V. U. Mme Claire Stievenart
Av. A. Huysmans 206, bte 10
1050 Bruxelles-Brussel

ISSN - 0250 - 5010

ANNALEN
VAN
DE BELGISCHE VERENIGING
VOOR
STRALINGSBESCHERMING

VOL. 43, N° 2, 2018

3e trim. 2018

Clearance and release from regulatory control of radioactive materials

Driemaandelijkse periodiek
1050 Brussel 5

Périodique trimestriel
1050 Bruxelles 5

ANNALES
DE
L'ASSOCIATION BELGE
DE
RADIOPROTECTION

Annales de l'Association belge de Radioprotection (BVSABR)
Ce numéro contient les textes des exposés présentés lors de la réunion du 25 mai 2018

Annalen van de Belgische Vereniging voor Stralingsbescherming (BVSABR)
Dit nummer bevat de teksten fan de uiteenzettingen ter gelegenheid van de vergadering van 25 mei 2018

Vol. 43/2/2018

Clearance and release from regulatory control of radioactive materials

SOMMAIRE INHOUD

Annales de l'Association belge de Radioprotection, vol. 43, n°2, 2018
Annalen van de Belgische Vereniging voor Stralingsbescherming, vol. 43, nr 2, 2018

CURRENT AND FUTURE BELGIAN REGULATORY REQUIREMENTS ON CLEARANCE AND RELEASE FROM REGULATORY CONTROL OF RADIOACTIVE MATERIALS AND SITES

Frederik Van Wonterghem - Federal Agency for Nuclear Control

An overview of the current and future regulatory requirements on clearance and exemption of materials and site release (after decommissioning) is given. For clearance and exemption, the current requirements of the General Regulation for radiological protection of the public, the workers and the environment (Royal Decree of July 20th, 2001) are described, as well as the intended changes to this regulation in accordance with the new European Basic Safety Standards. For site release (after decommissioning of a nuclear facility) the general principles of a recent FANC position paper on this topic are summarized.

Current regulatory requirements on clearance and exemption of artificial radionuclides in Belgium

The clearance and exemption of materials is a well-established concept in radiation protection regulations. Definitions of these terms can be found in the Basic Safety Standards:

> **Exemption level:** *value established by a competent authority or in legislation and expressed in terms of activity concentration or total activity at or below which a radiation source is not subject to notification or authorisation*;
>
> **Clearance levels:** *values established by the competent authority or in national legislation, and expressed in terms of activity concentrations, at or below which materials arising from any practice subject to notification or authorisation may be released from the requirements of this Directive*

Exemption values for radioactive materials containing artificial radionuclides are defined in annex IA of the General Regulation for radiological protection of the public, the workers and the environment [1]. These radionuclide specific values are expressed in terms of total activity (Bq) and in terms of activity concentration (kBq/kg) for moderate amounts. The values in this annex IA are taken from the previous Basic Safety Standards 96/29/Euratom [2].

General clearance values for radioactive materials containing artificial radionuclides are defined in annex IB of the same Royal Decree [1]. These radionuclide specific values are only applicable for solid materials and are expressed in activity concentration (kBq/kg). The values in this annex IB are taken from a European guidance document RP 122 [3] and are based on calculations taking in to account dose constraints for persons exposed to the cleared materials

- - Effective dose ≤ 10 µSv/year
- - Collective dose ≤ 1 man.Sv/year
- - Skin dose ≤ 50 mSv/year

In 2010 a FANC Guidance document [4] on measurement procedures and techniques to comply with annex IB was also published.

In the current regulatory framework there are no surface activity clearance levels (Bq/cm²) however.

In application of article 18 of [1], a specific clearance license can be requested at the FANC for clearance of solid materials with (higher) activity concentrations. These specific clearance levels are defined in the clearance license and can be higher than the general clearance levels (annex IB) but must be lower than the exemption levels of annex IA. The licensee should prove that the dose impact for the cleared materials, taking into account their specific destination (landfill, incinerator…) is ≤ 10 µSv/year for members of the public.

In recent years, several licensees have obtained such clearance levels for different types of materials: For example, SCK.CEN (2016)

- Destination: INDAVER landfill

- Quantity: max. 80 tons of soil
- Activity levels: ^{137}Cs < 10 kBq/kg (annex IA)
- Origin: renovation of underground piping

For example, FBFC International (2018)

- Destination: INDAVER landfill
- Quantity: max. 12.450 tons of soil
- Activity levels: U isotopes < 10 kBq/kg (annex IA)
- Origin: clean-up of site and nearby waterways

Future regulatory requirements on clearance and exemption of artificial radionuclides in Belgium

A regulatory project is ongoing to transpose the requirement of the new Basic Safety Standards 2013/59/Euratom [5] to be transposed in Belgian legislation. The draft modification of [1] has already undergone stakeholder consultation and should be published shortly.

The mass specific clearance levels in the new BSS are taken from an IAEA Safety Guide RS G-1.7 *Application of the Concepts of Exclusion, Exemption and Clearance* [6] and are to be used both as default exemption values and as general clearance levels. These values are still based on a dose constraint of 10 µSv/year. The new BSS Directive also states that specific clearance levels (for example those of RP89 [7] and RP113 [8]) are important tools for the management of large volumes of materials arising from dismantling of nuclear facilities.

In the following paragraphs the main modifications to the current regulatory requirements of [1] are summarized.

In article 3.1 and annex IA and IB the values for clearance and exemption will be defined.

For total activity (Bq), the exemption values from the new BSS annex VII table B column 3 will be used for annex IA. This does not induce changes in current values.

For activity concentration (kBg/kg or Bq/g), exemption values for moderate amounts of any type of material (≤ 1 ton) from the new BSS annex VII table B column 2 will also be used in annex IA. Again, this does not induce changes in current values. Exemption and clearance values for any amount of any type of material will be taken form the new BSS annex VII table A and will be used for annex IB. This will lead to some changes for commonly used radionuclides, for example C-14, Cs-137.

The table below gives an overview of some of the old and new values for clearance and exemption.

	GRR-2001		GRR-2018 After Transposition BSS 2013/59/Euratom	
	Annex IB	**Annex IA**	**New Annex IB (BSS annex VII table A)**	**New Annex IA (BSS annex VII table B)**
Radionuclide	**Clearance values Bq/g**	**Exemption values for moderate amounts + Maximum accepted values for clearance license article 18 Bq/g**	**Clearance /Exemption values for any amount Bq/g**	**Exemption values for moderate amounts Bq/g**
H-3	100	1000000	100	1000000
C-14	10	10000	1	10000
S-35	100	100000	100	100000
Co-60	0,1	10	0,1	10
Sr-90	1	100	1	100
Tc-99	1	10000	1	10000
Cs-137	1	10	0,1	10
Eu-152	0,1	10	0,1	10
Ir-192	0,1	10	1	10
U-238	1	10	1	10
Pu-239	0,1	1	0,1	1
Am-241	0,1	1	0,1	1

Article 18 of [1] dealing with clearance licenses will also be modified and extended to solid and liquid waste. A clearance license will be needed when the activity concentration is higher than the values of annex IB. However, a predefined upper limit of activity concentration values allowed via the clearance license will no longer exist. As before, an impact study is needed to demonstrate compliance with a dose constraint of 10 µSv/year. For smaller quantities (< 1 ton) such an impact study will not be required, if the activity concentration is lower than the values of annex IA, as this is already covered by the underlying BSS studies.
A new article 34.6 will be introduced in [1] to cover the clearance of liquid radioactive waste which is not applicable for discharge in sewers or surface

waters due to its chemical composition. For smaller quantities (< 1 ton/year), the generic clearance values of annex IB can be used, for larger quantities (> 1 ton/year) or for concentration levels higher than annex IB, a FANC clearance license must be obtained in accordance with article 18.

A new article 35.6 will allow FANC to define via a FANC decree additional specific clearance levels and associated requirements for specific materials or for materials originating from specific types of practices. This FANC decree will be drafted in line with "FANC/Bel V position papers" on clearance of buildings and materials and will use the (surface activity) clearance values expressed in RP89 [7] & RP113 [8]).

Site release (after decommissioning): general principles used by the regulatory body

In the current regulatory framework [1] of Belgium, no specific clearance levels exist for site materials. The question can be raised if the general clearance levels for radioactive waste available in annex IB of [1] can be used for this purpose.

In 2016 FANC and Bel V issued a Position Paper on the release of sites [9]. The scope of this position paper is installations of class I and IIA and it proposes certain dose constraints and clearance levels.

Two options for clearance levels of site materials are acceptable for the Belgian regulatory body:

- \- Option 1: The licensee uses general clearance levels of annex IB of [1] based on samples averaged on max. 1 ton (in line with an individual dose constraint of 10 μSv/year)
- \- Option 2: The licensee will propose specific clearance levels for site materials based on exposure scenario's for radionuclides present on site. The specific clearance levels, scenario's and models are to be approved by FANC.

For current decommissioning projects of nuclear facilities (for example the fuel production facilities of Belgonucleaire and FBFC International) the clearance values of annex IB of [1] are used (option 1). For these two sites, the objective is to reach an unconditional release of the site by 2018-2019.

The proposed process for site release is as follows:
The licensee provides its final dismantling report (containing an overview of dismantling activities, and the results of the final radiologic characterisation of buildings and site) and proposes a final state of the site (greenfield or brownfield).

This site release is reviewed and assessed by FANC and Bel V, which will take into account the results of previous inspections of clearance activities by the licensee, the results of independent clearance measurements performed by or on behalf of FANC and Bel V, and the documentary review of the final dismantling report.

The final decision on site release is taken by FANC. In case of greenfield, this will lead to the abolishment of the dismantling license so that the licensee is fully released from regulatory control. In case of brownfield, FANC will consult with competent regional authorities to evaluate which site restrictions are necessary. A stakeholder consultation can be foreseen in the latter case.

Conclusions

The clearance of materials is a well-established process within the Belgian regulatory framework. The ongoing regulatory project to transpose the Basic Safety Standards in Belgian regulations will confirm this. Some challenges can be foreseen in the next years

- - Increasing use of clearance licenses for decommissioning projects?
- - Site release decisions in the near future for some sites in the final stages of decommissioning
- - Strict regulatory supervision of licensee clearance practices required to ensure compliance

References:

[1] General Regulation for radiological protection of the public, the workers and the environment, Royal Decree of July 20^{th},2001.
[2] Basic Safety Standards Directive 96/29/Euratom.
[3] Radiation protection 122: Practical use of the concepts of clearance and exemption (European Commission, 2000)
[4] FANC Guidance on measurement procedures and techniques for clearance (FANC Decree of 30^{th} April 2010)
[5] Basic Safety Standards Directive 2013/59/Euratom
[6] IAEA Safety Guide RS G-1.7 Application of the Concepts of Exclusion, Exemption and Clearance
[7] Radiation protection 89: Recommended radiological protection criteria for the recycling of metals from the dismantling of nuclear installations, Recommendations of the group of experts set up under the terms of Article 31 of the Euratom Treaty (European Commission, 1998)
[8] Radiation protection 113: Recommended radiological protection criteria for the clearance of buildings and building rubble from the dismantling of nuclear installations, Recommendations of the group of experts set up under the terms of Article 31 of the Euratom Treaty (European Commission, 2000)
[9] FANC Position Paper on the regulatory process for release of a nuclear site (2015, Ref2014-06-26-GK-5-4-1-NL)

Annales de l'Association belge de Radioprotection, vol. 43, n°2, 2018
Annalen van de Belgische Vereniging voor Stralingsbescherming, vol. 43, nr 2, 2018

REVISION OF THE IAEA SAFETY GUIDE RS-G-1.7 « APPLICATION OF THE CONCEPT OF EXCLUSION, EXEMPTION AND CLEARANCE»

Chantal Mommaert, Bel V

1. Introduction

The International Basic Safety Standards (General Safety Requirements No. GSR Part 3 [1]) are published in the IAEA Safety Standards Series, which includes other related international standards, such as the Regulations for the Safe Transport of Radioactive Material (the IAEA Transport Regulations (No.SSR-6)); Governmental, Legal and Regulatory Framework for Safety (General Safety Requirements No. GSR Part 1); Preparedness and Response for a Nuclear or Radiological Emergency (No. GS-R-2); The Management System for Facilities and Activities (No. GS-R-3); Safety Assessment for Facilities and Activities (General Safety Requirements No. GSR Part 4); Predisposal Management of Radioactive Waste (General Safety Requirements No. GSR Part 5); and Decommissioning of Facilities (General Safety Requirements No. GSR Part 6[2]).

Notification and authorization are fundamental requirements in GSR Part 3 [1] for the control of planned exposure situations. Provision however has been made for the clearance of material from authorised practices from further regulatory control. Numerical values for clearance of material are provided in Schedule 1 of GSR Part 3 [1], in Table I.2 and I.3.

The numerical clearance values in GSR Part 3 [1] were taken from the existing Safety Guide RS-G-1.7 [3] "Application of the Concepts of Exclusion, Exemption and Clearance" that was issued by the IAEA in 2004 [5]. This Safety Guide was based on the 1996 version of the Basic Safety Standards (SS-115 [4]) and issued prior to the publication of the Fundamental Safety Principles (SF-1). Although some terminology has changed between the 1996 and 2014 versions of the International Basic

Safety Standards, the concepts of exemption and clearance remain in GSR Part 3 [1]. Hence, the guidance on the application of the clearance levels that is given in the original version of Safety Guide RS-G-1.7 [3] is still valid even though it would require updating to the new GSR Part 3 [1] terminology.

