiation.

Among several valuable results of WG NAT work is the document on the application of exemption and clearance concepts in the regulation of NORM, which has been developed by the establishment of a Working Party on NORM, in collaboration with relevant stakeholders.

The document, which is now available on HERCA web site, presents an overview of national approaches in this field and illustrates well how HERCA is helping national authorities to find an effective way for implementation of the EU BSSD provisions on NORM as well as to move them forward to a higher level of harmonization within Europe.

I would like to acknowledge the hard work of all members of the WP NORM and others who helped to prepare and finalize this publication with admirable enthusiasm and completely on a voluntary basis.

> Karla Petrová Chair of HERCA May, 2021

Executive summary

The EU Directive 2013/59 (EU BSSD) gives unprecedented attention to the control of natural radiation sources, requiring naturally occurring radioactive materials (NORM) involving activities to be managed within the same regulatory framework as other practices causing exposure to ionizing radiation.

The present HERCA document seeks to help national authorities achieve a more effective implementation of the EU BSSD provisions on NORM, as well as to explore the prospects of international harmonization, by examining national approaches to the use of exemption and clearance in the regulation of NORM.

The document addresses a number of aspects including the application of general and specific exemption and clearance levels, the control of liquid discharges, the establishment of dose criteria and the scenarios considered in dose assessments, the provisions on recovery, reuse and recycling of NORM, and the options available for disposal of NORM waste.

Analysis of the different national approaches showed that the transposition of the EU Directive has resulted in a wide adoption of the general exemption/clearance levels laid down in Annex VII Table A, part 2 (1 kBq kg⁻¹ for uranium and thorium series radionuclides; 10 kBq kg⁻¹ for ⁴⁰K), although with some countries setting conditions or constraints on the applicability of the above mentioned levels. In some cases, higher exemption (or clearance) values have been set in national regulations for specific segments of the decay chains, or for particular materials or practices.

Additionally, most countries allow the exemption of practices involving NORM on a case-to-case basis provided that compliance is shown with pre-defined dose criteria. These dose criteria are 1 mSv a⁻¹ for workers and a value ranging from 0.01 to 1 mSv a⁻¹, depending on the country, for public exposure.

Recycling or reuse of NORM and disposal of NORM waste from notified or authorised practices are bounded to the same general dose criteria as exemption. Although half of the countries surveyed define all NORM waste as radioactive waste in their legislation, around 80% of countries allow the disposal of NORM waste below certain activity concentration values or dose levels in conventional landfills (i.e. landfills not holding a license for radioactive waste disposal).

INTRODUCTION

HERCA is a European association of radiation protection authorities, currently comprising 52 authorities from 32 countries, out of which 27 are EU Member States, hence bounded to EU law. The remaining 5 countries have national radiation protection laws consistent with the 2013 European Basic Safety Standards Directive (EU BSSD) or are committed to adapt their national legislation in order to comply with the EU BSSD requirements.

One of the most challenging aspects of the new EU BSSD is the regulation of exposure to natural radiation sources. Following a series of workshops aimed at achieving a common understanding on the directive requirements on that matter, HERCA created a new Working Group on Natural Radiation (WG NAT), committed to pursuing work related to the EU BSSD provisions pertaining to natural radiation. This document on the application of exemption and clearance corresponds to one of the items of the WG NAT action plan for 2018-2021 and has been developed by its Working Party on NORM, in collaboration with relevant stakeholders.

1.1 | Background

Exemption and clearance are essential tools of the radiological protection system. Both concepts have been widely used in the case of practices where radionuclides are employed for their fissile, fertile or radioactive properties, and, more recently, in the regulatory control of naturally occurring radioactive material (NORM). Exemption and clearance are part of the graded approach to regulatory control and are implemented through both the *IAEA Basic Safety Standards* (IAEA BSS) and the *EU Basic Safety Standards*

(EU BSSD) for protection against ionizing radiation.

The ICRP first used the term 'exemption' in Publication 60. This was further developed in Publication 82, being defined in Publication 103, in the context of planned exposure situations, as "the determination by a regulatory body that a source or practice activity involving radiation need not be subject to some or all aspects of regulatory control". Exemption should be granted on the basis that the exposure and the potential exposure due to the source or practice are too small to warrant the application of radiation protection controls or that this is the optimum option for protection. Exemption provides benefit for the regulator and the regulated parties, by releasing them from undue administrative burdens.

In the EU BSSD, NORM involving work activities are regulated as practices (see glossary in Annex II). NORM practices may be exempted from notification either directly, based on compliance with defined generic exemption levels (i.e., activity concentration values of 1 kBq kg-1 for ²³⁸U and ²³²Th series and 10 kBq kg⁻¹ for ⁴⁰K, laid down in EU BSSD Annex VII, Table A, part 2), or based on higher values, established by the competent authority, satisfying a general exemption and clearance criteria of the order of 1 mSv or less in a year above the prevailing natural background, for types of practices or specific pathways of exposure.

Practices not complying with the above generic automatic exemption levels are subject to notification. Nonetheless, notified practices may be exempted from authorisation (i.e. registration or licensing)

by an *ad-hoc* regulatory decision (termed as specific exemption), based on a demonstration of compliance with the regulatory exemption criteria, to be provided by the undertaking in conjunction with the notification of the practice (see diagram in Figure 1).

The concept of clearance also applies to planned exposure situations. It is defined as the removal of regulatory control by the regulatory body from radioactive materials or objects within notified or authorised practices. Clearance is a regulated process, and as such, the criteria and procedures on how an undertaking might be granted clearance of a given material or object should be clearly defined in the national regulation.

Specific clearance applies to specific materials within practices or (also referred to as conditional clearance) in circumstances where conditions must be placed on, for example, the destination of the material being discharged or released from regulatory control, in order to ensure that the associated radiation doses are of no concern. Although using a single set of generic values for both the concepts of exemption and clearance is not necessary in principle, the EU BSSD endorses the values recommended in IAEA publication *Application of the Concepts of Exclusion, Exemption and Clearance* (IAEA, 2004) both as default exemption values and as general clearance levels for naturally occurring radionuclides and artificial radionuclides. For NORM, these values are laid down in EU BSSD Annex VII, Table A, part 2 and replace the values previously recommended by the Commission, in *Radiation Protection 122* part II (EC, 2001).

These generic values are applicable to solid material only. Deriving activity concentration values for exemption/clearance for liquids or emissions to air or water would require additional consideration.

The EU BSSD provides some flexibility for Member States to set different national generic exemption/clearance levels provided that they are in compliance with the general exemption and clearance dose criteria set in Annex VII.

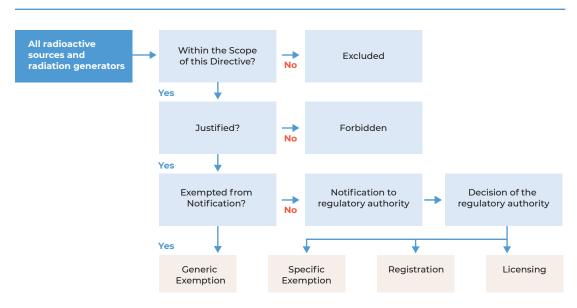


Figure 1. Graded approach to regulatory control of planned exposure situations as per EU BSSD (Directive 2013/59/Euratom)

1.2 | Objective and scope

The objective of this document is to get an overview of how HERCA members have interpreted and transposed the provisions in EU BSSD related to exemption and clearance of NORM and how both concepts are applied in practice. This overview is based on a questionnaire prepared by the HERCA Working Group on Natural Radiation Sources (WG NAT) and distributed to HERCA member authorities. Responses to the questionnaire were received from the 21 countries listed in Annex I. National examples are also provided on the application of exemption and clearance to specific industry sectors or materials in different countries.

This document seeks to help national authorities achieve a more effective implementation of the EU BSSD and of the national provisions on NORM and to contribute to a more harmonized European approach to exemption and clearance in the regulation of NORM.

While provisions on exemption and clearance clearly have implications for the international trade of commodities and the transboundary movements of NORM residues, an analysis of these questions is beyond the scope of this document.

1.3 | Structure

This document contains seven sections and three Annexes. Section 1 provides an introduction to the document, including the motivation for this work as well as the scope and objectives. Section 2 describes the EU regulatory framework relevant to the control of exposure to NORM, together with an outline of other international regulations and relevant international treaties. Section 3 briefly discusses the practical application of exemption and clearance at the national level. An overview of general exemption and clearance provisions, including the general exemption and clearance levels for solid materials approved across HERCA countries, is given in section 4. Exemption of NORM practices, including the use of specific exemption is further developed in section 5, while clearance of NORM from regulated facilities is addressed in section 6. Lastly, the main conclusions of the document are presented in section 7.

Annex I provides the HERCA WG NAT questionnaire, together with the list of respondents. Annex II contains a glossary of the most relevant terms and definitions used throughout the document, and Annex III gives information on radioactivity in soils and other natural materials in Europe for comparison with the given exemption/clearance level.

2 REGULATORY FRAMEWORK ON NORM MANAGEMENT

The EU BSSD gives unprecedented attention to the control of natural radiation sources. In particular, it requires that NORM involving activities are managed within the same regulatory framework as other practices causing exposure to ionizing radiation. Nevertheless, for NORM, the general criterion for exemption and clearance is of the order of 1 mSv a⁻¹, in excess of the natural radiation background, compared to 10 microSv a⁻¹ for artificial radiation sources.

Article 23 of the EU BSSD requires Member States to identify practices involving NORM, taking into account the industrial sectors listed in EU BSSD Annex VI. While most countries have directly adopted the list proposed in the Annex, several differences exist among national positive lists, as identified in the *HERCA Workshop on NORM and building materials*, held in Bergen (Norway) in 2016 (HERCA, 2016).

Moreover, the EU BSSD establishes that not only any new classes or types of practices that result in exposure to ionizing radiation that cannot be disregarded from a radiation protection point of view should be justified, but also that a review of the justification of existing practices should be undertaken whenever there is new evidence on their consequences, or information on alternative technologies or techniques (Article 19).

Justification of NORM involving practices still leaves many open questions and the few countries who have actually put this requirement into practice make different interpretations on the scope and criteria for the decision-making process, leading to dissimilar outcomes. For instance, the retail trade in thoriated electrodes is banned in the Netherlands as this practice is deemed not to be justified for the general public, whereas in other countries, the practice is allowed, although recommendations are given on substituting thoriated electrodes for other alternatives.

Practices involving materials in compliance with the general exemption/clearance levels laid down in Annex VII Table A, part 2 (1 kBq kg⁻¹ for uranium and thorium series radionuclides; 10 kBq kg⁻¹ for ⁴⁰K) may be exempted from the notification requirement. In addition, higher (or lower) exemption values may be set in national regulations for specific segments of the decay chains, or for particular materials.

The above-mentioned generic exemption and clearance levels are based on IAEA Safety Guide RS-G-1.7 (IAEA, 2004)⁽¹⁾, later endorsed by the IAEA Basic Safety Standards (GSR Part 3, 2014). Thus, EC and IAEA guidance are now aligned, resulting in a greater international harmonization.

Nevertheless, the so-called general exemption/clearance levels are not intended to be applied to the full range of situations. In particular, the values of activity concentration provided in RS-G-1.7 "are not intended to be applied to the control of radioactive discharges of liquid and airborne effluents from authorised practices, or to radioactive residues in the environment"; consequently, they are not applicable to legacy contamination or other existing exposure situations, such as indoor exposure to radiation from building

⁽¹⁾ RS-G-1.7 is currently under revision. Two draft Safety Guides (DS499 on exemption and DS500 on clearance) are in preparation.

materials. These situations are regulated in the EU BSSD under Articles 100 (on *Programmes on existing exposure situations*) and 75 (on *Gamma radiation from building materials*), respectively.

Regardless of compliance with the exemption levels, where there is concern that a practice identified in accordance with Article 23 may lead to the presence of naturally occurring radionuclides in water liable to affect the quality of drinking water supplies or significantly affect any other exposure pathways, the competent authority may require that the practice be subject to notification (Article 25.3). This is because in those situations the 1 kBq kg⁻¹ for uranium- and thorium-series radionuclides rule might neither ensure a negligible risk nor an optimized level of protection.

On the other hand, the EU BSSD also establishes that specific exemption from notification may be allowed for practices for which, in spite of involving material with activity concentrations above the exemption/clearance level, it can be demonstrated that workers do not need to be classified as exposed workers and the dose to members of the public, allowing for the prevailing natural background, is of the order of 1 mSv or less in a year (Article 26; Annex VII). These same dose criteria are proposed for specific clearance for recycling, reuse, disposal or incineration of NORM (Article 30; Annex VII).

