Application of radiological exclusion and exemption principles to sea disposal

The concept of 'de minimis' for radioactive substances under the London Convention 1972



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FOREWORD

At the first Consultative Meeting of the Contracting Parties to the Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter (London Convention 1972) in 1975, the IAEA submitted to the Contracting Parties the provisional definition of high level wastes not suitable for dumping at sea and the recommendations concerning low level waste dumping, thus responding to the request of the Convention. In this context the IAEA made a remark that because no material is totally devoid of radioactivity, the competent authorities of the Contracting Parties would wish to define some 'de minimis' levels of specific activity below which material would not be regarded as 'radioactive', for the purposes of the Convention. The Contracting Parties accordingly requested the IAEA to develop further the concept of 'de minimis'.

Since this time the IAEA has prepared several reports on the subject, which reflect the continuing development of the concept of 'de minimis'. The current understanding of the concept is that it includes two distinct concepts: the concepts of exclusion of radiation exposure and of exemption of practices and sources, *de minimis non curat lex* and *de minimis non curat praetor*, respectively. Parallel to the progress in the field of radiation protection, there has been development within the London Convention 1972, notably in 1993, when the decisions on prohibition of dumping of industrial and radioactive wastes were made. After that, the list of materials candidate for dumping at sea became very limited.

The objective of this report is to respond to the request made by the Contracting Parties at their Nineteenth Consultative Meeting in 1997. It provides guidance for making judgements on whether the radiological concepts of exclusion, or exemption without further consideration, can be applied for materials planned to be dumped or whether a specific assessment is needed.

The IAEA wishes to acknowledge the work of the experts who took part in the development of this report. The IAEA officer responsible for this work was K.-L. Sjoeblom from the Division of Radiation and Waste Safety.

EDITORIAL NOTE

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1. INTRODUCTION

1.1. BACKGROUND

The First Consultative Meeting of Contracting Parties to the Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter (the London Convention 1972) requested, in 1976, the IAEA to clarify and develop the concept of 'de minimis' levels of radioactivity which the IAEA had initially discussed in 1974 in its document "Provisional Definition and Recommendations Concerning Radioactive Wastes and Other Radioactive Matter Referred to in Annexes I and II to the Convention" [1].

In 1985, the Ninth Consultative Meeting, this time in connection with the extension of the temporary moratorium on low level radioactive waste dumping¹ at sea, again requested the IAEA to "define quantitatively the exempt levels of radionuclides for the purposes of the Convention" [2].

In 1993, when adopting the resolution prohibiting sea dumping of all types of radioactive matter, the Consultative Meeting noted its earlier request to the IAEA, as follows: "to develop quantitative limits for 'de minimis' (exempt) levels of radioactivity" for the purposes of the London Convention [3].

On a related subject, in 1988 the IAEA and the OECD/NEA jointly reached consensus on the criteria for determining which sources and practices may in a general sense be exempted² from regulatory control because they present trivial radiation risks and detriments. Accordingly, the IAEA later published the IAEA–OECD/NEA "Principles for the Exemption of Radiation Sources and Practices from Regulatory Control" (Safety Series No. 89) [4], which established the general criteria for exemption, including values of trivial individual and collective dose for the purposes of radiological protection.

The International Commission on Radiological Protection (ICRP) subsequently proposed new recommendations on radiological protection including two concepts to avoid excessive regulatory procedures in cases where exposures or sources need not enter regulatory control [5]. These concepts are **exclusion** of exposures and **exemption** of sources.

In the light of these new recommendations of the ICRP, the IAEA with the FAO, ILO, OECD/NEA, PAHO and WHO revised its basic safety standards (the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources). The new Basic Safety Standards [6] which were adopted in 1996 include the concepts of exclusion and exemption and exemption criteria and numerical values for exempt activity concentrations and exempt activities for about 300 radionuclides. However, the relevant Schedule of the Basic Safety Standards specifies that these figures apply to moderate quantities of material and contains a footnote regarding the need for national regulatory

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¹ For the purposes of the London Convention, 'dumping' means any deliberate disposal at sea of wastes or other matter from vessels, aircraft, platforms, or other man-made structures at sea; and any deliberate disposal at sea of vessels, aircraft, platforms, or other man-made structures at sea. 'Dumping' does not include placement of matter for a purpose other than the mere disposal thereof, provided that such placement is not contrary to the aims of this Convention (Article III) [15].

² Throughout the report, unless otherwise indicated by direct reference to the London Convention, the terms 'exempt', 'exempted' and 'exemption' are to be interpreted in a radiological context having the meanings set out in the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (Basic Safety Standards) [6].

authorities³ to give additional consideration to bulk amounts of materials. The Basic Safety Standards also introduced the concept of **clearance** of materials from regulatory control.

In 1997, the Nineteenth Consultative Meeting was asked by the IAEA to review its request concerning the concept of 'de minimis' with a view to clarifying the task required of the IAEA. The revised task was defined as follows [7]:

"The Meeting agreed that the IAEA should be requested to provide guidance for making judgements on whether materials planned to be dumped could be exempted from radiological control or whether a specific assessment was needed. The IAEA would then further be requested to provide guidance to national authorities responsible for conducting specific assessments."

1.2. OBJECTIVE

The objective of this report is to respond specifically to the contemporary request from the Consultative Meeting of the London Convention, namely:

"To provide guidance for making judgements on whether materials planned to be dumped could be exempted from radiological control or whether a specific assessment was needed."

It should be emphasized that this report does not address the last sentence of the 1997 statement of the Contracting Parties to the London Convention, namely:

"The IAEA would then further be requested to provide guidance to national authorities responsible for conducting specific assessments."

If such a request is made subsequently, the IAEA will consider a further response specifically to this task.

1.3. SCOPE

Whilst it is not necessary to recall all historical details here on the development of the London Convention 1972, it seems appropriate to trace the history of the 'de minimis' issue in the light of developments in radiological protection. It is now appreciated that, in the context of the requirements for the London Convention 1972, the term 'de minimis' subsumes two distinct concepts: that of triviality and that of activities which are not amenable to control (see Box 1).

All materials contain primordial radionuclides and may include artificial radionuclides. It is presumed that the intent of the Contracting Parties to the London Convention is not to consider all material as radioactive in implementing the provisions of the Convention. Thus the task stemming from the Consultative Meetings' request is to address the question of how to discriminate between 'radioactive' and 'non-radioactive' materials for the purposes of the Convention. Materials defined as 'non-radioactive' could then be considered for dumping at sea without any consideration of their radioactive constituents or the radiological consequences associated with their disposal.