GSR Part 3 [1] does not expand upon the application of the concepts of exemption and clearance, but assumed that further guidance would be provided in two IAEA Safety Guides: a Safety Guide on the Application of the Concept of Clearance (DS500), and another Safety Guide on the Application of the Concept of Exemption Including Criteria for Trade in Contaminated Commodities (DS499).

The original Safety Guide RS-G-1.7 [3] contains much information that can be used directly in the new Safety Guide on the Application of the Concept of Clearance, e.g.:

- The list of substances/situations to which the clearance values do not apply;
- The basis of the derivation of the values (it should be noted that the concept of exclusion, used in the GSR Part 3, is no longer applied to naturally occurring radionuclides, but that the concept of existing exposure situations applies instead);
- The dose criteria and the calculation procedures and models;
- The values to be used for noble gases;
- The application of the values.

2. Justification of the revision of Safety Guide RS-G-1.7

The original Safety Guide RS-G-1.7 [3] did not address all the aspects of the clearance process. For example it did not discuss conditional (specific) clearance and the use of surface contamination levels, nor did it address the management and organisational aspects of the clearance process.

A new Safety Guide therefore needs to provide guidance on the clearance process and on the application of the clearance levels, in particular on the organisation and regulation of the process, and its verification. It also needs to address conditional clearance and the use of surface contamination levels.

A detailed description of the calculations used to derive the clearance levels is provided in Safety Report 44 [5] and therefore it does not need to be included within the new Safety Guide.

The original version of Safety Guide RS-G-1.7 [3] was based on an older version of the BSS. With the incorporation of the basic information from the Safety Guide RS-G-1.7 [3] into the new BSS (GSR Part 3 [1]), much of the information in Safety Guide RS-G-1.7 [3] is redundant. Although the information in Safety Guide RS-G-1.7 [3] regarding the application of the clearance principle is still relevant, it has been noted by Member States that it should be expanded to provide more detailed guidance on the clearance process; establishment of national regulations; planning, organization and implementation, technical and safety implications and resources needed to implement the clearance process. The process of clearance is a regulated process and hence the procedures and processes leading to the act of clearance need to be well defined. As noted above, the original Safety Guide RS-G-1.7 [3] also contains no guidance on the clearance of buildings (typically, clearance of buildings is part of the site release, but sometimes it needs to be done during decommissioning, before the release of the site) and equipment based on surface contamination measurements and, hence, there is a need for this to be included in a new Safety Guide. The new Safety Guide should also address the concept of clearance for liquids and gases, and the boundary between clearance and discharge should be established. The new Safety Guide will also discuss whether the existing clearance levels for solids could be relevant to liquids and gases.

Based on discussions among the IAEA staff regarding the revision of basic documents pertaining to the clearance concept, it was suggested that a new document be prepared to expand on the application of this concept as defined in the BSS (GSR Part 3 [1]) to address the issues identified above. As a result of the development of the new Safety Guide on the Implementation of the Clearance Concept, the Safety Guide RS-G-1.7 [3] would be superseded.

It is proposed to separate the material currently in RS-G-1.7 [3] into two separate safety guides: one dealing with clearance and the other dealing with exemption. Guidance related to the control of contaminated non-food commodities that can be traded freely will be included in the safety guide dealing with exemption. Both documents will be developed in parallel to ensure consistency of approach and application.

It is recognized that the values for exemption and clearance currently defined for artificial radionuclides are unnecessarily restrictive and that the exposure scenarios used in their derivation are highly conservative. The direct application of the values for artificial radionuclides to commodities in national and international trade introduces an additional level of conservatism due to the different dose criteria of 10 μSv/y (for exemption and clearance) and 1 mSv/y (for trade). It is not intended that the revision of RS-G-1.7 [3] will include the derivation of new values for exemption and clearance but, as part of the revision process, the groundwork will be laid for possible revision of these numbers in the future.

Noting that there are inherent conservatisms incorporated in the numerical clearance values, it is important not to compound the overall level of conservatism unduly in the practical application of the clearance process. The guide will take account of these considerations in developing its recommendations. The same considerations will also be taken into account regarding clearance levels and clearance processes for surface contamination.

The new guide should provide guidance on the application of the values for clearance, reflecting the use of the graded approach, in particular in the light of the conservative nature of the values.

The process of clearance has always been a part of the lifecycle of a facility, but it becomes of utmost importance during the decommissioning phase. Decommissioning typically generates large amounts of material (potential to be recycled and reused) and waste (no intention to reuse). Those amounts are larger than during operation and are generated in a relatively short period of time. Most of that material and waste is expected to be radiologically clean or just slightly contaminated. It could be practical and economically viable to separate the part that has to be managed as radioactive waste or reused within the nuclear applications (under continued regulatory control), and the part that can be taken out of the regulatory control (through clearance) immediately after decontamination or after decay.

3. Objective and scope

The objective of the Safety Guide is to provide detailed guidance on the application of the clearance concept for materials and buildings that are to be released from regulatory control. It will be especially applicable during decommissioning to contribute to minimizing the amount of waste that will require disposal as radioactive waste. However, the guidance will also be applicable for releasing material for unconditional reuse or for non-radiological disposal during the normal operation of a facility, and may be applicable to other situations. The Safety Guide will also provide guidance on the development of conditional clearance values for the reuse of material, with direct reuse or after recycling. It will not address exclusion as it is no longer defined in the BSS (GSR Part 3 [1]), and it will not address exemption as this will be addressed in another Safety Guide.

The information presented in this new Safety Guide is applicable to facilities that use, manufacture, process or store radioactive material. The types of facilities that may be included under this category are nuclear power plants, research reactors, other nuclear fuel cycle facilities, industrial plants, medical facilities, research facilities and accelerators. It also applies to industries processing naturally occurring radioactive material (NORM).

The scope of this new Safety Guide is to describe the process of clearance from regulatory control. It will include the following aspects:

- Clarification on the use of terminology, especially the use of terms clearance and release;
- Responsibilities of the operator and the regulatory body;
- All relevant steps of the clearance process including characterization, determination of the nuclide vector, measurement techniques, sampling, management of the clearance process;

- Volumetric and surface specific clearance criteria for unconditional clearance;
- Examples of derivation of volumetric and surface specific clearance criteria for conditional clearance (actual values would depend on specific conditions applied, so no universal set of values could be proposed);
- Case by case approach which can be used for small quantities of material, or for other situations where the assumptions for the generic derivation of clearance levels do not apply (e.g. where the water pathway is not relevant), or for radionuclides for which clearance values have not been given in GSR Part 3 [1], or e.g. for cases where it is proposed that the rounding procedure or other features from the model in Safety Report 44 [5] are not applied or are modified;
- Clearance in an area affected by consequences of a nuclear or radiological accident (in an existing exposure situation)
- Considerations of clearance of liquids;
- Consideration of clearance of gases;
- Additional requirements for building materials containing naturally occurring radionuclides;
- Considerations of averaging masses and averaging areas;
- Discussion of the degree of homogeneity that was assumed in the calculation of the clearance levels and the implications for application of the clearance levels to non-homogenous material;
- Discussion of confidence in and uncertainties of clearance measurements
- Discussion of the derivation of unconditional clearance levels for radionuclides for which there are no values in Table I.2 of GSR Part 3 [1], noting the methodology described in Safety Report 44 [5] and the relevance of any values for exemption of moderate amounts that are already listed in Table I.1;
- Discussion of the independence of exemption levels and conditional clearance levels, noting that conditional clearance levels can be above the values given in Tables I.1 and I.2 in GSR Part 3 [1] since the destination and final fate of the material is known;
- Consideration should be given of whether the clearance levels given in GSR Part 3 [1] are reproduced in the Safety Guide;
- Consideration should be given of whether clearance values for other radionuclides, that have already been calculated using the same

methodology described in Safety Report 44 [5], are also presented in the Safety Guide;
- Involvement of interested parties.

This new Safety Guide will differentiate between:

- Clearance and exemption, describing the concepts and the scope of this document and of the separate document on exemption and reference levels for commodities;
- Unconditional and conditional clearance;
- Clearance and discharges for gaseous and liquid releases;
- Material that is eligible for clearance and material that is considered as part of existing exposure situations (commodities);
- Clearance of materials and release of contaminated sites;
- (Conditional) clearance and transport.

The issue of exclusion will be addressed in the introductory sections of the proposed new safety guide using text that will be duplicated in the new safety guide on clearance. The text will explain the principle of exclusion as well as its relationship to exemption and clearance, but no specific guidance will be provided.

4. Interfaces with existing and/or planned publications

The proposed Safety Guide will be a new document that will provide Member States with complementary information necessary when implementing the existing Safety Standards. In particular, the following documents have identified the importance of establishing clearance criteria and its application:

1 Decommissioning of Facilities, General Safety Requirements Part 6 [2]
2 Radiation Protection and Safety of Radiation Sources: International Safety Standards, General Safety Requirements Part 3 [1]
3 Decommissioning of Nuclear Power Plants, Research Reactors and Other Nuclear Fuel Cycle Facilities, Draft IAEA Safety Guide DS452
4 Decommissioning of Medical, Industrial and Research Facilities, Draft IAEA Safety Guide DS403

5 Management of Radioactive Residues from Uranium Production and Other NORM Activities, Draft IAEA Safety Guide DS459;
6 Remediation Process for Areas Affected by Past Activities and Accidents, Draft IAEA Safety Guide DS468 (Revision of Safety Guide WS-G-3.1)

The following documents are relevant to the context of the new Safety Guide:

1 IAEA Safety Report 44 on Derivation of activity concentration values for exclusion, exemption and clearance [5];
2 IAEA Safety Report 67 on Monitoring for compliance with exemption and clearance levels [6];
3 The new Safety Guide DS499 on Application of the Concept of Exemption Including Criteria for Trade in Contaminated Commodities, planned to be developed in parallel;
4 IAEA TECDOC on Clearance levels for landfill disposal (in preparation);
5 Draft IAEA Safety Guide DS442 on Regulatory control of radioactive discharges to the environment;
6 ICRP Publication 104, Scope of Radiological Protection Control Measures.

References

[1] EUROPEAN COMMISSION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014).

[2] INTERNATIONAL ATOMIC ENERGY AGENCY, Decommissioning of Facilities, IAEA General Safety Requirements No. GSR Part 6, IAEA, Vienna (2014).

[3] INTERNATIONAL ATOMIC ENERGY AGENCY, Application of the Concepts of Exclusion, Exemption and Clearance, IAEA Safety Standards Series No. RS-G-1.7, IAEA, Vienna (2004).

[4] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No.115, Vienna (1996).

[5] INTERNATIONAL ATOMIC ENERGY AGENCY, Derivation of Activity Concentration Values for Exclusion, Exemption and Clearance, Safety Reports Series No. 44, IAEA, Vienna (2005).

[6] INTERNATIONAL ATOMIC ENERGY AGENCY, Monitoring for Compliance with Exemption and Clearance Levels, Safety Reports Series No. 67, IAEA, Vienna (2012).

Annales de l'Association belge de Radioprotection, vol. 43, n°2, 2018
Annalen van de Belgische Vereniging voor Stralingsbescherming, vol. 43, nr 2, 2018

HOW THE NEW CLEARANCE LEVELS OF THE EU-BSS WILL AFFECT CLEARANCE IN GERMANY

Dr. Stefan. Thierfeldt - Brenk Systemplanung GmbH

Introduction

This paper gives an overview of the development of clearance in Germany at the verge of the introduction of a new Radiation Protection Ordinance (Strahlenschutzverordnung) planned to enter into force at the beginning of 2019, and how these intended new regulations might or will affect the practice of clearance in Germany. Some of the considerations presented here are specific to the German regulatory framework on clearance and radiation protection in general, but some might also be encountered in other countries.

The Current Legal Situation

Germany is currently transforming the Basic Safety Standards of the European Commission 1 into national legislation. So far, this has resulted in a new Radiation Protection Act (Strahlenschutzgesetz) 2, which has partially entered into force in October 2017. For becoming effective in all of its parts, the relevant ordinances need to be present and must be ready to enter into force as well. It is envisaged that this will be the case on 31 December 2018. The following ordinances have been developed to support the Radiation Protection Act:

- Radiation Protection Ordinance (Strahlenschutzverordnung, StrlSchV),
- Ordinance establishing dose values for early emergency response measures,
- Ordinance on the disposal of radioactive waste,
- Ordinance on protection against the harmful effects of non-ionising radiation when used on humans.

A number of other ordinances will be changed accordingly. In this paper, only the envisaged regulations of the Radiation Protection Ordinance are addressed.

The new Radiation Protection Ordinance is currently available as a mature draft, which, however, is still under discussion. In order to distinguish it from the current version of the Radiation Protection Ordinance which is still in force, it is henceforth referred to as the "Draft Radiation Protection Ordinance of 2018" 3. This ordinance will replace:

- the current Radiation Protection Ordinance (Strahlenschutzverordnung, StrlSchV) 4,
- the X-Ray Ordinance,
- parts of the Atomic Energy Act,
- parts of the Precautionary Radiation Protection Act,
- other minor parts of the current regulatory framework.

