WNA Working Group Position Statement on Removal from Regulatory Control of Material Containing Radioactivity – Exemption and Clearance

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ABSTRACT

The removal from regulatory control of materials containing trace levels of radioactivity, often referred to as 'exemption' or 'clearance', is of considerable importance to the nuclear industry and is subject to ongoing international debate. Its significance is indeed increasing as some sites move towards decommissioning, with much material being capable of recovery, recycling and re-use or simple disposal while maintaining the highest levels of public safety. This Statement outlines the key issues under consideration within the regulatory framework. Moreover, it identifies those aspects necessary for the successful application of a practical system of control. In this regard, the recent IAEA safety guide called *Application of the Concept of Exclusion, Exemption and Clearance* (RS-G-1.7) is paving the way towards implementing greater international convergence and consistency.

INTRODUCTION – THE ISSUE

All substances contain radioactivity. Most of the radioactivity arises from natural processes whilst some is man-made in a variety of industrial and scientific processes. Any resulting potential risks from ionizing radiation depend on many factors such as the concentration and type of the radioactivity, and the form and quantity of the material, but are independent of whether the radioactivity is of natural or man-made origin.

Because virtually all materials naturally contain some radioactivity, society needs a practical and pragmatic method to focus attention on the significant areas of potential public harm from radioactivity. In order to support a sustainable use of resources, industry, commerce and the healthcare sector need a simple, practical and legally based decision-making framework within which to provide the appropriate consistent level of control over radioactivity. Such a framework also needs to contribute to the effective management of risk related to assuring the safety and security of sources and to preventing the illicit use of radioactivity.

The nuclear industry is no different from other sectors in the need to have clear expectations and standards for controlling material that contains substances that can become harmful at higher levels. For the ongoing operations of the nuclear industry and, increasingly and importantly, for the management of material arising from decommissioning activities, there needs to be a clear framework for identifying those materials which must be subject or not to ongoing control.

Under this framework, appropriate materials could be removed from sites for unrestricted recovery, recycling and re-use or disposal, and as such have the potential to become engaged in national and international trade. For this reason, it is of the greatest importance to seek consistent international practice on the identification of those materials that should be subject or not to regulatory control.

The principal international bodies working in this area, in particular the International Atomic Energy Agency (IAEA) – the UN body that sets radiation safety standards - and the International Commission on Radiological Protection (ICRP) – an authoritative non-governmental organization of worldwide radiological protection experts that issues international recommendations - have given significant attention to this topic, and there is much national and international discussion and continued development.

In 2004, the IAEA published an important Safety Guide called *Application of the Concept of Exclusion, Exemption and Clearance* (RS-G-1.7), which reflects a wide consensus among the UN Member States on a common set of rules for adequately governing the use or disposal of bulk materials containing trace levels of natural radioactivity and artificial radioactivity[1]. The implementation of this Safety Guide by all Members States is of vital importance. It would enable the necessary transition from the current situation where there are almost as many rules as there are Member States, to the far better and realizable goal of a shared and consistent international framework. This framework can then evolve on a common path of international review and improvement.

This Statement presents the international nuclear industry's perspective on the issue as a contribution to the ongoing debate on exemption and clearance. This perspective has been developed through the activities of the two WNA Working Groups (WGs) on radiological protection (RPWG) and on waste management and decommissioning (WM&DWG). Each of these two WNA WGs consist of industry experts (policy-making and operations) from all sectors broadly representing the nuclear fuel cycle and the generation of nuclear power from all around the world. Currently, the RPWG and WM&DWG each comprise about 30 members – see Appendices I and II.

PRINCIPAL REQUIREMENTS

To adequately address the above, WNA believes that it is essential to establish internationally agreed criteria that identify those materials that must be subject to regulatory control. National authorities then have the ability to declare that efforts to control materials with lower levels of radioactivity would result in a disproportionate use of societal resources. This will provide a common understanding and basis for national and international trade. It will improve safety by establishing clarity and by focusing regulatory effort (and the associated use of national resources) onto controlling those materials of most concern to society. Such an approach would provide a clear basis for public understanding, confidence and acceptance.