³ Throughout the report the (national) regulatory authority means the competent authority in radiological protection matters.

The 'de minimis' concept comprises two quite different considerations. The first is that of **exclusion** which is equivalent to the expression *de minimis non curat lex*, i.e. a situation that is outside the **regulation** because it is unamenable to control by the regulation irrespective of the magnitude of the dose. The second is that of **exemption** which is equivalent to the expression *de minimis non curat praetor*, i.e. it is a situation of no concern to the **regulator**, because of its triviality, even though it is of relevance to the regulation.

Box 1

This report translates, for the purposes of the London Convention, the concepts of exclusion and exemption and clearance, as applied in the contemporary system of radiological protection.

1.4. STRUCTURE

This report is structured in the following manner:

- Section 2 describes developments within the framework of the London Convention regarding radioactive waste disposal and the concept of 'de minimis';
- Section 3 describes the current system of radiological protection which has been developed by the ICRP [5] and incorporated into the Basic Safety Standards [6], with specific emphasis on exclusion, exemption and clearance;
- Section 4 lays out the criteria that can be used as a basis for making judgement on "whether materials considered for dumping at sea could be exempted from radiological control for the purposes of the London Convention or whether a specific assessment was needed". The generic criteria are then considered in relation to the six categories of material that are candidates for dumping at sea;
- Appendix I reproduces Annexes I–III to the London Convention 1972;
- Appendix II deals with the development of the 'de minimis' concept in the context of the London Convention and related early IAEA considerations.

2. THE LONDON CONVENTION AND RADIOACTIVE WASTES

Throughout the period covered by the London Convention, dumping activities have changed considerably. Whereas high level radioactive wastes, or other high level radioactive matter, had been prohibited from the start, other radioactive material could be dumped under special permit, and thus a distinction was drawn between what was, and what was not, high level radioactive material for the purposes of the Convention. A related complication, however, was the fact that virtually any material likely to be a candidate for dumping at sea is radioactive for one reason or another, i.e. because of primordial radionuclide content or because of widespread contamination from other sources of radionuclides, such as global

⁴ The term 'de minimis' has been mistakenly used as an adjective to qualify substantives as dose and radioactivity. It was dervied from ablative latin expressions such as 'de minimis non curat lex' or 'de minimis non curat praetor'. The ablative grammatical case expresses **cause** (or source, agent or instrument) **of** rather than an attribute added to a noun to describe and qualify it.

fallout from nuclear weapon tests. There were therefore essentially three categories of material pertinent to the implementation of the London Convention:

- high level radioactive wastes prohibited from dumping;
- low level radioactive wastes permitted for dumping under special permit; and
- all other 'non-radioactive' wastes and other matter permitted for dumping, virtually all of which are likely to contain some level of radioactivity.

The present situation is different. Since the entry into force in 1994 of the 1993 Amendments, both high level radioactive material and any other type of radioactive material that might have been dumped under a special permit are now prohibited under the London Convention. Nevertheless, there still remains the problem of how to define 'non-radioactive' material in order to distinguish it from radioactive material that can now no longer be dumped.

The initial position of the IAEA, in its 1974 statement [1], was that "it is clearly not the intention of the Convention that every material should be treated as a potential radioactive pollutant". This is still the case. Resolution of the application of the concept 'de minimis' for the purposes of the London Convention is now achievable because of recent developments in the field of radiological protection. These developments recognize that there are radionuclides which give rise to radiation exposures in a manner that is not amenable to any form of practical control. They also recognize that there are sources and practices that can conceptually be controlled but the radiation risks and detriments arising from them can essentially be regarded as trivial. Both of these concepts are relevant to the provision of guidance to the London Convention on the concept of 'de minimis'.

The London Convention [8] under Article I provides that Contracting Parties "take all practicable steps to prevent pollution of the sea by the dumping of waste and other matter that is liable to create hazards to human health, to harm living resources and marine life, to damage amenities, or to interfere with other legitimate uses of the sea". Its first two annexes respectively list materials and substances that are prohibited from dumping at sea (Annex I) and those requiring special care when dumped at sea (Annex II). Annex I specifically allows consideration of materials containing some of the prohibited substances if they occur as trace contaminants or are rapidly rendered harmless. (Annexes I-III to the London Convention are reproduced in Appendix I of this report.)

Of particular importance are the changes resulting from the 1993 Amendments to the original paragraph 6 of Annex I and Section D of Annex II. These amendments completely redefined the categories of materials that could be considered for dumping at sea, by prohibiting all radioactive waste and other radioactive matter, while recognizing that this would not apply to wastes containing what are termed 'de minimis' levels of radioactivity as defined by the IAEA and adopted by the Contracting Parties. The amendments entered into force on 20 February 1994 [3]. The precise wording is important and is quoted verbatim in Box 2.

A new paragraph 11 of Annex I of the London Convention was adopted in 1993 that also bears upon the application of 'de minimis' This amendment (Resolution LC.49(16)) [8] was adopted to introduce a prohibition on dumping at sea of industrial wastes. It entered into force on 1 January 1996. However, the actual form of this amendment to Annex I was not simply the introduction of 'industrial waste' to the list of prohibited substances, but specifies

Before the adoption of the 1993 amendments [3] to the London Convention, which entered into force on 20 February 1994, paragraph 6 of Annex I referred to "High-level radioactive wastes or other high-level radioactive matter, defined on public health, biological or other grounds, by the competent international body in this field, at present the International Atomic Energy Agency, as unsuitable for dumping at sea".

Annex I, paragraph 6, has now been replaced with the words "radioactive waste and other radioactive matter" [3].

Paragraph 9 was also amended in 1993 and provides qualification of paragraph 6 as follows: "Paragraph 6 above does not apply to wastes or other materials (e.g. sewage sludges and dredged material) containing 'de minimis' (exempt) levels of radioactivity as defined by the IAEA and adopted by the Contracting Parties. Unless otherwise prohibited by Annex I, such wastes shall be subject to the provisions of Annexes II and III as appropriate."

Section D of the original Annex II, "Radioactive wastes or other radioactive matter not included in Annex I. In the issue of permits for the dumping of this matter, the Contracting Parties should take full account of the recommendations of the competent international body in this field, at present the International Atomic Energy Agency" has therefore been deleted.