Like until now, regulations with respect to clearance will be contained in the Radiation Protection Ordinance in the future. In the current draft version of this ordinance, the structure of these regulations and the envisaged clearance levels are already fully elaborated, as presented below. But before future regulations are presented, a short digression is made on the long-term stability of the clearance regulations.

Long-term Stability of Boundary Conditions for Clearance

When assessing the changes currently pending in the area of clearance, it should not be overlooked that the conditions for clearance in Germany have been surprisingly stable for almost three decades and will remain so in the future. Therefore, these boundary conditions are dealt with first.

The concept of clearance is mainly related to the effective individual dose, which is regarded as trivial or negligible in society. For this purpose, a quantitative value was specified for the first time in 1988 in the document Safety Series 89 7, which was set in the range from 100 to several 100 µSv/a. To take into account the possibility that several practices (e.g. use of several clearance options simultaneously, exempted practices, etc.)

may contribute to exposure together, it was proposed to limit the effective individual dose from a single practice to 10 µSv/a (in this case a single clearance option).

Since then, this dose guideline has been the basis for all SSK recommendations dealing with clearance. The first recommendation of this series was published in 1988, the last before the Radiation Protection Ordinance of 2001 in 1998, and the most recent SSK recommendation for clearance for disposal is based on the same dose constraint. In accordance with the IAEA and the ICRP, the German government has never considered the dose value of 10 µSv/a as a fixed limit value, but always as a constraint that can be exceeded in the practical application of clearance.
However, not only the underlying constraint for the effective individual dose has remained constant, the clearance level themselves also show remarkable constancy - at least for the most relevant radionuclides. If a clearance level of 0.1 Bq/g for unconditional clearance and 1 Bq/g for the clearance for melting of metallic materials was stated in the first SSK recommendation of 1987 for the clearance of metal scrap with beta/gamma activity (at that time still for the total activity, which is essentially given by Co-60 and Cs-137), the relevant values are specified in the current Radiation Protection Ordinance in Appendix III Table 1 columns 5 and 10a StrlSchV for Co-60 at 0.1 Bq/g and 0.6 Bq/g and in Annex VII Table A Part 1 of the EU BSS 1 for unconditional clearance also at 0.1 Bq/g. A very relevant clearance level will thus remain unchanged for at least four decades.

Current and Future Regulations with Respect to Clearance

In its current version, the Radiation Protection Ordinance (StrlSchV) contains two sets of clearance options: options for unconditional clearance and those for clearance for a specific purpose (specific clearance).

In the case of unconditional clearance, the substances can freely be used after clearance from a radiological point of view. The following four clearance options are available:

- unconditional clearance of (solid or liquid) substances that may afterwards be reused, recycled or also disposed of,

- unconditional clearance of rubble and excavated soil of more than 1,000 Mg/a that after clearance may be used for any chosen purpose, e.g. for the backfilling of excavations, as road bedding, etc.,
- unconditional clearance of buildings that afterwards may be demolished or also be reused,
- unconditional clearance of soil areas that may subsequently be used for any purposes, e.g. for the construction of houses and apartment buildings, industrial buildings, etc.

Other clearance options are:

- clearance of solid substances for disposal in a (conventional) landfill with masses of up to 100 Mg/a and up to 1,000 Mg/a, respectively,
- clearance of (solid or liquid) substances for removal in an incinerator with masses of up to 100 Mg/a and up to 1,000 Mg/a, respectively,
- clearance of buildings for demolition, with any conventional use of the buildings prior to their demolition not being permitted,
- clearance of scrap metal for recycling by smelting in a conventional melting shop, e.g. a foundry, a steel works, etc.

For these clearance options, clearance levels are provided in Appendix III Table 1 StrlSchV. The following two tables show examples of these clearance levels for a selection of radionuclides that are of importance in connection with the decommissioning and dismantling of nuclear facilities. The respective clearance levels are given as values per unit mass or area (Bq/g and Bq/cm²), respectively). This depends on the type of measurement to be carried out for demonstrating compliance with these clearance levels. Once clearance is completed and the material has left the scope of supervision under nuclear law, the general provisions of waste management law still apply.

a) Options for unconditional clearance

	Exemption level			Unconditional clearance of:				
Radionuclide	Activity	Specific activity	Surface contamination	Solid substances, liquids with the exception of Column 6	Building rubble, excavated soil of more than 1,000 Mg/a	Soil areas	Buildings for reuse or further use	Half-lives
	[Bq]	[Bq/g]	[Bq/cm^2]	[Bq/g]	[Bq/g]	[Bq/g]	[Bq/cm^2]	[a]
1	2	3	4	5	6	7	8	11
H-3	$1 \cdot 10^{09}$	$1 \cdot 10^{06}$	100	$1 \cdot 10^{03}$	60	3	$1 \cdot 10^{03}$	12.3
C-14	$1 \cdot 10^{07}$	$1 \cdot 10^{04}$	100	80	10	0.04	$1 \cdot 10^{03}$	$5.7 \cdot 10^{03}$
Cl-36	$1 \cdot 10^{06}$	$1 \cdot 10^{04}$	100	0.3	0.3		30	$3.0 \cdot 10^{05}$
Fe-55	$1 \cdot 10^{06}$	$1 \cdot 10^{04}$	100	200	200	6	$1 \cdot 10^{03}$	2.7
Co-60	$1 \cdot 10^{05}$	10	1	0.1	0.09	0.03	0.4	5.3
Ni-63	$1 \cdot 10^{08}$	$1 \cdot 10^{05}$	100	$3 \cdot 10^{02}$	$3 \cdot 10^{02}$	3	$1 \cdot 10^{03}$	100.0
Sr-90+	$1 \cdot 10^{04}$	$1 \cdot 10^{02}$	1	0.6	0.6	0.002	30	28.5
Ag-108m+	$1 \cdot 10^{06}$	10	1	0.2	0.1	0.007	0.5	127.0
Ag-110m+			1	0.1	0.08	0.007	0.5	0.68
I-129	$1 \cdot 10^{05}$	$1 \cdot 10^{02}$	1	0.06	0.06		8	$1.6 \cdot 10^{07}$
Cs-137+	$1 \cdot 10^{04}$	10	1	0.5	0.4	0.06	2	30.2
Eu-152	$1 \cdot 10^{06}$	100	1	0.2	0.2	0.07	0.8	13.3
Eu-154	$1 \cdot 10^{06}$	10	1	0.2	0.2	0.06	0.7	8.8
U-238+	$1 \cdot 10^{04}$	10	1	0.6	0.4		2	$4.4 \cdot 10^{09}$
Pu-238	$1 \cdot 10^{04}$	1	0.1	0.04	0.08	0.06	0.1	87.7
Pu-241	$1 \cdot 10^{05}$	$1 \cdot 10^{02}$	10	2	2	4	10	14.4
Am-241	$1 \cdot 10^{04}$	1	0.1	0.05	0.05	0.06	0.1	432.6

b) Options for clearance for a specific purpose

	Exemption level		**Clearance of:**						
Radio-nuclide	Ac-tivity	Spe-cific activ-ity	Solid substanc-es up to 100 Mg/a to be disposed of in landfills	Solid substanc-es and liquids up to 100 Mg/a for re-moval in incinera-tors	Solid sub-stances up to 1,000 Mg/a to be dis-posed of in landfills	Solid sub-stances and liq-uids up to 1,000 Mg/a for removal in incinera-tors	Build-ings for demoli-tion	Scrap metal for recy-cling	Half-lives
	[Bq]	[Bq/g]	[Bq/g]	[Bq/g]	[Bq/g]	[Bq/g]	[Bq/ cm^2]	[Bq/g]	[a]
1	2	3	9a	9b	9c	9d	10	10a	11
H-3	$1\cdot10^{09}$	$1\cdot10^{06}$	$6\cdot10^{04}$	$1\cdot10^{06}$	$6\cdot10^{03}$	$1\cdot10^{06}$	$4\cdot10^{03}$	$1\cdot10^{03}$	12.3
C-14	$1\cdot10^{07}$	$1\cdot10^{04}$	$4\cdot10^{03}$	$1\cdot10^{04}$	$4\cdot10^{02}$	$1\cdot10^{04}$	$6\cdot10^{03}$	80	$5.7\cdot10^{03}$
Cl-36	$1\cdot10^{06}$	$1\cdot10^{04}$	3	3	0.3	0.3	30	10	$3.0\cdot10^{05}$
Fe-55	$1\cdot10^{06}$	$1\cdot10^{04}$	$1\cdot10^{04}$	$1\cdot10^{04}$	$7\cdot10^{03}$	$1\cdot10^{04}$	$2\cdot10^{04}$	$1\cdot10^{04}$	2.7
Co-60	$1\cdot10^{05}$	10	6	7	2	2	3	0.6	5.3
Ni-63	$1\cdot10^{08}$	$1\cdot10^{05}$	$1\cdot10^{04}$	$6\cdot10^{04}$	$1\cdot10^{03}$	$6\cdot10^{03}$	$4\cdot10^{04}$	$1\cdot10^{04}$	100.0
Sr-90+	$1\cdot10^{04}$	$1\cdot10^{02}$	6	40	0.6	4	30	9	28.5
Ag-108m+	$1\cdot10^{06}$	10	9	10	1	1	4	0.8	127.0
Ag-110m+			6	6	2	0.6	4	0.5	0.68
I-129	$1\cdot10^{05}$	$1\cdot10^{02}$	0.6	0.6	0.06	0.06	8	0.4	$1.6\cdot10^{07}$
Cs-137+	$1\cdot10^{04}$	10	10	10	8	3	10	0.6	30.2
Eu-152	$1\cdot10^{06}$	10	10	10	4	4	6	0.5	13.3
Eu-154	$1\cdot10^{06}$	10	10	10	4	4	6	0.5	8.8
U-238+	$1\cdot10^{04}$	10	6	10	0.6	5	10	2	$4.4\cdot10^{09}$
Pu-238	$1\cdot10^{04}$	1	1	1	1	1	3	0.3	87.7
Pu-241	$1\cdot10^{05}$	$1\cdot10^{02}$	100	100	40	100	90	10	14.4
Am-241	$1\cdot10^{04}$	1	1	1	1	1	3	0.3	432.6

* The figures in the fourth line refer to the column numbering acc. to Appendix III Table 1 StrlSchV.

In the Draft Radiation Protection Ordinance of 2018 3, the clearance options remain basically unchanged, only their denomination is slightly adjusted. In addition, clearance levels for all clearance options with the exception of unconditional clearance remain also unchanged or will undergo minor changes. Changes that these regulations on clearance will bring about are mainly related to clearance levels for unconditional clearance. The following table highlights a few important radionuclides.

Comparison of clearance levels for selected radionuclides for unconditional clearance according to App. III Tab. 1 Col. 5 StrlSchV and according to Ann. VII Tab. A Part 1 of the EU Basic Safety Standards, in Bq/g

Nuclide	App. III Tab. 1 Col. 5 StrlSchV	Ann. VII Tab. A Part 1 BSS
H-3	1,000	100
C-14	80	1
Co-60	0,1	0,1
Sr-90+	0,6	1
Cs-137+	0,5	0,1
Am-241	0,05	0,1

There are no significant changes of clearance levels for Co-60, Sr-90+ and Am-241. However, the changes for Cs-137+ are problematic, where the clearance level is reduced by a factor of 5, and for C-14, for which the reduction is even a factor of 80. The reasons for this cannot be discussed in more detail at this point, but they are explained, for example, in the extensive study 6. In short, the low clearance levels, especially for H-3 and C-14 in Annex VII Table A Part 1 of the EU BSS, result from a very conservative modelling of groundwater paths, while for many other radionuclides the rounding to decimal powers (0 significant digits) causes differences compared to the rounding to 1 significant digit in Appendix III Table 1 StrlSchV.

Impact on the Practice of Clearance

The new regulations will certainly have an impact on the practice of clearance in Germany. It is of course not yet possible to draw any final conclusions on this matter.

Up to now, unconditional clearance was the most frequently selected clearance option, i.e. the “workhorse” of clearance, but this will be made more difficult in the future by the changes of the clearance levels mentioned. The exact effects can of course only be assessed in detail in the course of the clearance practice in the coming years, but from today’s perspective at least the following challenges can be identified specifically for unconditional clearance:

- The strong reduction of the clearance levels of H-3 and C-14, but also of Cs-137+, causes the relation of the clearance levels of key nuclides and correlated nuclides to become imbalanced. In general, clearance levels should reflect the radiological relevance of radionuclides relative to each other. This is no longer the case when radiologically less relevant radionuclides are assigned clearance levels that are very close to those of radiologically relevant key nuclides. The equality of clearance levels for Co-60 and Cs-137+ is artificially generated by the application of rounding and does not correspond to the radiological relevance of both radionuclides.

