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THE SCOPE OF RADIOLOGICAL PROTECTION REGULATIONS

Editor
J. VALENTIN

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ABSTRACT

This report recommends criteria of a universal and generic nature for defining the radiation exposure situations that *can* and *need* be subject to radiological protection regulations and those that *cannot* or *need not*. It suggests that the relevant legislation should specifically define those situations that should be covered by the legislation, because they *can* be controlled, and those that may be *excluded* from legislation because they *cannot* be controlled by any reasonable means. It also recommends that the legislation should empower regulators to define the extent of application of regulatory requirements to the situations covered by the legislation. Regulators should identify the situations than *need* be controlled with the full system of regulatory requirements and those that are *exempted* from compliance with particular regulatory requirements on the grounds that they *need not* be controlled because those requirements are unwarranted.

Legislative systems for purposes of radiological protection may *exclude* situations of radiation exposure to cosmic radiation at ground level, to natural radioactive constituents of the human body (such as the radionuclide potassium-40), to substances containing an activity concentration of less than around 1 Bq per kilogram for α emitting artificial radionuclides and around 10 Bq per kilogram for β and γ emitting artificial radionuclides, to ambient radon below concentrations of 40 Bq m^{-3} and to any source that is unamenable to control by any reasonable means.

Exemption criteria were originally introduced for exempting *a priori* practices involving limited amounts of 'artificial' radioactive materials. The concept was then extended to the exemption *a posteriori* of radioactive materials already regulated but for which regulation was no longer warranted. These materials, therefore, could be *cleared* from the regulatory requirements. Clearance criteria were developed for bulk amounts of materials. A fundamental exemption principle was to keep individual risk at low levels, which became an individual dose criterion of 10 μSv in a year. The report recommends, however, that the criteria for exemption should be broader and focus on unwarranted control, being situation specific and with multiple attributes. While they should respect the low individual risk criteria, they should not be determined by individual doses alone but include societal factors involved in determining whether or not it is warranted to control certain exposure situations. Different situations may lead to different dose criteria for exemption. For situations involving naturally occurring radioactive materials and for interventional situations the use of an individual dose criterion of up to 1mSv in a year may be appropriate.

Exposure situations to naturally-occurring radioactive material may be considered either for a generic regulatory exemption or for exclusion from legislative instruments, providing that the activity concentrations of the radionuclides in the primordial uranium and thorium series are lower than 1000 Bq kg^{-1} and of potassium-40 lower than 10000 Bq kg^{-1}. However, building materials may warrant additional restrictions of the sum of the activity concentrations of uranium-238, thorium-232 and potassium-40. Moreover, wherever ambient radon would otherwise be regulated, exemption can be granted provided that the time-averaged radon concentration does not exceed a minimum value of 200 Bq m^{-3} in dwellings or 500 Bq m^{-3} in workplaces

Exposure situations to foodstuff and drinking-water containing radionuclides in activity concentrations smaller than those specified by the Codex Alimentarious Commission and the World Health Organization respectively are candidates for automatic exemption. Situations involving exposure to non-edible radioactive materials may be considered candidates for automatic exemption from regulatory requirements if the activity or the activity concentration does not exceed the values specified in the agreements reached under the aegis of international organizations, as referenced in this report.

PREFACE

At its meeting in Paris, France, in March 2005 the International Commission on Radiological Protection (ICRP), hereinafter referred to as *'the Commission'*, established a Task Group to develop recommendations for defining the scope of radiological protection regulations by exploring particularly the already established regulatory concepts of exclusion and exemption.

The final membership of the Task Group was as follows:

- Roger Clarke,
- John Cooper,
- Abel J. González (coordinador),
- Ches Mason and
- Anthony D. Wrixon.

For the preparation of the report, the Task Group met at the Laboratories of the UK Health Protection Agency (HPA) in Chilton, U.K. The Commission wishes to express its appreciation for the support received by the Task Group from HPA.

The report was first reviewed by the Commission at its meeting in Bern, on September 17th, 2005.

The Task Group benefited from further discussions with consultants convened by the International Atomic Energy Agency (IAEA) to develop working material on scope within the framework of the process being undertaken by international intergovernmental organizations for reviewing of the *International Basic Safety Standards for the Protection against Ionizing Radiation and the Safety of Radiation Sources*, or *BSS*. The consultancy, which was chaired by the coordinator of the Task Group and took place in the IAEA headquarters on January 30th – February 2nd 2006, included the participation of Georges H. Coppée, representing the International Labour Organization, John R. Cook (transport aspects), Alan Melbourne, Denis Wymer and Trevor Boal as well as the IAEA officers who are Task Group members. The Commission wishes to express its appreciation to the consultants and the IAEA for their contribution to the Task Group work.

The final edition was prepared by the Coordinator and approved by the Commission through postal ballot for publication in the ICRP website for comments.

CONTENT

EXECUTIVE SUMMARY

(a) The Commission's radiological protection recommendations are not limited in extent and cover all types of radiation exposure situations regardless of the size and origin of the exposure. However, radiological protection regulations for controlling exposures and their sources, which are usually derived from the Commission's recommendations, need a precise definition of their scope for both legal and practical reasons. In this report the Commission provides recommendations to legislators and regulators for determining the scope of radiological protection regulations.

(b) The report recommends criteria of a universal and generic nature for defining the radiation exposure situations that *can* and *need* be subject to radiological protection regulations and those that *cannot* or *need not*. It suggests that the relevant legislation should specifically define those situations that should be covered by the legislation, because they *can* be controlled, and those that may be *excluded* from legislation because they *cannot* be controlled by any reasonable means. It also recommends that the legislation should empower regulators to define the extent of application of regulatory requirements to the situations covered by the legislation. Regulators should identify the situations than *need* be controlled with the full system of regulatory requirements and those that are *exempted* from compliance with particular regulatory requirements on the grounds that they *need not* be controlled because those requirements are unwarranted.

(c) Thus, the distinct concepts of *exclusion* and *exemption* are recommended to define the extent of radiological protection regulations. *Exclusion* refers to the process of identifying radiation exposure situations that need not be covered by radiological protection legislation because they are considered to be unamenable to control by any reasonable means. *Exemption* refers to the process of identifying situations that are within the scope of legislation but can be released from specified requirements because their application is not warranted. While *exclusion* is a concept to be used by those entrusted to establish radiological protection legislation, *exemption* is a concept to be used by the competent authorities entrusted to regulate the radiation exposure situations covered by the applicable legislation. The concepts are modern parallels to the ancient legal principles of *de minimis non curat lex* and *de minimis non curat prætor*, respectively, which from Roman times have governed the legal problem of regulating trifles – that is, of regulating situations that are considered inconsequential or infeasible to control on one hand, or unimportant or irrelevant on the other hand.

(d) The system of radiological protection recommended by the Commission influences the formulation of the regulations and the definition of their scope. The system's crucial principles are the *justification* of actions entailing changes of radiation exposure, the *optimization* of the measures undertaken for radiological protection and the *limitation* of individual exposures. It is apparent that these principles should provide the basis for deciding the scope of the radiological protection regulations. Another factor influencing the definition of scope is the variety of possible circumstances involving radiation exposure. The system of radiological protection deals coherently and consistently with three different situations, namely prospective situations or practices, extant situations and emergency situations, but its quantitative recommendations are

diverse reflecting the uniqueness of each situation. The distinctiveness of these radiation exposure situations logically influences the concept of scope and its quantitative definition. However, the classification of exposures in occupational, patients and public should not influence the definition of the scope of the regulatory system. The definition of scope occurs *a priori* of the classification of exposure and whether a source is going to be used to expose workers, patients or members of the public has no bearing on the decision of whether or not such source should be regulated

(e) Dichotomous approaches to control radiation exposure have been not uncommon in radiological protection. They seem to be an unavoidable result of the various degrees of controllability among the possible exposure situations. But they also reflect different public expectations under different circumstance of exposure. Such dichotomy, which obviously influences decisions on the scope of the regulations, is particularly apparent when pondering 'natural' versus 'artificial' exposure situations. While the detrimental effects of radiation exposure relate to the amount of the exposure rather than to the origins of the exposure, the degree of controllability varies considerably with the particular situation. Experience shows that the desire for regulatory control appears to be generally stronger when the source of the exposure is perceived to be a technological by-product, and therefore 'artificial', than when it is considered to be 'natural'. The Commission recommends that radiological protection regulations should control coherently and consistently any exposure regardless its origin, but – as the magnitude of the exposure is not the only factor that should determine the degree of control – they should also take account of the amenability of control as well as relevant social and economic factors, such as the concerns of those affected by the different exposure situations.

(f) Radiation exposure situations that should be excluded from radiological protection legislation are those that cannot reasonably be considered as amenable to control. For naturally-occurring sources of exposure, these include exposures from potassium-40 incorporated into the body, potassium being a basic constituent of tissue, from cosmic rays at ground level, from radon in ambient air with activity concentration below 40 Bq m^{-3}, and from unmodified concentrations of radionuclides in most raw materials (see paragraph (i)). For radionuclides of artificial origin, it is recommended that substances containing an activity concentration of less than around 1 Bq per kilogram for α emitting radionuclides and around 10 Bq per kilogram for β and γ emitting radionuclides may be excluded from legal instruments. Definition of other exposures that cannot reasonably be considered as amenable to control requires a judgment on the part of the legislator, which may be influenced by cultural perceptions. There has been a lack of consensus as to whether some exposures to naturally occurring radioactive materials should be excluded from the scope of regulations, or treated with some kind of generic exemption. National legislative practices should be allowed to determine the mechanism by which the scope of regulatory requirements is defined. However, the Commission suggests that, depending on national practice, exclusion and generic exemption can be considered for exposure situations to ambient radon.

(g) The legislative framework should in addition provide for exemption of radiation exposure situations that are considered unwarranted for regulation. However, exemption should not be granted to exposure situations that are deemed to be unjustifiable, such as the deliberate incorporation of radioactive substances in food, beverages, cosmetics or any other commodity or product intended for ingestion, inhalation, percutaneous intake by, or application to, a human being, and the frivolous use of radioactive substances in products such as toys and personal jewellery or adornments. Moreover, potential exposure situations cannot be exempted if the uncertain exposure, if it occurs, could be significant.

(h) The basis for exemption is that control be not considered to be warranted. Strictly, the term '*exemption*' has a legal context and can only apply to persons, either physical or legal persons, as it relates to the waiving by the regulatory authority of requirements that would otherwise apply to a person as a legal obligation. The general principles governing the process of exemption were agreed internationally several years ago. The consensus can be summarized as follows: (i) the individual risk attributable to the radiation exposure caused by an exempted practice or source should be low (this was judged to correspond to a trivial average individual dose in the critical group of around 10 μSv in a year within a distribution that may include values much higher than the average); (ii) radiological protection should be optimized taking into account the commitment of resources required to implement regulatory control; and, (iii) any exempted practice should be justifiable and its sources should be inherently safe. The Commission recognizes these previously accepted principles but emphasizes that exemption should no longer be linked primarily to triviality of individual dose. Some situations could be considered as not warranting control, and subject to exemption, even if they may lead to individual average doses above 10 μSv in a year. For exemption of situations involving naturally occurring radioactive material and of interventional situations (see paragraph (n) below), the dose criterion could justifiably be established in the order of 1 mSv in a year.

(i) Exposure situations to cosmic radiation above ground level are obvious candidates for exemption. Moreover, taking into account the ubiquity of naturally occurring radioactive material and the international agreements reached on whether to control these materials, legislators may provide either for empowering regulators to establish a generic regulatory exemption for such materials or, depending on national practice, for their straightforward exclusion from legislative instruments. The conditions for such generic exemption would be that the activity concentrations of the radionuclides in the primordial uranium and thorium series should be lower than around 1000 Bq kg^{-1} and of potassium-40 lower than around 10000 Bq kg^{-1}. However, building materials may warrant a more restrictive consideration of the sum of the activity concentrations of uranium-238, thorium-232 and potassium-40. Exposure situations to ambient radon are not generally subject to regulatory control, and the concept of exemption in this case is more elusive. Nevertheless, exemption may be considered for ambient radon (i) in dwellings provided that the time-averaged radon concentration does not exceed a minimum value of 200 Bq m^{-3} and (ii) in workplaces provided that the time-averaged radon concentration does not exceed a minimum value of 500 Bq m^{-3}.

Kommentar [AM1]: The provision for exemption on a case by case basis as described in para 94 should also be summarised here.

(j) Food containing radionuclides in activity concentrations smaller than those specified by the Codex Alimentarious Commission [Codex Alimentarius, 2004] and drinking-water containing radionuclides in activity concentrations smaller than those specified in the drinking-water quality guidelines of the World Health Organization [WHO, 2004] are candidates for exemption.