Box 2

six categories of material that are **not** to be considered as 'industrial waste'. These six categories or material therefore remain legitimate candidates for dumping at sea and are specified in Box 3 below. In addition there are other, non-industrial wastes that are not prohibited from dumping, such as human remains.

Finally, for those not familiar with the subject, a brief summary is provided in Appendix II of the events relevant to the 'de minimis' concept, in the context of the London Convention, prior to the Consultative Meeting's request of 1997.

'Industrial waste' means waste materials generated by manufacturing or processing operations and does not apply to:

- (a) dredged material;
- (b) sewage sludge;
- (c) fish waste, or organic materials resulting from industrial fish processing operations;
- (d) vessels and platforms or other man-made structures at sea, provided that material capable of creating floating debris or otherwise contributing to pollution of the marine environment has been removed to the maximum extent;
- (e) uncontaminated inert geological materials the chemical constituents of which are unlikely to be released into the marine environment;
- (f) uncontaminated organic materials of natural origin.

Dumping of wastes and other matter specified in subparagraphs (a)–(f) above shall be subject to all other provisions of Annex I, and to the provisions of Annexes II and III.

This paragraph shall not apply to the radioactive wastes or any other radioactive matter referred to in paragraph 6 of this Annex.

Box 3

3. THE CURRENT SYSTEM OF RADIOLOGICAL PROTECTION

This section outlines the major concepts of the current system of radiological protection devised by ICRP [5] and incorporated into the Basic Safety Standards [6]. The system allows for a range of procedures by which the regulatory authority can exercise control for the purposes of radiological protection, including notification, authorization by registration or licensing, and so on. Simpler means of control may also be used. In the following subsections the main concepts of radiological protection relevant to exemption for the purposes of the London Convention are briefly summarized. They include the concepts of practices and intervention, exclusion, exemption and clearance.

The current system of radiological protection is based entirely on the protection of human health. There are at present no internationally agreed criteria for protection of the environment itself from the effects of ionizing radiation and this aspect is therefore not considered in the document. The IAEA is, however, together with other relevant national and international bodies working on the subject and may be in position to offer guidance and advice in the future.

3.1. PRACTICES AND INTERVENTION

The system of radiological protection has to be applied to two different situations. Human activities that either add radiation exposure to that which people normally incur due to background radiation, or increase the likelihood of their incurring radiation exposure, are termed **practices**. Human activities that seek to reduce the existing radiation exposure, or the likelihood of incurring exposure, which is not part of a controlled practice, are termed **interventions**.

A practice that entails, or that could entail, exposure to radiation should only be adopted if it yields sufficient benefit to the exposed individuals, or to society, to outweigh the radiation detriment it causes or could cause (i.e. the practice must be **justified**). Radiation sources and installations should be provided with the best available protection and safety measures under the prevailing circumstances, so that the magnitudes and likelihood of exposures and the numbers of individuals exposed are as low as reasonably achievable, economic and social factors being taken into account (i.e. protection and safety should be **optimized**). Individual doses due to the combination of all relevant practices should not exceed specified **dose limits**. Radiation exposures due to sources of radiation that are not part of a practice should be reduced by intervention, when this is justified, and the intervention measures should be optimized.

3.2. EXCLUSION

Some radiation exposures can be regarded as essentially unnameable to control through regulation. Examples of such exposures are those from naturally-occurring potassium-40 in the body, cosmic radiation at the surface of the Earth, and exposures from unmodified concentrations of radionuclides in natural materials. In addition, there are low concentrations of artificial radionuclides, such as those arising from radioactive residues from the global fallout caused by nuclear weapons tests, which are so widely dispersed in the environment that exposures to them are not, in practice, amenable to any form of regulatory control. All of these exposures are therefore **excluded** from regulatory requirements because they cannot, in any practical sense, be controlled.

3.3. EXEMPTION

A different concept is that of exemption. The conceptual basis of exemption is that, because of the triviality of the exposure, it is of no concern to the regulator.

When considering exemption of practices and sources within practices from regulatory control on radiological protection grounds, it should be assured that the individual risk and total health detriment connected with them will be so small as not to warrant the application of full regulatory control. Both the public and workers should be considered in risk and detriment assessments. Furthermore, an exempted practice must both be justified as offering net overall benefit to society and be inherently safe. It is therefore important to take account of the probability and severity of possible accidents with, and misuse of, sources. Consideration of the radiological consequences of accidents may preclude exemption of a practice even if it gives rise to very small doses under normal conditions. The principles and criteria for exemption are discussed in more detail below.

Conditions, such as those relating to the physical or chemical form of the source, may be attached to exemptions by the regulatory authority. However, it is important that the conditions do not imply a need for any continuing regulatory surveillance from a radiological perspective.

Importantly, when a practice is being considered for exemption, all facets of that practice, including a consideration of radioactive wastes from the practice, must be taken into account. Accordingly, once exempted, all aspects of the practice, apart from its initial justification, would be exempted from the provisions of the regulations. Consequently, when putting the concept of exemption into effect, the scope of each practice must be carefully defined.

Principles and criteria for exemption

From a radiation protection standpoint, the three general principles for determining whether or not a practice or source can be a candidate for exemption are [4, 6]:

- (a) the radiation risks to individuals caused by the exempted practice or source be sufficiently low as to be of no regulatory concern; and
- (b) the collective radiological impact of the exempted practice or source be sufficiently low as not to warrant regulatory control under the prevailing circumstances; and
- (c) the exempted practices and sources be inherently safe, with no appreciable likelihood of scenarios that could lead to a failure to meet the criteria in (a) and (b).

The individual risk and collective radiological impact principles have been developed into criteria as described below.

The individual dose criterion

Compliance with principle (a) is achieved if individual doses due to the practice or source are shown to be trivial. In the Basic Safety Standards [6] an effective dose of the order of $10~\mu Sv$ in a year is taken for this purpose. It is derived on the basis of consideration of the associated risk of health effects and also from consideration of natural background [4].

The limitation of individual risk is applied by considering the radiation doses in a group of individuals most likely to receive the highest effective doses from the practice, i.e., the critical group. The individual dose criterion should thus be applied to the average individual in the critical group. Depending on the practice, the critical group may consist of workers or members of the public.