- The concept of the application of key nuclides runs through practically all clearance procedures in Germany and is also anchored in all parts of DIN 25457. It is based on the fact that the activities of difficult-to-measure radionuclides such as Sr-90, Fe-55, Ni-63 etc. can be calculated from measurement of easily measurable radionuclides such as Co-60 and Cs-137 and the application of previously determined scaling factors and do not have to be determined each time by complex measurements. This concept could be severely impaired if H-3 and especially C-14, which are of minor radiological relevance, will have low clearance levels in the future but cannot be correlated with key nuclides by scaling factors.
- As a result, many radionuclides will have to be included in nuclide vectors which currently can be screened out due to the “10% rule” in Appendix IV Part A Letter e StrlSchV (this regulation allows to exclude a set of radionuclides from a nuclide vector if they together contribute less than 10 % to the result of the sum of fractions). This would not be a problem per se if the radionuclides in question, such as H-3 and C-14, would contribute to the measuring effect in standard measurement methods (in particular bulk monitors or contamination monitors). Since this is not the case, however, a way must be found of proving compliance with the clearance levels for these radionuclides without artificially filling up the sum of fractions and without considerable sampling effort.
- Specifications for measurement procedures, for example in the context of a revision of DIN 25457, must therefore include regulations for cases in which the low clearance levels will make it necessary to include these radionuclides, especially C-14, in nuclide vectors, but have no radiological relevance at the same time. One example would be separate regulations for the application of the “10% rule” for cases in which radionuclides with low radiological relevance and low clearance

levels now have high proportions in the sum of fractions, while the measurements yield merely detection limits for these radionuclides. This will be a common case for C-14.

- Further changes in DIN 25457 may affect the interrelation between clearance levels and exemption values. By simultaneously using the values in accordance with Annex VII Table A Part 1 of the EU BSS not only as clearance levels, but now also as (mass-related) exemption values, the previous concept that clearance levels should never exceed exemption values for systematic reasons is completely obsolete anyway. The future abolition of the mass-related exemption values according to Appendix III Table 1 Col. 3 StrlSchV for small material quantities, which is planned by the German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety as part of the redesign of the clearance regulations, means that there are no longer any numerical limits for (mass-related) clearance levels. Corresponding relationships, which are shown in various parts of DIN 25457, therefore require adaptation.

Challenges for unconditional clearance will in the future therefore arise primarily from issues of measurements.

Further Challenges to Clearance

In addition to the points discussed in the previous section, other challenges for clearance will continue to determine the reconciliations in forefront of implementing clearance procedures and in some cases limit the selection of clearance options. The following points in particular should be mentioned here:

- The use of the specific clearance options: Clearance for disposal (landfill, incineration plant) and clearance of metal scrap for melting is only possible to a limited extent in many federal states of Germany, as in many cases the disposal facilities and the metal processing plants have reservations when approached with requests to accept cleared material from nuclear facilities. Nevertheless, these clearance options using the clearance levels in accordance with Appendix III Tab. 1 Col. 9a-9d and 10a StrlSchV are necessary for the effective design of the clearance procedure. This is all the more likely to apply in the future as it will at least become more difficult to prove compliance with the clearance levels for unconditional clearance (as discussed above). While it is true that only a few suitable melting plants or landfills, respectively, accept material cleared for a specific purpose, one should not all too easily conclude that these clearance options are superfluous.

- The clearance of cleared material as conventional waste for disposal is connected to the highest clearance values of all clearance options, but at the same time also suffers from the most significant restrictions with regard to the total mass cleared annually to a disposal facility plant and with regard to other boundary conditions. Material that cannot be cleared in this way is necessarily radioactive waste. It should therefore be in the interest of all parties involved in the procedure to make effective use of the available clearance options and to rely on the models tested in detail by the SSK for deriving the clearance levels 5. Unfortunately, past experience has shown that in many cases this clearance option is hindered by inappropriate barriers that have been erected against it.
- Clearance of metal scrap for melting is an important clearance option for residual metallic materials, since for metals the disposal on a landfill is often not feasible for waste law reasons. There are some smelting plants in Germany that accept scrap that has been cleared using the clearance levels in accordance with Appendix III Table 1 Col. 10a StrlSchV. In many cases, the scrap industry itself should overcome fears of contact with cleared material from nuclear facilities through better internal information.
- In recent years, it has become increasingly customary in licensing and supervisory procedures concerning clearance that compliance with individual parameter values used in the studies on which the derivation of the clearance values are based is questioned in a concrete context, although the situation is within the realm encompassed by the radiological models used in the derivation of clearance levels. Even in the case of routine clearance procedures (i.e. those based on standard provisions as laid down in Sec. 29 StrlSchV), e.g. for disposal at a landfill site, the assumptions on the annual working time of the landfill personnel installing waste is questioned, or in the case of clearance of buildings for demolition whether utilisation of the clearance levels on average does not cause a certain value to be exceeded. Unfortunately, in these cases it does not take only a short discussion with the competent authority to resolve these issues, but often many

weeks or months elapse before clarification has been brought about. It is completely overlooked here by the authorities and the independent experts acting on their behalf that the radiological models are robust against the variation of single parameters and very well ensure that the dose constraint of 10 µSv/a is complied with even if certain parameter values may be exceeded.

- Similarly, experts often question the models used to date to derive the clearance levels without there being a concrete reason. For example, differences in the values of individual parameters, which can be found in studies to derive the clearance levels in Appendix III Table 1 StrlSchV and in Safety Report 44 9, are cited and given as a reason for recalculation. This includes K_d values for some elements (these values determine the migration behaviour of radionuclides in groundwater and surface waters). Although the database is transparent in all cases, these differences are taken as a justification to start extensive discussions, causing production of many pages of documents, and thus delaying licensing procedures further.

Discussion and Outlook

There is general agreement that clearance is and must remain an indispensable part of management of radioactive waste and residual materials from nuclear facilities in Germany. The continued use of clearance in all facets can only succeed, however, if all parties involved are oriented towards the radiological protection goal, i.e. the dose constraint of 10 µSv/a, in any case. The fact that clearance has been a success story in Germany for several decades unfortunately also has the downside that those experts who were directly and primarily involved in the derivation of clearance levels and of boundary conditions for the implementation of clearance procedures are increasingly no longer in active professional life or in many cases have changed their field of work. Therefore, clearance as regulated in Sec. 29 StrlSchV in conjunction with Annexes III and IV StrlSchV is often only understood with regard to the wording of the law, but without relation to the original relevant protection goal. As in many other areas, a reflection on history is a prerequisite for a meaningful and goal-oriented application in the future.

Literature

1 Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom, Official Journal of the European Union, L13, ISSN 1977-0642, 17 January 2014

2 Gesetz zur Neuordnung des Rechts zum Schutz vor der schädlichen Wirkung ionisierender Strahlung – Artikel 1: Gesetz zum Schutz vor der schädlichen Wirkung ionisierender Strahlung (Strahlenschutzgesetz – StrlSchG), Bundesrat Beschlussdrucksache 342/17(B) (12. Mai 2017) - Radiation Protection Act

3 Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU): Entwurf einer Verordnung zur weiteren Modernisierung des Strahlenschutzrechts (contains the draft of the Radiation Protection Ordinance (Strahlenschutzverordnung)), February 2018

4 Verordnung über den Schutz vor Schäden durch ionisierende Strahlen (Strahlenschutzver-ordnung – StrlSchV) vom 20. Juli 2001 (BGBl. I 2001, Nr. 38, S. 1714), berichtigt am 22. April 2002 (BGBl. I 2002, Nr. 27, S. 1459), zuletzt geändert durch Artikel 8 des Gesetzes vom 26. Juli 2016 (BGBl. I S. 1843) - Radiation Protection Ordinance

5 German Commission on Radiation Protection (Strahlenschutzkommission): Freigabe von Stoffen zur Beseitigung; Recommendation passed on 6 December 2006

6 Thierfeldt, S.; Barthel, R.; Wörlen, S.: Comparative Study of EC and IAEA Guidance on Exemption and Clearance Levels - Radiation Protection 157; Final Report of Contract TREN/07/NUCL/S07.76852, prepared on behalf of the European Commission by Brenk Systemplanung, Aachen, 2010

7 International Atomic Energy Agency: Principles for the Exemption of Radiation Sources and Practices from Regulatory Control; Safety Series No. 89; STI/PUB/817; Vienna, 1988

8 International Atomic Energy Agency: Application of the Concepts of Exclusion, Exemption and Clearance, Safety Standards Series No. RS-G-1.7, Safety Guide, Vienna 2004

9 International Atomic Energy Agency: Derivation of Activity Concentration Values for Exclusion, Exemption and Clearance; Safety Report Series No. 44, Vienna, 2005

10 International Commission on Radiological Protection: The 2007 Recommendations of the International Commission on Radiological Protection; ICRP Publication 103, Published by Elsevier Ltd., 2007

11 Deutsches Institut für Normung e. V. (German Standardisation Institute): DIN 25457: Activity measurement methods for the clearance of radioactive substances and nuclear facility components – Parts 1, 4, 6, 7.

Annales de l’Association belge de Radioprotection, vol. 43, n°2, 2018
Annalen van de Belgische Vereniging voor Stralingsbescherming, vol. 43, nr 2, 2018

CURRENT STANDARDS AND FUTURE DEVELOPMENTS RELATING TO THE RELEASE OF SITES IN THE UK

Shelly Mobbs, Eden Nuclear and Environment Ltd., UK

In the UK, the Nuclear Installations Act 1965 (NIA65) controls hazards associated with nuclear licensable activities and the site containing the nuclear facilities is defined as a ‘licensed site’. It continues to be a licensed site under NIA65 during decommissioning, until it can be demonstrated ‘that there has ceased to be any danger from ionising radiations’ on the site or on the portion of the site being considered for delicensing. In addition, the site has a Permit for disposals of liquid, gaseous and solid radioactive wastes. UK Government, the nuclear regulators and the environmental regulators are reviewing the regulation of the final stages of nuclear site decommissioning and clean-up and the release of sites from regulatory control. Consultation documents containing detailed proposals have recently been published by UK Government and by the environmental regulators.

Introduction

In the UK, the Nuclear Installations Act 1965 (NIA65) controls hazards associated with nuclear licensable activities and the site containing the nuclear facilities is defined as a ‘licensed site’. The Office for Nuclear Regulation (ONR) is the nuclear regulatory body and it regulates the site through a set of Licence Conditions that have to be met by the site operator. These Licence Conditions require prior authorisation for activities such as the commencement of nuclear operations, modifications to plant, or undertaking decommissioning, i.e. the operator must apply to ONR, and receive authorisation from ONR, before these activities are undertaken. NIA65 also provides the legal framework for nuclear third party liability and requires that financial provision is in place to meet claims in the event of a nuclear incident, as required under international law on nuclear third party liability.

In 2016 two documents were published regarding the decommissioning and clean-up of nuclear sites. These were the environment agencies' consultation document on 'Guidance on Requirements for Release of Nuclear Sites from Radioactive Substances regulation' (draft GRR), in February 2016 [1], and a discussion paper published by the UK Department for Business, Energy and Industrial Strategy (BEIS) on 'The regulation of nuclear sites in the final stages of decommissioning and clean-up', in November 2016 [2]. Following analysis of the responses, BEIS subsequently published a formal consultation document on 'Nuclear Decommissioning: Consultation on the Regulation of Nuclear Sites in the Final Stages of Decommissioning and Clean-Up' on 8th May 2018 [3].

The UK is transposing the provisions of Council Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation (2013 BSS). The 2013 BSS is broad in scope and hence transposition requires changes to several different UK legislative regimes. On 2nd May 2018 revisions to the radioactive substances regulations in England and Wales came into force [4] to transpose the radioactive substances requirements of the 2013 BSS, in particular to include the new unconditional clearance levels. The 2013 BSSD incorporates a new set of values for the purpose of clearance and exemption of radioactive materials, taken from the IAEA safety standards series RS-G 1.7 [5], and these are the default values for clearance and exemption.

The current regulatory regime for nuclear sites, the 2016 GRR consultation document, the 2018 BEIS consultation document and the revised clearance levels in the UK radioactive substances regulations are summarised here.

Current regulatory regime for nuclear sites

As described above, ONR regulate a nuclear licensed site through site Licence Conditions, under the NIA65. ONR regulate nuclear operations, including the accumulation and storage of radioactive waste. They also notify the licensee when, in its opinion, there has ceased to be any danger from ionising radiations from anything on the site; this is known as the "no danger" criterion. After that point the nuclear third party liability regime no longer applies to that site, the NIA65 no longer applies, and the site is no longer termed a licensed site. This 'no danger' criterion can also be used to delicense part of a nuclear site and this release of specific parts of the site has been achieved at several nuclear sites (e.g. 25% of the Harwell site has been delicensed using this approach). In addition, the NIA65 currently allows the licensee to surrender the licence at any time, after which ONR would continue to regulate the site via "directions" until the 'no danger' criterion is met. This approach has not yet been used at any site (note that NIA65 would still apply and the site would still be termed a licensed site until the 'no danger' criterion is met).

The discharge and disposal of radioactive waste, and of non-radioactive waste, on or from a nuclear site is regulated by the relevant environment agency (Environment Agency in England, Natural Resources Wales in Wales, and Scottish Environment Protection Agency in Scotland). The environment agencies grant environmental permits for radioactive waste disposal under the Radioactive Substances Act 1993 (RSA 93) in Scotland, and the Environmental Permitting Regulations 2016 (EPR 16), as amended, in England and Wales. These permits include limitations and conditions to protect people and the environment from the hazards presented by radioactive waste. ONR and the environment agencies work closely with one another to ensure the effective co-ordination of their respective regulatory activities on nuclear sites throughout the full lifecycle.

The cessation of the site operator's responsibilities for decommissioning and clean-up occurs only when:

- the nuclear licence is ended (revoked by ONR) and ONR is satisfied that the licensee's period of responsibility under the NIA65 is ended; and,
- the relevant environment agency decides the environmental permit for the management of any radioactive substances or wastes can be surrendered.