[1] RS-G-1.7 complements the IAEA Basic Safety Standards (1995) that already included a set of provisions for addressing small quantities of materials containing trace levels of natural radioactivity and artificial radioactivity. RS-G-1.7 is more relevant to the context of industry-scale activities, including the decommissioning of facilities.

WNA believes that for this framework to have a practical effect, there is an over-riding need to have international agreement on defining reference levels of bulk activity (e.g. in becquerels per kilogram: Bq kg^{-1}) and surface activity (e.g. in becquerels per square centimetre: Bq cm^{-2}), above which some form of regulatory control would be expected. These are the two parameters on which all practical control regimes for materials containing radioactivity are based.

WNA recognizes the subtle differences between the concepts of *exclusion, exemption* and *clearance* (e.g. as defined by IAEA RS-G-1.7[2]) within the overall radiological protection framework. However, we believe that for practical purposes, and to secure public understanding, there must be particular emphasis on establishing simple common terminology that applies to substances and materials that are not subject to regulatory control, no matter what decision route has led to that situation. Such material, which of course still contains some radioactivity, is clearly 'unrestricted'.

CURRENT POSITION - THE FRAMEWORK FOR PROTECTION

The underpinning philosophy in this context is that material should be subjected to regulatory control whenever such control is beneficial to society i.e. unless control is unfeasible or disproportionate. In applying this philosophy, to establish a practical framework, it is then necessary to make judgements relating to the practicability of control, the level of risk (and hence dose), and to take due account of public sensitivity and perception.

In establishing agreement on the practical control values (e.g. Bq kg^{-1}, Bq cm^{-2}), there would be an expectation that national authorities would apply appropriate control regimes to all materials that exceeded the criteria. If an authority chooses to apply controls at lower levels of activity, thereby departing from broad international practice, it would need to recognize that such materials could enter the country without any declaration or control, thus potentially creating uncertainty within the internationally agreed framework.

WNA recognizes that there are differences in practicability of control between natural and man-made radioactivity. When translated into practical control levels, this can imply that society may choose to impose differing control levels on such activity, with higher dose and activity concentration levels applying to natural radionuclides. We also recognize that in some situations, there are higher levels of perceived public concern regarding artificial radionuclides. We believe that the overall objective for control should be to seek a greater convergence over a period of time towards a simpler and more risk-based system. We acknowledge that greater public confidence and understanding, than is currently the case, would aid this convergence process.

There has been a substantial international debate on establishing a level of dose above which there would be an expectation to consider regulatory control. There is a consensus that the principal criterion should be based on an individual dose of around 10 microsieverts (µSv) per year or 0.01 millisieverts (mSv) per year. WNA subscribes to this dose level in principle, but has concern over its wider context and its application in practice. We note, for example, as indicated in IAEA Safety Guide RS-G-1.7, that the original justification supported a dose level *of the*

[2] Exclusion relates to exposures that are essentially unamenable to control. Exemption means exemption from the requirements for practices. Clearance is similar to exemption, but relates specifically to the removal of radioactive material within authorized practices from any further control by the regulatory body.

order of 10 µSv per year rather than a precise numerical value. We are also aware that the underpinning science for this approach is essentially based on the Linear No Threshold (LNT) assumption, which is currently perceived as a prudent philosophical assumption but which may over-estimate the risks of very low-level radiation. However, under any consideration, it is evident that any risk relating to this dose level is at most very small. This dose level is also a small fraction of the variability of natural background radiation levels and would make no significant contribution to the overall radiation risk incurred by any individual person. Additionally, on simple pragmatic grounds, this dose level cannot be incorporated into the control framework for materials containing naturally occurring radioactivity because such radioactivity, which is inherent to all materials, generally leads to higher doses.