The collective dose criterion

The 'trivial' individual risk level is most helpful in putting radiation risks to individuals into perspective. In most practical situations, however, the regulatory need for an exemption arises from the consideration of source related assessments, where the total health detriment is also of interest. It was concluded in both Safety Series No. 89 and the Basic Safety Standards [6] that, for continuing practices, a commitment of about 1 man·Sv per year could be considered as a 'trivial' collective dose for exemption purposes. This figure was derived from the cost of a formal optimization analysis and represents a level at which further efforts to reduce dose do not provide benefits commensurate with the cost of the assessment. An alternative approach is to show, by a specific optimization assessment, that exemption is the optimum solution [6].

Reservation about bulk amounts of materials

The Basic Safety Standards [6] also contain (in Schedule I) values for exempt activity concentrations and for exempt activities of radionuclides based on the principles and numerical dose criteria for exemption. However, the footnote to Table I-I of the Basic Safety Standards states that: "The guidance exemption levels set forth in Table I-I of Schedule I are subject to the following considerations: (a) They have been derived using a conservative model based on (i) criteria of para. (I-3) and (ii) a series of limiting (bounding) use and disposal scenarios. The values of activity concentration and total activity represent the lowest values calculated in any scenario for a moderate quantity of material.(d) Unless the exposure is excluded, exemption for bulk amounts of materials with activity concentrations lower than the guidance exemption levels of Table I-I may nevertheless require further consideration by the Regulatory Authority."

3.4. CLEARANCE

Radioactive materials arising within a practice that is under regulatory control may be released from control under conditions specified by the regulatory authority. If it can be shown that any exposures resulting from the release of such materials will be trivial (specifically, that they meet the criteria for clearance), the materials may be cleared (i.e. released) from regulatory control. Clearance levels in terms of activity and activity concentration are based on the same dose criteria as exemption. Clearance can apply both to materials that are being discarded as waste and to materials intended for further use or recycling. It is implicit to the concept of clearance that materials, once cleared, are subject to no further regulatory restriction or control. Consequently, cleared waste may be treated as normal waste; and materials cleared for re-use or recycling may be sold or transferred to any other party and used for any purpose without being considered to be radioactive.

3.5. APPLICATIONS OF THE EXEMPTION/CLEARANCE CRITERIA

The exemption/clearance criteria have recently been applied in the IAEA for transport regulations [10] and guidance has been given on clearance levels for radionuclides in solid

materials that can be moved out of the originating facility, within a controlled practice, and recycled, re-used or disposed of without restriction [11]. A third recently-developed application concerns clearance of materials resulting from the use of radionuclides in medicine, industry and research [12]. However, neither the exemption levels of Table I-I of the Basic Safety Standards [6] nor any of these three reports [10–12] are directly applicable to sea disposal (this follows from the footnote of Table I-I of [6] and is also explicitly stated in [11]). Section 4 in the present report will describe how exclusion and exemption criteria should be applied to disposal at sea.

4. GUIDANCE ON THE EXEMPTION⁵ OF MATERIALS FROM RADIOLOGICAL CONTROL FOR THE PURPOSES OF THE LONDON CONVENTION

General considerations

This report now considers the specific request for guidance for making judgements on whether materials planned to be dumped could be exempted⁵ from radiological control without further consideration for the purposes of the London Convention, or whether a specific assessment carried out by the relevant national authority would be needed. This guidance applies only to those wastes and other matter not otherwise prohibited from dumping under the London Convention.

On the grounds of being unamenable to control in a practical way, radiation exposures can be excluded from radiological control if they derive from any of the following:

- natural radionuclides in environmental and raw materials, unless there is concern on the part of the national regulatory authority that the radiation field would be substantially modified;
- radionuclides in materials derived from activities involving some modification of the natural radionuclide composition that has been considered by the national regulatory authority and deemed not to warrant radiological control, having taken proper account of the marine environmental exposure pathways relevant to the disposal, re-use and relocation of such material; and
- widely-distributed radionuclides resulting from global fallout from nuclear weapons tests, satellite burnup in the stratosphere, and accidents, that have led to widespread dispersion of radionuclides that are deemed by the national regulatory authority not to warrant intervention.

Materials containing only the above categories of radionuclides would not be subject to radiological control and would, in the terminology of the London Convention 1972, thus be exempted⁵ from consideration of their radioactive properties for the purposes of assessing their suitability for disposal at sea.

Radiation practices and sources within practices may be exempted from regulatory control on the grounds that the associated risks to health are trivial. As specified in the Basic Safety Standards [6], "the general principles for exemption are that:

⁵ The term 'exemption for the purposes of the London Convention' is taken to mean 'de minimis', that is, it includes both of the radiological concepts of exclusion and exemption.

- (a) the radiation risks to individuals caused by the exempted practice or source be sufficiently low as to be of no regulatory concern;
- (b) the collective radiological impact of the exempted practice or source be sufficiently low as not to warrant regulatory control under the prevailing circumstances; and
- (c) the exempted practices and sources be inherently safe, with no appreciable likelihood of scenarios that could lead to a failure to meet the criteria in (a) and (b).

A practice, or a source within a practice, may be exempted without further consideration provided that the following radiological criteria are met in all feasible situations:

- (a) the effective dose expected to be incurred by any member of the public due to the exempted practice or source is of the order of 10 µSv or less in a year; and
- (b) either the collective effective dose committed by one year of performance of the practice is not more than about 1 man·Sv or an assessment for the optimization of protection shows that exemption is the optimum option.

The above criteria for exemption also apply to clearance of materials by regulatory authorities.

Materials containing radionuclides which originate from practices and sources previously exempted or cleared by the national regulatory authority from regulated practices, may also be exempted⁵ for the purposes of the London Convention provided that in granting the exemptions or clearances proper account has been taken of the marine environmental exposure pathways relevant to potential disposal, re-use and relocation of such materials.

'De minimis' (exemption 5) criteria for candidate materials for sea dumping under the London Convention

Materials eligible for consideration for dumping at sea under the London Convention that can be assigned as 'de minimis' (exempt⁵) without further consideration from the perspective of their radionuclide content are therefore those containing only:

- (1) natural radionuclides in environmental and raw materials, unless there is concern on the part of the national regulatory authority that the radiation field would be substantially modified;
- (2) radionuclides in materials derived from activities involving some modification of the natural radionuclide composition that has been considered by the national regulatory authority, and deemed not to warrant radiological control, having taken proper account of the marine environmental and other conditions relevant to the disposal, re-use and relocation of such materials;
- (3) widely-distributed radionuclides resulting from global fallout from nuclear weapons tests, satellite burnup in the stratosphere, and accidents, that have led to widespread dispersion of radionuclides that are deemed by the national regulatory authority not to warrant intervention; and
- (4) radionuclides arising from sources and practices that have been exempted or cleared nationally from radiological control, pursuant to the application of the international criteria for exemption and clearance, where proper account has been taken of the marine

environmental and other conditions relevant to potential disposal, re-use and relocation of such materials.