ONR have issued guidance [6] on the 'no danger' requirement, stating that it is achieved once the nuclear site has been cleaned up to the extent that it is suitable for any reasonably foreseeable future use (i.e. unrestricted use). The guidance equates 'no danger' to a risk of 10^{-6} y^{-1}, and states that this risk criterion would be considered to be met if the site is cleaned up to the IAEA clearance levels specified in IAEA R-S-G1.7 [v] or to a dose to the public of 10 μSv y^{-1}, plus the reduction of dose to As Low As

Reasonably Practicable (ALARP). In addition, the ONR guidance states that the approach to demonstrating 'that there has ceased to be any danger from ionising radiations' should be based on the following principles:

- I Residual radioactivity on the site (or portion of the site to be released) has been reduced below out-of-scope levels defined by relevant UK legislation.
- II The licensee has taken action to reduce levels of radioactivity on the site below the levels defined in (I), so far as is reasonably practicable.
- III The licensee has demonstrated that the requirements of (I) and (II) have been met by showing that the site is radiologically indistinguishable from the parts of the surrounding area that have not been influenced by previous nuclear operations on the site.
- IV An independent check has confirmed that the requirements of (I) and (II) have been met.

The environment agencies' have specified criteria for near surface disposal facilities and for the post closure period these include a risk guidance level of 10^{-6} y^{-1} and a dose guidance level of 3-20 mSv y^{-1} for intrusion. The current regime discourages the construction of waste disposal facilities on nuclear licenced sites as they will not meet the ONR interpretation of 'no danger' until long after the permit relating to the disposal facility (under the radioactive substances regulations) can be surrendered. However, in the past some disposal facilities have been built on nuclear licensed sites.

An amendment to the NIA65 was passed in 2016 (the 2016 Order) [7] and it is expected to come into force in summer 2018. This order introduces the term 'relevant disposal sites' to cover disposal facilities for radioactive waste (coming from nuclear licensed sites) that are located outside the nuclear site boundary. When the 2016 Order comes into force, these "relevant disposal sites" will be included within the nuclear third party liability regime in NIA65, in line with international requirements [8]. However, they will not be nuclear licensed sites. The environment agencies will determine when the period of responsibility can end for these sites. The 2016 Order does not cover disposal facilities located on a nuclear site. For these facilities, the decision to end the period of responsibility rests with ONR.

There are 37 licensed nuclear sites located across England, Wales and Scotland, each comprising one or more nuclear facilities. A subset of

these sites (17 sites including Sellafield) have been designated by UK Government to the Nuclear Decommissioning Authority (NDA) for decommissioning and clean-up. The NDA's mission is to decommission and remediate its sites and release them for other uses. The ultimate NDA goal is to achieve the end state at all sites by 2125. Nearer-term goals are also described in the 2016 NDA Strategy [9].
Other sites to be decommissioned in the future include the operational nuclear power stations owned by the private sector and other installations in the nuclear fuel cycle, defence, pharmaceutical, research and waste treatment sectors. There is also the potential for new nuclear facilities to be built in England and Wales which would in turn need to be decommissioned at some future date.

GRR consultation

The environment agencies' draft Guidance on Requirements for Release from Radioactive Substances Regulation (draft GRR) [1] addresses the control of residual hazards (radioactive waste) on a nuclear site and drives the environmental standards required for final site clean-up. The draft guidance defines a Site Reference State (SRS), the state that would enable unrestricted use of the site. It also proposes that Radioactive Substance Regulation (RSR) can be ended before the SRS is achieved if the environment agencies receive sufficient assurance that administrative controls will restrict land use to protect the public from the risks associated with residual contamination. The Permit holder would therefore provide assurance to the environment agencies that the controls that were placed on the land would be appropriate. This period of restricted release would have a maximum timescale of 300 years. Even if the SRS is achieved immediately on completion of all planned work, there will be a minimum period before release from RSR for the purposes of validation monitoring. Under the current regulatory regime the site transitions from nuclear regulation by ONR directly to land use regulation by the planning regime once the 'no danger' criterion is met. However, under the BEIS proposed approach (see below), regulatory control at the end of the site clean-up and decommissioning process would be by the environment agencies once licensable activities have ceased; it would then transition to the planning regime once the environmental permit is surrendered. The planning process and property law then provide land use control and information on residual hazards that is transferred to subsequent owners.

Buried structures, such as foundations, drains and pipes, if they are sufficiently contaminated, will become radioactive waste once they are no longer in use. Although areas of undisturbed ground or groundwater contaminated by radioactivity are not themselves radioactive waste, their clean-up may produce radioactive waste. In regulating radioactive waste disposal, the environment agencies are obliged, by international and domestic standards and law, to ensure that exposures of people to radiation are kept below certain limits and constraints, and that exposures must be kept as low as reasonably achievable, taking account of economic and societal factors (optimisation). Applying optimisation to nuclear site decommissioning and clean-up should ensure that radioactive waste and contamination are managed in a way that is safe, but may not necessarily lead to all radioactive waste being removed from the site.

The draft GRR describes 5 principles and 14 Requirements. In particular, as a condition of the Permit it requires the operator to establish and maintain:

- a site-wide environmental safety case (SWESC) demonstrating that people and the environment are, and at all future times will continue to be, adequately protected from the radiological hazard and any non-radiological hazards associated with all the anthropogenic radioactivity (excluding background) remaining on or adjacent to the site (Requirement R3); and
- a waste management plan (WMP) setting out the current intent for dealing with this anthropogenic radioactivity (Requirement R4). The waste management plan (WMP) may be regarded as part of the wider decommissioning and clean-up plan for the site.

The radiological criteria for release from RSR are that the assessed risk should be consistent with a risk guidance level of 10^{-6} y^{-1} and the assessed dose from human intrusion after the site reference state has been reached should not exceed a dose guidance level that lies in the range 3 mSv y^{-1} to 20 mSv y^{-1}. Values towards the lower end of this range are applicable to assessed exposures continuing over a period of years (prolonged exposures), while values towards the upper end of the range are applicable to assessed exposures that are only short term (transitory exposures).

The nuclear site operator must submit a SWESC and WMP to the relevant environment agency at intervals throughout the lifetime of the site. In the final stages of decommissioning, the SWESC should include a description of the clean-up operations that need to be taken such that the site can be eventually be released from RSR.

The draft GRR includes consideration of the chemotoxic properties associated with radioactive contamination and waste (Requirement R12) but does not directly extend hazards related to non-radioactive contaminants and wastes on site. However, operators are encouraged to extend the WMP and the SWESC to consider all hazards on site, both radiological and non-radiological, so as to develop a single integrated approach. In particular, operators should take an integrated approach to the management of the generation and disposal of wastes from contaminated structures, for example demolition wastes, to ensure that there is an integrated plan that best addresses all regulatory requirements. That plan should be in place before demolition commences.

Three NDA sites are trialling the draft GRR (Dounreay, Trawsfynydd and Winfrith) and these are called the 'lead and learn' sites. They are providing useful feedback to the environment agencies prior to the finalisation of the GRR.

Eden-NE, under contract to NDA, has also performed specific research to inform the development of the final version of the GRR. In 2016 we investigated the administrative controls designed to limit land and/or resource use that can be used on their own or in conjunction with engineering controls to limit, reduce or control hazards. We concluded that the currently available administrative tools in the UK will allow sufficient control over the very small hazards that may remain on former nuclear licensed sites. There are areas where existing controls would benefit from greater guidance or relatively small adjustments. In 2017/8 we investigated the experience of the 'lead and learn' sites regarding the implementation of the requirements of the Groundwater Daughter Directive 2006 (GWD 2006), as transposed into UK legislation. Analysis of the discussions and case studies identified that uncertainty regarding the obligations under GWD 2006 has the potential to impact on the NDA site decommissioning and remediation strategy and the timescale for achieving a site end state. The key issues arising from these uncertainties were identified and the results of the work were presented to NDA and regulators at a workshop.

The issues identified and appropriate ways forward were discussed and agreed between all parties.

The final version of the GRR is expected to be published in summer 2018. It may, of course, subsequently be revised sometime after this as part of a periodic review of guidance.

BEIS consultation

BEIS is responsible for the development of policy, legislation and regulation of nuclear energy and nuclear installations across the UK. The BEIS consultation [3] seeks views on proposals to amend the legislation that underlies the regulatory framework for nuclear sites in the final stages of decommissioning and clean-up.

The proposals are intended to enable a more flexible approach that can optimise waste management, thereby realising environmental benefits and reducing costs. A discussion paper on the principle of these proposals was published in November 2016 [2] and BEIS are now consulting on the detailed proposals, in particular the arrangements for exiting the nuclear third party liability regime and for ending the nuclear site licence. The consultation closes on 3rd July 2018.

In the final stages of decommissioning and clean-up, risks and hazards fall to the point that regulation under the nuclear site licensing regime and application of the nuclear third party liability regime are no longer warranted. BEIS summarise the main reasons for the proposed change to be:

- nuclear third party liability currently continues beyond the point at which it is no longer required. The UK has not yet implemented the decisions of the OECD Steering Committee for Nuclear Energy concerning the exclusion of certain sites from the nuclear liability regime [10,11];
- site operators wishing to exit the NIA65 licensing regime are required to clean-up the site in a way that does not allow them to balance the overall safety and environmental risks and this may result in unnecessary costs; and
- disposal facilities for radioactive waste located on nuclear licensed sites remain subject to nuclear licensing. Such sites are also regulated by the environment agencies. BEIS consider this dual regulation unnecessary after nuclear safety matters have been resolved.

The BEIS consultation contains the following four proposals.

1. To change the NIA65 to allow licensees to exit the licensing regime once the site has reached internationally agreed standards and nuclear safety and security matters have been fully resolved. After the licence has been ended[1], the site would be regulated by the relevant environment agency and the Health and Safety Executive (HSE), in the same way that non-nuclear industrial sites undergoing clean-up for radioactive or other contamination are regulated. Proposals for further clean-up would be assessed by the relevant environment agency under the RSR. This process would enable the site operator to work with the community to establish the most appropriate end state for the site and would result in improved waste management and other environmental benefits.
2. To allow ONR to exclude certain disposal facilities for radioactive wastes from the nuclear licensed site, if it is content that nuclear safety and security matters have been fully resolved. The facilities would be regulated by the relevant environment agency and HSE and the relevant environment agency would be responsible for deciding when nuclear third party liability should end.
3. To implement two recent decisions by the OECD Steering Committee for Nuclear Energy concerning the exclusion of certain sites from the nuclear third party regime: the Paris Convention Decommissioning Exclusion [10] and the Paris Convention Low Level Waste Disposal Sites exclusion [11].
4. To tighten the licence surrender process to require a licensee to apply to ONR to surrender the licence. BEIS also propose to strengthen requirements for ONR to consult with HSE when the licence is surrendered or varied.

Under the proposed framework:

- The nuclear third party liability regime would cease to apply when ONR was satisfied that the site had met the Paris Convention Decommissioning Exclusion criteria [10]. The ending of the period of responsibility would not mean that the owner or occupier of the site has no liabilities or responsibilities to third parties. When the nuclear

1 Using the proposed new surrender process described in proposal 4

liability regime ceases to apply, third party liability (under ordinary law) would then apply to the site, providing an alternative but nevertheless still robust legal regime for third party damage or injury.

- Separately and potentially at a later date, the site operator would have to apply to ONR to surrender the site licence. ONR would be able to accept the surrender of the licence once content that the period of responsibility for nuclear third party liability had ended and that nuclear safety and security were no longer a concern. ONR would consult with HSE and the relevant environment agency before taking this decision.
- Once the site licence has been surrendered (following application and acceptance by ONR), the health and safety of work activities on the site would be regulated by HSE.
- Any further site remediation, and waste management and disposal, would continue to be regulated by the relevant environment agency, until the site operator could demonstrate to the satisfaction of the relevant environment agency that the RSR permit could be surrendered (the "Site Reference State" has been reached).
- The site operator could apply to ONR to exclude certain disposal facilities from the nuclear licensed site. ONR would consult with HSE and the relevant environment agency before taking a decision and would accept the application if satisfied that nuclear safety and security matters had been resolved. The relevant environment agency would determine the period of responsibility for these facilities.
- Low level waste disposal facilities which meet stringent internationally agreed requirements [11] would be excluded from the requirement for nuclear third party liability.

These proposals would allow the optimisation of waste management and site end states to take place, including the disposal of low levels of radioactive waste on existing nuclear sites.
Eden-NE supported NDA in earlier work exploring potential proposals for regulatory options, and in the preparation of the case studies that are included in the BEIS consultation.

Clearance levels

The radioactive substances regulations (RSA93 and EPR16 as amended) specify the scope of the legislation in a table of activity concentrations.