Notwithstanding the use of the exemption/clearance dose criteria of the order of 1 mSv a⁻¹ or less, above background levels, for notified and authorised practices (including practices involving NORM), dose constraints for workers and public exposure need to be applied, where appropriate, for the purpose of optimisation of protection (Article 6). The concept of dose constraints was introduced in ICRP Publication 60, as an individual-related criterion, to be applied to a single source in order to ensure that dose or risk limits are not exceeded. A dose constraint would therefore be set at a fraction of the dose limit (with regard to public exposure, typically 0.3 mSv a⁻¹ for a single source or 0.5 mSv a⁻¹ for multiple sources) as a boundary in the optimization of radiation protection from that source; see Figure 2.

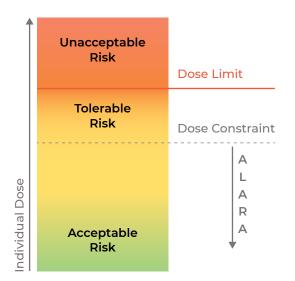


Figure 2. Planned exposure situations. Application of dose constraints (modified from ICRP 103)

The highest level of regulatory control, *licensing*, is required for practices discharging significant amounts of radioactive material with airborne or liquid effluent into the environment (EU BSSD Article 28.f). In order to ensure protection of the public in the long-term, examination and approval of plans for the discharge of radioactive effluents are required (EU BSSD Article 65), as well as environmental monitoring and reporting, and, where appropriate, evaluation of the discharges (Article 67.1).

Finally, the EU BSSD also contains provisions on the application of radiation protection principles in relation to practices involving consumer products, including those containing natural radionuclides in concentrations that might be of concern. In the context of practices, Article 20.4 states that Member States shall prohibit the sale or the making available to the public of consumer products if their intended use:

- is likely to be a new class or type of practice,
- is not justified,
- or their use would not fulfil the criteria for exemption from notification under Article 26.

Depending on the specific situation, increased exposures due to the presence of natural radionuclides in consumer products do not always need to be regulated in the context of practices. They may be regulated as existing exposure situations, as in the case of building materials or, as indicated in Annex XVII of EU BSSD, of commodities incorporating naturally occurring radionuclides.

Moreover, additionally to the EU BSSD, other legal European instruments may apply to NORM, such as directive 2011/70/ Euratom establishing a Community framework for *the responsible and safe* management of spent fuel and radioactive waste.

Whereas in some countries all NORM waste is defined as radioactive waste and the 2011/70 directive is fully applicable (see section 6), in some others, NORM waste is either not considered radioactive waste, or is defined as such only when the activity concentration of the relevant radionuclides is above certain levels. or when a dose criterion related to waste management is exceeded (see section 6). Factors influencing the regulatory decision to define NORM waste as radioactive waste may include structure of the legal framework, availability of infrastructure for waste treatment and disposal, or risk perception by the public.

Also, in relation to NORM waste, directive 2006/117/Euratom on the supervision and control of shipments of radioactive waste and spent fuel excludes "transboundary shipments of waste that contains only naturally occurring radioactive material which does not arise from practices" from its scope. Given that the EU BSSD regulates NORM involving industries as practices, in countries where NORM waste is regulated as radioactive waste, directive 2006/117 is currently applicable to shipments from NORM industries.

Notwithstanding the above, transport of NORM needs to be done according to the IAEA Regulations for the Safe Transport of Radioactive Material (SSR-6 (Rev-1)). The exemption for NORM is provided in §107(f) of SSR-6, stating that the Regulations do not apply to:

 (f) Natural material and ores containing naturally occurring radionuclides, which may have been processed, provided the activity concentration of the material does not exceed 10 times the values specified in Table 2, or calculated in accordance with par. 403(a) and 404-407. The "10-times" factor criterion, applies to activity concentrations only; the total activity of the consignment criterion will always be exceeded in the case of transport of a few tonnes of NORM.

Moreover, Directive 2013/51/Euratom laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption represents an additional constraint in relation to the protection of groundwater. This directive provides a framework for controlling radioactivity in drinking water and the radiation dose received from its consumption, based on a comparison of water supplies monitoring results with parameter values. These parameters include an indicative dose of 0.1 mSv a⁻¹ and a radon concentration of 100 Bql⁻¹, which might be taken as a reference when assessing the long-term health impact of potentially water polluting NORM practices.

In relation to protection of the sea, several HERCA countries are signatory to the Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR). In particular, its Radioactive Substances Strategy sets the objective of preventing pollution of the OSPAR maritime area from ionizing radiation through progressive and substantial reductions of discharges, with the ultimate aim of concentrations in the environment being near background values for naturally occurring radioactive substances. To monitor the strategy's effectiveness, regular reporting on discharges from several NORM industrial sectors is required. In addition, all Baltic Sea coastal countries are also signatory to the Convention on the Protection of the Marine Environment of the Baltic Sea Area – also known as the Helsinki Convention (HELCOM) – which defines similar objectives with respect to ionizing radiation including NORM.

Lastly, the HERCA WG NAT acknowledges that, internationally, there is an increasing awareness that protection standards aimed uniquely at humans, do not necessarily ensure adequate protection of non-human biota and related ecosystems. Out of the surveyed HERCA countries, Norway has requirements in its regulation to account for potential risk to the environment *per se*, including non-human biota, when assessing the impact of authorised practices.

Nonetheless, in view of the activity concentration levels which exempted NORM practices or cleared NORM might produce in the different environmental compartments, given the current environmental standards for industrial pollution control in Europe, consideration of potential doses to biota is not deemed to be necessary for exemption or clearance purposes.

3

PRACTICAL APPLICATION OF THE CONCEPTS OF EXEMPTION AND CLEARANCE AT THE NATIONAL LEVEL

Implementation of radiation protection regulation pertaining to NORM poses a challenge to governments and regulatory authorities from various standpoints, such as the integrated management of radiological and chemical hazards, the application of a graded approach to regulation, or the resources needed to ensure compliance with the new regulation.

In this context, the practical application of the concepts of exemption and clearance to the regulation of NORM is paramount to a sound and effective system of control. Because natural radionuclides are ubiquitous in the environment, it is essential to have a practical rule which allows one to determine when further regulatory control is not warranted. Such a rule is provided by general exemption/clearance levels, or alternatively, by other operational quantities (in terms, of, for example, surface activity).

The EU BSSD sets the basic principles for both exemption and clearance and provides general exemption/clearance levels, but flexibility is given to national authorities to allow for their specific national circumstances, as long as the general dose criteria (EU BSSD Annex VII) are met. These national circumstances may include consistency with other legislation, the characteristics of the industrial sectors operating in the country, the availability of waste disposal routes, or public acceptability. In the following sections of this document, different aspects of the flexibility provided by the EU BSSD are explored, based on the responses to the *Questionnaire on exemption and clearance of NORM*, distributed to HERCA members in November 2018 (and revised in 2021), and on the further work of WG NAT Working Party NORM.

In particular, the questionnaire has addressed: generic exemption/clearance level for solid materials; requirements on airborne and liquid discharges; dose criterion for the protection of workers and members of the public, and; the use of specific exemption and specific clearance.

4

GENERAL EXEMPTION AND CLEARANCE IN HERCA MEMBER COUNTRIES

As stated in section 2, according to the EU BSSD, NORM involving practices may be exempted from notification either: *i*) directly, on the basis of compliance with exemption levels in the Annex VII section 2, Table A, part 2, or *ii*) on the basis of higher values that, for specific applications, are established by the competent authority, satisfying the general exemption and clearance criteria set out in the Annex VII, section 3.

In particular, the general exemption/clearance activity concentration values for NORM in solid materials of any amount provided in the EU BSSD are the following:

- Natural radionuclides from the uranium-238 series: 1 kBq kg⁻¹
- Natural radionuclides from the thorium-232 series: 1 kBq kg⁻¹
- ⁴⁰K: 10 kBq kg⁻¹.

These exemption/clearance general levels for radionuclides of natural origin are equivalent to those provided by IAEA Safety Guide RS-G-1.7 (2004; accompanying Safety Report Series SR 44 (2005)) and later endorsed in the IAEA Safety Standard Series GSR Part 3 (2014). Additionally, the IAEA provides a 1 kBq kg⁻¹ exemption/ clearance level for radionuclides from the uranium-235 series and for other primordial radionuclides, whereas Radiation Protection 122 Part 2 – the previous EC guidance on exemption and clearance of NORM-proposes an exemption/clearance level of 5 kBq kg⁻¹ for ²³⁵U-series radionuclides. However, note that, for NORM, the isotopic ratio ²³⁸U/²³⁵U will present only slight variations from the natural abundance ratio and, thus, limiting ²³⁸U-series

radionuclides content will indirectly limit that of radionuclides in the ²³⁵U-series.

Exemption/clearance levels for artificial radionuclides in IAEA RS-G-1.7 are derived from calculations based on the relevant exposure scenarios and the corresponding dose criteria. In contrast, for natural radionuclides, such levels have been set "on the basis of consideration of the worldwide distribution of activity concentrations for these radionuclides", as described in IAEA Safety Report 44 (IAEA, 2005). Nevertheless, it is acknowledged that "doses to individuals as a consequence of the use of these levels are unlikely to exceed about 1 mSv in a year, excluding the emanation of radon and cases of bulk volumes contaminating water pathways, which could require case by case evaluation of possible doses" (IAEA, 2005).

For raw material in secular equilibrium for the ²³⁸U and ²³²Th decay chains, there is a rough agreement between the 1 kBq kg⁻¹ criterion and the values in RP 122, Part II (EC, 2001), when adjusting for the different dose criteria applied (1 mSv a⁻¹vs 0.3 mSv a⁻¹ in RP-122 Part II). In comparison, for practices utilizing artificial radionuclides a much lower dose criterion of 10 microSv a⁻¹ is used. The rationale given in RP 122 Part II for using a higher dose value for NORM is that "the definition of values for natural sources cannot proceed on the basis of the trivial risk criteria" given that individual annual exposures from NORM involving work activities may be much higher than 10 microSv and collective doses can be very important. It is further argued that it would in general not be practicable to implement a control scheme for such a

small increment to the natural radiation background, well below the natural variability.

For comparison, the average annual effective dose worldwide due to natural sources other than radon is estimated to be 1.14 mSv, with exposure to radon contributing an additional 1.26 mSv a⁻¹ (UNSCEAR, 2000). Annex III provides further information on natural radiation levels in Europe.

In addition, practices subject to notification may be exempted from authorisation by law or general administrative act, or through an ad-hoc regulatory decision, on the basis of the information provided in conjunction with the notification of the practice and in line with general exemption criteria. Specifically, radiation doses from NORM likely to be received by an individual should be of the order of 1 mSv a⁻¹ or less, above background levels, according to the EU BSSD.

4.1 | General exemption/clearance levels by country

The new EU BSSD general exemption/ clearance levels have been adopted in the majority of national legislations of HERCA member countries (see Table 1). Generally, they are applied individually as a maximum not to be exceeded by any radionuclide in the ²³⁸U- and the ²³²Th-series.

However, several differences among countries were identified as per the questionnaire responses, such as:

- Adoption of the exemption and clearance levels given in RP 122, part 2 (EC, 2001) in Belgium and Spain for exemption from notification and for generic clearance.
- Adoption of higher exemption/clearance levels for specific segments of the ²³⁸U chain in the UK and Italy and ²³²Th chain in the UK in case of disequilibrium.

 Establishment of exemption/clearance levels for other primordial radionuclides (such as ¹³⁸La or ¹⁷⁶Lu) in Austria, Denmark, Hungary, the Netherlands and Norway; and for ²³⁵U-series radionuclides (a level of 1 kBq kg⁻¹ for ²³⁵⁺U has been adopted in Norway and the Netherlands and of 5 kBq kg⁻¹ in the UK).

 Application of a summation rule, in Germany, when radionuclides from both the ²³⁸U-series and the ²³²Th-series are present in the material:

 $C(U_{max}) + C(Th_{max}) \le 1 \text{ kBq kg}^{-1}$ [4.1]

where $C(U_{max})$ is the maximum radionuclide activity concentration (in kBq kg⁻¹) for the ²³⁸U-series; and $C(Th_{max})$ is the maximum radionuclide activity concentration (in kBq kg⁻¹) for the ²³²Th-series. Nonetheless, for specific situations modifications of the formula may apply.

• Application of a summation rule, in Denmark, Norway and the UK, for mixtures of radionuclides:

$$\sum_{i=1}^{n} \frac{c_i}{c_{Li}} \le 1.0$$
[4.2]

where c_i is the radionuclide activity concentration (kBq kg⁻¹) and c_{Li} the exemption/clearance level of particular radionuclide (kBq kg⁻¹).

In addition, some exceptions are made to the applicability of the general exemption/clearance levels in some national regulatory frameworks. For instance, for disposal in mono-landfills, exemption/ clearance levels of 0.1 kBq kg⁻¹ applies in Belgium. In Spain, the general exemption/clearance levels are not allowed to be applied to NORM involving activities potentially affecting groundwater (such as mining), for which a site-specific radiological assessment is required. In Italy, additional restrictions are applied for disposal of NORM to landfills and use in road building materials and the generic values are not applicable to NORM incineration.