These 'de minimis' (exemption⁵) criteria for the purposes of the London Convention are now considered in relation to the six categories of candidate materials for dumping at sea (i.e. under Annex I as amended by Resolution LC.49(16) of the London Convention 1972).

- Dredged material: Dredged materials containing only radionuclides defined in the previous paragraph can be exempted⁵ from radiological considerations for the purposes of the London Convention. Dredged material contaminated by radionuclides from other sources and practices will require a specific assessment to determine if it can be treated as non-radioactive for the purposes of the Convention.
- Sewage sludge: Sewage sludges containing only radionuclides defined in the previous paragraph can be exempted⁵ from radiological considerations for the purposes of the London Convention. Sludges contaminated by radionuclides that have entered the sewerage system from other sources and practices will require a specific assessment to determine if such sludges can be treated as non-radioactive for the purposes of the Convention.
- Fish waste or organic materials resulting from industrial fish processing operations: Fish wastes containing only radionuclides defined in the previous paragraph can be exempted from radiological considerations for the purposes of the London Convention. Some fish wastes may be contaminated by radionuclides from other sources and practices. These will require a specific assessment to determine if such wastes can be treated as non-radioactive for the purposes of the Convention.
- Vessels, platforms and other man-made structures at sea: Items containing only radionuclides defined in the previous paragraph can be exempted⁵ from radiological considerations for the purposes of the London Convention. Items contaminated by other sources and practices will require a specific assessment to determine if they can be treated as non-radioactive for the purposes of the Convention. Special attention needs to be paid to residues and contamination from sources and practices associated with manmade structures at sea.
- Uncontaminated materials (i.e. uncontaminated inert geological materials and uncontaminated organic materials of natural origin): Because these materials are defined as uncontaminated and natural, criteria 2, 3 and 4 in the previous paragraph are not applicable. Therefore, if a specific material does not give rise to concern on the part of the national regulatory authority that the radiation field would be substantially modified (i.e. it satisfies the first criterion of the previous paragraph), it can be exempted⁵ from radiological control for the purposes of the London Convention.

The preceding analysis reveals that not all candidate materials for dumping can be exempted⁵, without further consideration, from radiological control for the purposes of the London Convention. Candidate materials that cannot be exempted⁵ without further consideration may then be subjected to a specific assessment to determine if they still qualify as exempt⁵ for the purposes of the London Convention. Such specific assessments would need to be carried out by national regulatory authorities using the radiological criteria for exemption set out in Section 3. It should be noted in this context that assessments are required for proposed dumping activities in relation to other characteristics and properties of candidate

materials than radioactivity pursuant to the provisions of Article IV and Annex III of the Convention. The specific assessment required to consider further exemption⁵ of materials for determining if they can be treated as 'non-radioactive', would include an evaluation of the radiological implications for human health and the environment (see Section 3).

In cases where candidate materials are either contaminated by, or derived from, authorized or unauthorized releases, each situation would have to be reviewed in its specific context. The need for intervention may also be a relevant consideration in certain cases.

Appendix I

ANNEXES I, II AND III OF THE LONDON CONVENTION 1972

Annex I

(as amended before the year 1993)

- 1. Organohalogen compounds.
- 2. Mercury and mercury compounds.
- 3. Cadmium and cadmium compounds.
- 4. Persistent plastics and other persistent synthetic materials, for example, netting and ropes, which may float or may remain in suspension in the sea in such a manner as to interfere materially with fishing, navigation or other legitimate uses of the sea.
- 5.* Crude oil and its wastes, refined petroleum products, petroleum, distillate residues, and any mixtures containing any of these, taken on board for the purpose of dumping.
- 6. High-level radioactive wastes or other high-level radioactive matter, defined on public health, biological or other grounds, by the competent international body in this field, at present the International Atomic Energy Agency, as unsuitable for dumping at sea.
- 7. Materials in whatever form (e.g. solids, liquids, semi-liquids, gases or in a living state) produced for biological and chemical warfare.
- 8. The preceding paragraphs of this Annex do not apply to substances which are rapidly rendered harmless by physical, chemical or biological processes in the sea provided they do not:
 - (i) make edible marine organisms unpalatable, or
 - (ii) endanger human health or that of domestic animals.

The consultative procedure provided for under article XIV should be followed by a Party if there is doubt about the harmlessness of the substance.

- 9. This Annex does not apply to wastes or other materials (e.g. sewage sludges and dredged spoils) containing the matters referred to in paragraphs 1–5 above as trace contaminants. Such wastes shall be subject to the provisions of Annexes II and III as appropriate.
- 10.**Paragraphs 1 and 5 of this Annex do not apply to the disposal of wastes or other matter referred to in these paragraphs by means of incineration at sea. Incineration of such wastes or other matter at sea requires a prior special permit. In the issue of special permits for incineration the Contracting Parties shall apply the Regulations for the Control of Incineration of Wastes and Other Matter at Sea set forth in the Addendum to this Annex (which shall constitute an integral part of this Annex) and take full account of the Technical Guidelines on the Control of Incineration of Wastes and Other Matter at Sea adopted by the Contracting Parties in consultation.

^{*} Paragraph 5 was amended by the Fifth Consultative Meeting of Contracting Parties in 1980. The original text of paragraph 5 reads as follows: "5. Crude oil, fuel oil, heavy diesel oil, and lubricating oils, hydraulic fluids, and any mixtures containing any of these, taken on board for the purpose of dumping." The amendment entered into force on 11 March 1981.

^{**} Paragraph 10 was added to the original text by the Third Consultative Meeting of Contracting Parties in 1978. The amendment entered into force on 11 March 1979.

Annex I

(as amended in 1993)

- 1. Organohalogen compounds.
- 2. Mercury and mercury compounds.
- 3. Cadmium and cadmium compounds.
- 4. Persistent plastics and other persistent synthetic materials, for example, netting and ropes, which may float or may remain in suspension in the sea in such a manner as to interfere materially with fishing, navigation or other legitimate uses of the sea.
- 5. Crude oil and its wastes, refined petroleum products, petroleum, distillate residues, and any mixtures containing any of these, taken on board for the purpose of dumping.
- 6. Radioactive wastes or other radioactive matter.
- 7. Materials in whatever form (e.g. solids, liquids, semi-liquids, gases or in a living state) produced for biological and chemical warfare.
- 8. With the exception of paragraph 6 above, the preceding paragraphs of this Annex do not apply to substances which are rapidly rendered harmless by physical, chemical or biological processes in the sea provided they do not:
 - (i) make edible marine organisms unpalatable, or
 - (ii) endanger human health or that of domestic animals.