From 2011 onwards this table has contained the general clearance levels specified in EC publication RP122, Parts I and II [12]. In 2017 consultations on revisions to the revised radioactive substances regulations were published as part of the transposition of the 2013 BSS [13,14]. These introduced a revised table of activity concentrations, as well as other changes, and on 2nd May 2018 the amendments to EPR16 came into force in England and Wales. The values in the revised table are those specified in 2013 BSS, with the exception that C-14, and Cs-137+ retain the previous clearance values. This is because the 2013 BSSD provides some flexibility (set out in Articles 26 and 30) in particular circumstances for Member States to set their own exemption and clearance values, provided that they are in keeping with the general exemption and clearance criteria in Annex VII. This flexibility is provided in recognition that there can be a high variability in local circumstances and the values produced by a single generic model will not always be appropriate. UK has used this flexibility to allow the higher "out of scope" values in existing UK radioactive substances legislation for carbon-14 and caesium-137 to continue to be used in the waste management regime. This will reduce the amount of waste that would otherwise be categorised as radioactive, so will minimise the environmental and economic impacts. The consultation supporting this approach stated that PHE advised that the adoption of the new values has little or no benefit from a radiation protection perspective when compared to the existing values, and would result in significant adverse environmental impacts associated with excess generation and treatment of radioactive wastes.

The revised regulations also transpose the 2013 BSS provisions regarding the deliberate dilution of material or waste with the intention of reducing the concentration of radioactivity below the out of scope (general clearance) level. If this occurs then the substance or article is to be treated as having a concentration above that level.

As well as making the minimum changes required to transpose the 2013 BSS, additional measures were included to improve the regulatory framework. One change addresses the remediation of historic contamination with Ra-226 and progeny. If the contamination occurred prior to 13th May 2000, the revised regulations define the out of scope levels for wastes arising from remediation of historic contamination to be 1 Bq g^{-1} for solids and relevant liquids, 1 Bq l^{-1} for liquids and 0.01 Bq m^{-3} for gases. Other changes revise levels for the exemption from reporting and authorisation for disposal of NORM wastes (this concept is roughly equivalent to the concept of specific clearance). These increase the concentration values for NORM waste containing lead-210+ or polonium-210 that can qualify for exemption. The revised levels are 100 Bq g^{-1} for Type 1 NORM wastes (5 Bq g^{-1} remains for other NORM radionuclides), and 200 Bq g^{-1} for Type 2 NORM wastes (10 Bq g^{-1} remains for other NORM radionuclides). Landfill disposal of up to 10,000 GBq g^{-1} of Type 1 NORM waste containing lead-210+ or polonium-210 is now exempt (50 GBq g^{-1} remains for the other NORM radionuclides). Exemption for disposal by incineration remains at 100 MBq g^{-1} of Type 1 NORM waste for all NORM radionuclides. Landfill disposal of Type 2 NORM waste does not require prior notification or authorisation but it does require prior submission of an environmental safety case to the environmental regulator demonstrating that it meets the appropriate dose and risk criteria.

The revised Scottish regulations are not yet in force as they are part of a wider consultation on an Integrated Authorisation Framework that will bring together environmental authorisations relating to water, waste, radioactive substances and pollution prevention and control.

Conclusions

There are many nuclear sites in Great Britain that are currently undergoing decommissioning and clean up. Although in some cases it will be many years before all this work is completed, decisions are needed now about the level of clean-up required and whether to leave some radioactive waste in situ. The proposed revisions to the regulatory regime will enable optimisation of waste management on nuclear sites to occur, under a regulatory regime that is in line with international agreements. The final version of the GRR will provide a set of requirements to enable site operators to make the decisions they need to bring a site to a state in which it can then be made available for other uses, and eventually released from RSR for unrestricted use. The revised out of scope levels in the UK support a sustainable approach to decommissioning whilst meeting the 2013 BSS requirements.

References

1. "Guidance on Requirements for Release of Nuclear Sites from Radioactive Substances Regulation", Scottish Environment Protection Agency, Environment Agency and Natural Resources Wales, February 2016 https://consultation.sepa.org.uk/operations-portfolio/grr/user_uploads/2016_02_01-grr published-consultation-document.pdf
2. "Discussion Paper on the Regulation of Nuclear Sites in the Final Stages of Decommissioning and clean-up", BEIS, November 2016 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/565233/Discussion_Paper_3_November_2016_.pdf
3. NUCLEAR DECOMMISSIONING Consultation on the Regulation of Nuclear Sites in the Final Stages of Decommissioning and Clean-Up. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/705217/Regulation-of-nuclear-sites-in_the_final-stages-of-decommissioning-and-cleanup-consultation.pdf
4. The Environmental Permitting (England and Wales) (Amendment) (No. 2) Regulations, SI No. 428, 2018. See http://www.legislation.gov.uk/uksi/2018/428/contents/made
5. Application of the Concepts of Exclusion, Exemption and Clearance, IAEA Safety Guide R-S-G1.7, 2004. https://www-pub.iaea.org/MTCD/publications/PDF/Pub1202_web.pdf
6. "Guidance to Inspectors on the interpretation and implementation of the HSE policy criterion of "no danger" for the de-licensing of nuclear sites", Health and Safety Executive (HSE), 13 August 2008 http://www.onr.org.uk/delicenceguide.pdf and "HSE Criterion for Delicensing Nuclear Sites", HSE, May 2005, http://www.onr.org.uk/delicensing.pdf
7. The Nuclear Installations (Liability for Damage) Order 2016 https://www.legislation.gov.uk/uksi/2016/562/contents/made
8. See summary https://www.oecd-nea.org/law/paris-convention.html
9. NDA Strategy effective from April 2016. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/518669/Nuclear_Decommissioning_Authority_Strategy_effective_from_April_2016.pdf
10. "Decision and Recommendation of the Steering Committee Concerning the Application of the Paris Convention to Nuclear Installations in the Process of Being Decommissioned", OECD Nuclear Energy Agency, 30 November 2014. https://www.oecd-nea.org/law/decommissioning-exclusion.html
11. "Decision and Recommendation concerning the Application of the Paris Convention on Third Party Liability in the Field of Nuclear Energy to Nuclear Installations for the Disposal of Certain Types of Low Level

Radioactive Waste", OECD Nuclear Energy Agency Steering Committee, 3-4 December 2016 https://www.oecdnea.org/cen/docs/2016/ne2016-7-final.pdf
12. Practical use of the concepts of exemption and clearance Part I Guidance on General Clearance Levels for Practices https://ec.europa.eu/energy/sites/ener/files/documents/122_part1.pdf and Practical use of the concepts of clearance and exemption Part II Application of the concepts of exemption and clearance to natural radiation sources https://ec.europa.eu/energy/sites/ener/files/documents/122_part2.pdf
13. Consultation on an Integrated Authorisation Framework: Draft Environmental Authorisations (Scotland) Regulations 2018. https://consultation.sepa.org.uk/regulatory-strategy/iaf-supporting-guidance/
14. BEIS and the devolved administrations, 2017. REVISED REQUIREMENTS FOR RADIOLOGICAL PROTECTION Regulation of Public Exposures and the Justification of Practices, consultation document, October 2017. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/649935/Consultation_on_BSSD_Public_Exposures_and_Justification.pdf

Annales de l'Association belge de Radioprotection, vol. 43, n°2, 2018
Annalen van de Belgische Vereniging voor Stralingsbescherming, vol. 43, nr 2, 2018

ETHICAL BASIS OF THE CONCEPT OF CLEARANCE WITHIN THE OVERALL PHILOSOPHY OF RADIATION PROTECTION

Augustin Janssens[1]

Abstract

Taking the new draft publication of ICRP on the ethical foundations of the radiation protection system as a starting point, this paper offers an analysis of the core ethical values and procedural values that are relevant to the issue of exemption and clearance. A further analysis of the historical development of the concepts of exemption and clearance and the underlying criteria leads to their interpretation in the light of these ethical values. This analysis eventually leads to a reformulation of the principles of clearance, and concludes that while the work carried out so far remains valid, the criteria and regulatory enforcement of the principles could be handled with some flexibility. The main message is that the dosimetric criteria for clearance should be related to the principle of Justification. It is further advocated that there is a need for traceability, documentation and transparency, as well as engagement of stakeholders, despite clearance implying a release from regulatory control.

1. Guidance of ICRP

The current system of radiological protection was laid down in Publication 103 of ICRP [1]. The system remains based on three main principles of protection: Justification, Optimisation and (dose) Limitation. These principles now apply to all categories of exposure (occupational, medical and public exposures) and to all exposure situations (existing, planned and emergency exposure situations.) In planned exposure situations ICRP has introduced the concept of individual dose constraints in the optimisation of protection (similar to reference levels in the two other exposure

---

1 Augustin Janssens was formerly head of the EC's radiation protection unit; no part of this paper however should be regarded as representing the views of the European Commission. For correspondence: janssens@pt.lu .

situations). In Table 5 of publication 103 ranges of possible dose constraints or reference levels are put in perspective to the societal context of the exposure situation. Doses above 100 mSv are not regarded as tolerable except for informed volunteer (emergency) workers in situations where their exposure is justified "to save lives, prevent severe radiation-induced health effects, or prevent the development of catastrophic conditions". Typical ranges for constraints in planned exposure situations for workers are 1 to 20 mSv/y and for members of the public 1 mSv per year or less. Section 2.4 of Publication 103 explains the difference between the exclusion of exposures and the exemption of practices from specific regulatory requirements, but offers no further guidance on the matter, since it is regarded merely an issue for regulatory authorities. In the next publication, 104 [2], an elaborate discussion is offered on the concepts of exemption and clearance, but it is descriptive rather than prescriptive. It refers to the concept of "trivial risk" that was developed elsewhere [3] but does not put it in the overall framework of the system of protection. In addition, it did not allow for the recent introduction of exposure situations. In the international [4] and Euratom [5] Basic Safety Standards (BSS) the concepts of exemption and clearance apply to planned exposure situations only, and exclusion relates to an existing exposure situation (note that the definitions of exposure situations in the international standards slightly differ from those of ICRP [6]). A practice that is exempted is still part of an existing exposure situation, and the same applies to materials that have been cleared within a practice.

It would be welcome if future recommendations of ICRP would shed more light on the radiological basis of exemption and clearance. In the absence of such guidance the criteria for exemption lack a solid foundation, and hence are difficult to explain and defend. The present paper attempts to draw lessons from the societal and regulatory experience with the development of criteria for clearance and with their application [7] and to put these in perspective to the ethical foundations of the system of radiation protection. For this purpose, we refer to a recent publication by ICRP [8]. While quoting freely from this publication, we will use in this paper to a large extent the same definitions of ethical principles and procedural values as identified by ICRP.

ICRP identifies as core ethical values:

- Beneficence and non-maleficence
- Prudence
- Justice
- Dignity

Procedural values allocate responsibilities to those involved in the radiological protection process, for instance:

- accountability,
- transparency,
- inclusiveness (stakeholder participation).

Beneficence and non-maleficence

Beneficence means promoting or doing good, and non-maleficence means avoiding causation of harm. Non-maleficence is closely related to prevention, which aims to limit risk by eliminating or reducing the likelihood of hazards. Beneficence includes consideration of direct benefits, for individuals, communities, and the environment.

This core ethical value is closely related to the *principle of justification* within the radiation protection system. In our remit it is important to consider whether the management of radioactive waste resulting from a practice should be justified as part of the planned practice or whether different waste management options should be considered irrespective of the origin of the waste. The fundamental option is whether radioactive substances generated in a practice ought to be discharged with airborne or liquid effluent or extracted and concentrated for the purpose of disposal as radioactive waste. Similarly, the clearance of solid materials from a practice can be regarded as a form of dispersal in the environment, in the same way as an effluent. It is often taken for granted that concentration and disposal are *a priori* beneficial, but there is neither an intrinsic ethical basis for this assumption nor is there an evident justification for it, except at high concentrations of radionuclides in the waste material. For low concentrations of activity there should be some borderline below which disposal is no longer justified.

Prudence

ICRP relates the value of Prudence first of all to the assessment of the probability of health risks. With regard to deterministic effects: "It is prudent to take uncertainties in the current estimates of thresholds for deterministic effects into account … . Consequently, annual doses rising towards 100 mSv will almost always justify the introduction of protective actions." With regard to stochastic effects: "At radiation doses below around 100 mSv in a year, the increase in the incidence of stochastic effects is assumed to occur with a small probability and in proportion to the increase in radiation dose … . The Commission considers that the LNT model remains a prudent basis for radiological protection at low doses and low dose rate.".

The LNT model should indeed be regarded as a striking demonstration of prudence in extrapolating health effects observed at high doses. It is the basis of the principle of optimisation, since it allows low and high individual doses to be amalgamated in a collective dose. This does not mean however that a large collective dose that is the sum of very low individual doses should be translated into a predicted health effect.

In the context of exemption and clearance one may advocate prudence also with regard to the exposure scenarios that are worked out in order to assess possible individual exposures resulting from exemption or clearance. This is what was labelled in the work of the EC as a "prudently realistic approach", in some cases using probabilistic techniques [9]. Scenarios could actually be based on the combination of probabilities of exposure and of the resulting health risk (probability of cancer). There are limits to this approach however: any doses, even with very low probability, should remain below the dose limit for public exposure.

Justice

Justice is usually defined as fairness:

- in the distribution of advantages and disadvantages among groups of people (distributive justice),
- in compensation for losses (restorative justice), and
- in the rules and procedures in the processes of decision-making (procedural justice).

The principle of equity reflects the personal circumstances in which individuals are involved. It is the role of dose constraints and reference levels to reduce the range of individual exposures, for individuals subject to the same exposure situation.

The principle of equal rights guarantees equal treatment for all as regards higher levels of exposure. It is the role of dose limits to ensure that all members of the public, and all occupationally exposed workers, do not exceed the level of risk deemed tolerable by society and recognised in law.