(k) Situations involving exposure to non-edible radioactive materials can be exempted on the basis of the activity or activity concentration in the materials. The Commission has taken note of the international agreements reached for this type of situations. These agreements imply that such situations could be considered for automatic exemption from regulatory requirements, including those for notification, registration or licensing and subsequent inspection, under the following conditions: the activity, at any one time, of material in a practice, should not exceed the values specified in the BSS (see [IAEA, 1996], Schedule 1, Table I-1), or the activity concentration in materials in a practice in amounts of 1 ton or less should not exceed the values specified in the BSS (see [IAEA, 1996] Schedule 1, Table I-1); while in transport, the activity of material should not exceed the values specified in the Transport Regulations [IAEA, 2004 (c)], or the activity concentration of materials in transport irrespective of their amount should not exceed the values specified in the Transport Regulations [IAEA, 2004 (c)], or the activity concentration in materials, irrespective of their amount, in a practice or for unrestricted release from a practice, should not exceed the values specified in the guidance on *Application of the Concepts of Exclusion, Exemption and Clearance* [IAEA, 2004 (b)] and established in the Resolution GC(44)/RES/15 of the IAEA General Conference [IAEA, 2004 (a)].

(l) The following sources of exposure may be considered as candidates for a generic exemption of universal application: (i) apparatuses and devices emitting adventitious radiation, if they are of a type approved by the regulatory authority and they do not cause in normal operating conditions an ambient dose equivalent rate or a directional dose equivalent rate, as appropriate, exceeding around 1 $\mu Sv\ h^{-1}$, at a distance of 0.1 m from any accessible surface of the apparatus, or the maximum energy of the emitted radiation is no greater than around 5 keV; and, (ii) apparatuses and devices containing radioactive substances, if they are of a type approved by the regulatory authority and are not otherwise exempted, provided that the radioactive substances are in the form of sealed sources that effectively prevent any contact with radioactive substances or their leakage and, in normal operating conditions, they do not cause an ambient dose equivalent rate or a directional dose equivalent rate, as appropriate, exceeding around 1 $\mu Sv\ h^{-1}$ at a distance of 0.1 m from any accessible surface of the apparatus.

(m) The use of the term *exemption* has been mainly limited to the process that determines *a priori* the nature and extent of application of regulatory requirements to the introduction of a practice involving radiation exposure or of radiation sources within the practice. But there is also the possibility (and necessity) of using exemption *a posteriori*, i.e., of relinquishing control on materials that originally were not exempted but then may be freed from some regulatory requirements because their control is no longer warranted. The term *clearance* was introduced to describe this process of exempting from within, i.e.

surrendering regulatory control. It is recommended that the concept be used with care: the word *clearance* has an ambiguous meaning and is not easily and reliably translatable into other languages, which can sometimes cause confusion and misunderstanding. An extraordinary situation of removal of radioactive materials within authorized practices from any further control is the case of release from hospitals of nuclear medicine patients who have incorporated them while in radiotherapeutical treatments or radiodiagnosis. Exposure to any discharge of radioactive material into the environment, if it is duly authorized by the competent authority and complies with the requirements of the Commission's system of radiological protection, need not be subject to further control; but the discharge is a process of authorized release not of clearance.

(n) The report uses the term exemption also for exemption from requirements for intervention. This is a new use of the term, as up to now it has been used primarily for exemption from requirements for practices (except its use in the context of intervention exemption levels for commodities in international trade). The concept of exemption within the context of interventions presents a particular challenge. Interventions may or may not be subject to a formal system of regulations. In the case of practices, it is expected that there will be an *increase* of exposure due to the introduction of the practice and, when the expected increase is sufficiently low, the source causing the *increase* may be exempted from regulations because it may be unwarranted to regulate such low doses. Conversely, in the case of interventions, an increase of exposure is not expected as result of the intervention but, on the contrary, a *reduction* in exposure should be anticipated. Thus, in an interventional situation, such as an extant situation of very high background or a post-accident situation, the crucial radiological protection decisions are (i) whether it is justifiable to intervene with protective actions, and (ii) if so, how much the doses have to be reduced. An annual dose of around 1mSv could be construed to be the lower bound for selection of action levels for interventions and this level could operate as a *de facto* exemption level. However, in some situations, particularly in emergency situations, protective actions to reduce a dominant component of the annual dose below 1mSv in a year may still be possible below the exemption level of and might be justifiable. On the other hand, the 1mSv in a year value should not be taken as an automatic trigger for consideration of action levels, as this level can prove impractical for intervening in some specific situations such as radon in dwellings and workplaces. In summary, exemption levels for intervention must be used with caution and regulatory bodies wishing to establish action levels at these low dose levels should carefully considered the whether intervention is warranted by balancing the consequences of the intervention against the benefit in terms of improved radiation protection.

(o) While the framework set out above provides a basis for establishing the scope of regulatory control, some regulatory authorities may wish still to keep in force some requirements for the notification, and in some cases even for the registration, of specific sources complying with the criteria for exemption described in this report. Such decisions are a matter for national legal practice. Also supplementary to the general framework, separate recommendations may be needed for sources causing rare circumstances of exposure, such as from radioactive releases and residues in the aftermath of accidents or acts of war or terrorism involving radiation exposure.

(p) Whether the principles of *de minimis non curat lex* or ‘exclusion’, or *de minimis non curat prætor* or ‘exemption’ are used to give legal effect to the various components of the recommendations in this report depends on national legal and regulatory practice. The Commission is sensitive to the fact that throughout the world there are different legislative cultures that are the origin of diverse regulatory approaches. The concept of defining what is 'controllable' up front through a system of defined scope is certainly consistent with international standards, but it need not be the only approach, and indeed it may well be unacceptable to some countries. Thus, while the Commission recognises the mechanisms of exclusion and exemption for determining regulatory scope, it is careful about being categorical on their use by national authorities. The Commission wishes to stress that the controllability of radiation exposure is an issue that can be addressed on a situation-by-situation basis and through the principle of optimization of protection, but also points out that the quantitative recommendations in this report can be used to solve in practice the problem of defining the scope of radiological protection regulations.

THE SCOPE OF RADIOLOGICAL PROTECTION REGULATIONS

1. INTRODUCTION

1.1. Purpose

(1) The Commission provides radiological protection recommendations that apply to any situation involving *radiation*[1] *exposure*[2], regardless the origin of the exposure, the characteristics of its *source*[3] and the magnitude of the resulting *doses*[4]. Following the Commission's recommendations and in order to exercise an effective *control*[5] of exposures and their sources, competent authorities establish legally binding systems of radiological protection *regulations*[6]. In contrast to recommendations, which have a general application, these systems need to have a defined and finite *scope*[7]. The definition of the regulatory scope requires ascertaining which radiation exposure situations *can* be brought under legal obligations and which of those *need* be subjected to subsequent regulatory control.

(2) The determination of the scope of radiological protection regulations has been a major challenge. Both at the national and international level, approaches to define the extent of regulatory systems have not been completely consistent. Simple definitions of regulatory scope are incorporated in the *International Basic Safety Standards for the Protection against Ionizing Radiation and the Safety of Radiation Sources*, or *BSS* [IAEA, 1996], which are based on the latest Commission's recommendations in ICRP

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[1] The term *radiation* is used to mean *ionizing radiation*.

[2] The term *exposure* is used in a generic sense to mean the process of being exposed to radiation or radionuclides, the significance of the exposure being determined by the resulting radiation dose (See ICRP Publication 60, paragraph 40 [ICRP 1991]).

[3] The term *radiation source* (or *source* in short) is used to mean individual physical sources of radiation, such as radiation generators and radionuclides (e.g. as sealed radioactive materials), and also, more generally, to indicate the cause of exposure to radiation or to radionuclides in radioactive substances. For instance: if radioactive materials are released from an installation to the environment, the installation as a whole may be regarded as a source; if they are already dispersed in the environment, the portion of them to which people are exposed may be considered a source.

[4] The Commission uses the term *'dose'* as a generic term that can apply to any of the relevant dosimetric quantities [ICRP 1991,paragraph S4]. The principal dosimetric quantities in radiological protection are the mean absorbed dose in a tissue or organ, D_T, the energy absorbed per unit mass; the equivalent dose in a tissue or organ, H_T, formed by weighting the absorbed dose by the radiation weighting factor, w_R; and the effective dose, E, formed by weighting the equivalent dose by the tissue weighting factor, w_T, and summing over the tissues. . . .The unit of absorbed dose is the gray (Gy), and the unit of both equivalent and effective dose is the sievert (Sv) [ICRP 1991, paragraph S2]. In this report, the Commission will use as relevant quantity the effective dose. This is the sum of the time integral, over a period of time, of the effective dose rate due to external irradiation and the committed effective dose due to internal contamination caused by all intakes of radinuclides during that time. The effective dose, unless otherwise indicated, will be simply termed 'dose' in this report and the unit used for this quantity will be one thousandth of a sievert (Sv), or millisievert (mSv).

[5] The term *control* is used to mean *restrictions* imposed by law through regulatory authorities on a *practice* involving *radiation exposure*, or on a particular *radiation source*, or on the *radiation exposure* itself. The term can be directly translated into many languages because of its Latin origins. The Commission notes and warns, however, that both in English and notably in other languages, the term is sometimes confused with the distinct concepts of verifying, authenticating, substantiating, corroborating, confirming, etc, perhaps because the term derives from the Latin word *contrarotulare*, from *contrarotulus* 'copy of a roll', from *contra-* 'against' + *rotulus* 'a roll'.

[6] The term *regulation* (and its derived qualifier, *regulatory*) is used with the wider connotation of a system of rules recognized by a country or community for regulating the protection against exposure to ionizing radiation. The term encompasses both the *legislation*, or assembly of laws providing the legal basis for the system, and its derived *regulations proper*, i.e., the byelaws, the governing principles, procedures and code of practice, the standards and norms, the directives (or authoritative instructions, directions or order), guidelines (or general piece of advice) as well as any other authoritative decision or pronouncement established by a competent regulatory authority in matters of radiological protection.

[7] The term *scope* is used to mean the extent to which regulatory systems should deal with exposures and sources, i.e. the extent to which it is relevant the opportunity or possibility for exercising regulatory control.

Publication 60 [ICRP, 1991], and also in other multinational instruments. However, a comprehensive international agreement on the issue of regulatory scope has been elusive.

(3) In this report the Commission provides recommendations for determining the scope of radiological protection regulations, which could be used by for *legislators*[8] and *regulators*[9]. Its main purpose is therefore to recommend universal and generic criteria for deciding: (i) which radiation exposure situations should be covered by the relevant legislation and, conversely, which may be considered by the legislator for *exclusion* from the legislation; and, (ii) which situations, among those covered by the legislation, should be fully regulated by the regulatory systems and, conversely, which may be considered by the regulator for *exemption* from complying with specific regulatory requirements. The quantitative recommendations in the report are intended only as *indicators*[10] for defining the regulatory scope, because the definitive boundaries establishing the situations that can or need be regulated would depend on national approaches.

1.2. Regulations

(4) The risk of harm is ever present, with some hazards occurring naturally and others resulting from human activity. When a human activity carries a risk of harm, as is the case with activities involving radiation exposure, the person responsible for the activity is ethically responsible for the protection of affected people and for the overall safety of the activity. Modern societies give legal expression to such responsibility through regulation. The regulatory system sets out what the legislator requires and how regulators apply the legal requirements. It provides society with the assurance that responsible persons will be held to account to fulfil their obligations.

(5) There is an expectation, deriving from principles of good governance, that the application of regulatory systems for protection and safety will strike an appropriate balance between what is necessary to avoid harm, on the one hand, and the optimal use of societal resources on the other. It would clearly require a disproportionate expenditure of societal resources to regulate all human activity, without taking account of the scale of associated risk or the efficacy of regulatory controls. Furthermore, the stringency of regulatory requirements placed on an activity should be commensurate with the scale of risk arising from the activity. This policy of optimal regulatory control directs the required protection and safety measures to areas where they should be effective and avoids wasteful expenditure of resources and unnecessary restrictions on civil freedoms – because any regulatory system ought to guarantee the preservation of individual and societal freedoms recognized by the society. Consequently, there is a need to define the extent of regulatory requirements by ascertaining what *can* be regulated (or, conversely, what is unamenable to regulatory control and *cannot* be regulated) and what *need* be regulated (or, conversely, what does not warrant regulatory control and *need not* be

[8] The term *legislator* is used to mean the members of the national legislative bodies entrusted to draft laws for purposes of radiological protection and, in an analogous sense in regard to international bodies, those members of the governing bodies of international organizations that establish international radiological protection standards.
[9] The term *regulator* is used to mean those entrusted by the legislation to control or supervise radiation sources and the exposure they entail by means of rules and regulations. In legal systems derived from Roman civil law, it is used as a synonym of the term procurator in the sense that it is a governmental agent representing the interest of those exposed to radiation.
[10] The term *indicator* is used to mean an amount of a quantity that suggests regulatory control is feasible and warranted.

regulated). The regulations are then applied to situations that fall within the defined range, but not to others.

(6) While the concept of optimal regulatory control can be stated quite simply, as above, it has proved difficult to reach an international consensus on defining in detail the boundary of application of regulatory requirements for radiological protection. The lack of a universal agreement on the scope of radiological protection regulations may breed ambiguity and inconsistency in regulatory approaches and consequently inhibit a much-needed international coherence in the control of radiation sources and their exposures. Considerable resources could be spent unnecessarily if the regulatory scope is not properly defined and radiation exposures and sources that *cannot* or *need not* be regulated are subjected to formal controls. In addition, if controls are not coherent and consistent worldwide, irregularities may arise that affect the efficiency of radiological protection and that impose unjustified barriers to trade and commerce in the global economy. In this regard, the Commission's intention with this report is to be helpful to international intergovernmental organizations, which have been instrumental in trying to stimulate global harmony in the characterization of the scope of radiological protection regulations.