The consultative procedure provided for under article XIV should be followed by a Party if there is doubt about the harmlessness of the substance.

9. Except for industrial waste as defined in paragraph 11 below, this Annex does not apply to wastes or other materials (e.g. sewage sludge and dredged material) containing the matters referred to in paragraphs 1–5 above as trace contaminants. Such wastes shall be subject to the provisions of Annexes II and III as appropriate.

Paragraph 6 does not apply to wastes or other materials (e.g. sewage sludge and dredged material) containing de minimis (exempt) levels of radioactivity as defined by the IAEA and adopted by the Contracting Parties. Unless otherwise prohibited by Annex I, such wastes shall be subject to the provisions of Annex II and III as appropriate.

- 10. (a) Incineration at sea of industrial waste, as defined in Paragraph 11 below, and sewage sludge is prohibited.
 - (b) The incineration at sea of any other wastes or other matter requires the issue of a special permit.
 - (c) In the issue of special permits for incineration at sea Contracting Parties shall apply regulations as are developed under this Convention⁶.
 - (d) For the purposes of this Annex:
 - (i) 'Marine incineration facility' means a vessel, platform, or other man-made structure operating for the purpose of incineration at sea.
 - (ii) 'Incineration at sea' means the deliberate combustion of wastes or other matter on marine incineration facilities for the purpose of their thermal destruction. Activities incidental to the normal operation of vessels, platforms or other man-made structures are excluded from the scope of this definition.

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⁶Regulations for the Control of Incineration of Wastes and Other Matter at Sea, as adopted in 1978, have not been reproduced in this report.

11. Industrial waste as from 1 January 1996.

For the purposes of this Annex:

'Industrial waste' means waste materials generated by manufacturing or processing operations and does not apply to:

- (a) dredged material;
- (b) sewage sludge;
- (c) fish waste, or organic materials resulting from industrial fish processing operations;
- (d) vessels and platforms or other man-made structures at sea, provided that material capable of creating floating debris or otherwise contributing to pollution of the marine environment has been removed to the maximum extent;
- (e) uncontaminated inert geological materials the chemical constituents of which are unlikely to be released into the marine environment;
- (f) uncontaminated organic materials of natural origin.

Dumping of wastes and other matter specified in subparagraphs (a) - (f) above shall be subject to all other provisions of Annex I, and to the provisions of Annexes II and III.

This paragraph shall not apply to the radioactive wastes or any other radioactive matter referred to in paragraph 6 of this Annex.

12. Within 25 years from the date on which the amendment to paragraph 6 enters into force and at each 25 year interval thereafter, the Contracting parties shall complete a scientific study relating to all radioactive wastes and other radioactive matter other than high level wastes or matter, taking into account such other factors as the Contracting parties consider appropriate, and shall review the position of such substances on Annex I in accordance with the procedures set forth in Article XV.

Annex II

(as amended before the year 1993)

The following substances and materials requiring special care are listed for the purposes of article VI(1)(a).

A.	Wastes containing significant amounts of the matters listed below:				
	arsenic)			
	lead)			
	copper)	and their compounds		
	zinc)			
	organosilicon compounds				
	cyanides				
	fluorides				
	pesticides	and t	heir by-products not covered in Annex I.		
B. In the issue of permits for the dumping of large quantities of acids a consideration shall be given to the possible presence in such wastes of the listed in paragraph A and to the following additional substances:					
	beryllium chromiun nickel vanadium	n)	and their compounds		
C.		,	ap metal and other bulky wastes liable to sink to the sea bottom which		
○ .	Containe	,	up metal and other banky wastes hable to shik to the sea bottom which		

- h may present a serious obstacle to fishing or navigation.
- Radioactive wastes or other radioactive matter not included in Annex I. In the issue of D. permits for the dumping of this matter, the Contracting Parties should take full account of the recommendations of the competent international body in this field, at present the International Atomic Energy Agency.
- E.* In the issue of special permits for the incineration of substances and materials listed in this Annex, the Contracting Parties shall apply the Regulations for the Control of Incineration of Wastes and Other Matter at Sea set forth in the Addendum to Annex I and take full account of the Technical Guidelines on the Control of Incineration of Wastes and Other Matter at Sea adopted by the Contracting Parties in consultation, to the extent specified in these Regulations and Guidelines.
- F.** Substances which, though of a non-toxic nature, may become harmful due to the quantities in which they are dumped, or which are liable to seriously reduce amenities.

^{*} Additional paragraph adopted as an amendment by the Third Consultative Meeting of Contracting Parties in 1978. The amendment entered into force on 11 March 1979.

^{**} Additional paragraph adopted as an amendment by the Fifth Consultative Meeting of Contracting Parties in 1980. The amendment entered into force on 11 March 1981.

Annex II

(as amended in 1993)

The following substances and materials requiring special care are listed for the purposes of article VI(1)(a).

A.	Wastes containing	significant amounts	of the matters	listed below:

arsenic)	
beryllium)	
chromium)	
copper)	and their compounds
lead)	
nickel)	
vanadium)	
zinc)	
organosilicon	compo	ounds
cyanides		
fluorides		
pesticides and	l their b	by-products not covered in Annex I

- B. Containers, scrap metal and other bulky wastes liable to sink to the sea bottom which may present a serious obstacle to fishing or navigation.
- C. In the issue of special permits for the incineration of substances and materials listed in this annex, the Contracting Parties shall apply the Regulations for the Control of Incineration of Wastes and Other Matter at Sea set forth in the Addendum to Annex I and take full account of the Technical Guidelines on the Control of Incineration of Wastes and Other Matter at Sea adopted by the Contracting Parties in consultation, to the extent specified in these Regulations and Guidelines.
- D. Materials which, though of a non-toxic nature, may become harmful due to the quantities in which they are dumped, or which are liable to seriously reduce amenities.