While distributive justice in general terms aims at a fair distribution of advantages and disadvantages among groups of people, one may wonder whether, with regard to the "disadvantage" of radiation exposure, this distribution really matters at very low doses that may result from the application of the concepts of exemption and clearance. In addition, in most exposure scenarios it is not even possible to identify which actual individuals would be concerned. The scenarios introduce broad categories of people with specific occupation or living conditions, but it is not demonstrated that these categories would apply to any single individual. The *a priori* application of distributive justice among hypothetical individuals seems rather meaningless.

Procedural justice concerns fairness in the rules and procedures in the processes of decision-making. In general, it advocates Stakeholder involvement, which relates to the procedural value of inclusiveness.

Dignity

Dignity is an attribute of the human condition: the idea that something is due to a person because she/he is human. It is the central value in many ethical theories: "Act in such a way that you treat humanity, …, never merely as a means to an end, but always at the same time as an end." [10]. Dignity is closely related to Justice, but with the corollary of personal Autonomy. This is the idea that individuals have the capacity to act freely (i.e. to make uncoerced and informed decisions). ICRP has emphasised the promotion of autonomy through stakeholder involvement and empowerment of individuals to make informed decisions, for example, when living on contaminated land [11].

Within the category of public exposures, resulting for instance from radioactive effluent, the usual approach however is that people should ignore their exposure; individuals should certainly not be expected to adjust their behaviour. In the same way, while people may choose to abstain from using a consumer product, the idea of clearance is that people should feel confident that they can ignore their possible exposure.

Procedural values

The procedural values of accountability, transparency and inclusiveness are closely correlated. Accountability is the procedural ethical value to the effect that people who are in charge of decision-making must answer for their actions to all those who are likely to be affected by these actions. In terms of governance this means the obligation of individuals or organisations to report on their activities, to accept responsibility, and to be ready to account for the consequences if necessary. The concept of accountability explicitly appeared in Publication 60 [12] and was reaffirmed in much the same terms in Publication 103 [1]: "There should be a clear line of accountability running right to the top of each organisation. (…) Advisory and regulatory authorities should be held accountable for the advice they give and any requirements they impose".

Transparency concerns the fairness of the process through which information is intentionally shared between individuals and/or organisations. Transparency does not simply mean communication. It relates to the accessibility of information about the activities, deliberations, and decisions that are at stake and also the honesty with which this information is transmitted.

Transparency on exposures and protective actions for workers has been integrated into ICRP recommendations since the 1960s. It was not until the 2000s however that transparency became a general principle applicable not only to information about exposures but also to the decision-making processes concerning the choices of protective actions by policy makers. Publication 101 [13], dedicated to the optimisation of protection, says: "Due to its judgemental nature, there is a strong need for transparency of the optimisation process."

Inclusiveness is one of the essential procedural values, along with transparency and accountability, needed to make ethical decisions in organizations. An important means of pursuing inclusiveness is stakeholder involvement, or engagement. In recent decades, stakeholder involvement has become an essential part of the ethical framework in private and public-sector organizations. We will discuss stakeholder involvement or participation in the section 4 on the societal context of clearance.

2. The principles of exemption

The principles underlying the concept of exemption were laid down in 1988 in Safety Series 89 [3], co-sponsored by IAEA and NEA. The purpose of this document was to recommend a policy on exemptions from the Basic Safety Standards system of notification, registration and licensing.

From the radiation protection standpoint, two basic criteria were identified for determining whether or not a practice could be a candidate for an exemption from the Basic Safety Standards:

- individual risks must be sufficiently low as not to warrant regulatory concern; and
- radiation protection, including the cost of regulatory control, must be optimized.

The first aspect was addressed by defining a level of individual dose that could be defined as ‘trivial’. The second aspect should be addressed “by using optimization analysis techniques such as cost-benefit analysis, intuitive or formal, or other methods.”

With regard to the first aspect, the document advocated that “*it is widely recognized that values of individual risk which can be treated as insignificant by the decision maker correspond to a level at which individuals who are aware of the risks they run would not commit significant resources of their own to reduce these risks. ... There is likely to be a wide range of individual views on this subject .... However, there is a widely held, although speculative, view that few people would commit their own resources to reduce an annual risk of death of* 10^{-5} *and that even fewer would take action at an annual level of* 10^{-6}*. Most authors ... have set the level of* *annual risk of death which is held to be of no concern to the individual at 10^{-6} to 10^{-7}. Taking a rounded risk factor of 10^{-2} Sv^{-1}..., the level of trivial individual effective dose ... would be in the range of 10-100 µSv per year.*" In 1990 there was a meeting to discuss whether the document ought to be reviewed in the light of the higher risk per unit dose then recommended by ICRP in Publication 60 [12]. One of the reasons for not doing so was that the translation of "a range of 10-100 µSv per year" into "of the order of 10 µSv in a year" (allowing for a hypothetical exposure to several exempted practices) had already been very cautious so that the new risk coefficients did not warrant a further reduction of the dose criterion.

With regard to the second criterion, applying optimization to the examination of a practice that is candidate for exemption, it was highlighted that "the implementation of regulatory control may be costly in terms of regulatory time and resources". A further important argument was that the cost of performing the optimization analysis may in itself outweigh the cost savings in terms of a further potential reduction in health detriment: "In such situations, the rigorous use of cost-benefit or other method of optimization analysis would not be justified".

The document concluded on a 'trivial' collective dose for exemption purposes of the order of a few man-Sv per year of practice.

A third very important criterion was that exemption was intended only for sources and practices that are inherently safe. "Exemption must not be granted if there is a possibility of scenarios leading to doses in excess of those specified in granting the exemption."

3. The concept of clearance

3.1. Scope defining levels

In September 2000, the General Conference of IAEA requested the Secretariat "to develop, using the Agency's radiation protection advisory mechanisms and in collaboration with the competent organs of the United Nations and with the specialized agencies concerned, […] radiological criteria for long-lived radionuclides in commodities, particularly foodstuffs and wood, and to submit them to the Board of Governors for its approval." (GC (44)/21).

The IAEA undertook the establishment of such “Scope Defining Levels”, SDL, for any type of commodity. This soon turned out to be a big problem. It proved impossible to define a unique set of values for any type of materials, for instance foodstuffs, building materials, metals or wood.

After many years of difficult discussions, it was eventually agreed that the SDL’s for artificial radionuclides fit in the conceptual framework of exemption, rather than exclusion, and should be regarded as the lower boundary to a graded approach of regulatory control. IAEA Safety Guide RS-G-1.7 on Application of the Concepts of Exclusion, Exemption and Clearance [14] provides values of activity concentration for radionuclides (both of natural and of artificial origin) in bulk amounts of materials. The Safety Guide merely suggested that the levels established for the exemption of bulk materials may also “find use by regulatory bodies as a basis for the clearance of such materials”. Eventually, the numbers in RS-G-1.7 were incorporated in the international [4] and Euratom BSS [5], both for general exemption and for general clearance.

3.2. “Authorised release”

The above development led to a sharp distinction between the concepts of exemption of a planned activity (practice) and of clearance of material from within a regulated practice. In line with ICRP [2] the term “conditional clearance” was scratched. The idea was that post clearance no conditions should be met, there should be no need for regulatory follow-up. While options for conditional release of materials for a given purpose should be considered, these were regarded as a specific case of “authorised release”, rather than clearance. On the other hand, the term “specific clearance” was coined for levels specific to a type of material. Guidance on specific clearance levels for metals and for building rubble from dismantling on nuclear installations was offered by the EC, and received legal status through references in the Euratom BSS [5]. The “conditions” imposed for specific clearance should be met -prior to release. Consequently, the scenarios should not assume a particular fate of the material, and hence, if relevant for the type of material, recycling, reuse, landfill disposal or incineration were all considered possible paths.

It should be noted that today there seems to be a need for levels that are appropriate to landfill disposal only. This case, just as was discussed in the early days [3], is more a matter of exemption of the recipient (landfill operator) than of clearance for the producer of the (waste) material. The term "conditional clearance" may still seem appropriate for this particular purpose. It is also still not quite clear whether the release of sites after dismantling is a matter of clearance or a matter of authorised reuse of the land area or buildings". A site that has been released from regulatory control after clean-up is still registered as far as possible residual environmental contamination is concerned. It is then a known existing exposure situation, and if necessary the authorities may impose certain restrictions on the use of or the operations conducted on the land. This means that a reference level can be applied, which will most certainly be well below 1mSv/y, but which is not related to the 10 μSv/y criterion for the release of materials. The consideration that materials may be removed from the site and reused, recycled or disposed of elsewhere does not seem to be relevant (bearing in mind that removal for subsequent surface disposal does not make much sense).

3.3. General exemption criteria

The prime general criterion is that individual exposures should be sufficiently low. This is interpreted in both Standards as being satisfied if the effective dose incurred by any member of the public " … is of the order of 10 μSv or less in a year". The IBSS add a criterion that "the effective dose … for… low probability exposure scenarios does not exceed 1 mSv in a year (this boundary had been used in the work of the EC yielding the first set of exemption values for moderate amounts [15]). The Euratom BSS add a criterion for workers, who "should not be classified as exposed workers". This reflects the new more comprehensive definition of occupational exposures ("occupational exposure" means exposure of workers, …, incurred in the course of their work). The 10 μSv criterion should indeed apply only to actual public exposures. Hence one should now consider occupational exposures not only those that are related, at least potentially, to the kind of work, but also those for which the employer or undertaking has a legal responsibility. These workplaces do not need to be regulated however if no worker needs to be classified as an exposed worker, i.e. is liable to exceed the dose limit for members of the public.

The criterion of 1 mSv/y may for instance apply to workers on a landfill, if they are informed of the possible receipt of radioactive material, and to workers in metal scrap yards or metal works. Such workers anyway need to know how to act in case of an alarm at portal monitors. While it may be superfluous to recalculate clearance levels on the basis of this new criterion, one should nevertheless be aware that the currently available concentration levels may be very conservative. Indeed in many cases the limiting exposure scenarios are those for which the affected individuals belong to a category of workers, and the criterion of 10 µSv/y that was applied hence led to most restrictive values.

It is worth noting that in the new standards the criterion of collective dose (1 man-Sv per year) has disappeared. This resulted from the observation that while applying the criterion of individual dose of 10 µSv/y, the number of possibly affected individuals, if any, would be in a range far below say 1000 people, hence contributing very little to collective dose. Neither did a general additional scenario involving widespread dispersal combined with some typical population density yield a significant collective dose. Indeed the total amount of radioactive substances released to the environment as a result of a clearance policy would always remain relatively small. Of course the principle of optimisation prevails, and the argument that the conduct of a formal optimisation assessment is not warranted below say 1 man-Sv per year is still relevant.

3.4. Criteria for NORM

In RS-G-1.7 it was considered that for naturally occurring radionuclides in principle the concept of “amenability to control” underlying the concept of exclusion would apply. This approach is no longer in line with the regulatory control of NORM industries. The initial Euratom approach [16] was not so much different from the approach for artificial radionuclides, albeit on the basis of a dose criterion of 0.3 mSv/y rather than 10µSv/y. Eventually the international consensus was to keep the values of RS-G-1.7 but to refer to an even higher exemption criterion of 1 mSv/y.

3.5. Mixing and dilution

The Euratom BSS [5] introduce in Art. 30.4 a very important clarification about dilution of radioactive materials. This paragraph distinguishes between “deliberate dilution … for the purpose of (the materials) being released from regulatory control” and the “mixing of materials that takes place in normal operations where radioactivity is not a consideration”. The former, deliberate dilution, is prohibited. In addition to the latter, deliberate mixing may be justified and authorised, in specific circumstances, for re-use or recycling.

This clarification lifts any doubt on the validity of the scenarios that have been used, for instance for the recycling of metals. No metalwork processes a single batch of metals from a certain origin. There is always a mix of scrap metal with different origins and with different specifications, to obtain the desired metallurgic properties and quality. On the other hand, the explicit prohibition of deliberate dilution is firm enough to lift the concerns raised in 1988 [3] “However, the formulation of exemptions from regulatory control should not allow the circumvention of controls that would otherwise be applicable, by such means as deliberate dilution of material or fractionation of a practice.”

The approach to dilution and mixing has implications for the sorting of materials from dismantling. If measurements are carried out on excessively large volumes or surfaces, this may cause the inadvertent or deliberate incorporation of smaller items with higher activity concentrations. Hence the guidance on the use of clearance levels included limits to the mass (of the order of 1 ton) or surface (typically 1 m^2) for which compliance should be demonstrated. It should be noted that in terms of the exposure scenarios such restrictions are mostly irrelevant. The throughput of typical steel works or landfill sites is very large as compared to the total volumes of potentially radioactive materials that can be received. Nevertheless, the scenarios conservatively assume a mixing ratio of typically 10%. As long as no single batch of material is liable to invalidate this assumption, its volume does not affect the calculated doses. There also is no merit in being overly prudent with the demonstration of compliance in terms of confidence levels applicable to the results of measurements. This requires strict regulatory supervision of the sorting and measurement strategy. Excessive conservatism should however be avoided.