Table 1General exemption/clearance levels for 238U- and 232Th-series radionuclidesand 40K in HERCA member countries

List of countries in alphabetical order	Generic exemption/clearance levels
Austria, Czech Republic, Finland, France, Hungary, Ireland, Lithuania, Luxembourg, the Netherlands, Poland, Romania, Slovenia, Sweden, Switzerland	1 kBq kg ⁻¹ for ²³⁸ U series radionuclides*; 1 kBq kg ⁻¹ for ²³² Th series radionuclides*; 10 kBq kg ⁻¹ for ⁴⁰ K
Denmark Norway	1 kBq kg ⁻¹ for ²³⁸ U series radionuclides**; 1 kBq kg ⁻¹ for ²³² Th series radionuclides**; 10 kBq kg ⁻¹ for ⁴⁰ K
Germany	1 kBq kg ⁻¹ for ²³⁸ U series radionuclides+; 1 kBq kg ⁻¹ for ²³² Th series radionuclides+;
Italy	1 kBq kg ⁻¹ for ²³⁸ U series radionuclides; except for ²¹⁰ Pb+, ²¹⁰ Pb: 5 kBq kg ⁻¹ ; 1 kBq kg ⁻¹ for ²³² Th series radionuclides; 10 kBq kg ⁻¹ for ⁴⁰ K;
UK	1 kBq kg ⁻¹ for ²³⁸ U _{sec} ; ²²⁶ Ra+; ²³² Th _{sec} ; ²²⁸ Ra+; ²²⁸ Th+; ²³⁵ U _{sec} ; ²²⁷ Ac+;** 5 kBq kg ⁻¹ for ²³⁸ U+; ²³⁴ U; ²¹⁰ Pb+, ²¹⁰ Pb; ²³² Th; ²³⁵ U+; ²³¹ Pa;** 10 kBq kg ⁻¹ for ²³⁰ Th;**
Belgium, Spain	RP 122, part II exemption/clearance levels

* Apply to individual isotopes.

** A summation rule applies (see formula 4.2) for mixtures of radionuclides.

+ A summation rules applies (see formula 4.1) for the U and Th decay series; Currently, there are no industries with relevant ⁴⁰K exposures identified in Germany, hence the exemption level for ⁴⁰K does not apply

On the other hand, while the generic exemption/clearance levels in the EU BSSD may be applied to any amount of material, several countries allow higher values for small quantities of NORM, as identified in the HERCA NORM questionnaire:

- Moderate quantities (lower than 1 tonne) are exempted from notification if the activity concentration does not exceed the defined exemption values for transportation of radioactive substances in Belgium (i.e. 10 times the exemption/ clearance levels), and;
- Geological samples, collections of minerals and rocks containing less

than 10 g natural Th or 100 g natural U are exempted from authorisation in Switzerland.

4.2 | Use of operational quantities

The general exemption/clearance level for solid materials are expressed in terms of activity concentration values (kBq kg⁻¹). However, to facilitate the practical application of exemption and clearance, some countries use *in situ* measurable quantities (such as surface contamination values). An internationally recognized reference on the application of release standards based on operational quantities is Surface and Volume Radioactivity Standard for Clearance (ANSI/HPS, 2013).

Few of the HERCA countries responding to the questionnaire have included such derived values in their national regulatory framework for NORM in an explicit manner (such as the Netherlands). Nonetheless, in several other countries (Belgium, Denmark, Finland, Romania, Spain), the use of operational criteria for clearance may be approved for specific practices in the context and process of authorisation.

5 EXEMPTION OF NORM INVOLVING PRACTICES

As aforementioned, exemption from notification for identified NORM processing industries may be granted: *i*) when the activity concentration levels of NORM in material of concern are below the general exemption levels defined by regulation, and/or; *ii*) for specific applications, when the activity concentration levels are below higher values that are established by the competent authority, satisfying the general exemption and clearance criteria set out in the national regulation. In addition, in such cases special requirements may be defined and imposed by the responsible regulatory body.

Exemption from authorisation may be granted, on a case-by-case basis, when radiation risks arising from the facility are (and are likely to remain) sufficiently low as not to warrant regulatory control (of the order of 1 mSv a⁻¹ or less). Exemption may be also granted from some specific aspects of regulatory control. For example, exemption from authorisation of discharges may be granted for a given facility, but regulatory control pertaining to occupational exposures may be required.

Notwithstanding the above, it is important to highlight that the notification requirement in Article 23 places the responsibility on the industry to have in place the adequate means to monitor the occurrence of NORM. On the one hand, exposure to NORM depends on the raw materials used for which the radioactive content may vary widely depending on their origin; on the other hand, in some industries radioactive scales might built up in pipes and equipment increasing dose rates over time. A radiological survey provides a snapshot of the facility, but in most cases that is insufficient to ensure that radiation risk will remain negligible in the long-term. Moreover, detection and characterization of NORM relies on adequate radiological instrumentation and on especially skilled and trained personnel.

HERCA considers it good practice to ensure a reasonable degree of regulatory oversight – commensurate with the level of risk – not only of notified facilities, but of all facilities included in the national positive/indicative list (for example, by conducting inspections to a representative number of randomly selected facilities), in order to guarantee that they have the appropriate means in place to detect NORM and, thus, to adequately comply with the notification requirement.

5.1 | List of NORM involving industries

According to the EU BSSD, industries involving NORM, and thus potentially leading to exposures of workers or members of the public which cannot be disregarded from a radiation protection point of view, shall be identified by appropriate means.

The following indicative list of industrial sectors of potential concern regarding exposure to NORM, is given in the EU BSSD Annex VI:

- Extraction of rare earths from monazite,
- Production of thorium compounds and manufacture of thorium-containing products,
- Processing of niobium/tantalum ore,
- Oil and gas production,
- Geothermal energy production,

- TiO₂ pigment production,
- Thermal phosphorus production,
- Zircon and zirconium industry,
- Production of phosphate fertilisers,
- Cement production, maintenance of clinker ovens,
- Coal-fired power plants, maintenance of boilers,
- Phosphoric acid production,
- Primary iron production,
- Tin/lead/copper smelting,
- Ground water filtration facilities, and
- Mining of ores other than uranium ore.

The responsibility for the identification of NORM involving industries is assigned to Member States (EU BSSD, Article 23, 2013). For most countries, such identification has been carried out by the regulatory body, by means of national surveys, guided by the international knowledge and experience on the field. Over the years, both IAEA and EC have published several reports or guidance documents to provide orientation on which industries might be of radiological concern (EC RP 135, 2003; IAEA 2012, 2013a and b).

Furthermore, periodical reviews of the national positive list of NORM industries should be conducted. Exchange through HERCA of the national positive lists, together with the basis for including new industries on the list, can be a useful tool in conducting such reviews.

5.2 | Dose criteria and exposure scenarios

Where amounts of radioactive substances or activity concentrations do not comply with the exemption values laid down in EU BSSD Annex VII, Table A, part 2, exemption may be granted on the basis of higher values that, for specific applications, are established by the competent authority, satisfying the general exemption and clearance criteria set out in the national regulation.

Annex VII, also indicates that "practices subject to notification may be exempted from authorisation by law or general administrative act, or through an ad-hoc regulatory decision, on the basis of the information provided in conjunction with the notification of the practice and in line with general exemption criteria". Specifically, radiation doses from NORM likely to be received by an individual should be of the order of 1 mSv a⁻¹ or less. Accordingly, all HERCA countries responding to the questionnaire have adopted a dose criterion of 1 mSv a⁻¹ for workers, whereas, for public exposure, half of them have adopted more restrictive criteria (Table 2).

Table 2Dose criteria for public exposure used by HERCA countries for exempting
notified practices from authorisation

Austria, Belgium, Czech Republic, Denmark, France, Germany, Hungary, Ireland, Lithuania, Poland, Romania, Slovenia	1 mSv a ⁻¹	
Italy*, the Netherlands (on-site), Spain, UK	0.3 mSv a ⁻¹	
Finland	0.1 mSv a ⁻¹	
Luxembourg, the Netherlands (off-site)	0.01 – 0.03 mSv a ^{.1}	
Norway, Sweden	All NORM involving practices subject to authorisation	

* 0.1 mSv a⁻¹ if the drinking water pathway is affected.

Dose assessments supporting exemption must account for the relevant pathways of radiation exposure associated to the practice (including waste disposal and recycling scenarios, where applicable) and, generally, should use ICRP dose coefficients. ICRP has recently updated its dose coefficients for natural radionuclides both for occupational internal exposure (Publication 137; OIR part 3), based on ICRP Publication 103, and for external exposures to environmental sources (ICRP Publication 144). New dose coefficients for internal exposure of the public are expected to be soon published.

Different exposure scenarios to NORM were considered in the document RP 122, part II (EC, 2001).

For workers, the most important exposure pathways are the following:

- External gamma radiation
- Dust inhalation

With respect to exposure scenarios, dose calculations have been done (RP 122, part II) for the following scenarios pertaining to workers:

- Transport over long/short distances
- Indoor storage of moderate quantities of material
- Outdoor storage of large quantities of material
- Road construction with NORM material
- Building construction work using building materials containing NORM
- Building construction work using undiluted NORM as unshielded surface cover
- Disposal on a heap or a landfill
- Road construction

Similarly, the NORM exposure pathways considered for the members of public are the following:

- External gamma radiation exposure
- Inhalation (excluding radon indoors)
- Ingestion (excluding consumption of drinking water)

The following exposure scenarios for members of public were considered:

- NORM as surface layer in public places/ sport grounds
- Dweller of a house built with building materials containing NORM
- Dweller of a house built with undiluted NORM as unshielded surface cover
- Dweller of a house near a heap or land-fill.

Concerning the groundwater pathway for public exposure, the drinking water directive (2013/51/EURATOM) limits the amount of natural radionuclides in drinking water by setting a parametric value for the total indicative dose of 0.1 mSv a⁻¹. Individual supplies providing on average less than 10 m³ a day, or serving fewer than 50 persons, may be exempted from the directive. In case monitoring of water intended for human consumption indicates non-compliance with the parametric value, Member States should consider whether consumption of such water poses a risk to human health and, where necessary, take remedial action to improve the quality of the water. In general, remediation of drinking water that exceeds the parametric indicative dose is costly and NORM residues might be produced in the treatment process.

As per the questionnaire, only in a few HERCA countries (Belgium, Finland, Italy, Spain, Switzerland, the Netherlands and the UK) must the drinking water pathway be considered, when appropriate, in longterm dose assessments, in order to grant exemption from notification or authorisation of NORM involving practices.

5.3 | Discharges to water bodies and atmosphere

The EU BSSD sets requirements on authorisation and environmental monitoring of practices making radioactive discharges to the air or water.

In particular, Article 27 requires licensing for practices discharging significant amounts of radioactive material with airborne or liquid effluent into the environment. However, the EU BSSD does not provide general exemption/clearance levels for liquid or gaseous effluents, as it does for solid material, and countries have established different criteria to define which NORM practices are subject to the notification or authorisation requirements.

In order to ensure protection of the public in normal circumstances, examination and approval of plans for the discharge of radioactive effluents (and where appropriate, the establishment of authorised limits as part of the discharge authorisation and conditions for discharging radioactive effluents) should be required (EU BSSD Article 65).

Furthermore, according to Article 67, proper environmental monitoring and reporting of results to relevant national authority must be required from practices where authorisation for discharge is granted.

In spite of a drastic reduction in industrial discharges to the environment in the EU along the past decades, deliberate discharge to water bodies and atmosphere is made by several NORM processing industries.

Examples of NORM practices discharging to waterbodies (usually, after effluent treatment) are the oil and gas industry; the phosphate industry; production of titanium dioxide; deep geothermal energy production; hydrometallurgical processes; or groundwater treatment. According to the OSPAR annual report data (OSPAR Commission, 2020), the oil and gas industry is the main source of total alpha radioactive discharges to the European marine OSPAR area, accounting, for about 97% of the total discharge from all sectors (non-nuclear and nuclear) to the sea.

Discharges to air (mainly ²¹⁰Po and ²¹⁰Pb associated with thermal treatment) occur, for example, in primary metal production, coal-fired power plants, cement production, ceramic industry or brick production. A study commissioned by BfS (Kunze et al, 2019) used a generic approach to estimate radiological impact for NORM industrial sectors with significant dust emissions operating in Germany; namely cement production, primary iron production, lead smelters and coal-fired power plants. It was found that taking into account the average production capacity of a facility under typical meteorological conditions prevailing in Germany, effective doses did not significantly exceed 100 microSv a⁻¹ for any of the sectors considered. Similar conclusions have been found in the UK and Spain for coal-fired power plants and primary steel production (NRPB, 2001; CSN, 2012).