Annex III

(as amended before the year 1993, no amendments in 1993)

Provisions to be considered in establishing criteria governing the issue of permits for the dumping of matter at sea, taking into account article IV(2), include:

A. Characteristics and composition of the matter

- 1. Total amount and average composition of matter dumped (e.g. per year).
- 2. Form, e.g. solid, sludge, liquid, or gaseous.
- 3. Properties: physical (e.g. solubility and density), chemical and biochemical (e.g. oxygen demand, nutrients) and biological (e.g. presence of viruses, bacteria, yeasts, parasites).
- 4. Toxicity.
- 5. Persistence: physical, chemical and biological.
- 6. Accumulation and biotransformation in biological materials or sediments.
- 7. Susceptibility to physical, chemical and biochemical changes and interaction in the aquatic environment with other dissolved organic and inorganic materials.
- 8. Probability of production of taints or other changes reducing marketability of resources (fish, shellfish, etc.).
- 9.* In issuing a permit for dumping, Contracting Parties should consider whether an adequate scientific basis exists concerning characteristics and composition of the matter to be dumped to assess the impact of the matter on marine life and on human health.

B. Characteristics of dumping site and method of deposit

- 1. Location (e.g. co-ordinates of the dumping area, depth and distance from the coast), location in relation to other areas (e.g. amenity areas, spawning, nursery and fishing areas and exploitable resources).
- 2. Rate of disposal per specific period (e.g. quantity per day, per week, per month).
- 3. Methods of packaging and containment, if any.
- 4. Initial dilution achieved by proposed method of release.
- 5. Dispersal characteristics (e.g. effects of currents, tides and wind on horizontal transport and vertical mixing).
- 6. Water characteristics (e.g. temperature, pH, salinity, stratification, oxygen indices of pollution dissolved oxygen (DO), chemical oxygen demand (COD), biochemical oxygen demand (BOD), nitrogen present in organic and mineral form including ammonia, suspended matter, other nutrients and productivity).
- 7. Bottom characteristics (e.g. topography, geochemical and geological characteristics and biological productivity).
- 8. Existence and effects of other dumpings which have been made in the dumping area (e.g. heavy metal background reading and organic carbon content).

^{*} Additional paragraph adopted as an amendment by the Twelfth Consultative Meeting of Contracting Parties in 1989. The amendment entered into force on 19 May 1990.

9. In issuing a permit for dumping, Contracting Parties should consider whether an adequate scientific basis exists for assessing the consequences of such dumping, as outlined in this Annex, taking into account seasonal variations.

C. General considerations and conditions

- 1. Possible effects on amenities (e.g. presence of floating or stranded material, turbidity, objectionable odour, discolouration and foaming).
- 2. Possible effects on marine life, fish and shellfish culture, fish stocks and fisheries, seaweed harvesting and culture.
- 3. Possible effects on other uses of the sea (e.g. impairment of water quality for industrial use, underwater corrosion of structures, interference with ship operations from floating materials, interference with fishing or navigation through deposit of waste or solid objects on the sea floor and protection of areas of special importance for scientific or conservation purposes).
- 4. The practical availability of alternative land-based methods of treatment, disposal or elimination, or of treatment to render the matter less harmful for dumping at sea.

Appendix II

THE DEVELOPMENT OF 'DE MINIMIS' IN THE CONTEXT OF THE LONDON CONVENTION

In 1974, in the discharge of its responsibilities set out in the London Convention, the IAEA developed a "Provisional Definition and Recommendations Concerning Radioactive Wastes and Other Radioactive Matter Referred to in Annexes I and II to the Convention" [1]. This raised the general question of 'de minimis' (paragraph 2.3.13 of the Annex), described in the following way: "It should be noted that no material is totally devoid of radioactivity. However, it is clearly not the intention of the Convention that every material should be treated as a potential radioactive pollutant and the competent authorities of parties to the Convention will wish to define some 'de minimis' level of specific activity below which a material will not be regarded as 'radioactive' for the purposes of the Convention. No such numbers are suggested at this time and some flexibility of interpretation is therefore left to the appropriate national authorities."

In 1976, the First Consultative Meeting of the Contracting Parties to the London Convention considered the above Provisional Definition and Recommendations [1] and requested the IAEA to develop further the concept of 'de minimis' levels of radioactivity, possibly with a numerical standard [13].

In 1978, the IAEA revised its Definition and Recommendations [14]. This was submitted to the Third Consultative Meeting of the Contracting Parties to the London Convention that same year. That Meeting again called upon the IAEA to develop "a numerical definition of 'de minimis' quantities" [15].

In 1983, the Seventh Consultative Meeting adopted a non-binding resolution LDC.14(7) [16] calling for the suspension of all dumping at sea of radioactive materials pending the presentation of a final report of an expert meeting on radioactive matters.

In 1985, the IAEA submitted to the Ninth Consultative Meeting of Contracting Parties a further revision of the Definition and Recommendations which was published as IAEA Safety Series No. 78 [17]. This contains a section entitled "Interpretation of the term radioactive" as follows: "Virtually all materials contain some radionuclides, but it is clearly not the intention of the Convention that all materials be treated as radioactive when considering their suitability for sea dumping. For example, sewage sludge, dredge spoils, fly ash, agriculture wastes, construction materials, vessels which are not nuclear powered, artificial reef building materials and other such materials that have not been contaminated with radionuclides of anthropogenic origin (except global fallout from nuclear weapons testing) are not considered to be radioactive for the purposes of sea disposal. If there is a question as to whether the material to be dumped should be considered non-radioactive for the purposes of the Convention, the Parties shall take into account the relevant recommendations, standards and guidelines being developed by the IAEA. The IAEA is at present working towards the formulation of advice on this subject. Until advice is provided, national authorities should exercise discretion in deciding whether materials are radioactive waste, bearing in mind the principles and purposes of the Convention."

At the same Consultative Meeting, Contracting Parties adopted resolution LDC.21(9) [18] by which they agreed to continue the suspension of all dumping at sea of radioactive

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⁷ Reference to the development of Safety Series No. 89.

wastes and other radioactive matter, pending the completion of additional studies and assessments of the wider political, legal, economic and social aspects of radioactive waste dumping at sea plus the completion of several outstanding scientific and technical tasks by the IAEA, including the need to define quantitatively exempt levels of radionuclides for the purposes of the Convention.