1.3. Excluding and exempting: *'de minimis'*

(7) The two distinct concepts universally used for defining the scope of radiological protection regulations are the *exclusion* from radiological protection legislation and the *exemption* from radiological protection regulatory requirements. Any regulatory system should define the radiation exposure situations that *can* be regulated and should be covered by the legislation and, conversely, those that can be *excluded* from the law and its scheme of regulations. In addition, the system may also define non-excluded situations that *need* be fully regulated and, conversely, those that could be *exempted* from some regulatory requirements because the application of such requirements is unwarranted. Thus, while *exclusion* is related to defining the legislative scope of radiological protection, e*xemption* is related to a release from compliance with specific regulatory obligations.

(8) The concepts of *exclusion* and *exemption* are modern parallels to the ancient legal principles of *de minimis non curat lex* and *de minimis non curat prætor,* respectively, which originated in Roman law two millennia ago and since then have governed the legal problem of regulating *trifles*. It should be noted that, within the context of this report, the concept of trifle is used to mean inconsequential or infeasible, unimportant or irrelevant from a regulatory point of view and not necessarily as a synonym of triviality (e.g., of a small amount of radiation dose). The *de-minimis-non-curat-lex* principle addresses the situations that the *law* should (or should not) take account of, or cover. The *de-minimis-non-curat-prætor* principle addresses the situations, among those covered by the law, which can be freed by the *procurator* or regulator from some or all-regulatory controls. In radiological protection regulatory terms the concept of *exclusion* derives from *de minimis non curat lex* and simply determines what situations should - and what may not - be subject to regulatory legislation and subsequent control. The concept of e*xemption* derives from *de minimis non curat prætor* and determines what situations should not -

and what may - be freed *a priori* from some or all regulatory control established by the law.

(9) The Commission notes that '*de minimis*' expressions have not always been properly used in radiological protection. In particular, the grammatically erroneous[11] phrase '*de minimis dose*' has been mistakenly interpreted as a dose below which any risk can be taken to be zero. This has created unnecessary problems, as it has been perceived by some critics as an attempt by vested interests to trivialize the risk of harm from exposure to radiation. The Commission has never recommended the use of the concept of '*de minimis dose*' and strongly suggests to those who may still be employing it that they abandon its usage.

1.4. Content: Issues for Defining Scope

(10) The report addresses the major issues surrounding the definition of the scope of radiological protection regulations, which mainly relate to the controllability of radiation exposure situations. They are as follows:

- Control may be influenced by the radiological protection approaches implicit in the Commission's recommendations. Control may be different in the various types of situations addressed in the recommendations. For instance, while the control of planned situations is, in principle, always possible, the control of existing situations may be subject to practical limitations.
- Control can appear to be *dichotomous*[12] in some circumstances. While the detrimental effects of radiation exposure relate to the amount of the exposure rather than to the exposure situations, the degree of controllability may vary considerably according to the circumstances and this produces a sense of dichotomy. For instance, the societal desire for regulatory control is generally stronger when the source of the exposure is perceived to be a technological by-product, and therefore 'artificial', than when it is considered to be a 'natural' outcome. As discussed later, this appearance of inconsistency is resolved when the question of controllability is properly addressed.
- Some situations may be *unamenable*[13] to control through any reasonable means. For instance, certain exposures are simply unavoidable and in some situations control is unfeasible, at least without inordinate effort.
- Control may be *unwarranted*[14]. For instance, some sources may be amenable to control but they deliver such low amounts of exposure that control is neither justifiable nor necessary.

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[11] In the expression '*de minimis non curat lex* (or *prætor*)', '*de minimis*' is an ablative phrase, serving as the object of the verb '*curare*' – 'to take care of'. The expression has the meaning: 'of the smallest (of things) the law (or the procurator or regulator) does not take care', which is usually rendered in English as: 'the law does not concern itself with trifles'. Unfortunately, some unknown author used '*de minimis*' incorrectly as an adjectival phrase in the contrived expression '*de minimis dose*', which proved to be more than just a syntactical blunder as it came to be interpreted as a dose below which there is no attendant risk. Such a misuse and misinterpretation flies in the face of the presumption that there is no threshold of risk, and it has thereby caused much confusion.

[12] The adjective *dichotomous* is used in the report to express the division and contrast existing between the control of different exposure situations, such as natural and artificial exposure situations, which are perceived to be based on entirely different criteria.

[13] The adjective *unamenable* (and its derivatives unamenability, etc) is widely used in the report with the meaning of incapable of being acted on. Thus, a radiation exposure situation is said to be unamenable to control if the competent authorities cannot in practice impose restrictions on the situation.

[14] The adjective *unwarranted* is used in the report to indicate that regulatory requirements for radiological protection purposes are unjustified or unnecessary.

This report first discusses all these issues and explores how regulators have been dealing with them. It then provides recommendations aimed at helping legislators and regulators to define the regulatory scope of radiological protection.

2. COMMISSION'S RECOMMENDATIONS VIS-À-VIS REGULATORY SCOPE

(11) While the Commission's role is to provide radiological protection recommendations, national or international competent authorities have the mandate to establish the radiological protection regulations. Recommendations and regulations are distinct notions. The recommendations provide the fundamental epistemological framework and the basic paradigm for protecting people against radiation exposures. In contrast, the regulations provide the legal and formal structure for controlling radiation sources and their exposures. The recommendations are not limited in extent and cover all exposures whatever their magnitude and origin. Conversely, the regulations need a clear definition of their scope for practical and legal purposes. In spite of this distinction, radiological protection recommendations and regulations also retain a robust association. Some issues that relate the recommendations vis-à-vis the regulations are discussed below.

2.1. The Assumption of No Threshold of Risk

(12) A significant issue associating the Commission's recommendations with the definition of the regulatory scope is their basic assumption that any exposure – however small – can be detrimental to health. While the risk of radiation harm is presumed to be minute at low radiation doses, the Commission's position is that following any incremental increase in dose above the unavoidable background dose there is assumed to be a proportional, small but finite, increase in the likelihood of occurrence of some cancers and hereditary effects. This hypothesis forms the basis of the Commission's radiological protection policy for low-level exposures and is applicable to all exposures, however small, regardless of their origin – whether natural or artificial. Thus, the Commission's recommendations are based on the circumstances giving rise to exposure, and not on whether the exposure originates from a natural or an artificial source or on whether its amount is high or low.

(13) The premise that there is no threshold below which detrimental properties cannot be assigned to radiation can confuse the assessment of what should be regulated, as it may induce a desire to extend the regulatory scope indefinitely. The fact that even trivial levels of radiation and radioactivity are detectable with current measuring techniques may strengthen such perception. These, however, should not be considered convincing arguments for including all exposures and sources within the scope of the formal regulatory systems used to control radiation exposure situations. The definition of the spectrum of situations that such systems should cover is actually a far more complicated challenge, and raises a number of societal, cultural and legal issues. For instance, account needs to be taken of the amenability of controlling the exposure situation and of whether or not control is warranted. Legislators and regulators should concentrate on situations

where regulatory systems can be applied and, when applied, they can bring about positive net benefits in terms of radiological protection. The fact that the Commission's recommendations are concerned with any level of radiation exposure however small does not mean that all radiation exposure situations *can* or *need* be formally regulated and controlled.

2.2. The System of Radiological Protection

(14) The system of radiological protection recommended by the Commission influences the formulation of the regulations and the definition of their scope. The system's crucial principles are the *justification*[15] of actions entailing changes of radiation exposure, the *optimization*[16] of the measures undertaken for radiological protection, and the *limitation*[17] of individual exposures. It is apparent that these principles should provide the fundamental basis for deciding the scope of the radiological protection regulations.

2.3. Radiation Exposure Situations

(15) Another factor influencing the definition of scope is the variety of possible circumstances involving radiation exposure. The Commission recognizes two broadly circumstances of exposure, namely:

- Exposures introduced by new human endeavours, which would not exist in the absence of such endeavours. The endeavours and the exposures they produce are fully controllable in the sense that, in principle, they could be prohibited and the exposure avoided altogether, or the increase in exposure they cause can be restricted by regulatory means in a prospective manner. The Commission gives the name '*practices*' to these circumstances of prospective controllable exposure.

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[15] The Commission uses the term *justification* to refer to the process of proving that actions that entail a change in radiation exposure are right or reasonable, i.e. that there are a good reason for undertaking the actions because they will produce more good than harm. It has been used by the Commission in the context of justifying the introduction of a practice and the undertaking of protective actions. The Commission's recommendations on justification are as follows (see [ICRP 1991, paragraphs S 18 and 113]): (i) no practice involving exposures to radiation should be adopted unless it produces sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes (the justification of a practice); and (ii) the proposed intervention should do more good than harm, i.e. the reduction in detriment resulting from the reduction in dose should be sufficient to justify the harm and the costs, including social costs, of the intervention (justification of interventions).

[16] The Commission uses the term *optimization* to refer to the process of achieving the best protection against radiation exposure while taking account of the prevailing circumstances. It is considered a synonym to the aim of keeping doses as low as reasonably achievable (or ALARA), social and economic considerations being taken into account. . It has been used by the Commission in the context of optimizing the radiation protection at the introduction of a practice and during the undertaking of protective actions. The Commission's recommendations on optimization are as follows[ICRP 1991, paragraphs S 18 and 113]:: (i) in relation to any particular source within a practice, the magnitude of individual doses, the number of people exposed, and the likelihood of incurring exposures where these are not certain to be received should all be kept as low as reasonably achievable, economic and social factors being taken into account, where the procedure should be constrained by restrictions on the doses to individuals (dose constraints), or the risks to individuals in the case of potential exposures (risk constraints), so as to limit the inequity likely to result from the inherent economic and social judgments; and, (ii) the form, scale, and duration of the intervention should be optimized so that the net benefit of the reduction of dose, i.e. the benefit of the reduction in radiation detriment, less the detriment associated with the intervention, should be maximized. The Commission has issued specific recommendations on the implementation of the optimisation principle (see [ICRP, 1983 and 1989])

[17] The Commission has formulated the principle of individual *limitation* as follows (see [ICRP 1991, paragraph S 18]): exposure of individuals resulting from the combination of all the relevant practices should be subject to dose limits, or to some control of risk in the case of potential exposures. These are aimed at ensuring that no individual is exposed to radiation risks that are judged to be unacceptable from these practices in any normal circumstances. Not all sources are susceptible to control by action at the source and it is necessary to specify the sources to be included as relevant before selecting a dose limit.

- Exposures already present in the human habitat, either because they were always there (extant exposures) or because they were generated by an unexpected situation such as an accident. These exposures are less readily controllable. The regulator may *intervene* to apply regulatory measures that restrict the magnitude of the total exposure. Thus, they can be reduced but cannot be avoided entirely. The Commission has used the term '*intervention*' to describe the action taken to reduce exposure in these circumstances [ICRP 1991].

This description of controllable and interventional circumstances forms the core of the Commission's current system of radiological protection[18]. As will be seen, the definition of scope varies considerably according to these circumstances.

(16) Usually it is not difficult to distinguish circumstances of prospective exposure, or practices, from interventional circumstances and, therefore, it should not be difficult to decide whether or not the circumstance should be considered under regulatory scope. Practices are adopted as a matter of a planned choice in order to gain some individual or societal benefit. There is a conscious decision to adopt a beneficial practice and to regulate it. Therefore, there can be a conscious decision to determine whether a practice is within or outside the regulatory scope. Conversely, an interventional circumstance is not generally a matter of choice but one that exist *de facto*. The intervention is intended to reduce extant exposures caused by such a *de facto* condition. The source already exists at the time when the interventional circumstance is being considered, is not tied to any particular societal benefit specifically related to the source and is usually not subject to a formal regulatory system. The consideration of scope in interventional cases is therefore more subtle: the issue is not whether the situation is inside or outside a formal regulatory system but rather whether it is worthwhile to consider intervention or not.

(17) Thus, the clearest distinction between practices and interventions is the ability to choose a priori whether to accept beneficial sources and the consequent exposures. If a choice is still available, the exposure can usually be said to be due to a practice and control can and should be planned in advance. If there is no choice, because the sources already exist, any action undertaken to reduce exposures is an intervention. It should be noted, however, the Commission has advised that when introducing the concepts of practice and intervention, it did not intend to imply that any human activity that might cause increases in an individual's exposure is a practice, nor that any human activity that might reduce an individual's exposure is an intervention[19]. For instance, normal modifications of living habits which may increase or reduce the individuals' background exposure (for example, a move to another part of the country or a change in the type of home) should not be treated either as a practice or as an intervention and should not be subject to the Commission's system of radiological protection. In these *background exposure* cases, the exposure is excluded from consideration unless it reaches a level at which intervention is called for.