As per the HERCA NORM questionnaire, half of HERCA member countries have included exemption or clearance regulatory provisions on discharges from NORM industries. These are either generic exemption/clearance criteria used on ad-hoc basis (Denmark) or established either:

i) in terms of specific radionuclide activity concentrations and total activity per year (in the Netherlands, Norway, and United Kingdom, as shown in Table 3) or of gross alpha and beta activity concentration in the discharge effluent (Czech Republic: 0.5 Bq I⁻¹ for alpha emitters, 1 BqI⁻¹ for beta emitters); or

• *ii)* in terms of a dose level in the range 0.1-0.3 mSv a⁻¹ for members of the public (Austria, Belgium, Finland, Italy, Spain and Switzerland).

In this later case, a graded approach to the safety assessment is usually required. An example on the three-tiered approach in place for discharges in Belgium is given in Text Box 1.

	The Netherlands		Norw	ау	UK	
Radionuclide	Water	Air	Water ar	nd Air	Aqueous	Air
	(GBq a⁻¹)	(GBq a [.] 1)	(Bq g [.]) (Bq a [.])		liquids (Bql [.])†	Bqm ⁻³
²¹⁰ Pb	10ª)	10ª)	J ^{a)}	1000ª)	0.1 ^{b)}	0.01 ^{b)}
²¹⁰ Po	10	10	1	1000	0.1	0.01
²²² Rn	-	10000ª)	Ja)	10E+07 ^{a)}	-	-
²²³ Ra	1000ª)	-	10 ^{a)}	10000ª)	-	-
²²⁴ Ra	1000ª)	-	la)	10000ª)	-	-
²²⁶ Ra	10ª)	10 ^{a)}	J _{a)}	1000ª)	^{(م} ار	0.01 ^{b)}
²²⁸ Ra	100 ^{a)}	J ^{a)}	la)	10000ª)	0.1 ^{b)}	0.01 ^{b)}
²²⁷ Ac	100ª)	10ª)	-	-	0.1 ^{b)}	0.001 ^{b)}
²²⁷ Th	1000	-	1	1000	-	-
²²⁸ Th	1000ª)	J _{a)}	0.1ª)	1000ª)	(df	0.001 ^{b)}
²³⁰ Th	100	1	0.1	1000	10	0.001
²³² Th _{sec}	100	1	0.1	100	0.1	0.001
²³⁴ Th	10000ª)	-	100 ^{a)}	10000ª)	-	-
²³¹ Pa	10000	0.1	0.1	100	1	0.001
²³⁴ U	1000	10	1	1000	10	0.01
²³⁵ U	1000 ^{a)}	10 ^{a)}	Ja)	1000ª)	10 ^{b)}	0.01 ^{b)}
²³⁸ U _{sec}	1000	10] ^{a)}	1000ª)	0.1	0.001

Table 3 Exemption/clearance provisions on discharge from NORM industries

a): including daughter nuclides

b): including the short-lived daughter nuclide

^{†:} liquids which are aqueous and not classified as toxic under EC Regulation No. 1272/2008 as having any of the following hazard classes and hazard categories (as defined in that Regulation) - (i) acute toxicity: categories 1, 2 or 3; (ii) skin corrosion/irritation: category 1 corrosive, sub-categories: 1A, 1B or 1C; or (iii) hazardous to the aquatic environment: acute category 1 or chronic categories 1 or 2.

TEXT BOX 1

REGULATORY CONTROL OF NORM DISCHARGES TO WATER IN BELGIUM

Art. 66.2 of EU BSSD requires Member States "to ensure the identification of practices for which an assessment of doses to members of the public shall be carried out". For practices involving NORM, doses to the public may occur as a consequence of either atmospheric or liquid discharges.

A graded approach needs to be applied in order to focus the assessment efforts on practices for which the risk of impacting the public is not trivial. A tiered assessment approach and the development of screening criteria allow for identification of activities for which a specific and detailed assessment is necessary while minimizing the burden for activities for which the discharges are not of concern.

The current Belgian Radiation Protection Decree defines activity concentration limits for the discharge of liquid effluents to surface water or into the sewer system. These limits correspond to one-thousandth of the annual limit by ingestion (1 mSv) of the corresponding radionuclide. Namely, the clearance level C_1 is:

$C_1 = 10^{-6}/h_a$

where h_{a} (in Sv/Bq) is the effective dose coefficient per unit of activity of the corresponding radionuclide for an adult based on ICRP 72 Publication.

Although dose-related (the ingestion of 1,000 l of liquid with this activity concentration would cause a dose of 1 mSv a-1), these clearance levels have not been derived from a proper dose assessment. Rather they are pragmatic values based on a rule of thumb that any discharge of liquid waste with this activity concentration would be diluted before reaching any human receptor. Table TB1.1 reproduces these clearance values for the natural radionuclides.

Table TB1.1 Clearance levels for natural radionuclides in liquid discharges in Belgium

238U 234U 230Th	22 20 4.8
²³⁰ Th	
	4.8
226 0	
²²⁶ Ra	3.6
²¹⁰ Pb	1.4
²¹⁰ Po	0.83
²³² Th	4.3
²²⁸ Ra	1.4
²²⁸ Th	14
⁴⁰ K	160

TEXT BOX 1 continued

These clearance levels are based on the instantaneous activity concentration in the discharged water. The total activity released per year would however better reflect the potential dose-impact of the discharges. In addition to the clearance levels based on activity concentration, Belgium decided to follow the approach of EC document Radiation Protection 135 (EC, 2003) as a second-tier assessment for the discharges of NORM activities.

RP 135 assumes three different sets of characteristics for a river (small, medium and large) and derives dose coefficient per unit of discharged activity (Sv/GBq) for these three types of rivers and for different exposure circumstances.

Using the assumptions and derived dose coefficients of RP 135 allows for instance the assessment of the dose for three examples: a) past discharges (pre-1990) of a former phosphate processing; b) discharges of a titanium dioxide (TiO₂) factory; and c) discharges of geothermal brines in surface water. The calculations take into account the actual volumes of the discharges.

	Total	Dose (microSv a³)					
	activity considered	Small river		Medium river		Large river	
	(GBq a ⁻¹)	Average consumption / occupancy	High consumption / occupancy	Average consumption / occupancy	High consumption / occupancy	Average consumption / occupancy	High consumption / occupancy
Phosphate (Cl process)	²²⁶ Ra: 300	1,200	2,610	30	66	6	12.9
TiO ₂	²²⁶ Ra: 3 ²²⁸ Ra: 2	27.2	62.5	0.7	1.6	0.1	0.3
Geothermal brines	²²⁶ Ra: 0.65 ²²⁸ Ra: 0.14	3.6	8.3	0.1	0.21	0.02	0.04

Table TB1.2Dose assessments for the different scenarios

The example of the former discharges from the phosphate industry into a small river lead to a dose higher than 1 mSv a⁻¹, which is consistent with the current contamination pattern resulting from these past discharges. The two other examples, on the other hand, do not cause significant doses.

The approach to the liquid discharges containing enhanced activity concentration of natural radionuclides has been implemented in the Belgian regulatory framework as a three-tiers approach based on the levels described in section 3:

- 1. Ist-tier: Clearance levels for natural radionuclides in liquids are not exceeded
 - practice is exempted from public dose assessment regarding the liquid discharge; notification only is sufficient (with respect to public exposure).

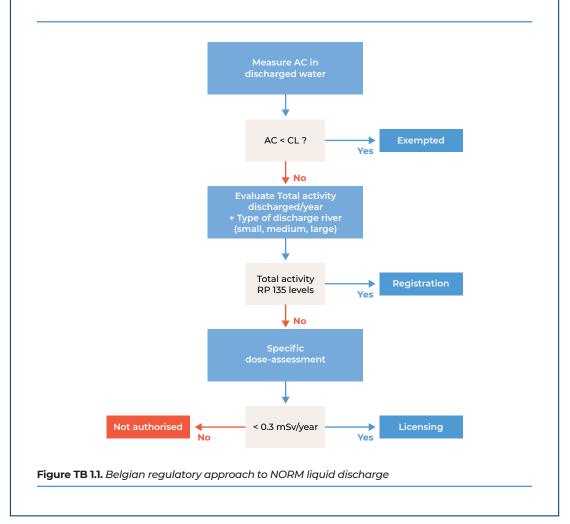
2. 2nd-tier: Clearance levels for natural radionuclides in liquids are exceeded

- screening assessment criteria of RP 135 are used for total yearly activity discharged;
- if values of RP135 are not exceeded, practice is authorised under "registration" form;

TEXT BOX 1 continued

- 3. 3rd-tier: Values of RP 135 are or may be exceeded
 - realistic assessment;
 - if impact is below 0.3 mSv a⁻¹, practice is authorised under "licensing " form.

This process is summarized in the flowchart herefater (AC = activity concentration, CL = clearance level):



5.4 | Use of specific exemption

The EU BSSD allows Member States to approve exemption levels higher than the general exemption levels for specific materials or for material originating from specific types of practices.

Based on the HERCA questionnaire, eight countries (Austria, Denmark, Finland, Italy, the Netherlands, Spain, Switzerland, Sweden) have legal provisions allowing for the specific exemption of NORM at the request of the interested party. These specific levels are then approved as a formal decision by the competent authority. Alternatively, the regulatory body may derive and establish such specific exemption levels in order to facilitate the practical application of the EU BSSD at the national level.

Case studies on the use of specific exemption from the Netherlands and Spain are presented in text boxes 2 and 3, respectively.

TEXT BOX 2

SPECIFIC EXEMPTION FOR ⁴⁰K IN THE NETHERLANDS

General clearance and exemption levels, equal to those in EU BSSD 2013/59/ Euratom Annex VII, are set in the Dutch Decree on Basic Safety Standards for Radiation Protection. For additional radionuclides, not included in the EU BSSD, they are determined using the general clearance and exemption criteria from EU BSSD Annex VII-3 and set in the Regulation on Basic Safety Standards for Radiation Protection.

Specific exemption/clearance levels can be determined for justified practices, provided that the general criteria for exemption/clearance from notification, registration or licencing are met. These criteria are the implementation of EU BSSD general criteria as specified in EU BSSD Annex VII-3. To prove compliance with the dose criteria, methodologies according to the recommendations of the European Commission or the IAEA relating to exemption and clearance should be used, or methodologies that the regulator has approved to be equivalent.

Restrictions in use, disposal or reuse may be a condition for granting higher specific clearance or exemption levels. They can, upon request, be granted to an undertaking or, for reasons of efficiency, set in the ANVS-regulation on Basic Safety Standards for Radiation Protection instead.

Specific exemption of ⁴⁰K

Prior to 2018 the clearance and exemption level for ⁴⁰K amounted to 100 kBq kg⁻¹, well above the activity concentration encountered in potassium and its chemical compounds. Due to the implementation of the EU BSSD, the exemption level for ⁴⁰K, for potassium quantities of more than 1,000 kg, was set to 10 kBq kg⁻¹ in Dutch regulation. That would require a registration for many practices using common potassium compounds: as an example, the activity concentration of KOH is 21 kBq kg⁻¹.

The oil- and gas production and geothermal industry expressed their concern on the effect of EU BSSD on the exemption of 40 K. They use large quantities of

TEXT BOX 2 continued

potassium salts, for instance, as constituents of the brine and mud that is used during drilling. Potassium is also used in large amounts in the chemical industry and fertilizer and food-production.

The stakeholders indicated that the 10 kBq kg $^{\rm -1}$ exemption level for $^{\rm 40}{\rm K}$ would result in:

- High administrative burden and cost due to the requirement for registration of the practices;
- Confusion amongst workers at facilities where large amounts of potassium compounds are used: contrary to the past a registration would be required. This might lead to questions about whether the previous situation was safe.

Research has shown that the exemption criterion is consistent with a specific exemption level for ⁴⁰K of 22 kBq kg⁻¹. Therefore, considering the expected issues without this specific exemption level, it was decided to set this specific exemption level of ⁴⁰K in Dutch regulation, with some restrictions. Consequently, the ANVS-regulation states that practices with material containing ⁴⁰K (in the natural abundance), are exempted from the requirement for registration when:

1. the activity concentration is not more than 22 kBq kg⁻¹: higher activity concentrations are not encountered in practical applications;

2. the distance between the bulk storage of potassium and the workplaces is at least 5 m. This assures the protection of workers and the public on-site and that the general exemption criterion on-site of 0.3 mSv a⁻¹ (workers and public on-site) is met;

3. a minimum distance (R) between the bulk amount of potassium and the site boundary is maintained. This ensures that the dose to the public living outside the site fulfils the general exemption criterion for the public of 0.01 mSv a⁻¹.