In 1993, notwithstanding the still outstanding completion of the definition of exempt levels, for the purposes of the Convention and "Recognizing that in the interim [i.e. until 'de minimis' levels have been adopted], the Parties shall be guided by IAEA Safety Series 78 and 89 and decisions and recommendations taken at Consultative Meetings" the Sixteenth Consultative Meeting adopted Resolution LC. 51(16) amending the London Convention with regard to the dumping at sea of radioactive wastes and other radioactive matter [3]. The resolution entered into force on 20 February 1994 for all Contracting Parties, except the Russian Federation which had submitted to the Secretary-General of IMO a declaration of non-acceptance of the amendment of Annexes I and II contained in Resolution LC.51(16).

Resolution LC.51(16) amended Annex I to the London Convention to replace the original text of paragraph 6 with: "Radioactive wastes and other radioactive matter". The Annex, as amended, contains a further clause (paragraph 9) stating: "Paragraph 6 above does not apply to wastes or other materials (e.g. sewage sludge and dredged material) containing de minimis (exempt) levels of radioactivity as defined by the IAEA and adopted by the Contracting Parties. Unless otherwise prohibited by Annex I, such wastes shall be subject to the provisions of Annexes II and III as appropriate".

These amendments effectively meant that any dumping at sea of radioactive wastes and other radioactive matter was prohibited unless it fall within the provisions of paragraph 9 of Annex I.

It is also relevant that the Scientific Group of the London Convention (which does not deal with radiological matters) has defined what were and were not 'trace contaminants' for non-radioactive substances listed in Annex I of the Convention as follows [19]: "substances.... shall not be regarded as trace contaminants under the following three conditions:

- .1 if they are present in otherwise acceptable wastes or other materials to which they have been added for the purposes of being dumped;
- .2 if they occur in such amounts that the dumping of the wastes or other materials could cause undesirable effects, especially the possibility of chronic or acute toxic effects on marine organisms or human health whether or not arising from their bioaccumulation in marine organisms and especially in food species; and
- .3 if they are present in such amounts that it is practical to reduce their concentrations further by technical means."

The relevance of the Scientific Group's definition is, first, that it recognizes that there are substances in materials that could cause undesirable effects, but are unamenable to any form of control. Second, it reflects the fact that small amounts of some hazardous substances only give rise to trivial effects. In other words, some substances in some materials are not amenable to a system of regulation and some are of no concern to the regulator because of the triviality of their effects.

Finally, reference needs to be made to the adoption of the 1996 Protocol to the London Convention 1972 [20]. The Protocol is intended to replace the London Convention when it

comes into force, which may be several years hence. Its Annex I defines permissible candidate materials for dumping at sea is, in large part, similar to the terminology in the industrial waste amendment of Annex I to the 1972 Convention containing reference to "de minimis (exempt) concentrations as defined by the IAEA and adopted by Contracting Parties".

Early consideration of the 'de minimis' issue by the IAEA

The IAEA has responded to requests of the Consultative Meetings of the London Convention since its adoption in 1972. The first detailed consideration by the IAEA of 'de minimis' in the context of sea dumping was published in 1981 (TECDOC-244) [21]. This formulated a qualitative definition of 'de minimis' for materials and discussed individual dose criteria that might be used to derive numerical values of activity concentration for materials falling outside this qualitative definition. The general issue of trivial levels of exposure to ionizing radiation was subsequently considered by the IAEA, and the results were published in 1988, in Safety Series No. 89 [4].

Matters were not taken further on the issue of 'de minimis' for the purposes of the London Convention by the IAEA until 1990; but in 1986, as a result of advice provided by the IAEA, Parties to the Noumea Convention (which covers protection of the South-West Pacific) adopted a definition of 'de minimis' in its Article 2 as follows [22]: "The following wastes or other matter shall be considered to be non-radioactive: sewage sludge, dredge spoil, fly ash, agricultural wastes, construction materials, vessels, artificial reef building materials and other such materials, provided that they have not been contaminated with radio nuclides (sic) of anthropogenic origin (except dispersed global fallout from nuclear weapons testing), nor are potential sources of naturally occurring radio nuclides (sic) for commercial purposes, nor have been enriched in natural or artificial radio nuclides (sic)."

This definition clearly owed a great deal to the earlier (1981) qualitative definition set out in IAEA-TECDOC-244 [21] containing predominantly considerations of sources of exposure which would be unamenable to control.

The Noumea Convention also referred to the need for the dumping proponent to confirm:

"that such dumping would not exceed the individual and collective dose limits of the International Atomic Energy Agency general principles for the exemption of radiation sources and practices from regulatory control."

This clause essentially embodies the concept of triviality of effect.

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DEFINITIONS

The definitions given below define terms as they are used in this report, and may not necessarily conform to definitions adopted elsewhere for international use

authorized discharge

The process of releasing liquid or gaseous radioactive effluents from a regulated practice to the environment within the discharge limits approved by the regulatory authority.

clearance

The removal by a regulatory authority of all aspects of regulatory control previously applied to materials within a practice, on the grounds that the exposures (including potential exposures) resulting from any further use or disposal of the materials are too low to warrant regulation.

exclusion

The deliberate omission by a regulatory authority of a particular category of exposures (including potential exposures) from regulatory control on the grounds that they are not considered amenable to control through regulation. Such exposures are termed excluded exposures. This term is normally applied to those exposures from natural sources that are least amenable to control, such as cosmic radiation at sea level or potassium-40 in the human body.

exemption

The deliberate omission by the regulatory authority of a source or practice from some or all aspects of regulatory control on the grounds that the exposures (including potential exposures) resulting from the source or practice are too low to warrant the application of those aspects.

intervention

Any actions intended to reduce or avert exposure or the likelihood of exposure to sources which are not part of a controlled practice (or an exempt practice) or which are out of control as a consequence of an accident.

practice

Any human activity that introduces additional sources of exposure or exposure pathways or extends exposure to additional people or modifies the network of exposure pathways from existing sources, so as to increase the exposure or likelihood of exposure of people or the number of people exposed.

CONTRIBUTORS TO DRAFTING AND REVIEW

Bewers, J.M. Bedford Institute of Oceanography, Canada

Calmet, D. Institut de protection et de sûreté nucléaire, France

Engler, R. US Army Corps. of Engineers, United States of America

Johansson, G. Swedish Radiation Protection Institute, Sweden

Nauke, M. International Maritime Organization
Pentreath, R.J. Environment Agency, United Kingdom

Salo, A. Finland

Sjoeblom, K.-L. International Atomic Energy Agency Thierfeldt, S. Brenk Systemplanung, Germany

Rudjord, A.L. Norwegian Radiation Protection Authority, Norway

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