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[18] The concept of the *system of radiological protection for practices* and *for interventions* were introduced by the Commission in Publication 60 [ICRP 1991], paragraph 106. *Practices* were defined as 'human activities [that] increase the overall exposure to radiation. . .' and *interventions* as 'human activities [that] can decrease the overall exposure. . .', respectively. The concepts were further discussed in ICRP Publication 82 [ICRP, 1999], Section 1.4 and Annex D. The Commission is now considering to merge these systems into a common system mainly based on individual dose constraints and optimisation of protection.

[19] See [ICRP 1999], paragraph D25.

(18) The Commission notes that some difficulties may have arisen from the regulatory use of concepts such *'practice'*, *'intervention'* and *'natural'* spelled out in its 1990 recommendations. For instance, while the Commission's recommendations contain a conceptual definition of 'practice', for regulatory purposes, it may be necessary to tighten up the description of what a practice really is. A practice is an *endeavour* that causes an increase in exposure to radiation or in the risk of exposure to radiation. An endeavour can be a business, trade, industry or any other productive enterprise; it can also be a government undertaking or a charity. The qualification of a practice as an endeavour helps to better define what the Commission means by practices and to specify the boundary of what should be regulated and what need not. It also has the benefit that endeavours, such as those described above, are already defined in legislation for other purposes and moreover the legal person responsible for them is also defined, so that it becomes clear to whom the regulations apply.

(19) There are, however, some circumstances of exposure that are not easy to categorize and therefore difficult to decide whether to regulate or not. One particular case relates to the use of materials that may have been contaminated by authorized radioactive discharges into the environment, which has been argued previously by the Commission[20]. The Commission advises that any environmental radioactive materials from authorized discharges should not be subject to further controls unless the environmental pathways to humans change. However, if a new use of environmental materials is proposed, for example the harvesting and consumption of a type of shellfish not previously considered in the assessment of the discharges, it may be possible to include the new circumstance under the typical regulatory control for practices. If that is not feasible, it may be necessary to deal with the environmental accumulation as an interventional circumstance with its corresponding influence on scope. In this context, a notable difficulty for categorization arises from the incorporation of radionuclides into commodities: this particular case will be treated separately in Chapter 6.

(20) Another difficult case is presented by exposure situations caused radioactive residues from earlier human endeavours that were not regulated at their origins. Moreover, these endeavours may continue to be active. A controversial issue related to the definition of scope is whether these types of situations should be subject to regulations[21]. The origins (and originators) of some of these endeavours may not be even traceable. It may not be reasonable or even feasible to impose on society today the efforts and other disadvantages of the protective actions needed for restricting exposures, *a posteriori*, to levels that were not considered, *a priori*, by those who decided to carry out the original activity or event at the time. Authorities can therefore consider these cases as lying outside of the scope of regulatory systems unless exposures reach a level at which intervention is justified. However, in principle, there are no impediments in these cases to regulate the situation restricting exposures to *ad hoc* levels. In fact, there do exist radioactive residues that are traceable to a precise original activity or event that

[20] See [ICRP 1999], paragraph D26.
[21] See [ICRP 1999], paragraphs 107 and 108.

sometimes occurred not long ago. Moreover, in many of these cases, those who caused the situation can still be made retrospectively liable for the required protective actions. For example, the radioactive residues remaining from recent accidents usually have traceable origins and the liabilities of the originators are sometimes (although not always) straightforward. In these cases the imposition of regulatory actions to those responsible for the situation, in order to achieve some pre-selected individual dose restriction, could be considered by the competent authorities a reasonable and justifiable measure. These actions would need a limitation in their scope. If the endeavour continues to be active, it could in principle be treated as a practice in its own right but keeping in mind that it may be unfeasible to impose restrictions that were not originally envisaged. A case-by-case consideration seems to be the only option in these cases.

(21) In summary it follows that, while there are many specific circumstances of exposure, in general terms the common *radiation exposure situations*[22] can be described as follows:

- *prospective exposure situations* in which the introduction of a radiation exposure arises from a particular human endeavour that is planned in advance and where therefore radiological protection can be controlled *a priori*;
- *existing exposure situations*, which describe extant circumstances of exposure, and *background exposure situations*, where the only practicable action is intervening with protective measures; and,
- *emergency exposure situations*, which are the result of unplanned and unexpected circumstances such as accidents.

The Commission's system of radiological protection deals coherently and consistently with these three different situations but its quantitative recommendations are diverse and reflect the uniqueness of the situations. The distinctiveness of these radiation exposure situations logically influences the concept of scope and its quantitative definition. Therefore, whether an exposure situation is considered prospectively for introduction, or is extant, or is the result of an anticipated accident or emergency, has a bearing on the decision of whether or not such situation should be regulated.

2.4. Classification of Exposure

(22) Another feature to be considered in the definition of scope is the classification of exposures according to those exposed. The Commission's recommendations categorize radiation exposure into three types, namely: *occupational exposure*, which is the exposure incurred at work, and principally as a result of work; *medical exposure*, which is principally the exposure of persons as part of their diagnosis or treatment; and *public exposure*, which comprises all other exposures[23]. This categorization has an enormous influence in the formulation of radiological protection requirements. However, the type of exposure should not in principle influence the definition of the scope of the regulatory system. In fact, the definition of scope occurs *a priori* of the classification of exposure. Therefore, whether a source is going to be used to expose workers, patients or members

[22] The term *radiation exposure situation* will be hereinafter used in the report to mean any set of circumstances in which people are exposed to radiation.
[23] See [ICRP 1991], paragraph 109.

of the public has no bearing on the decision of whether or not such source should be regulated.

(23) The Commission has also divided radiation exposure into two broad categories: *normal exposures* and *potential exposures*[24]. As will be discussed hereinafter, situations of potential exposure, where the exposure -if it occurs- is expected to be high, should always be covered by the regulatory scope even in the case that the corresponding normal exposures are minute.

3. DICHOTOMOUS CONTROL

(24) Dichotomous approaches to control radiation exposure have been common in radiological protection. They seem to be an unavoidable result of the various degrees of controllability among the possible exposure situations. But they also reflect different public expectations under different circumstance of exposure. Dichotomous control obviously influences decisions on the scope of the regulations.

3.1. Regulatory Attitudes to Exposure Situations

(25) Societal and regulatory attitudes in relation to the possible diverse radiation exposure situations have been extremely variable. For prospective exposure situations or practices, experience has shown that society expects a significant expenditure of resources to be applied to containing the expected exposures. Regulators have been reacting to this societal demand with very stringent regulations with an inclusive scope. For instance, exposure of members of the public from all regulated practices is required to be limited at very low levels and regulatory controls are expected to apply to even minute levels of dose. This attitude may reflect a perception that the societal efforts for such control measures are warranted and commensurate with the societal benefits arising from the practice. Conversely, experience has shown that societal expectations for the scale of resources to be applied to restricting extant exposures are much lower. For example, regulatory controls are usually not applied to extant exposure situations involving 'natural' radiation in spite of the fact that the levels of exposure can be high (this issue is discussed further in the next section). This may reflect a judgement that – for these circumstances – the societal efforts for meeting regulatory requirements to reduce extant exposure would be out of proportion to the benefit achieved. Logically, this attitude should have a parallel consideration when deciding the scope of regulations for dealing with these situations. In contrast again, experience is different with emergency situations. While the exposure situation in the aftermath of an emergency can be considered to be also an interventional situation, the ambition in these cases seems to be much higher than for extant situations. The societal attitude in these cases seems to be that, because a failure has occurred, society expects to be as fully protected as possible.

[24] In the Commission's terms (ICRP 1993a, paragraph 2; ICRP 1997b, paragraph 6), *normal exposures* are those exposures which can be reasonably expected to occur, i.e. the exposure is predicted to occur with the probability of one or near one, and *potential exposures* are those exposures for which there is a potential, but not a certainty, of occurrence. They may be foreseeable and their probability of occurrence estimated, but they cannot be predicted in detail. A conceptual framework for protection from potential exposure is presented in ICRP Publication 64 [ICRP 1993], while some applications to selected radiation sources are presented in ICRP Publication 76 [ICRP 1997].

3.2. Considering 'Natural' Exposure Situations

(26) An issue that seems to influence this dichotomy is the ubiquity of radiation exposure and its influence on the perception of 'natural' exposure situations. Radiation exposure is an unavoidable natural phenomenon. Every human being, every constituent of the biota, everything on Earth is subject radiation exposure arising from two main types of sources: those characterized as 'of *natural* origin', such as cosmic radiation and primordial radionuclides; and, those attributable to human activities, which are often considered as 'of an *artificial* origin' (this is a peculiar distinction that will be discussed hereinafter). Virtually all substances in the world are radioactive to some extent because they inevitably contain *radionuclides of natural origin* and traces of radioactive residues remaining in the human habitat from past human activities. Only for the purpose of this report, when the Commission refers to radionuclides of natural origin it is referring to potassium-40 and to the decay chains of the primordial radionuclides[25].

(27) The average radiation dose to the world's population from background radiation (mainly natural radiation) is estimated by the United Nations Committee on the Effects of Atomic Radiation (UNSCEAR) to be around 2.4 mSv in a year [UNSCEAR, 2000]. But many large populations live in areas of the world experiencing doses of around 10 mSv in a year with extremes up to 100 mSv and more. It is to be noted that UNSCEAR estimates exposure to radionuclides of natural origin is the largest contributor to human exposure. Logically, this fact should have triggered more stringent radiological protection measures against natural exposures, but the opposite happened. In fact, natural radiation exposure has not been dealt with comprehensively in radiological protection standards. As a result, there has been also a dichotomy in the way that the scope of the standards has been defined for 'natural' versus 'artificial' exposure situations.

(28) Thus, radiation and radioactivity have been qualified with the adjectives '*natural*' and '*artificial*'. Seemingly, it was considered useful to deal separately with primordial radiation and radioactivity and those defined as '*manmade*'. However, as any material may contain both natural and artificial radionuclides, in many situations it is difficult to separate the exposure attributed to the artificial component from that due to the natural component. For instance, some radionuclides that are of natural origin can also be produced 'artificially'. Conversely, others, which are produced by humans, and are therefore considered 'artificial', are also produced by natural phenomena. Moreover, protective measures against the artificial component can affect the exposure due to the natural component and vice versa. It seems, therefore, that the application of the qualifiers 'natural' and 'artificial' to radiological protection situations is not necessarily helpful. Further controversy may arise if the qualifiers are applied to sources and even

[25] The primordial radionuclide decay chains are: (i) the thorium series, headed by thorium-232, the most abundant of all naturally occurring radionuclides, with a half-life of 1.41 10^{10} years, and constituted by ^{228}Ra(5.75 a), ^{228}Ac (6.15 h), ^{228}Th (1.913a), ^{224}Ra (3.66 d), ^{220}Rn (55.6 s), ^{216}Po (0.145 s), ^{212}Pb (10.6 h), ^{212}Bi (60.6 m), ^{212}Po (0.299 ms), ^{208}Tl (3.05 m), and ^{208}Pb (stable); (ii) the uranium series, headed by uranium-238, with a half-life of 4.47 10^{9} years, and constituted by ^{234}Th (24.1 d), ^{234}mPa (1.17 m), ^{234}U (2.45 10^{5} a), ^{230}Th (7.54 104 a), ^{226}Ra (1600 a), ^{222}Rn (3.82 d), ^{218}Po (3.10 m), ^{214}Pb (26.8 m), ^{214}Bi (19.9 m), ^{214}Po (164 ms), ^{210}Pb (22.3 a), ^{210}Bi (5.01 d), ^{210}Po (138 d), and ^{206}Pb (stable); and, (iii) the actinium series (which is the less important for the purpose of this report), headed by uranium-235, with a half-life of 7.04 10^{8} years, and constituted by ^{231}Th (25.5 h), ^{231}Pa (32,800 a), ^{227}Ac (21.8 a), ^{227}Th (18.7 d), ^{223}Fr (22.0 m), ^{223}Ra (11.4 d), ^{219}Rn (3.96 s), ^{215}Po (1.78 ms), ^{211}Pb (36.1 m), ^{211}Bi (2.14 m), ^{207}Tl (4.77 m), and ^{207}Pb (stable).

more so to exposures. In summary, the distinction between ‘natural’ and ‘artificial’ radiation exposure has proved to be peculiar, certainly not precise, and unconstructive.

(29) Notwithstanding the above arguments, the Commission has noted that members of the public and their representatives seem to maintain a distinction between natural and artificial exposure. They appear to have different views on how to deal with ‘natural’ versus ‘artificial’ situations of radiation exposure. It seems they wish to weight highly those radiation risks attributable to technological sources (considered ‘artificial’) versus those due to truly ‘natural’ sources. As a result, the societal expectation for protection, and consequently for regulatory control, has been generally stronger when the source of exposure is a technological by-product rather than when it is considered to be a product of nature. This has usually resulted in differently perceived needs for response and, again, in a dichotomous scale of protection, depending on the origin of the exposure. Typically elevated exposures due to natural radiation sources have not generated a social anxiety, while relatively minor exposures to radioactive residues from human endeavours have been a cause of concern sometimes prompting unwarranted protective actions.