Whilst dose, and hence risk, is one important consideration for establishing a basis for regulatory control, there is broad international recognition that such judgements cannot be precise and that this should not be the sole basis for any framework. Broader judgements relating to the avoidance of unwarranted control should also be taken into account. On this basis, WNA would therefore have great concern at an over-rigorous or restrictive application of a prescriptive 10 µSv per year dose level to artificial radionuclides, which if applied unintelligently and inflexibly could result in the imposition of unbalanced restrictions on society's use of resources.

DERIVING PRACTICAL ACTIVITY CONCENTRATION VALUES

In moving from dose considerations to the practical world of materials control it is necessary (at least for man-made radioactivity) to consider various scenarios that model the potential exposure of people to radiation from materials containing radioactivity. Activity concentrations (Bq kg^{-1} and Bq cm^{-2}) in materials are derived from the modelling and assessment of these exposure scenarios. Where scenarios are realistic, expected and credible, WNA agrees that a dose level of the order of 10 µSv per year should be used as the underpinning basis for such assessments. In considering abnormal or unexpected scenarios, which are by definition events that have a lower probability of occurrence, assessment should be based on dose levels not less than the public dose limit of 1 mSv per year.

Modelling assessments in this field must be transparent, robust, consistent and properly peer-reviewed. It is absolutely essential to use numerical values for modelling parameters that are reasonable and credible. The compounding of multiple conservatisms within an assessment is likely to lead to outcomes where the actual dose in practice from a scenario is very significantly lower than the intended baseline dose. Put another way, the numerical activity concentrations (Bq kg^{-1} and Bq cm^{-2}) could have been significantly higher and still comply with the required dose level: this would permit a more effective re-use or disposal of material. It is important to ensure that the resulting numerical values are practical and pragmatic, capable of meaningful implementation (including monitoring capability) and maintain proportionality with the underpinning criteria.

WNA believes that the IAEA is well placed to lead the international debate on the practical implementation of these issues. Indeed, the recent IAEA Safety Guide RS-G-1.7 is broadly compatible with most of the considerations outlined above, although we are not convinced that the modelling underpinning the declared values of activity concentration has taken these views fully into account or that sufficient flexibility has been allowed in judging the final numerical

values. However, we consider the document to be a good basis for initiating international agreement, provided that the scientific underpinning of the numerical values and the broader judgements relating to establishing banded values are subject to an ongoing programme of review and improvement. (Moreover, when applicable, for surface activity, the corresponding IAEA generic limits[3] should also be used to trigger the concepts of exemption and clearance in a similar manner than for the activity concentration values set in RS-G-1.7, including the graded approach.) It is recognized that Safety Guide RS-G-1.7 relates to activity concentrations in commodities, which are relevant to most practical situations in the nuclear industry. Although not directly relevant to the removal of material from sites, WNA recognizes for completeness that it will be necessary to supplement these considerations with additional values that relate to activity concentrations in food (ref. Codex Alimentarius Commission of the UN Food and Agriculture Organization) and drinking water (ref. World Health Organization).

APPLICATION OF THE SYSTEM OF CONTROL

The above framework of activity concentration levels, often currently referred to as exemption or clearance levels, is used to delineate those materials which must be subject to further regulatory control. Once such material has been defined as 'subject to control' there is the ability to apply a graded approach to defining the relevant control regime. For example, for material above these levels but where the risks may be simply controlled, the authorities may agree to release subject to placing restriction on the end use of the material. At higher levels of activity concentration, such as for normal low-level waste disposal, case-by-case authorization may be appropriate. This graded regulatory approach ensures that the stringency of control is commensurate with the risk and that society is appropriately protected from radiation risks without imposing a disproportionate regulatory burden. It is worth mentioning that the IAEA Safety Guide RS-G-1.7 incorporates such a 'graded approach' which introduces the necessary extra flexibility into the framework.