The dose to the public outside the site depends on the distance of the bulk amount of potassium to the site boundary, the density of the material, the time this amount is actually present at the site and the activity concentration of 40 K in the material. To account for these dependencies, *R* (the minimum distance to be kept) is calculated according to

 $R \ge R(M) \times C$ DENSITY × CTIME × CCONCENTRATION

with

- *R(M)*: the uncorrected distance of the bulk amount of potassium containing material to the nearest site boundary. *R(M)* depends on the potassium containing material mass *M* only. *R(M)* is shown in table TB2.1.
- CDENSITY: the correction factor that has to be applied when the density of the potassium containing material is not equal to 2,000 kg m⁻³ and is given in table TB2.2.
- CTIME: the correction factor that can be applied when the potassium containing material is only present on-site during a part of the year;
- CCONCENTRATION: the correction factor that can be applied when the ⁴⁰K activity concentration is less than 22 kBq kg⁻¹.

TEXT BOX 2 continued

The corrections for time and concentration are optional and shown in table TB2.2. Some details on these calculations are described in the next section.

Table TB 2.1(M) in meters for various amounts of material,
expressed in tonne (1,000 kg)

Mass of potassium containing material <i>M</i> (tonne)	<i>R(M</i>) (m)
1 – 10	5
10 – 20	15
20 – 50	25
50 – 100	40
100 – 1,000	60
1,000 – 10,000	80
> 10,000	100

Table TB 2.2 The mandatory correction factor CDENSITY and the correction factors CTIME, and CCONCENTRATION

Density (kg m³)	CDENSITY	On-site presence (days year¹)	CTIME	⁴⁰ K activity concentration (kBq kg ⁻¹)	CCONCENTRATION
>1,900	1.00	>270	1.00	>17	1.00
1,700 – 1,900	1.02	180 – 270	0.86	15 – 17	0.90
1,500 – 1,700	1.10	90 – 180	0.70	13 – 15	0.85
≤1,500	1.15	≤ 90	0.50	10 – 13	0.79

Dose modelling: scenario and risk assessment

Potassium-40 is a non-typical radionuclide in the sense that, under normal conditions, it only results in a dose due to external radiation. This is caused by the potassium homeostasis: the mechanism that the human body tries to maintain a constant level of potassium, irrespective of the intake. That means that, for potassium in its natural composition (i.e.: not enriched in ⁴⁰K) the intake does not lead to an excess dose due to ingestion or inhalation (see also RP-122-II, §5.4 and §5.5).

Clearly, for a fixed amount of material, the shape of the heap of material will have an effect on the dose, for instance due to absorption within the material and geometrical effects. Since absorption plays an important role, the density of the material will also affect the dose.

The dose modelling was performed with the Microshield computer code. In order to take the effects of spatial distribution into account the effective dose was calculated for various distributions of the material. The simulation quickly

TEXT BOX 2 continued

showed that, at a distance of 5 m to the material, the 0.3 mSv a⁻¹ limit for protection of workers and public on site, was easily met.

Based on these calculations, the distance was determined where the dose was below 0.04 mSv a⁻¹. This corresponds to a dose of 0.01 mSv a⁻¹ for a person living at that distance due to the dose reduction caused by living in a house and is consistent with the criterion for the requirement for registration of a practice in the Netherlands. These calculations were repeated for various amounts of material, resulting in the values in table TB2.1. The corrections for exposure time, density of the material and ⁴⁰K activity concentration (Table TB2.2) were established using the relation between dose and distance, and the approximately linear relation between dose and respectively time, activity concentration and density.

TEXT BOX 3

SPECIFIC EXEMPTION FOR ²¹⁰Po AND ²¹⁰Pb IN CLINKER OVENS IN SPAIN

Cement is a powdered substance mainly used as the binding agent in the making of concrete. It is produced through several stages, basically made up of the two following essential phases:

- Manufacture of a semi-finished product, so-called "clinker", obtained from the calcination in a high-temperature kiln (1,450 °C) of a "raw mix" made up of a mixture of clay, limestone, and several other additives.
- Manufacture of cement as a finished product, obtained by the homogeneous mixture of the ground clinker and calcium sulphate (gypsum) with or without depending on the type of cement one or more additional components: slag, fly ash, pozzolana, limestone, etc.

All kilns (clinker ovens) are made of steel lined with refractory bricks. Kilns are fed from their upper end and the raw materials tumble towards the lower end, progressively increasing in temperature. At the lower end, where the combustion takes place, the combustion gases reach 2,000 °C and the material temperature reaches around 1,450 °C. In this process, volatilization of radionuclides with low boiling point (²¹⁰Pb and ²¹⁰Po) occurs. Part of the volatilized ²¹⁰Pb and ²¹⁰Po inventory is emitted to air, whereas the remaining part is deposited in a kiln coating that progressively builds over the refractory surface until an equilibrium is reached, where the coating will maintain itself.

Maintenance of clinker ovens is listed as a NORM involving activity in the EU BSSD. Worker exposure to NORM during maintenance tasks potentially arises from the refractory brick and the kiln coating. Since residues from the maintenance operations are fed into the kiln, radiological risk associated to oven maintenance is exclusively related to occupational safety.

To minimize exposure to dust, and particularly to respirable crystalline silica, maintenance workers wear appropriate respiratory protection (use of a properly fitted, particulate filter respirator), hand protection (impervious, waterproof, abrasion and alkali-resistant gloves), body protection (impervious, waterproof, abrasion and alkali-resistant boots and protective long-sleeved and long-legged clothing to protect the skin) and footwear. Maintenance work is typically carried by contractors. In relation to the protection of outside workers, Article 51 of the EU BSSD established minimum requirements for the undertaking, including to:

- check whether the categorisation of the outside worker is appropriate in relation to the doses liable to be received within the undertaking;
- for entry into controlled areas, ensure that, in addition to the basic training in radiation protection, the outside worker has received specific instructions and training in connection with the characteristics of the workplace and the conducted activities, in accordance with points (c) and (d) of Article 15(1);
- for entry into supervised areas, ensure that the outside worker has received working instructions appropriate to the radiological risk associated with the sources and the operations involved, as required in point (c) of Article 38 (1);

TEXT BOX 3 continued

 ensure that the outside worker receives individual exposure monitoring appropriate to the nature of the activities, and any operational dosimetric monitoring that may be necessary;

In order to determine whether controlled or supervised areas need to be established during maintenance of clinker ovens, thus providing appropriate protection to outside workers, a sectorial study has been undertaken by Oficemen (the Spanish association for cement producers), in collaboration with IECA (The Spanish Institute of Cement and its Applications) and supervised by CSN. Out of the 35 associated factories, five reference plants were selected in order to carry out a detailed safety assessment of maintenance works. The selection of factories was made on the basis of the following information:

- Types of cement produced and radioactivity in the end products;
- Types of potential NORM residues used as clinker additives;
- Kiln design features.

The most limiting scenario is that of outside maintenance workers. Calculations, accounting for inhalation and external exposure, were performed based on the following conservative assumptions:

- 8 h per day work shift; manual repairing;
- worker wearing FFP3 mask (98% nominal filtration efficiency; with a 20% reduction due to poor fit);
- Respirable dust concentration 3 mg/m³ (AMAD 4 μm);
- Solubility class S for ²¹⁰Po, ²¹⁰Pb.

Moreover, probabilistic distribution functions were used for the following parameters: dimensions of the kiln, thickness of the kiln coating; and activity concentration of the uranium- and thorium-series radionuclides in the refractory brick.

The resulting specific exemption levels for 210 Po and 210 Pb are rounded to 150 Bq g⁻¹. These levels been adjusted so that the effective dose for a maintenance worker would not exceed 1 mSv a⁻¹ over background for a 2,000 h exposure.

6

CLEARANCE OF NORM

Countries must ensure a safe and sound management of NORM residues generated from notified and authorised NORM facilities, accounting for the NORM waste inventory in the country. Besides NORM waste produced at the operating industries, a substantial part of the national inventory might come from the dismantling of old facilities or the remediation of contaminated sites, for which no radiation protection considerations related to waste treatment, storage and disposal had been previously made.

Application of clearance concepts is key in ensuring that NORM waste management is done in an optimized way and is commensurate to radiation risk, and that reuse, recycling and recovery solutions are promoted while guaranteeing radiation safety.

The EU BSSD defines clearance levels as values established by the competent authority or given in national legislation, and expressed in terms of activity concentrations, at or below which materials arising from any practice subject to regulatory control may be released from the requirements.

According to the IAEA BSS (Schedule I), the general criteria for clearance, supporting the general or specific clearance levels, are the following:

- Radiation risks arising from the cleared material are sufficiently low as not to warrant regulatory control, and there is no appreciable likelihood of occurrence for scenarios that could lead to a failure to meet the general criterion for clearance; or
- Continued regulatory control of the material would yield no net benefit, in

that no reasonable control measures would achieve a worthwhile return in terms of reduction of individual doses or reduction of health risks.

Risk assessments should account for recycling, reuse, recovery and disposal of NORM, and be made using conservative assumptions, covering a wide variety of dose modelling scenarios. For this reason, clearance values might be over-conservative for some specific scenarios or disposal routes. To avoid undue burdens, an authorisation may be granted by the competent authority for releasing materials of regulatory control subject to specific requirements and conditions. This authorisation is known as specific (conditional) clearance.

It may be granted for materials from a specific facility or industrial sector or for a certain type of material, provided that the two above mentioned requirements are complied with, and that the necessary arrangements have been made to ensure that the conditions are met (for example, by overseeing the transport to the specified destination).

Examples of the use of this regulatory tool in Denmark, Italy and the Netherlands can be found in the management of wet sludge from the oil and gas industry. Clearance levels higher than the general exemption/levels are applied, subject to restrictions on their final disposal. In particular, values for wet sludge from RP-122, part II, table 2 have been adopted.

The basis for the adoption of these specific clearance values in the Netherlands are included in Text Box 4.

TEXT BOX 4

SPECIFIC CLEARANCE FOR DISPOSAL OF WET SLUDGE FROM OIL AND GAS PRODUCTION AND GEOTHERMAL FACILITIES IN THE NETHERLANDS

In the preparation of the implementation of the EU BSSD 2013/59/Euratom many responses from industry and other stakeholders were received. The oil and gas production and geothermal industry expressed their concern on the effect of the EU BSSD on the clearance of wet sludge. They contended that the application of the general, stricter, clearance levels for sludge would lead to:

- Higher cost due to the increased cost of waste storage;
- A significantly increased amount of radioactive waste;
- Possible insufficient storage capacity for the waste.

It was argued by the industry that higher clearance levels would still meet the general safety criteria. Since higher specific clearance levels can indeed fulfill the general criterion for clearance, as described in the next section, it was decided to set specific clearance levels for relevant radionuclides for wet sludge from oil and gas production and geothermal facilities in the ANVS-regulation on Basic Safety Standards for Radiation Protection. These specific clearance levels can be applied for "*mixtures of organic and mineral solid constituents in water or liquids containing hydrocarbon that is separated from the oil produced or the gas produced at a mining production site, or is produced at a mining production site as a result of the generation of geothermal energy*" or in short: wet sludge.

The higher specific clearance levels (see table TB4.1) are only applicable under the condition that the material is disposed of at specific, controlled, landfill sites. These sites are constructed such that they can safely store hazardous waste. They require, for instance, a water treatment system and a construction that ensures that leaching into the groundwater does not occur. A monitoring system is in place to ensure that this requirement is met. When the landfill has reached its maximum capacity, it will be sealed by a protective multi-layer system.

Note that when the specific clearance levels are used the weighted summation rule does apply and that these specific clearance levels do not apply to other materials precipitated in installations such as scales.

It was shown that the specific clearance levels are consistent with the general dose criterion for the clearance of NORM, as defined in Dutch regulations. This dose criterion is 0.3 mSv a⁻¹ (both for a member of the public and a worker),which is equal to the value in publication RP 122 part II of the European Commission and in compliance with the dose limit "of the order of 1 mSv/y" in EU BSSD Annex VII-3.

Calculations by the National Institute for Health and the Environment (RIVM, 2017) showed that the relevant scenarios from RP-122-II are generally consistent with the situation in the Netherlands. Where the scenarios deviate somewhat from the situation in the Netherlands this was either due to less conservative

TEXT BOX 4 continued

assumptions in the parameters in RP-122-II or for scenarios that do not determine the clearance levels (i.e.: do not represent a limiting dose). Therefore, considering the expected issues if no specific clearance was defined, it was decided to adopt the RP-122, part II, clearance levels for wet sludge in Dutch regulation.

Table TB 4.1The specific clearance level for wet sludges from oil and gasproduction and geothermal facilities. The general clearancelevels are included for comparison.