(30) The public concern for artificial exposures may reflect the way the Commission’s radiological protection recommendations, and the derived regulatory systems of control, have developed over the years…or vice versa!. It is plausible that the advent of the nuclear age led automatically to a focus on ‘artificial’ radionuclides, with less attention paid to a few situations involving ‘natural’ radionuclides that were sometimes controlled previously such as the extraction and use of some primordial radioelements, for instance radium, uranium and thorium. Furthermore, societal views seem to have developed to be much more risk-averse to readily controllable ‘artificial’ sources than to other circumstances of exposure from not-so-controllable ‘natural’ sources. This is partly because of public perceptions about radiation risks, and also because it has been found feasible to control minute doses from ‘artificial’ practices and usually prohibitively costly to exercise control in existing situations of natural exposure.

(31) In dealing with the above-described ‘natural’ versus ‘artificial’ controversy, the Commission confronts a dilemma with contradictory premises: on the one hand, the Commission recognises that the societal level of ambition has historically been higher for those radiation exposures that society perceives as a by-product of technological development; on the other hand, it recognises that it is the relative magnitude of the exposure that correlates with risk. The Commission has resolved this difficult dilemma by recommending that radiological protection regulatory systems should include natural sources of exposure and should regulate coherently and consistently any exposure regardless its origin but should also take account of the amenability of control as well as the expectations of those affected by the different exposure situations.

4. UNAMENABILITY TO CONTROL: EXCLUSION

(32) The Commission has addressed the concept that certain exposures may be excluded from regulatory systems in its latest recommendations[26]. The concept is reflected in the BSS[27]. Excluded exposures are those that are essentially unamenable to control, regardless of their magnitude, and include exposure to natural radioactive constituents within the human body that are homostatically controlled (such as the radionuclide potassium-40), to cosmic rays at ground level and to unmodified concentrations of the naturally occurring radionuclides in most raw materials. Exposures of this kind are to be excluded from radiological protection legislation simply because they are deemed to be unamenable to be controlled.

(33) The determination of what exposure situations are essentially unamenable to control requires a judgment on the part of the legislator, which may be influenced by cultural expectations and therefore can differ substantially around the world. It should result from analyses similar to those used in the application of the Commission's principles of justification and optimization. For instance, exposures to cosmic rays at the earth's surface could theoretically be modified but the cost and disruptive consequences of protection measures seem to be unjustified. Thus, exposure to cosmic rays at ground level is universally considered unamenable to control and protection *de facto* optimized. Large cities have been sited at high altitudes (e.g. La Paz, the populous capital of Bolivia is located at an altitude of around 4000 metres) and their inhabitants incur a substantively higher cosmic ray exposure than those living at sea level; however, public authorities have not considered 'amenable' or 'optimum' to move these cities to lower altitudes in order to avoid the public exposure of the residents.

(34) An important and controversial issue related to the exclusion concept is whether or not exposures to so-called *natural occurring radioactive material* (sometimes referred to as *NORM*[28]) should be considered amenable to control (the issue will be further discussed in Chapter 6, as an important specific case). National attitudes to the regulation of natural occurring radioactive material are extremely variable. For instance: people in many countries enjoy beaches with monazite sands, which are rich in naturally occurring radioactive material able to deliver high radiation exposures, but legislators in these countries have not considered it reasonable to enforce radiological protection regulations against this type of exposure; conversely, in other countries, the transport of even relatively small amounts of similar types of sands is under strict regulatory control. The diversity of national approaches to the protection against naturally occurring radioactive material is generating an inconsistent regulatory control of the myriad of industries processing these types of materials.

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[26] See [ICRP 1991], paragraph 291, where the Commission recommended that "Sources that are essentially uncontrollable, such as cosmic radiation at ground level and potassium-40 in the body, can best be dealt with by the process of exclusion from the scope of the regulatory instruments,..."

[27] See [IAEA 1996], article 1.4, which establishes that "…*any exposure whose magnitude or likelihood is essentially unamenable to control through the requirements of* [the international radiological protection standards] *should be deemed to be excluded from the standards*"

[28] The term 'naturally occurring radioactive material' (NORM) has become widely accepted in the mining and minerals processing industry to denote any material associated with operations in this industry in which radionuclides from the ^{238}U, ^{235}U or ^{232}Th decay series, or ^{40}K, are present in concentrations sufficient to warrant the consideration of control measures. The term is, however, somewhat of a misnomer, since the descriptor 'naturally occurring' applies to the radionuclides in the material and not always to the material itself.

(35) The Commission's guidance on protection against exposure to naturally occurring radioactive material has not been thoroughly developed and, unsurprisingly, the subsequent international standards are ambiguous. The current international standards refer to exposure from *"unmodified concentrations of radionuclides in most raw materials"* as an example of an excluded exposure[29]. The reference to *"unmodified concentrations"* may be construed to point to the fact that processing some raw materials containing radionuclides of natural origin at low concentrations of radioactivity, may lead to radioactive byproducts or radioactive wastes or radioactive residues that have much higher levels of radioactivity concentration and therefore need be controlled by regulations. The reference to *"most raw materials"* in the international standards may be construed to indicate that there may well be a few industries using them where radioactivity concentrations are high enough to require consideration and control of their exposures. An extreme but generally accepted case is the production of uranium or thorium ores, which have traditionally been included in the scope of regulatory systems practically without exception; but exposures from some other raw materials may also be similar and need to be considered to be included in the regulatory system. There is a practical need for an international consensus on whether exposures to naturally occurring radioactive material should be excluded from (or perhaps, more appropriately, included within) the scope of regulations, or whether they should be treated with some kind of generic exemptions.

5. UNWARRANTED CONTROL: EXEMPTION

5.1 Exemption Concept

(36) The concept of exemption has been in international use for some years. It was recommended by the Commission in its main recommendations in Publication 60 [ICRP, 1991][30] and, in its Publication 64 [ICRP 1993(a)], the Commission provided guidance for exempting certain practices and their sources from some regulations [31]. The concept was elaborated by intergovernmental organizations [IAEA, 1988] and incorporated in the BSS [IAEA 1996]. It was originally envisaged within the context of the introduction of *practices*, mainly involving artificial radionuclides, and it was not foreseen for use in

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[29] See [IAEA 1996], footnote 2.

[30] The Commission policy was stated ICRP Publication 60, paragraphs 285-288, as follows: *'In order to avoid excessive regulatory procedures, most regulatory systems include provisions for granting exemptions…The Commission believes that the exemption of sources is an important component of the regulatory functions…There are two grounds for exempting a source or an environmental situation from regulatory control. One is that the source gives rise to small individual doses and small collective doses in both materials containing radionuclides of natural original and accident conditions. The other is that no reason- able control procedures can achieve significant reductions in individual and collective doses. The basis for exemption on the grounds of trivial dose is much sought after, but very difficult to establish. Apart from the difficult of deciding when an individual or a collective dose is small enough to be disregarded for regulatory purposes, there is a considerable difficulty in defining the source…The underlying problem is that exemption is necessarily a source-related process, while the triviality of the dose is primarily individual-related.'* Thus, the Commission has also indicated that: 'The second basis for exemption calls for a study similar to that needed in the optimization of protection. It provides a logical basis for exemption of sources that cannot be exempted solely on the grounds of trivial doses, but for which regulation on any reasonable scale will produce little or no improvement.'

31 In ICRP Publication 64, paragraph 86, the Commission summarized its current criteria for exemption levels for practices as follows *'In the case of materials containing radionuclides of natural original exposure, most regulatory systems include provisions for granting exemptions from the regulatory system where it is clear that a practice is justified but regulatory provisions are unnecessary. The grounds for exemption are that the source gives rise to small individual doses (of the order of 10 microsieverts per year) and the protection is optimised, i.e. regulatory provisions will produce little or no improvement in dose reduction. (If the collective dose is small, e.g. on the order of one man-sievert per year, protection is often assumed to be optimised).'*

interventions. Not surprisingly, national and international standards are rather detailed on the use of exemption for prospective situations and generally mute for extant or emergency exposure situations.

(37) The basic concept introduced in the BSS is that practices, and sources within practices, may be exempted from regulatory control if such control was not warranted. For instance, this would be the case if control would be not justified in radiological protection terms because protection is optimized without control. The BSS state that practices and sources within practices may be exempted from requirements of the standards provided that they comply with *exemption principles* (see next section) or with *exemption levels* defined by the regulatory authority on the basis of those exemption principles[32]. They also state that exemption should not be granted to permit practices that would otherwise not be justified[33].

(38) A practice, or a source within a practice, that is exempted is not supposed to be outside the legislative system of radiological protection or beyond the regulatory domain established by the legislation. Rather, the exemption is from some administrative aspects of the applicable regulations such as the requirements for notification, registration or licensing and subsequent compliance measures such as inspections and reporting.

(39) The Commission wishes to stress that the term 'exemption' has strictly a legal context and can only apply to persons, either physical or legal persons. It relates to the waiving by the regulatory authority of requirements that would otherwise apply to a person as a legal obligation. In international standards the term is in fact used to describe a practice for which regulatory requirements are not applied to the person responsible for the conduct of the practice. This usage – 'exempt practice' - is an extension of the strict meaning, which is now commonplace and clear. The word 'exempt' is also used in reference to the relinquishment from some, but not all, requirements that would otherwise apply: not an 'exempt practice', but a practice which is exempt from certain requirements –and it is important to state from "what" the practice is being exempted.

5. 2. Exemption Principles

(40) The principles for exempting practices were internationally established several years ago and published as the *Principles for the Exemption of Radiation Sources and Practices from Regulatory Control* [IAEA, 1988], hereinafter referred to as the *Exemption Principles*. They were incorporated in the BSS [IAEA 1996]. The international consensus can be summarized as follows: there are two basic principles for determining whether or not a practice can be a candidate for an exemption, namely (i) the expected individual risks attributable to the practice must be sufficiently low as not to warrant regulatory concern; and, (ii) radiation protection, including the cost of regulatory control, must be optimized. Thus, a person responsible for a practice or source may be exempted from radiological protection regulations if the individual risk attributable to the radiation exposure caused by the exempted practice or source is judged

[32] See [IAEA 1996], para. 2.17
[33] See [IAEA 1996], para. 2.18

to be low and the consequent detriment is irrelevant vis-à-vis the commitment of resources implied the protection to be achieved trough the regulatory control. An additional principle, which is an overriding condition for exemption, is that the exempted practice must be justifiable and its sources must be inherently safe.

5.2.1. The principle of low individual risk

(41) The *Exemption Principles* [IAEA, 1988] provided the first guidance on typical levels of individual risk, and corresponding dose, that were understood to be low for the purposes of exemption. They indicate two main approaches that can be considered in deciding whether a level of risk or dose is low: firstly, to choose a level of risk, and the corresponding dose, which is of no significance to individuals; secondly, to use the exposure to the natural background, to the extent that it is normal and unavoidable, as a relevant reference level. From risk-based considerations the *Exemption Principles* conclude that the level of low dose would be in the range of 10–100 μSv per year, and from natural background considerations, the conclusion is that it should be in the range 20–100 μSv per year[34]. Thus, they concluded that: "*…an individual radiation dose, regardless of its origin, is likely to be regarded as trivial if it is of the order of some tens of microsieverts per year. It is noted that this level of dose corresponds to a few per cent of the annual dose limit for members of the public recommended by the ICRP and is much smaller than any upper bound set by competent authorities for practices subject to regulatory control.*" This value was intended to refer to an average individual annual dose in the critical group. Moreover, the unavoidable statistical distribution of doses in any situation of exemption would imply that some individuals may be exposed to higher doses than '*some tens of microsieverts per year*', within a distribution that may include extremes that conveivably could be orders of magnitude higher than the average.

(42) Even taking account of upward revisions of risk factors over the last decade or so, the basis behind the derivation of an exemption criterion of the order of *some tens of microsieverts per year* as being representative of a trivial dose is still sound. If anything, this criterion could be regarded as being still rather conservative, bearing in mind the assumptions about an individual simultaneously receiving doses from several practices judged to be exempt.

(43) When the above principle of low risk was introduced in the BSS, its formulation was simplified as follows (see [IAEA 1999], Sch I, para I-3): "*A practice or source*

[34] The international *Principles for the Exemption of Radiation Sources and Practices from Regulatory Control* state that [IAEA 1988] "*…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 proposing values of trivial individual dose 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} for whole body exposure as a broad average over age and sex, the level of trivial individual effective dose equivalent would be in the range of 10–100 μSv per year.*" They also state "*…The natural background radiation has been estimated to give, as an average, an individual dose of about 2 mSv per year. This average conceals a wide variation due to different concentrations of radioactive materials in the ground and in building materials, as well as differences due to different altitudes and habits of living. On a global average, about half of this dose is due to radon exposure, a source for which controls are suggested. The other half comes from exposure to cosmic rays, terrestrial gamma rays and radionuclides in the body, for which control is impractical…Individual members of the public do not generally take account of the variation in exposure to natural background radiation when considering moving from one part of the country to another, or when going on holiday. It can, therefore, be judged that a level of dose which is small in comparison with the variation in natural background radiation can be regarded as trivial. A figure of whole body or effective dose equivalent of the order of one to a few per cent of natural background, i.e. 20–100 μSv per year, has been suggested*".

within a practice may be exempted without further consideration provided that…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". Thus, the original criterion of an average of some tens of microsieverts per year within a distribution of doses became 'of the order of 10 μSv in a year', and then, when imprecisely interpreted, came to be known as the *10 μSv in a year criterion* – a significant ratcheting down of the original judgment.