It is clear that in some situations, there is public sensitivity, together with a lack of public confidence, understanding and engagement, on issues involving low-level radiation. It is therefore important that both the industry and the national authorities seek to better engage with the public and their representatives in the further development of the control regime considered in this Statement. It is also important that all parties (i.e. public, regulators and the industry itself) have confidence in the overall waste management approaches adopted within the industry. Operators must be seen to apply the fundamental hierarchical principles of minimization of wastes at source, of material recovery, recycling and re-use, and of disposal only as a last resort. The application of practical 'clearance' levels, as outlined in this Statement, clearly aligns with and supports this overall approach. Hence, it is vital that there is the greatest confidence in the overall arrangements applied to the clearance of materials from sites. This requires the industry to ensure that operating management defines prudent quality-based procedures for controlling such activities, with strict adherence to their requirements.

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[3] The IAEA generic surface activity limits of 4 Bq cm^{-2} for beta and gamma emitters and low toxicity alpha emitters, and of 0.4 Bq cm^{-2} for all other alpha emitters, are set in the IAEA Safety Standards – *Regulations for the Safe Transport of Radioactive Material – 2005 Edition – Safety Requirements – No. TS-R-1.*

SUMMARY AND CONCLUSIONS

Because virtually all materials naturally contain some radioactivity, society needs a practical and pragmatic method to focus attention on the significant areas of potential public harm from radioactivity. For practical purposes it is important to have clearly defined and internationally-agreed bulk and surface activity levels (Bq kg^{-1} and Bq cm^{-2}), above which some form of appropriate regulatory control will be applied.

Because of the potential for movement of materials in national and international trade, it is important to achieve international convergence and consistency in the application of the framework.

In order to ensure public confidence, the framework should not be over-complicated and should be focused around delivering a practical outcome that can command public understanding and support.

Such a framework is essential to support public safety, through the focusing of regulatory effort and societal resources on those potential hazards of greatest significance. It will also support the long-term sustainable use of resources.

The recent IAEA Safety Guide RS-G-1.7 reflects a wide consensus among the UN Member States on a common set of rules for adequately governing the use or disposal of bulk materials containing trace levels of natural radioactivity and artificial radioactivity. Its implementation by all Members States is of vital importance because it would enable the necessary transition from the current situation where there are almost as many rules as there are Member States, to the far better and realizable goal of a shared and consistent international framework. This framework can then evolve on a common path of international review and improvement.

Appendix I: World Nuclear Association – WNA, Radiological Protection Working Group – RPWG

(Official List – January 31, 2006)

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BARC (India)	Ambika Shai Pradhan
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Barsebackkraft (Sweden)	Carl Göran Lindvall
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Cameco (Canada)	John Takala
Cogema Resources Inc. (Canada)	Dale Huffman
CEZ (Czech Republic)	Josef Koc
CNNC (China)	Xinhe Liu
CRIEPI (Japan)	Kenji Ishida
EDF (France)	Yves Garcier
Enusa (Spain)	Guillermo Sánchez
ERA (Australia)	Ian Marshman
IBRAE (Russia)	Oleg Pavlovsky
JAEA (Japan)	Sadaki Futura
JNFL (Japan)	Suzuki Akira
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KKG (Switzerland)	Marcel Lips
NEI (USA)	Ralph Andersen
OPG (Canada)	Robin Manley
RIARA (Russia)	Rudolf Alexakhin
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RWE NUKEM (UK)	Richard Birch
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UCIL (India)	Ramendra Gupta
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IAEA (International)	Didier Louvat
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Appendix II: World Nuclear Association – WNA Waste Management and Decommissioning Working Group – WM&DWG

(Official List – January 31, 2006)

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BARC (India)	Shri Kushwaha
Barsebackkraft (Sweden)	Carl Göran Lindvall
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