Radionuclide	Specific clearance level (kBq kg³)	General clearance level (kBq kg¹)
⁴⁰ K	100	10
²¹⁰⁺ Pb	100	1
²¹⁰ Po	100	1
²²⁶⁺ Ra	5	1
²²⁸⁺ Ra	10	1
²²⁸⁺ Th	5	1
^{232sec} Th ⁽¹⁾	5	1
235sec U ⁽¹⁾	10	1
238secU(1)	5	1
238secU ⁽¹⁾ Where ²¹⁰⁺ Pb = ²¹⁰ Pb, ²¹⁰ Bi	5	1

²²⁶⁺Ra= ²²⁶Ra, ²²²Rn, ²¹⁸Po, ²¹⁴Pb, ²¹⁴Bi, ²¹⁴Po

²²⁸⁺Ra = ²²⁸Ra, ²²⁸Ac

²²⁸⁺Th = ²²⁸Th, ²²⁴Ra, ²²⁰Rn, ²¹⁶Po, ²¹²Pb, ²¹²Bi, ²¹²Po (64.1%), ²⁰⁸Tl (35.9%)

(1): or individual nuclides of the respective decay series.

6.1 | Recycling, reuse and recovery

Recycling and reuse are not new concepts in the radiation protection field: they have been widely applied in the decommissioning of nuclear facilities, where large amounts of scrap and waste materials consisting of mainly concrete and steel, with low specific activities, are produced.

In the past few years, these concepts have gained increased attention in the wider context of sustainable waste management. Waste prevention and preference to reuse and recycle over incineration and disposal has been long promoted by the European Union. The EU Waste Framework Directive 2008/98/EC established the Waste Management Hierarchy (see below) and set up the concept of end-of-waste criteria to facilitate the reuse and recycling of waste material. These principles have been further reinforced in the first Circular Economy Action Plan adopted in 2015 (EC, 2015) and its follower adopted in March 2020 (EC, 2020), aimed at accelerating the transformational change required by the European Green Deal, while building on circular economy actions implemented since 2015.

Reduce, reuse, recycling and recovery are the so-called 4R waste management

hierarchy. The latter three concepts are defined as follows:

- *Reuse* means any operation by which products or components that are not waste are used again for the same purpose for which they were conceived.
- Recycling of waste is any operation by which materials are reprocessed into products, materials or substances whether for the original or other purposes. It includes the reprocessing of organic material, but does not include energy recovery and the reprocessing into materials that are to be used as fuels.
- Recovery of waste means any operation with the principal result of replacing other materials which would otherwise have been used to fulfill a particular function, or waste being prepared to fulfill that function, in the plant where the waste was produced or in the wider economy.

All industrial sectors in the EU (including NORM producing industries) have made important efforts to reduce waste production, and particularly, to avoid waste disposal to land or incineration, which have been charged with progressively higher deterrent taxes and fees in most countries.

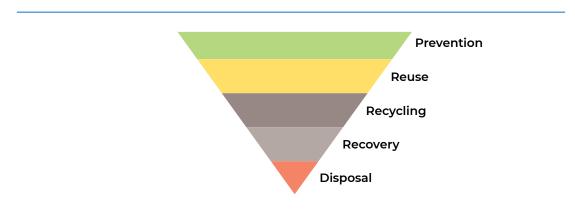


Figure 3. Waste management hierarchy. Adapted from European Directive 2008/98/EC

Some examples on safe uses of NORM residues are given below:

- Belgium: use of filter cakes from TiO₂ in construction (as sub-layers of the capping of landfills), and as secondary fuel.
- Slovenia: historic use of fly ash from the thermo plants for the bricks or concrete. The values of the activity concentration were below the values for the exemption and clearance for naturally occurring radionuclides and typically below the activity concentration used in the index for gamma radiation for building material. Fly ash was also used for stabilisation of slopes in the landfill.
- Spain: use of phosphogypsum as a soil amendment; valorization of red gypsum and mud from TiO₂ production for the construction of thermal insulator building walls.
- The Netherlands: use of NORM residues as stabilizers to improve the handling of other waste material on a designated landfill and as a sub layer for roads on this landfill.

Improved techniques in mining and in the metal processing industry have also expanded a market for legacy waste or residues from other NORM industries as input material for new NORM practices. For example, residues from the primary extraction of tin are imported in Belgium for further extraction of residual Pb and Sn, as well as copper-cement and cobalt-cement from primary zinc extraction, for Cu and Co extraction. In various countries, bottom ash and residues from the treatment of flue-gases from municipal solid waste incineration are exploited for metal extraction. In Norway, flue dust from TiO₂ and high purity pig iron production are used as raw material in zinc production.

Reprocessing of old mine tailings deposits is also on the rise. In Spain, exploitation licenses for a legacy W mine (for W extraction) and a legacy Sn mine (for Sn, Nb and Ta extraction) have recently been granted. Peak prices of uranium around 2007 brought forward several permit applications to extract uranium from several NORM legacy waste (such as phosphogypsum or uraniferous lignite tailings), but they were all withdrawn in subsequent years due to economic unfeasibility.

While recycling, reuse and recovery can be a source of valuable materials and reduce environmental impact and costs of production, regulatory provisions need be in place to ensure that they are used in a safe manner. Negative examples of the use of NORM, such as the use of alum shale in building materials or road construction, also exist in Europe.

With regard to radiation protection aspects, the EU BSSD requires that the disposal, recycling or reuse of radioactive materials arising from any authorised practice is subject to authorisation (Art. 30.1).

On the other hand, it should be implicit in national approaches that when a NORM production residue is considered as a by-product, a risk assessment is carried out to demonstrate that such use is in accordance with the radiation protection standards established in the EU BSSD.

Materials may be cleared (i.e. released from regulatory control) for recycling or reuse provided that the activity concentration for solid material:

- *i)* do not exceed the general clearance levels or,
- *ii*) comply with higher clearance levels (and associated requirements) for specific materials or for materials originating from specific types of practices, on the basis of the general dose criteria.

Typical dose modelling scenarios associated to reuse/recycling/recovery practices are listed below:

- Energy recovery (Incineration)
 - operators
 - air emissions
 - ash/slag disposal to landfill
- Metal recycling
 - scrap transport workers
 - scrap processing workers
 - workers at smelter and fabrication plant
 - use of potential consumer products
 - emissions to air
 - use of slag
- Reuse
 - small tools and equipment
 - large equipment
 - buildings (use and renovation)

Information and experience on the application of clearance can be drawn from the nuclear industry. In particular, two EC guidance documents (Radiation Protection 89 and Radiation Protection 113) develop release criteria for the clearance of waste materials arising from the decommissioning of nuclear facilities, accounting for the full inventory of potentially cleared radioactive waste arising from the decommissioning of nuclear power plants in Europe.

WG NAT has not identified similar studies for NORM facilities performed at the national or the European level.

In the case of the decommissioning of NORM facilities, although the building structure as such is less likely to be radioactively contaminated, care should be given to a proper identification, characterization and segregation of contaminated pieces of equipment. Metallic waste, in particular, may represent a substantial NORM waste stream: both in normal operation (due to maintenance) and in decommissioning. Scrap metal from NORM facilities would be typically contaminated by either: *i*) ²²⁶Ra and ²²⁸Ra (as in oil extraction, titanium dioxide production or phosphate processing industries); or, ii) ²¹⁰Po and ²¹⁰Pb (as in coal-fired power plants boilers, gas extraction platforms, or geothermal plants). Contamination or enhanced concentration in natural radionuclides may also be found on other types of material, such as plastic tubing, refractory material, etc.

6.2 | Disposal of NORM waste

Disposal is the final step in the waste management hierarchy. In the case of NORM waste, the most commonly used disposal options are:

- For large volumes of relatively low activity waste (e.g. < 5 kBq kg⁻¹), such as mining tailings or phosphogypsum, *in-situ* confinement.
- For moderate amounts of low activity NORM waste (e.g. < 5-10 kBq kg⁻¹) disposal in controlled landfills for non-hazardous or hazardous waste, authorised for accepting NORM waste.
- For low and intermediate volumes of high activity NORM waste (e.g. > 10 kBq kg⁻¹), such as scales or residues from the extraction of rare earths, disposal in repositories specifically licensed for NORM waste or in near surface radioactive waste repositories.

Blending of NORM waste with the purpose of deliberate dilution of radioactive materials in order for them to be released from regulatory control is not permitted as a disposal option by the EU BSSD.

The choice of the NORM waste disposal option depends on the national legislation and the overall regulatory approach for waste management, but also on practical considerations, such as waste volume, availability of disposal infrastructures and stakeholder acceptance. For landfills where NORM waste is disposed, the radiological risks for workers and members of public may be evaluated in the following exposure scenarios:

- Transport workers
- Landfill site workers
- Intrusion and disturbance of the site after closure
- Residential farmer (off-site)
- Recreational

• Accidental events in the landfill such as fire and flooding

In the UK, exemption/clearance levels for NORM waste disposal or incineration are significantly higher than the general exemption/clearance levels for NORM. The basis for deriving specific exemption/clearance levels for landfill disposal of ²¹⁰⁺Pb/²¹⁰Po-bearing waste is presented in Text Box 5.

TEXT BOX 5

SPECIFIC EXEMPTION/CLEARANCE LEVELS FOR ²¹⁰⁺Pb AND ²¹⁰Po WASTE DISPOSAL IN THE UK

In the UK, provisions are in place to exempt Type 1 NORM waste (high volume low level radioactive waste comprising NORM arising from NORM industrial activities or land remediation) and Type 2 NORM waste (higher activity high volume low level radioactive waste which does not meet the Type 1 NORM waste criteria). Values are given in Table TB5.1. Both are specific exemptions for land disposal or incineration, as there are conditions attached such as keeping adequate waste disposal records and that the waste must be transferred to a person for burial or incineration of the waste or a person defined as being waste permitted. The dose criteria selected in order to demonstrate exemption as a Type 1 or 2 NORM waste are 1,000 microSv a⁻¹ for any landfill worker and 300 microSv a⁻¹ for any member of the public. A generic radiological impact assessment has been carried out which demonstrates that for NORM waste concentrations up to the values given in Table TB5.1 for Type 1 NORM waste these criteria will be met (Anderson and Mobbs, 2010). For Type 2 NORM waste it is the responsibility of the waste producer to demonstrate that these criteria have been met by doing a site specific assessment. The exposure groups considered in the generic assessment are given in Table TB5.2.

A review for UK Government on the impact of changes to exemption and clearance values (Benson et al, 2016) surveyed different industries. From a review of the original calculations used to derive exemption values for the UK Radioactive Substances Regulations (RSR) (Anderson and Mobbs, 2010), it was determined that there was scope for safely increasing the exemption/clearance values for ²¹⁰Pb/²¹⁰Po This option was particularly welcomed by both the steel industry and the gas exploration/production sector. Both of these produce NORM wastes containing ²¹⁰Pb/²¹⁰Po, which currently require disposal under RSR permitting requirements at a significant cost. Given that there are potentially hundreds of tonnes of waste for disposal each year, the costs were reported as being of the order of millions of pounds per year. In 2018 the legislation was updated to increase the exemption/clearance levels for ²¹⁰Pb and ²¹⁰Po.

TEXT BOX 5 continued Table TB 5.1 NORM waste concentrations and maximum disposal quantities					
Radionuclide	Type 1 NORM concentration (kBq kg ⁻¹)	Type 1 NORM total activity for landfill (GBq a ⁻¹)	Type 1 NORM total activity for incineration (MBq a ⁻¹)	Type 2 NORM concentration (kBq kg ⁻¹)	
$^{238}\text{U}_{sec}$	5	50	100	10	
²³⁸⁺ U	5	50	100	10	
²³⁴ U	5	50	100	10	
²³⁰ Th	5	50	100	10	
²²⁶⁺ Ra	5	50	100	10	
²¹⁰⁺ Pb	100	1,000	100	200	
²¹⁰ Po	100	1,000	100	200	
²³⁵ U _{sec}	5	50	100	10	
²³⁵⁺ U	5	50	100	10	
²³¹ Pa	5	50	100	10	
²²⁷⁺ Ac	5	50	100	10	
²³² Th _{sec}	5	50	100	10	
²³² Th	5	50	100	10	
²²⁸⁺ Ra	5	50	100	10	

Table TB 5.2 Scenarios and exposure pathways considered

Scenario	Key groups*	Exposure pathways	
Operational phase	Sorting worker	External irradiation; inhalation of dust; skin contamination	
	Landfill worker	External irradiation; inhalation of dust; skin contamination; ingestion of dust	
Leachate discharge	Member of the public	External irradiation; inhalation of re-suspended sediment; ingestion of water, freshwater fish and terrestrial foods	
Migration with groundwater (post-closure)	Member of the public	External irradiation; inhalation of dust; ingestion of water, freshwater fish and terrestrial foods	
Inadvertent intrusion	Construction worker	External irradiation; inhalation of dust; ingestion of dust	
(post-closure)	Member of the public (i.e. resident)	External irradiation; inhalation of dust; ingestion of dust; ingestion of vegetables grown in the garden	
Residential landfill gases (²²² Rn)	Member of the public (i.e. resident)	Inhalation of radioactive gas	
		Inhalation of radioactive gas	

According to national legislations, NORM waste (i.e. waste with activity concentrations above the exemption/clearance levels) may or may not be regulated as radioactive waste. The situation by country is as follows:

- A. Denmark, France, Lithuania, the Netherlands, Norway, Poland, Slovenia and Sweden and the UK define all NORM waste as radioactive waste;
- B. Austria, Czech Republic, Finland, Germany, Hungary, Ireland, Italy, Luxembourg, Romania and Switzerland do not define any NORM as radioactive waste;
- C. In Belgium and Spain, NORM waste is regulated as radioactive waste when management through conventional waste management routes would result in doses to workers and/or the public above certain dose thresholds or exceeds activity concentration values consistent with such thresholds.