(44) At this stage, a *de facto* psychological association seems to have arisen between the principle of exemption and the so-called 10 μSv in a year criterion, which made them quasi-synonymous. The association broke down when the exemption concept was intended to be applied to 'natural' sources, as it would be quite unfeasible to apply a 10 μSv in a year criterion to situations involving exposure to naturally occurring radioactive material. Wider considerations are required for this type of situation, including consideration that a broad distribution of doses to very high values would be unlikely.

(45) It is worthwhile to repeat that the basic quantitative principles of exemption, including the criterion "of the order of 10 μSv per year" that was converted into the 10 μSv in a year criterion, were developed within the context of practices involving sources containing 'artificial' radioactive materials in moderate quantities. The application of such principles to situations involving radionuclides of natural origin, where these were not already excluded, was limited to the incorporation of such radionuclides into consumer products or their use as a radioactive source (e.g. ^{226}Ra, ^{210}Po) or for their elemental properties (e.g. thorium, uranium). If an exemption criterion of 10μSv in a year were imposed on situations involving naturally occurring radioactive material, it would in general not be practicable to implement a control scheme for such a small increment to the natural radiation background, an increment that is in fact one or two orders of magnitude below the variability of the natural background. This contrasts with the situation for radionuclides of artificial origin, where the natural background is close to zero.

(46) It should be recalled the original formulation of the *Exemption Principles* and the Commission's own position on the subject. The Commission had stated,…"*there are two grounds for exempting a source or an environmental situation from regulatory control. One is that the source gives rise to small individual doses and small collective doses in both normal and accident conditions. The other is that no reasonable control procedures can achieve significant reductions in individual and collective doses.*"[35] This wider approach is consistent with the original *Exemption Principles* and fully applicable to situations with naturally occurring radioactive materials (namely, uranium and thorium series and potassium-40). It has been so recognized by the European Commission, which has stated that"*… the definition of [exemption] values for natural sources cannot proceed on the basis of trivial risk criteria… If one would impose a restriction of 10 μSv it would in general not be practicable to implement a control scheme for such a small increment to the natural radiation background, in fact below the natural variability.*"[36]

[35] See [ICRP 1991], Paragraph 287.
[36] See Part II of [EU, 2001].

(47) Thus, the key point on the applicability of the individual principle for exemption to naturally occurring radioactive materials is that the background dose level due to these materials, and more importantly its variability, are one or two orders of magnitude above 10 μSv per year while, conversely, for other radionuclides the background dose is close to zero. The Commission has indicated that… *'a study similar to that needed in the optimization of protection…provides a logical basis for exemption of sources that cannot be exempted solely on the grounds of trivial doses, but for which regulation on any reasonable scale will produce little or no improvement."*[37] This approach to exemption is generally more appropriate and meaningful for situations involving exposure to naturally occurring radioactive materials. National authorities in an increasing number of countries are coming to the conclusion that regulation will not produce any significant improvement if the naturally occurring radioactive materials concerned gives rise to annual doses of less than around 1 mSv (excluding the dose from radon, which is dealt with separately), and are consequently deciding not to regulate such activities. This is consistent with recent international agreements on the *Application of the Concepts of Exclusion, Exemption and Clearance*, which state: *"Doses to individuals as a consequence of these activity concentrations* [selected on the basis of consideration of the upper end of the worldwide distribution of activity concentrations in soil provided by UNSCEAR] *would be unlikely to exceed about 1 mSv in a year, excluding the contribution from the emanation of radon …"*[38] .

(48) Therefore, for exemption of situations in practices involving exposure to naturally occurring radioactive material, the second of the two grounds for exemption (see [ICRP 1991], paragraphs 285-288) — exemption on the basis that "regulation on any reasonable scale will produce little or no improvement" — is more appropriate and meaningful than exemption on the grounds of trivial dose. Regional variations in total effective dose from the natural radiation background (external exposure only) are some hundreds of microsieverts per year [Green, 1993], and this should be borne in mind when determining a level below which regulation would not produce a significant improvement. This is effectively the approach that was taken by the Commission for the situation of occupational exposure (see [ICRP Publication 75], paragraphs 158-161), which recommended that "regulatory agencies choose activity concentrations of parent nuclides within the range 1–10 Bq/g to determine whether the exposures from these materials should be regarded as occupational" (and thus whether they should be considered for regulatory control). Although the approach in this case was based on activity concentrations in naturally occurring radioactive materials rather than on dose, it was noted that, when considering exposure to external radiation and inhalation of dust, this range of activity concentrations "will lead to an effective dose [received by a worker] of about 1–2 mSv in a year". Furthermore, it has been reported that, for releases of radionuclides of natural origin from "typical installations or operations of the minerals processing industry" (which are known to handle naturally occurring radioactive materials with typically a similar range of activity concentrations), the maximum effective doses received by members of the public ranged from 0.1–300 μSv in year

[37] See [ICRP 1991], Paragraph 290.
[38] See [IAEA 2004b], Paragraph 3.3).

[UNSCEAR, 2000]. Thus, the individuals receiving by far the highest dose from practices involving naturally occurring radioactive material are likely to be workers rather than members of the public. This implies that, should such practices be considered for exemption on the basis of dose, it is the dose received by workers that is important, and that a if the dose received by a worker does not exceed the Commission's dose limit for members of the public of 1 mSv per year, this might be an appropriate criterion for exemption from regulations of situations involving exposure to naturally occurring radioactive material.

(49) From the above discussion it is clear that the principle of low individual risk for the purpose of exemption of practices may be linked to a dose criterion but it should lose its historical and dogmatic connotation with the single value of 10 μSv in a year . Figure 1 describes how the principle is being applied in the most common situation of sources within practices. At the time when a practice is to be introduced, the expected dose attributable to the practice is tested against the dose exemption criterion, whatever it might be for the appropriate circumstances. If the expected dose is lower (and the other two principles complied with), the practice may be exempted. The 10 μSv in a year criterion has been widely used for exemption of artificial sources and its acceptance for this purpose is well recognized. For exposure from naturally occurring radioactive materials, the criterion might well be established in the order of 1 mSv in a year.

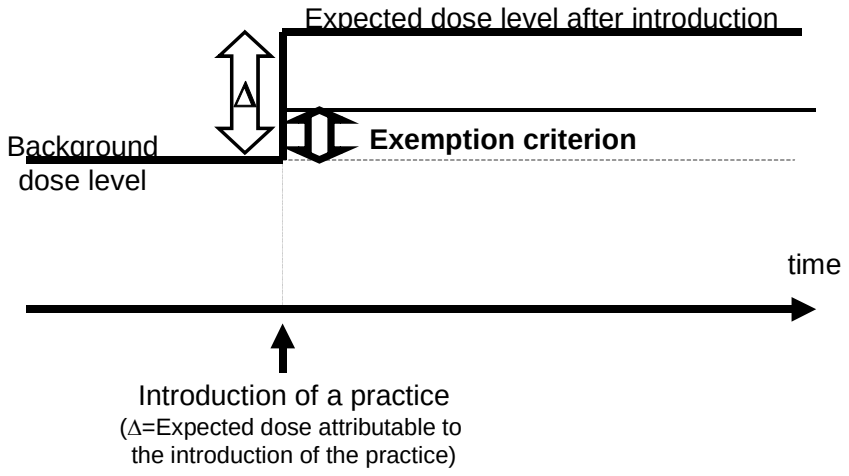

Figure 1

5.2.2. The principle of optimization

(50) A second condition for granting exemption is that exemption would be the optimum radiological protection option. The resources required for regulation are a factor to be considered in the assessment. On cost-benefit grounds, it was suggested [IAEA, 1988] that if the collective dose committed by one year of the unregulated practice were less than around 1 man-sievert, the expected detriment would be low enough to permit exemption (other conditions complied with) without more detailed consideration of other options. This does not mean that a practice giving rise to a larger collective dose could not be exempted. In fact, if no control is the optimum solution in radiological protection terms, exemption should be granted in such cases. In should be noted that this collective dose criterion has not been a determining factor in the exemption of practices, because the individual criterion has always been found to be more restrictive.

5.2.3. The principles of justification and safety

(51) Exemption from regulatory requirements cannot override the justification principle. Exemption could not be invoked to allow practices that are deemed to be unjustifiable. The BSS include in this category practices involving the deliberate addition of radioactivity to food, beverages, cosmetics or any other commodity or product intended for ingestion, inhalation or percutaneous intake by, or application to, a human being and the frivolous use of radioactive substances in commodities or products such as toys and personal jewellery or adornments.

(52) Moreover, potential exposure situations[39], where the exposure may be unlikely but significant, cannot be exempted either. Within this context the term 'inherently safe' used in the *Exemption Principles* means that there is very little likelihood of a mishap that could cause exposures that would fail the individual dose criterion.

5.3. Exemption Levels

(53) The exemption principles were applied to develop radionuclide-specific international *exemption levels* that could be used directly and universally for deciding whether or not to exclude a specific situation. As discussed before, the 10 μSv in a year criterion took prominence in the development of exemption levels. On the basis of some assumptions, a set of generic exposure scenarios was construed and used to derive (i) total activities and (ii) activity concentrations of radionuclides, both corresponding to the 10 μSv in a year criterion. Because of the unavoidable dose distribution, doses in excess of 10 μSv in a year could theoretically be received, although probably not in excess of the dose limit for members of the public.

(54) The derived exemption levels were established in the BSS[40]. Similar assessments were made for the specific case of transport of radioactive materials and *ad hoc* exemption levels were established in the international *Regulations for the Safe Transport*

[39] The concept of potential exposure was introduced by the Commission in Publication 60 (ICRP 1991a, paragraph 111), as an exposure having the potential `but not the certainty that it will occur'. The concept was further elaborated in Publication 64 (ICRP 1993a) and Publication 76 (ICRP 1997b).

[40] See [IAEA 1996], Schedule I (the same values were also incorporated in the Euratom Basic Safety Standards)

of Radioactive Materials [IAEA, 2004 (c)], hereinafter referred to as the *Transport Regulations*. The Transport Regulation exemption levels are coherent and broadly consistent with the levels established in the BSS.

(55) The defined scenarios for the exemption levels assumed small-scale usage of radionuclides. Situations involving large volumes of materials with very low activity concentrations were not explicitly considered. Candidate practices where those involving small-scale usage of radionuclides, such as medical research. Industries where large quantities of naturally radioactive ores or materials were being processed for other than their radioactive properties were not considered in the development of the exemption levels. This incompleteness in the assessment of exemption levels has been corrected recently. An international safety guide on the *Application of the Concepts of Exclusion, Exemption and Clearance* [IAEA, 2004 (b)] provides exemption levels of activity concentration in bulk amounts of materials.

(56) It is to be noted that international practice also provided for conditional exemption of radioactive materials that were not covered by the radionuclide specific levels described before. Such exemptions were supposed to be used for devices such as smoke detectors containing small amounts of radioactivity. It is also recognized that in establishing exemptions, the regulatory authority may set conditions, for example, on the physical or chemical form of the radioactive source and on use or disposal, so that the general principles for exempting a practice are complied with.

5.4. Exemption from within: 'clearance'

(57) The concept of *exemption* is used to determine *a priori* whether to regulate a specific practice. But, conceivably, the concept can also be used *a posteriori*, i.e. to consider the exemption *from within the system*. The BSS use the term '*clearance*' to describe the process of exemption from within, i.e., *a posteriori* exemption of sources that for one reason or another are under regulatory control and do not warrant continued regulation. Thus, clearance is defined in international standards as: *"removal of radioactive materials or radioactive objects within authorized practices from any further control by the Regulatory Authority"*[41]. Figure 2 describes how the system of exemption and clearance is expected to work in practice.