While the mixing of metals in recycling will mostly occur after clearance, the mixing of NORM residues is often carried out at the point of release, in close cooperation between the producer of the residues and the manufacturer of building materials. Similarly, ingots from on-site melting may be made from pre-mixed scrap so as to pose no problems for the recipient metal plant, or so as to enable the release of materials that are in a shape that does not facilitate their measurement, but obviously such mixing and melting merely in view of meeting the clearance levels is not allowed. The direct use of ingots, without mixing in general recycling, should also be precluded in order not to invalidate the exposure scenarios.

4. Societal context

The societal context of clearance policies affects their acceptance; this is in particular true for the recycling of metals, for which the volume of materials originating from dismantling of nuclear installations is very large and represents huge commercial interests. The stakeholders range from consumers to different branches of industry (metal scrap dealers, metal works, processors of semi-finished products (sheets and bars), and producers of finished products.

4.1. Concerns of the industry

Cleared materials are not subject to the requirements of the standards and hence, from a legal point of view, there is no need for traceability of cleared materials. Nevertheless, the societal context calls for appropriate documentation that should also allow stakeholders to be involved whenever this is warranted (e.g. for workers in metal works receiving materials from nuclear installations). The scrap dealer could request such information on the origin of the material as part of a commercial agreement; in the same way the steel work can request guarantees from the scrap dealer, and the industry processing metal sheets can make it part of its contractual arrangements that the metal be free of contamination. The metal industry is indeed not eager to receive materials from nuclear industries. It has a "clean" image and is very sensitive to public concerns about radioactivity. A car manufacturer for instance would not wish to face the risk that the steel used in some of its cars is found to exhibit a detectable level of radioactivity. The adverse publicity of such an event would have an important economic cost. It should be borne in mind that at the level of semi-finished products the material is very well characterised; most metal works keep a sample of the smelt (ingot) for quality assurance and to ensure traceability.

A further important consideration, which is also reflected upon in the recital of the Euratom BSS [5], is that "Council Regulation (EU) No 333/2011 establishes criteria determining when certain types of scrap metal cease to be waste under Directive 2008/98/EC on waste". In other words, scrap metals are regarded as waste as long as there is no demonstration that they satisfy all relevant quality criteria. The different branches of metal industries now seem to agree on the need for acceptance criteria for materials arising from the dismantling of nuclear installations. Such criteria should not trigger the portal monitors in scrap yards and steel works, and would still guarantee the detection of the presence of orphan sources. A consensus was reached at international level with a proposed Code of Conduct [17] that would have contributed to the harmonisation of alarm thresholds, but unfortunately was not endorsed by the IAEA General Conference.

4.2. Regulatory approaches

Clearance is tightly embedded in the regulatory supervision of authorized practices. Indeed, public acceptance will depend on effective and transparent regulatory surveillance. On the other hand, regulators must bear in mind that one of the main benefits of clearance is a reduction of the regulatory burden, hence a very strict application could be counter-productive.

The dismantling of nuclear installations (and other facilities such as hospital accelerators) gives rise to very large volumes of materials, most of which are neither contaminated nor activated. In some cases, the absence of radioactivity can be assumed from the nature of the premises and their history, on the basis of records demonstrating there has been no incident causing contamination (this strategy is often labelled as "zoning"). In many cases, in addition to such historical information, it is necessary to rely on measurements however. This requires the establishment of a decision threshold for positive results, which should obviously not be higher than the recommended clearance levels. In brief, the zoning approach requires clearance levels even without saying so.

While the new Euratom BSS still do not impose on Member States to introduce a clearance policy, and different options can indeed be considered, a harmonised approach and transposition of the Directive would be very beneficial. In addition, the explicit requirement on transparency of regulatory decisions in the Directive (Article 77) should foster further harmonisation. This would also be extremely beneficial to trans-border movements of cleared material within the EU.

4.3. Consumer response

The concept of clearance should allow large volumes of materials, arising e.g. from dismantling of nuclear installations, with no, or very low levels of contamination, to be released for recycling or reuse. Today, even very low levels of radioactivity can easily be detected, and whenever today even very low levels of radioactivity are found they receive media attention and may prompt huge public concern. People don't like the idea that anything in their daily environment would be "contaminated" with radioactive substances. This reaction is enhanced by people's negative perception of the nuclear industry as a cause of contamination. Hence it is important to explain that the need to dismantle nuclear installations arises irrespectively of the future of nuclear energy.

Aversion for radioactivity also explains why after the Fukushima accident it proved very difficult to find acceptance for the small amounts of slightly contaminated food and other goods imported from Japan. The radiation protection system of course aims at protecting the individual, and in terms of Justice and Dignity that is what it should achieve. The author holds the view that there is a disproportionate focus on individual rights, and that in peoples mind there is an unrealistic expectation that by eliminating all environmental hazards one could avoid e.g. cancer. In addressing such issues one should rely on other societal values, such as Solidarity.

People should become familiar with the unavoidable and acceptable omnipresence of radioactivity in their environment, now that for instance building materials are within the scope of the Euratom BSS. Radioactivity in building materials relates on the one hand to some natural stones, on the other hand to a wide range of materials in which residues have been recycled arising from industries processing naturally occurring radioactive materials (NORM).

5. The ethical framework of clearance

We pointed out in section 2 that one may question the relevance of distributive justice at very low doses. This is even more true when the distribution of exposures merely concerns hypothetical individuals. A lower boundary for constraints at around 10 µSv/y may seem an appropriate threshold for the consideration of individual doses from the perspective of this ethical principle.

In an earlier draft version of the recommendations in Publication 103 of ICRP a lower boundary in the range of constraints had been proposed, at 10 µSv/y. It was no coincidence that this boundary coincided with the exemption criteria laid down in other international guidance [3]. The proposal was misinterpreted as a lower boundary of doses to be considered in the optimisation process (and hence excluded from collective doses), and the consultation process eventually led to discarding this idea.

A lower boundary should not be interpreted as if exposures below this threshold should be dismissed: they should be included in the optimization of protection, and if there are practicable means of avoiding or reducing any such exposures then these should be implemented. On the other hand, in terms of the radiation protection system, materials could be released from regulatory control even though this would result in individual doses that are liable to exceed 10 µSv/y. This criterion is indeed not an expression of tolerability of exposures, which is the sole remit of dose limits. If doses remain below 1 mSv/y and if the release of materials is shown to be justified, then the concept of clearance is in full respect of the basic principles, and fundamental ethics, of radiation protection. In addition, one should not anymore worry that a member of the public can be exposed to different products/materials from different clearance practices. Indeed the new BSS [5] no longer include exempted practices in the sum of exposures that should be allowed for in order to comply with the dose limit (rather, the sum of exposures from all *authorised* practices).

The principle of Justification also explains why secondary NORM materials can be released in relation to a criterion as high as 1 mSv/y. It would be meaningless to impose a criterion of 10 μSv/y in view of the ubiquity of such materials in the earth's crust. Inversely, when the 10 μSv/y criterion for man-made radionuclides was proposed in the early nineties, there was a great deal of consensus that on this basis the dismantling of nuclear installations could proceed at a reasonable cost, and that it would save a significant fraction of materials for recycling or reuse. Hence, it was felt that the clearance of materials meeting this criterion was justified. The different treatment of naturally occurring radionuclides as compared to man-made radioactive substances is not a matter of perception. It is not argued that "natural" radiation would be less harmful. The different approach is easily explained in terms of the justification principle.

The justification of the release of materials with a given activity concentration of a specific radionuclide is not a matter of individual dose alone. The dose criterion only enters because it offers a unified basis for managing broad radionuclide vectors. The question of justification should be addressed very carefully but holistically. The issue is not whether the release of a batch of materials is justified, but whether the overall strategy of cleaning, dismantling, sorting, possibly mixing, measurement and eventually release is justified, and whether the entire chain is adequate for this purpose.

As a result of these reflections, we can conclude that:

- Criteria for clearance relate to the concept of justification (non-maleficence), rather than to any consideration of tolerability of exposures; "triviality" of exposure is not in itself a necessary requirement.
- If dosimetric criteria are preferred for clearance, these can range from 10 μSv to 1 mSv per year, depending on the exposure situation. This already applies to NORM materials and may apply to the release of sites as well.
- Criteria other than dosimetric ones may be equally important:
  - Avoid spread of contamination (enhancing background levels),
  - Radionuclide-specific issues.

Overall, it can be concluded that the current levels and criteria for exemption and clearance are in no contradiction with the radiation protection system nor with its ethical foundation. The analysis shows that in fact one may be more relaxed about compliance with the clearance levels than many authorities currently allow, or that industries apply in prudent self-regulation. A more pragmatic approach to the establishment of clearance levels, applying the principle of justification, offers perspectives for simplification. The above considerations foster a pragmatic approach to the clearance of materials, without a rigorous link to any level of exposure. This offers some perspective for simplification of the set of scope defining levels that have so far been introduced, or that should still be introduced.

Many radiation protection experts still argue that public acceptance would benefit from a single universal set of scope defining levels, despite the failure of earlier attempts (see section 3). The current disparity of concentration levels is discomforting. There might be a good perspective for harmonising the levels in food and in drinking water, or for combining food and non-edible agricultural produce. However, the prospect for unifying all situations and proposing the same activity concentration values on the basis of the same dose criteria is an illusion, in view of the very different exposure pathways that prevail in each situation.

A pragmatic approach may also allow to address emergency exposure situations and post-accidental residual levels of contamination of commodities and means of transport. The Fukushima accident prompted a lot of questions, for instance on the application of transport regulations, which still need to be resolved at international level.

Communication strategies should not focus on individual rights in terms of avoiding any exposure, but should build on the ethical value of societal solidarity, on a global scale. In this context the criteria for exemption and clearance of NORM materials may shed new light on the issue, and possibly result in a better perception.

As for the procedural values, the most important one is accountability in the licensing and surveillance of the dismantling of nuclear installations. This holds both for the industry and for the regulator, and requires transparent documentation. Regarding Inclusiveness, there is a need for dialogue with industries processing cleared materials and for the engagement of industries and workers in these industries as stakeholders. This means that one should abandon the idea that cleared materials should not be traceable at all.

It should be borne in mind that this plea for traceability is not related to the old concept of "conditional clearance". Traceability is not meant to allow, or justify, higher clearance levels. The idea is that even below (unconditional) clearance levels the recipient, e.g. a steel work, is entitled to know the origin of the material. Hence there is need for some documentation.

References

[1] The 2007 Recommendations of the International Commission on Radiological Protection. ICRP Publication 103. Ann. ICRP 37 (2-4) (2008)

[2] ICRP, Scope of Radiological Protection Control Measures, ICRP Publication 104, Annals of the ICRP (2008)

[3] Principles for the exemption of radiation sources and practices from regulatory control, International Atomic Energy Agency, Safety Series N° 89, Vienna (1988)

[4] Radiation protection and safety of radiation sources: international basic safety standards, IAEA safety standards series no. GSR part 3, STI/PUB/1578, Vienna (2014)

[5] Council Directive 2013/59/EURATOM of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (Official Journal N° L-13/1 of 17.1.2014)

[6] Augustin Janssens, The transposition of the principles of radiation protection in international and Euratom Basic Safety Standards, presented at the Fourth European IRPA Congress, Geneva, 22-27.6.2014, Annals of the Belgian Association for Radiological Protection BVS-ABR, Vol. 39 N° 4, 2014, pp 109-118 (2015)

[7] Augustin Janssens, The history of exemption of practices from regulatory control and of clearance of materials containing radioactive substances, Annales de l'Association belge de Radioprotection Annalen van de Belgische Vereniging voor Stralingsbescherming (BVSABR), Vol. 40 n°1, 2015, pp.1-30.

[8] ICRP, Ethical foundations of the system of radiological protection. ICRP Publication 138. Ann. ICRP 47(1) (2018).

[9] Recommended Radiological Protection Criteria for the Recycling of Metals from the Dismantling of Nuclear Installations, Radiation Protection N° 89, Luxembourg (1998)

[10] Kant, I., Groundwork of the Metaphysic of Morals [German: Grundlegung zur Metaphysik der Sitten; translated by H.J. Paton as The Moral Law, London: Hutcheson, 1953, p. 430 (Prussian Academy pagination), 1785).

[11] ICRP, Application of the Commission's recommendations to the protection of people living in long-term contaminated areas after a nuclear accident or a radiation emergency. ICRP Publication 111. Ann. ICRP 39(3), 2009

[12] 1990 Recommendations of the International Commission on Radiological Protection. ICRP Publication 60. Ann. ICRP 21 (1-3) (1991)

[13] ICRP, The optimisation of radiological protection - broadening the process. ICRP Publication 101. Ann. ICRP 36(3), 2006.
[14] Application of the Concepts of Exclusion, Exemption and Clearance, International Atomic Energy Agency, Safety Guide RS-G-1.7, Vienna (2004)
[15] Principles and Methods for Establishing Concentrations and Quantities (Exemption Values) below which Reporting is not Required in the European Directive, Radiation Protection N° 65, European Commission, Luxembourg (1993)
[16] Practical Use of the Concepts of Clearance and Exemption, Part II – Application of the Concepts of Exemption and Clearance to Natural Radiation Sources, Radiation Protection N° 122, Luxembourg (2000)
[17] Control of Trans-boundary Movement of Radioactive Material Inadvertently Incorporated into Scrap Metal and Semi-finished Products in Metal Recycling Industries, Results of the Meetings Conducted to Develop a Draft Code of Conduct, International Atomic Energy Agency, Vienna (2014)