As per the questionnaire, around 80% of HERCA member countries (including France, the Netherlands, Norway, Sweden and the UK, besides all group B and C countries) allows disposal of NORM waste below a certain activity concentration in landfills or repositories that are not licensed as radioactive waste repositories, subject to notification or approval by the competent authority. Landfill or repository operators accepting NORM waste, in their turn, are subject to registration or licensing, depending on the country, and need to comply with different requirements, depending on the country, pertaining to waste traceability and workplace and environmental monitoring.

Out of the countries where NORM waste is legally defined as radioactive waste, France may allow disposal in non-hazardous and hazardous waste landfills when the activity concentration of the uraniumand thorium-series radionuclides is below 20 kBq kg⁻¹. The same holds for Sweden for an activity concentration value of 10 kBq kg⁻¹. Norway establishes the same 10 kBq kg⁻¹ threshold for disposal of NORM hazardous waste either in hazardous waste landfills or in landfills or repositories licensed for radioactive waste. More details on the approach for the disposal of NORM waste in Norway, including requirements for NORM waste disposal facilities, is given in Text Box 6. The information on conventional NORM waste disposal the UK is given in Text Box 5.

Conversely, for group B countries, as well as for C group countries, there are mechanisms in place to classify and dispose the highest level NORM waste as radioactive waste.

TEXT BOX 6

DISPOSAL OF NORM WASTE IN NORWAY

In Norway, NORM waste containing the radionuclides from ²³²Th, ²³⁸U decay chains and ⁴⁰K over the values laid down in the national legislation is considered as radioactive waste. More specifically, the Regulations on the application of the Pollution Control Act to radioactive pollution and radioactive waste (2010) set two sets of limit values for various radionuclides:

- the lower limit values, given as specific activity concentrations (Bq g⁻¹), for what is considered as radioactive waste, and
- the limit values, given as specific activity concentrations (Bq g⁻¹) and total activity of radionuclide per year (Bq a⁻¹), for decision-making if such radioactive waste is subject to a special waste management requirement and obligatory final disposal.

Naturally occurring radionuclides (⁴⁰K, ²³⁵U, ²³²Th, ²³⁸U and their progeny) are included in both sets of values, and as aforementioned, all waste containing NORM higher than limits given by regulations is considered as radioactive waste.

A graded approach for control and disposal of radioactive waste, including NORM containing waste, has been developed (Figure TB6.1).

The main features of such graded approach are as follows (on example of ²²⁶Ra):

- Waste with activity concentration below 1 kBq kg⁻¹ is not considered as radioactive waste;
- Waste with specific activity concentration between 1 and 10 kBq kg⁻¹, which is also hazardous waste, can be send to a waste management facility that has licence either for hazardous waste disposal, issued by the Environment Agency (EA), or for radioactive waste disposal, issued by the Norwegian Radiation and Nuclear Safety Authority (DSA); If NORM waste is radioactive, but not hazardous, it must be sent to a waste management facility (e.g., disposal site, incineration, etc.) with license issued by the DSA;
- Waste with specific activity higher than 10 kBq kg⁻¹ and total activity higher than 10,000 Bq a⁻¹ is subject to obligatory final disposal and must be sent to a disposal site holding the licence for final disposal of radioactive waste, issued by the DSA.

A summation rule must be applied whenever the waste contains various radionuclides, and then, the waste is to be considered radioactive if the sum of the ratio between specific activity for each radionuclide and the corresponding value in the regulations is greater than or equal to 1:

$$\sum_k \frac{C_k}{C_{e,k}} \ge 1$$

Where C_k is specific activity concentration for radionuclide k, $C_{e,k}$ is limit value for specific activity of radionuclide k defined in the regulations.

A holistic solution for management of waste that includes radioactive and other hazardous substances has been developed. In practice, such an integrated approach needs properly integrated legislation and collaboration of responsible

TEXT BOX 6 continued

national authorities. The regulatory framework for NORM waste is equivalent to the system for radioactive waste containing anthropogenic radionuclides.

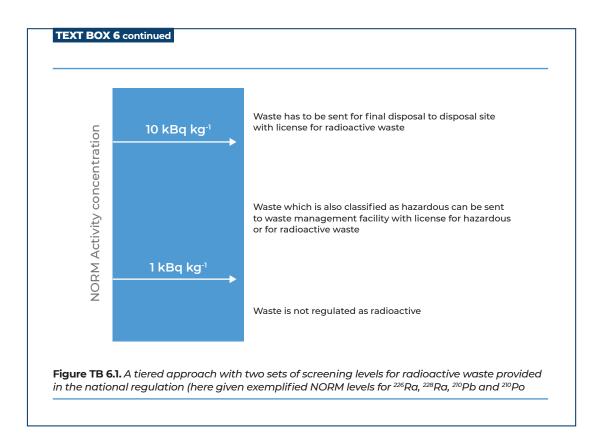
The Norwegian Radiation and Nuclear Safety Authority has responsibility to grant the licence for handling and disposal of NORM radioactive waste. Beside common requirements that include detailed description of the disposal site, information on security and safety measures, financial security, plan for disclosure, competence etc., an application of disposal site for permit to handle and dispose NORM waste must include the following information concerning:

- Radioactive waste
 - Detailed description of radioactive NORM waste that will be handled and disposed, such as, (a) waste type (b) NORM radionuclides of concern, (c) their activity concentrations (kBq kg⁻¹) and total activity per year (Bq a⁻¹), (d) projected waste quantities to be received per year (kg or tonnes), (e) description of other waste characteristics that can be of concern (e.g.,% TOC, physical characteristics, packaging),
 - Description of methods for safe handling, use of chemical methods in waste handling, storage conditions and final disposal conditions,
 - Description of waste streams at disposal site,
- Radioactive discharge from disposal sites to air, water bodies and ground detailed discharge description including (a) which NORM radionuclides will be discharged, (b) specific activity of radionuclides in discharge and total activity per year, (c) physical and chemical characteristics of discharge, (d) volume of expected discharge per year, (e) planned/existing purification and treatment systems, as well as consideration of measures to reduce potential or existing discharge,
- Mapping and estimation of risk to human health and biota related to handling and disposal of given radioactive waste and related to discharge from disposal site.

Based on NORM waste characteristics, infrastructure and waste management possibilities, proposals on NORM waste treatment and storage are made by waste management facilities, including disposal sites. Assessment reports, containing consideration of waste stability and/or change over time, leaching risk estimation, investigation of underground water, reaction with other chemicals etc. are commonly required in the process of giving permit/licence.

Results from monitoring programmes are regularly used in modelling and evaluation of risk related to radioactive waste, their handling and disposal. An assessment of risk and potential consequences must be done concerning both human health and biota organisms in the ecosystems of relevance. The general dose criterion of 1 mSv a⁻¹ for the effective dose to the public and non-occupationally exposed workers, given in the Radiation Protection Regulations (2000), must be satisfied. Further, the undertaking of concern shall plan the use of radiation and protective measures to ensure that exposure of the non-occupationally exposed workers and the public, shall not be exposed to an effective dose exceeding 0.25 mSv a⁻¹.

HERCA guidance on NORM exemption and clearance September 2021



CONCLUSIONS

The EU Directive 2013/59 (EU BSSD) gives unprecedented attention to the control of natural radiation sources, requiring NORM involving activities to be managed within the same regulatory framework as other practices causing exposure to ionizing radiation. A graded regulatory approach needs to be developed for the regulatory control of NORM, where the application of the concepts of exemption and clearance plays a key role.

The EU BSSD general exemption/clearance levels (i.e., activity concentration values of 1 kBq kg⁻¹ for ²³⁸U and ²³²Th series and 10 kBq kg⁻¹ for ⁴⁰K, laid down in the Annex VII, Table A, part 2 of the EU BSSD) have been adopted by the majority of HERCA countries. However, some differences among HERCA countries have been identified, such as (a) adoption of higher values for exemption/clearance for specific segments of the ²³⁸U chain in case of disequilibrium or in cases of small amounts of specific material, (b) adoption of exemption/clearance values for the additional primordial radionuclides, (c) application of summation rules in the case of mixture of radionuclides.

Where amounts of radioactive substances or activity concentrations do not comply with the exemption values laid down in EU BSSD, practices may be exempted from authorisation on a case-by-case basis, based on a demonstration of compliance with the general exemption and clearance criteria set out in the national regulation. The current analysis showed that all HERCA countries have adopted a dose criterion of 1 mSv a⁻¹ for workers, whereas half of HERCA member countries have adopted more restrictive dose criteria for exposure of the public, in range 0.01-0.3 mSv a⁻¹. Moreover, national examples have been provided on the exemption of specific materials or specific types of practices, based on higher activity concentration levels consistent with the general exemption/clearance dose criteria.

Although the general exemption/clearance levels in the EU BSSD for NORM do not apply to liquid or airborne discharges, requirements on discharge authorisation, including monitoring of public and environmental exposure, should be applied for NORM discharges. About half of HERCA member countries have implemented exemption or clearance regulatory provisions on NORM discharges.

Clearance of NORM from notified and authorised practices, and in particular the use of specific (conditional) clearance, should be encouraged, since these mechanisms provide a better use of regulatory efforts and allow for more efficient management solutions.

NORM waste (i.e. waste with activity concentrations above the exemption/ clearance levels) is or is not regulated as radioactive waste, depending on the country. Although half of the countries surveyed define all NORM waste as radioactive waste in their regulation, around 80% allow the disposal of NORM waste, below certain activity concentrations or dose levels, in conventional landfills, i.e. landfills for disposal of non-radioactive waste, at possibly specific conditions.

While circular economy is strongly supported by European Union policies, few countries were able to provide examples on the reuse, recycle or recovery of NORM residues, in compliance with the EU BSSD provisions, showing that common efforts are still needed in this area.



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ANNEX

HERCA WG NAT QUESTIONNAIRE ON EXEMPTION AND CLEARANCE OF NORM

Introduction

With this questionnaire the HERCA working group on "natural radiation sources" (WG NAT) tries to gather and disseminate information on the implementation of the concepts of exemption and clearance of naturally occurring radioactive materials (NORM). The European Basic Safety Standards (EU BSSD: Council directive 2013/59/EURATOM) treats natural radiation sources differently from the previous EU-directive, requiring NORM involving activities to be managed within the same regulatory framework as other practices. In order to help in the practical implementation of EU-BSS for NORM, sharing information on this topic can be beneficial.

In the implementation of the EU BSSD some decisions on how to implement exemption and clearance need to be made. This gives some flexibility as reflected in the recital of the Directive:

- Recital 37 states that general clearance and exemption levels from IAEA RS-G1.7 can be used, instead of the clearance levels from RP-122, to decide upon exemption and clearance. This implies replacing the previous EC recommendation on an exemption/clearance criterion of 0.3 mSv a⁻¹to a non-dose based criterion.
- *Recital 38* states that Member States "should be able to grant specific exemption from authorisation for certain practices involving activities above the exemption values".
- Recital 39 refers to, amongst others, the use of RP-122 as guidance for specific clearance levels for the management of

large volumes of materials arising from the dismantling of authorised facilities.

In order to get an overview of how the member states interpret and apply RP-122-2 and the EU BSSD regarding exemption from notification or authorisation of NORM involving activities as well as clearance of NORM, the HERCA WG NAT drew this questionnaire. The resulting overview is expected to help HERCA members in the further implementation of the EU BSSD regarding NORM, assist in a harmonized approach to exemption and clearance, and will served as an input in a revision of RP-122-2. As such, the resulting overview will be shared with all HERCA members in 2019.

Please, send your responses to the HERCA secretariat by 19. 12. 2018. In case that, in your opinion, more comprehensive explanation of your choice of answers is needed, please, do not hesitate to write down all the facts you find useful and of importance.