[41] See BSS, Glosary, page 297

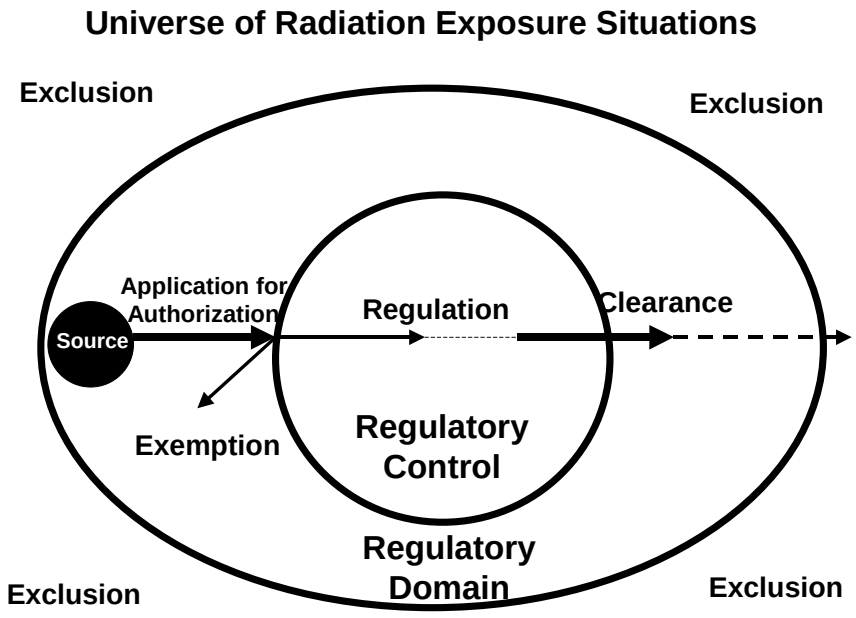

Figure 2

(58) Although the intention of international standards was to limit the concept of clearance to an administrative exemption from obligations already undertaken within the system, the English term used did not help to convey the anticipated idea. The term "clearance" has many different meanings in English[42], which are completely unrelated to the concept of exemption. Moreover, the English term is not directly translatable into other languages. It was translated as *"libération"* (liberation) in French and as *"dispensa"* (dispensation) in Spanish. Not surprisingly, this situation led to different interpretations of the concept and resulted in some confusion.

(59) In contrast to exemption, 'clearance' is specifically defined as applying to materials and objects. Materials that have been cleared have been released from any prior form of regulatory control or, more accurately, regulatory controls no longer apply to the person previously responsible for the materials. Clearance can be seen therefore as the process of relinquishing regulatory control. In professional parlance, the term 'cleared sources' has been used, but this then raises issues about the relationship between 'cleared source' and 'exempt source'. As the two terms have some common features but are not precisely synonymous, a further confusion can occur. One difference between these two terms is essentially that an exempt source is still within the scope of regulatory instruments while a cleared source usually becomes *de facto* outside any feasible control. For an exempt source, there remains a legal person who is theoretically identifiable in law

[42] The term clearance is commonly used in colloquial English to mean: the action or process of clearing or of being dispersed, a kick or hit (in soccer and other games) that sends the ball out of a defensive zone, the potting of all the balls remaining on the snooker table in a single break, official authorization for something to proceed or take place, and clear space allowed for a thing to move past. These meanings have no relation with the intended meaning of clearance in relation to exemption.

as responsible for the source and any consequences arising from its use –even though no specific regulatory requirements apply– and the exemption remains valid only as long as the criteria for exemption continue to be met. For a cleared source, on the other hand, any future exposure it causes is *de facto* excluded from the regulatory framework and the previously responsible person is freed of liability. Thus, in principle, regulatory requirements could be applied to the person responsible for an exempt source by retracting the exemption (although such action might lead to legal challenge), whereas a cleared source is beyond the reach of regulatory instruments unless it becomes part of a new practice that requires regulatory control.

(60) The Commission has noted an extraordinary situation of removal of radioactive materials within authorized practices from any further control by the regulatory authority where clearance criteria are not used. This is the case of relinquishing control of radioactive substances through release from hospitals of nuclear medicine patients who have incorporated such substances while undergoing radiotherapy or radiodiagnosis. The maximum activity for discharge is established in the BSS, which state that in order to restrict the exposure of any members of the household of a patient who has undergone a therapeutic procedure with sealed or unsealed radionuclides and members of the public, such a patient shall not be discharged from hospital before the activity of radioactive substances in the body falls below a predetermined guidance level. Such levels are extremely high by comparison with other situations of clearance: for example, 1100 MBq (!) for iodine-131[43]. The guidance provides some relief by footnoting that 'in some countries a level of 400 MBq is used as an example of good practice'[44]. While the Commission has issued a large number of detailed recommendations for proper radiological protection in the medical practice and the BSS specifically require that written instructions to the patient concerning contact with other persons and relevant precautions for radiation protection shall be provided as necessary, it is apparent that in this practice clearance is being given *de facto* for relinquishing control of large amounts of some radionuclides, such as iodine-131. It should be noted that the exemption level established in the BSS for this radionuclide is just 1 MBq, compared with hundreds of MBq 'cleared' within a patient. This is the only situation where clearance levels are higher than the exemption levels. It would be inappropriate to treat this practice as an *authorized discharge* in the conventional sense (see next paragraph): the activities involved are too large (the level per patient is similar to the annual release of a typical nuclear power plant) and the conditions attached to the release are too lax. The Commission is concerned with this situation and encourages international organizations to revisit the issue of relinquishing control of substantial amounts of radioactive substances used in medical practices through the discharge of patients.

(61) The Commission also notes that the term clearance has been used incorrectly in relation to the discharge of radioactive materials into the environment, for instance discharges from a nuclear installation. The Commission has recommended that controlled discharges of radioactive materials from approved practices should be governed by an *authorization of discharge*, which may have conditions attached including, for example,

[43] See [IAEA 1997] paragraph II.28.
[44] See [IAEA 1997], Schedule III, Table III-VI.

requirements for environmental monitoring [ICRP, 1985 (a)] –the lower the assessed dose to members of the public, the less stringent the requirements are likely to be. These recommendations cannot be substituted with the concept of clearance. Sometimes, however, regulators are tempted to define some point in the end of the spectrum of authorization of discharges where there would not be any further requirement. This point would define a concept that is subtly different than the concept of "exemption from within": it is the release of materials whose activity level is sufficiently low that any form of post-release regulatory involvement is not required in order to verify that the public is being sufficiently protected. In principle, the dose criteria developed for "exemption from within" or "clearance" might equally be applied to this analogous concept. However, the equalization of these concepts has been a cause of confusion and therefore is not recommended. For instance, it has been argued that the use of the clearance concept could be misused for promoting the dilution of discharges in order to circumvent regulatory control.

(62) The term clearance has also been used in legal texts as equivalent to the lower boundary for the definition of radioactive waste. Materials, for which no future use is foreseen with activity levels above clearance levels, would be regarded as radioactive waste; whereas, if their activity levels are at or below clearance levels, they would not be regarded as being radioactive for regulatory purposes. Again, this was not the intended use of the term. The legal definition of radioactive waste is a very complex process that involves other type of considerations than those used for exemption from within.

(63) Within this conundrum of usages, which seem equivalent but are subtly different and at times incorrect, the concept of *clearance levels* was established in the BSS as *"values, established by the Regulatory Authority and expressed in terms of activity concentrations and/or total activity, at or below which sources of radiation may be released from regulatory control"*[45]. A vast range of clearance level was, and continues to be, developed and is available for a number of materials[46].

(64) There have been some discussions as to whether one set of radionuclide-specific values should be used to allow both exemption of materials to be regulated and clearance of materials already regulated. While the activity levels applied to the application of regulatory requirements (exemption) might be different from those applied the release from regulatory requirements (clearance), because, for instance, the imposition of regulatory requirements on materials may require more regulatory resources than are freed by releasing materials from those requirements (clearance), such an approach has the advantage of simplicity; one set of values would be easy to apply and could be interpreted as a definition of a radioactive material, including radioactive waste, for regulatory purposes. There are, however, counter arguments. The values for clearance are being derived on the basis of different assumptions and sometimes for a different purpose than those derived for exemption. A consequence of choosing one set of values is likely

[45] See [IAEA 1997], glosary.

[46] Within the European Union, the Article 31 Group made recommendations on clearance levels for a number of important radionuclides in metals from the dismantling of nuclear installations. The IAEA has developed clearance levels for release of radioactive materials from medicine, industry and research and is also developing clearance levels for general application to any solid material.

to be selection of the lowest of those available. Nevertheless, there may be a case for choosing one set of values for clearance levels: a plethora of levels, each specific to a material or industry, will lead to confusion. Another tempting possibility was to use a specified fraction of the established exemption levels as a generic clearance level.

(65) The Commission has not used the term 'clearance' in its recommendations, *inter alia* because the term has caused so much confusion. However, because of the overlap between the concepts of 'exempt source' and 'cleared source', and the resulting possibility of further confusion and imprecision, the Commission does not intend to recommend unilaterally the discontinuation of the use of the term 'clearance', as this recommendation will be insufficient to solve the problems with the term. It will be unreasonable to expect the word clearance to disappear from usage, because it is too entrenched in professional parlance. The Commission also realises that it is impossible to prevent colloquial use of a term, especially when it has gained a foothold –as in the case of 'clearance'. However, the Commission notes that it may be necessary to develop separate and distinct definition of these concepts. It thus notes the regulatory problems caused by the equivocal use of the term clearance and strongly recommends that its imprecise use be discouraged. This can be done by refining the definitions used in regulatory and legal instruments, for instance reaffirming that exemption of a practice or a source refers to the waiving of requirements within the scope of regulatory control, whereas clearance of materials refers to relinquishing all regulatory control of those materials, in the sense of terminating any requirements that applied to the person previously responsible for them. Any other associated meanings for clearance should be subsumed within the concept of exemption from within in its sense of relinquishing control.

(66) The discussion above reinforces the Commission's conviction that it is not appropriate to define a *'conditional clearance'* – another unfortunate concept that has been used elsewhere. There is either *clearance proper*, where criteria for relinquishing control must be met in the understanding that there cannot subsequent restrictions, or *authorized release* of radioactive materials into the environment, where regulations might be applied to the method of release, the monitoring on its effects on the environment, etc.; but *conditional clearance*, requiring conditions to be met following release, is unfeasible.

5.5. Exemption in Interventional Situations

(67) The report uses the term exemption also for intervention. This is a new use of the term, as up to now it has been used primarily for exemption from requirements for practices (except its use in the context of intervention exemption levels for commodities in international trade). The concept of exemption within the context of interventions presents a particular challenge. Interventions may or may not be subject to the formal system of radiological protection regulations and they are usually undertaken by *ad hoc* organizations rather than by legal persons that apply for a registrations or license. Ther notion of exemption, therefore, is more subtle in this case: it is not exempting a legal person from regulatory requirements such as registration or licensing but rather providing criteria for releasing those ad hoc organizations from intervening. In addition, in the case

of practices, it is expected that there will be an *increase* of exposure due to the introduction of the practice and it is relatively straightforward to see that when the expected increase is sufficiently low the source causing the *increase* may be exempted from regulations because regulating such a low doses is not warranted (see Figure 1). Conversely, in the case of interventions there is no increase of exposure as result of the intervention but on the contrary a *reduction* in exposure. If there is an interventional situation, such as an extant situation of very high background or a post-accident situation, the crucial radiological protection decisions will be (i) whether it is justifiable to intervene, and (ii) if so, how much the doses have to be reduced. Therefore, the concept of exemption here does not address the issue of whether or not an increase in exposure is large enough to warrant regulations but rather whether or not an existing exposure is low enough for considering intervention unjustified under any circumstance. It then become clear that while the principle of exemption for practices can equate to low *additional* dose, such as the 10 μSv in a year criterion, the principle would be inapplicable to interventional situations where the issue is not the exemption from control of an prospective *additional* exposure but of an existing *total* exposure.

(68) It should also be noted that there is a subtle but significance difference between interventional situations following an emergency and an extant situation of high background. In the first, which is described in Figure 3, there is a previous background level that is commonly used as a reference by those affected. In the second situation described in Figure 4, this is not the case. This difference is usually responsible of a dichotomous use of exemption for these two situations. There is a perceived difference in the selection of an intervention level between an emergency situation and the case of long-term extant exposure situations, such as those involving high background. In the case of emergency there is a previous background level (prior to the emergency) that becomes a reference to those affected, whereas in the latter situation, this is not the case.