Definitions and abbreviations used in this questionnaire

 In this questionnaire "clearance" is used to indicate clearance of materials without further restriction (this is also referred to as general clearance). Clearance is governed by the clearance levels from EU BSSD. In contrast to clearance, the phrase "specific clearance" is used to indicate clearance of materials with other (usually higher) specific clearance levels subject to certain conditions. Requirements can be part of specific clearance (e.g. a limitation on the amount of material, or disposal has to be according to a prescribed type of site). A similar distinction is made for "exemption" versus "specific exemption". Specific clearance and specific exemption are referred to in some countries as conditional clearance and condition exemption.

- EU BSSD: Council directive 2013/59/ EURATOM of 5 December 2013.
- RP-122-2: Radiation protection 122
 Practical use of the concepts of clearance and exemption Part II Application of the concepts of exemption and clearance to natural radiation sources
- IAEA RS-G-1.7 Safety Guide Application of the Concepts of Exclusion, Exemption and Clearance
- IAEA SR44: Safety report series 44 Derivation of Activity Concentration Values for Exclusion, Exemption and Clearance

Exemption/clearance. Practical implementation

- In the transposition of the EU BSSD into your national regulatory framework, have you adopted, or are you planning to adopt, the values for exemption/ clearance for naturally occurring radionuclides in solid materials proposed in EU BSSD Annex VII Table A, part 2?
- 🗌 Yes.
- No. The 1 Bq/g for the U and Th-series radionuclides and 10 Bq/g for K-40 are established, but a summation rule is additionally applied.

Please, specify the summation rule applied

No. Different exemption/clearance values are used

Please, specify what these are

2. Have you defined, or are you planning to define, in your regulation additional general exemption and clearance levels for other nuclides e.g. U-235 or the primordial nuclides like Lu-176?

Yes.

Please, specify the nuclides and their general exemption and clearance levels

No.

 The EU BSSD sets exemption and clearance levels for any amount of material. Do you have additional (higher) exemption and clearance levels for moderate amounts of material (e.g. potassium salts, geological samples)? (See RP-122-2 p3)

Please specify the nuclides and their general exemption and clearance levels, the amount of material, additional requirements and the basis of the general exemption and clearance levels

4. Where amounts of radioactive substances or activity concentrations do not comply with the values laid down in Table A, part 2, the EU BSSD allows granting exemption from notification or approving clearance of NORM based on a demonstration of compliance with a dose criterion. Annex VII establishes this criterion as a dose increment liable to be incurred by an individual not higher than 1 mSv/year. Have you established, or are you planning to establish, in your regulation a 1 mSv/year dose criterion for granting exemption/clearance?

🗌 Yes.

No, a more restrictive dose criterion is applied.

Please specify the dose criteria for workers and for members of the public

Yes.

[🗌] No.

- 5. The drinking water directive (98/83/ EC, with amendment EU-2015/1787) limits the amount of natural radionuclides in drinking water by setting a limit for the "total indicative dose" of 0.1 mSv/a. Does this have an impact on the system of clearance and exemption in your country (as for instance, by setting additional constraints for work activities liable to affect groundwater or by establishing more restrictive exemption/clearance values than the ones endorsed in EU BSSD for certain radionuclides)?
- 🗌 Yes.

Please, specify how this affects the system of clearance and exemption.

🗌 No.

This is not yet considered in our implementation of the EU BSSD.

- 6. Does your regulation on NORM practices include exemption or clearance provisions for the discharge to water bodies or to the atmosphere?
- Yes.

Please, specify.

- No.
- 7. Exemption and clearance of NORM (both general and specific) are generally applied in terms of activity concentration levels. However, it is also possible to use other operational quantities (e.g. surface contamination level, Bq/cm²). Do you use other derived magnitudes as a criterion for exemption or clearance?

🗌 Yes.

Please, specify what quantity is used and the basis and context for its use.

🗌 No.

Specific exemption/clearance

8. Annex VI of the EU BSSD includes a list of industrial sectors involving NORM that shall be considered when applying Article 23. Out of the sector on this list, or of the NORM processing sectors in your country, have you exempted any of them from radiation regulatory control?

🗌 Yes.

Please, specify on which basis (e.g. sectorial study; international situation analysis).

🗌 No.

 In RP-122-2, table 2 (§6.3, p20), (higher) clearance levels for wet sludge from oil and gas production are allowed (subject to restrictions on final disposal). Have you included these values in your regulation?

Yes.

Yes, but we used other values than those is the last column of table 2.

Please specify the nuclides and their clearance levels.

- No.
- Do you have provisions allowing for specific exemption/clearance of NORM in your legal system?

Yes.

Please, specify whether an undertaker can file a request for specific exemption/clearance, the authorities involved and the legal form of approval. If specific exemption is based on a dose criterion, please state what the dose criterion is:

 for members of the public: for instance 0.01 mSv/year, 0.3 mSv/year or 1 mSv/y

– for workers: for instance 0.3 mSv/a or 1 mSv/a?

🗌 No.

- According to your national law, is all NORM waste with activity concentrations above the exemption levels defined as radioactive waste?
- 🗌 Yes.
- No.

Please, specify when NORM waste is defined/managed as radioactive waste.

- 12. Does your national law allow for disposal of NORM waste in landfills or repositories that are nor authorised as radioactive waste disposal facilities?
- 🗌 Yes.

Please, specify under which conditions this can be done, for the different types of facility (e.g. non-hazardous waste landfill, Hazardous waste landfill, NORM waste repository).

No.

Respondents to the Questionnaire

In total, twenty-one HERCA member countries have sent their responses on NORM questionnaire distributed by the HERCA WG NAT:

Austria (M. Tatzber, AGES), Belgium (S. Pepin, FANC), Czech Republic (H. Procházková, SUJB), Denmark (D. Ulfbeck, SIS), Finland (M. Markkanen, STUK), France (A.L. Joye, ASN), Germany (B. Klein, BMU), Hungary (A. Földi, HAEA), Ireland (D. Fenton, EPA), Italy (S. Venga, ISIN), Lithuania (R. Ladygiene, RPC), Luxembourg (P. Majerus, DRP), The Netherlands (P. Görts, ANVS), Norway (J. Mrdakovic Popic, DSA), Poland (M. Skotniczna, PAA), Romania (D. Dogaru, CNCAN), Slovenia (D.Škrk, SRPA and I. Osojnik, SNSA), Spain (M. García-Talavera, CSN), Sweden (P. Sopher, SSM), Switzerland (P. Steinmann, FOPH) and United Kingdom (K. Jones, PHE).

Information from responses (updated in January 2021) have been used in making the present document.

ANNEX

GLOSSARY

By-product [*CE 21.2.2007. COM (2007) 59*]: a production residue that is not a waste.

Clearance [*IAEA Safety Glossary, 2018*]: The removal of radioactive materials or radioactive objects within the authorised practices from any further regulatory control;

Consumer product [*EU BSSD*]: a device or manufactured item into which one or more radionuclides have deliberately been incorporated or produced by activation, or which generates ionising radiation, and which can be sold or made available to members of the public without special surveillance or regulatory control after sale;

Dose constraint [EU BSSD]: a constraint set as a prospective upper bound of individual doses, used to define the range of options considered in the process of optimisation for a given radiation source in a planned exposure situation;

Exemption [*IAEA Safety Glossary, 2018*]: The determination by a regulatory body that a source or practice need not be subject to some or all aspects of regulatory control on the basis that the exposure due to the source or practice is too small to warrant the application of those aspects;

Naturally occurring radioactive mate-

rial (NORM) [*IAEA Safety Glossary, 2018*]: Radioactive material containing no significant amounts of radionuclides other than naturally occurring radionuclides;

Practice [EU BSSD]: human activity that can increase the exposure of individuals to radiation from a radiation source and is managed as a planned exposure situation;

Production residue [*CE 21.2.2007. COM* (2007) 59]: a material that is not deliberately produced in a production process but may or may not be a waste.

ACTIVITY CONCENTRATION VALUES OF URANIUM AND THORIUM SERIES RADIONUCLIDES IN NATURAL MATERIALS

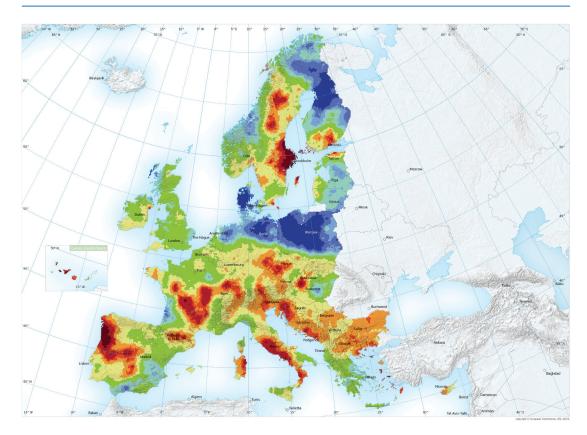
In Europe, the average annual effective dose to the general population due to natural radiation sources is 3.20 mSv (EC-JRC, 2012⁽²⁾), a slightly higher value than the worldwide estimate of 2.41 mSv (UNSCEAR, 2008).

Radon indoors represents the main contribution to the effective dose. The second important contribution is due to terrestrial external radiation, on average. The value estimated at the European level is 0.50 mSv a⁻¹. At country level, terrestrial external radiation presents different values due to varying geology, from 0.85 mSv a⁻¹in Portugal, via 0.6 mSv a⁻¹in Bulgaria, Croatia, Sweden and the Czech Republic, to the lowest values, around 0.3 mSv a⁻¹, found in Poland, the Netherlands, Denmark and Cyprus (EC-JRC, 2019). Terrestrial gamma radiation outdoors comes mainly from the uranium and thorium series radionuclides present in rocks and soils. Figures A1 and A2, represent, respectively, the uranium and thorium concentration in European soils (EC-JRC, 2019). Whereas the maximum scale value for thorium corresponds to a ²³²Th activity concentration of around 340 Bq kg⁻¹ – way below the generic exemption level for solid materials – for uranium the scale goes up to 1160 Bq kg⁻¹, slightly above it.

Uranium anomalies in European soils are associated to different geological conditions: for example, in Northern Europe they are usually related to the occurrence of alum black shale; in Spain and France, they correspond to uranium mineralisation, whether related to granitic intrusions or to hydrothermal deposits; in Italy, they are found in topsoil over Cenozoic alkaline volcanic rocks.

1 ppm uranium = 1 mg/kg uranium = 0.012348 Bq ²³⁸U per g of material 1 ppm thorium = 1 mg/kg thorium = 0.004057 Bq ²³²Th per g of material IAEA SRS N°49

⁽²⁾ European Commission Joint Research Centre (2019). Cinelli, G., De Cort, M., Tollefsen, T., editor(s). European Atlas of Natural Radiation, Publications Office of the European Union, Luxembourg, ISBN 978-92-76-08258-3 (online), 978-92-76-08259-0 (print), JRC116795, doi:10.2760/520053.

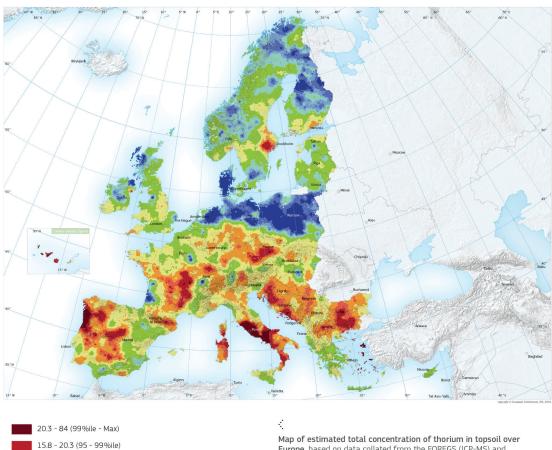


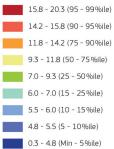


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Map of estimated total concentration of uranium in topsoil over Europe, based on data collated from the FOREGS (ICP-MS) and GEMAS (XRF) European datasets as shown in Figure 3-3 and Figure 3-5 in EANR, EC-JRC, 2019. The colours are attributed according to the percentiles of the EANR-estimated map points. Source: Map created by A. Ferreira, T. R. Lister, R. S. Lawley and A. M. Tye.

Figure A1. Map of estimated total concentration of uranium in topsoil over Europe (mg/kg)





Map of estimated total concentration of thorium in topsoil over Europe, based on data collated from the FOREGS (ICP-MS) and GEMAS (XRF) European datasets as shown in Figure 3-8 and Figure 3-10 in EANR, EC-JRC, 2019. The colours are attributed according to the percentiles of the EANR-estimated map points. Source: Map created by A. Ferreira, T. R. Lister, R. S. Lawley and A. M. Tye.

Figure A2. Map of estimated total concentration of thorium in topsoil over Europe (mg/kg)

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Saline eflorescences around retention pond over phosphogypsum stack © *M. García-Talavera*

Pile of contaminated tubings from the dismantling of a phosphate facility © *S. Pepin* Natural ionizing radiation

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