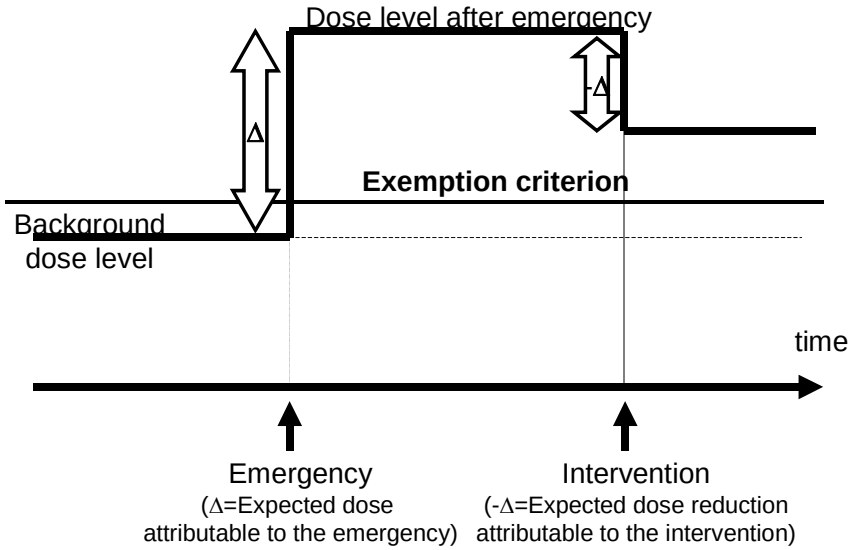

Figure 3

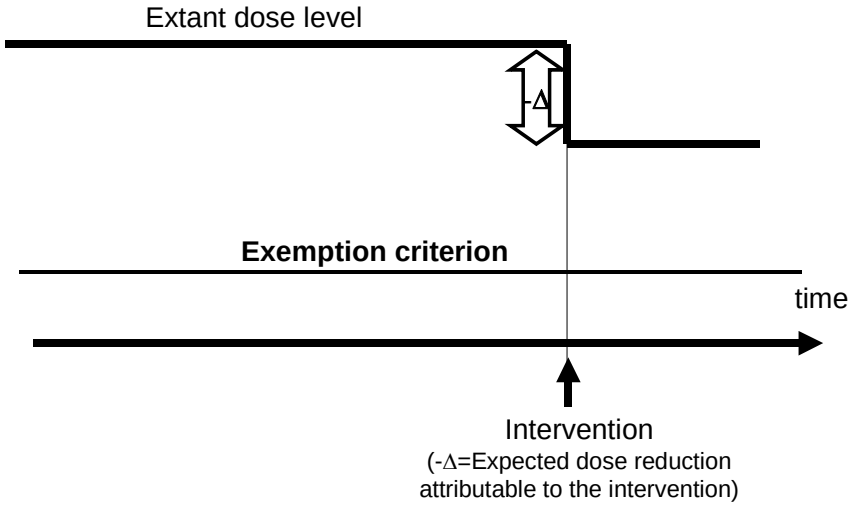

Figure 4

(69) Following the Commission's *Principles for Intervention for Protection of the Public in a Radiological Emergency* [ICRP, 1991b], the BSS established requirements for dose levels at which intervention is expected to be undertaken under any circumstances (see [IAEA 1999], section 3 and Schedule IV) and guidelines for intervention levels and action levels in emergency exposure situations (see [IAEA 1999], Schedule V). It also established guidelines for action levels in chronic exposure situations –mainly to radon (see [IAEA 1999], Schedule VI). The requirements include the establishment of *intervention levels* and *action levels*, expressed in terms of avertable dose (i.e. a protective action is indicated if the dose that can be averted is greater than the corresponding intervention level (see [IAEA 1999, Schedule V, V-1)[47]. These concepts of intervention and action levels could possibly be considered to be 'de facto' exemption criteria, because they imply that protective actions are not required below these levels. Here, it is emphasized again, the concept of exemption does not address the issue of whether an increase in exposure is large enough to warrant regulation but rather whether an existing exposure is low enough for considering intervention to be unjustified under any circumstances.

(70) The Commission addressed again the issue of intervention in its Publication 82 on the *Protection of the Public in Situations of Prolonged Radiation Exposure* [ICRP 1999]. There, the Commission introduced the concept of 'generic reference levels' for dealing with these situations and indicated that a total annual dose towards 100 mSv will almost always justify intervention. Below a total annual dose of around 10 mSv intervention is not likely to be justified, although protective actions to reduce a dominant component of the annual dose are still optional below this level and might be justifiable. The Commission warned that these recommendations should be interpreted with caution and regulatory bodies wishing to establish action levels for these purposes should carefully balance the consequences of the intervention against the benefit in terms of improved radiation protection.

(71) In the same Publication 82 the Commission notes that challenging situations of prolonged exposure include those where high levels of natural background radiation are present and where the exposure is controllable. One such situation is the presence of elevated ambient indoor levels of Rn-222. In its Publication 65, the Commission provides recommendations for controlling prolonged exposure to Rn-222 in dwellings and workplaces. Another case is the presence of natural gamma-emitting radionuclides in building materials, where the Commission recommends that '*Concerned national authorities and, as appropriate, relevant international organisations should derive standardised intervention exemption levels for activity concentrations of specific radionuclides in building materials, taking into account the recommendations for commodities containing radioactive substances presented in this report'*. Both of these situations presents a particular challenge for defining regulatory control. They will be treated separately in Chapter 6.

(72) The Commission's sole specific recommendation on exemption levels for interventional situations relates to intervention for trade in commodities –a topic that will

[47] The concepts and requirements for intervention were developed further in GS-R-2.

also be discussed in detail in Chapter 6. A generic intervention exemption level of around 1 mSv is recommended for the individual annual dose expected from a dominant type of commodity amenable to intervention, such as some building materials. The Commission also recommended that on the basis of this recommendation, concerned national relevant international organizations should derive generic, and radionuclide-specific, intervention exemption levels for individual commodities, in particular for specific building materials.

(73) In the absence of specific recommendations from the Commission, national and international standards have been generally mute on the important issue of regulatory criteria for exemption in interventional situations. While there have been some international agreements established for intervention, particularly in the case of trade of commodities, they do not satisfy the need for internationally recognized exemption levels for interventional situations.

(74) The Commission now wishes to extend its recommendations on exemption for commodities to other interventional situations. The Commission believes that an annual dose of around 1mSv is the lower bound for selection of action levels for interventions and that, therefore, this level would function as a *de facto* exemption level for these circumstances of exposure. As in its previous recommendations on interventions, the Commission wishes to issue a number of warnings. On the one hand, in some situations, particularly in emergency situations, protective actions to reduce a dominant component of the annual dose are still optional below the exemption level of 1mSv in a year and might be justifiable. On the other hand, the value of 1 mSv in a year should not be taken as an automatic trigger for consideration of action levels, as this level can probe impractical for intervening in some specific situations such as radon in dwellings and workplaces. In sum, the exemption level must be chosen with caution and regulatory bodies wishing to establish action levels at these low-dose levels should carefully balance the consequences of the intervention against the benefit in terms of improved radiation protection.

5.6. Outlook: The Use of Exemption

(75) As indicated at the beginning of this Chapter, the Commission first introduced the concept of exemption mainly for use within the context of *practices*. In fact it was introduced fundamentally for exempting *a priori* from regulatory control practices involving limited amounts of 'artificial' radioactive materials. The basic quantitative principles of exemption, including a principle of low individual risk, were developed within this context. The individual principle became a 10 μSv in a year criterion and applied to the exemption of practices. The concept was then extended to the exemption *a posteriori* of radioactive materials already regulated but for which regulation was no longer warranted and therefore could be *cleared* from the regulatory requirements. The 10 μSv in a year criterion was applied to the *clearance* concept, this time taking account of the possibility of bulk amounts of materials to be cleared.

(76) The Commission considers however that the exemption principle of insignificance of individual risk has been distorted into a principle of trivial dose through what seems an inflexible 10 μSv in a year criterion. The Commission underlines that the principle is

broader and refers to unwarranted control due to the insignificance of risk that may include but is not limited to triviality of dose. Moreover, the position proposed now by the Commission is that the criterion for deciding whether or not regulatory controls are warranted has multiple attributes and is situation specific. Namely, it is not determined by dose alone but also includes societal factors involved in determining whether or not it is warranted to control certain exposure situations. So it should not be surprising that different situations may lead to different dose criteria for defining whether or not regulatory control is warranted. For situations involving naturally occurring radioactive materials and for interventional situations, a generic intervention level of around 1mSv in a year seems to be more appropriate.

(77) The large difference between the dose criteria for exempting practices involving artificial radionuclides and those for exempting naturally occurring radioactive materials and interventional situations requires comment because it may attract criticism. Firstly, it should be recalled that the 10 μSv in a year criterion used for practices involving artificial radionuclides represents the average predicted value within an extended distribution of doses. For natural radionuclides the distribution is extremely narrow and in the case of interventional situations the exposures already exist, they are not predicted, and therefore the distribution should be small. However, it can still be argued that a dose is a dose and that the risk to humans incurring such a dose is the same whether the radiation comes from a practice or from another situation. The basic rationale would be that it is the magnitude of the dose to a person that is significant, not its origin. This obvious fact obscures a false premise: that standards of safety should be based on risk (i.e. on individual dose) alone. For instance, the question of whether intervention is justified, and how far to reduce the dose in an intervention, includes consideration of net benefit in particular situations. The Commission has indicated that the *'need, form, scale, and duration of protective actions should be determined on a case-by-case basis, following the principles of justification of intervention and optimisation of the protective actions, rather than through pre-selected individual dose restrictions'*.

(78) The Commission generally endorses the use of exemption levels expressed as activity or activity concentration values, but it also wishes to underline such levels are not directly applicable to situations where the radioactivity is present on the surface area. This suggests an apparent need for additional exemption values for surface contaminated materials in bulk quantities (and even territories) in terms of activity per unit area. The Commission recommends that the international agreements reached on exemption could be extended to cover these situations.

(79) The situations for exemption described in this Chapter are generic in nature, and specific situations may need particular considerations. Behind all the discussion on the use of exemption is the concept of doing what is appropriate according to the circumstances – a graded approach related to the degree of controllability of exposures and a form of optimization of protection. The commonly accepted 10μSv in a year criterion for 'artificial' practices is in fact at one end of the scale; the suggested 1 mSv in a year criterion for natural radionuclides and for interventions is at the other end. But they should not be seen as unique points but rather as indicating a region within which

exemption might be applied. If exemption is the best approach, then it should be used, irrespective of the level of average individual dose. Indeed, if the legislative approach is such that every radiation exposure should be included *a priori* in radiological protection regulations and there is only the possibility of case-by-case exemption, then a dosimetric boundary cannot be the only criterion for exemption.

6. CONSIDERATION OF SOME SPECIFIC SITUATIONS

6.1 Low-energy or – intensity Adventitious Radiation

(80) A large variety of apparatuses and devices generate very low-energy ionizing radiation (usually as X-rays) as an unwanted by-product. These include electron microscopes, electron beam welders, cathode-ray tubes, high-voltage electronic rectifiers and voltage regulators, vacuum switches, vacuum capacitors, magnetrons, klystrons, transmitting tubes, television and image tubes and other electronic devices where electrically charged particles are accelerated or decelerated. This process generates *bremsstrahlung* radiation, i.e., the electromagnetic radiation that is generated by the acceleration or deceleration of the charged particle on passing through the electric and magnetic fields or on interaction with the atoms of surrounding materials. In addition there are numerous consumer products, such as television sets, which generate adventitious ionizing radiation that is not of very low energy but that arise at relatively low intensities. In these situations it is debatable whether radiological protection controls are warranted or whether it is more convenient to exempt these apparatuses and devices from those controls albeit subject to some criteria.

(81) Years ago, in ICRP Publication 3 [ICRP, 1960], the Commission addressed the issue of low-energy and low-intensity radiation emitted by devices and apparatuses as an unwanted by-product[48]. In ICRP Publication 15 [ICRP 1970], the issue was discussed again[49]. At the time, the Commission recognised implicitly that apparatuses emitting ionizing radiation with energies lower than 5 keV and television sets delivering dose rates near the external surface lower that around 5 μSv per hour did not warrant radiation protection control. More recently, the Commission reaffirmed again with added precision

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[48] In ICRP Publication 3, paragraphs 115 and suc., the Commission recommended that: *"All equipment in which electrons are accelerated to an energy in excess of 5 keV shall be regarded as a potential source of ionizing radiations. Such equipment, e.g. electron microscopes, cathode-ray tubes, high-voltage electronic rectifiers, transmitting valves, television and image tubes shall be so constructed, installed and operated, as to provide adequate protection. Whenever practicable, such items of equipment shall be shielded and provided with interlocks so as to ensure that the places where they are used can be regarded as being outside "controlled areas"…Particular attention is drawn to the hazards which may arise during the manufacture, testing and repair of all such equipment. The dose-rate at any readily accessible point 5 cm from the surface of any [television] set used in the home or place where the public is likely to be in close proximity shall not exceed 0.5 mr/h under normal operating conditions. All other television equipment such as those used for projection purposes or in closed-circuit applications shall be shielded and operated in accordance with [the Commission's recommendations]"*.

[49] In ICRP Publication 15, paragraphs 288 and suc., the Commission addressed again the issue and recommended that: *"Items of equipment in which electrons are accelerated to an energy in excess of 5 keV should be regarded as potential sources of ionizing radiations, and appropriate protection measures should be taken unless radiation monitoring or experience with similar equipment indicates them to be unnecessary. Such items as electron microscopes, electron beam welders, cathode-ray tubes, high-voltage electronic rectifiers and voltage regulators, vacuum switches, vacuum capacitors, magnetrons, klystrons, transmitting tubes, television and image tubes are all potential sources of x rays; they should be installed, operated, and, where appropriate, constructed, so as to provide adequate protection for all persons. Attention should be paid to persons who test, service and use such equipment, as well as to members of the public if the equipment is installed in accessible places.…The exposure rate at any position 5 cm from any outer surface of domestic-type television sets and of television equipment used for projection purposes, closed-circuit applications and the like shall not exceed 0.5 mR/h ..."*.

its previous recommendations. In ICRP Publication 36 [ICRP, 1982], the Commission indicated that: *"It is convenient to distinguish apparatuses that produce x rays by design from electrical devices that are sources of unwanted x rays. The former include x-ray sets for analysis, radiography and irradiation. The latter include a number of low-pressure high-voltage devices in which accelerated electrons impinge on matter, examples being discharge tubes, cathode-ray tubes, microwave oscillators and amplifiers, as well as electron microscopes. External irradiation is the main hazard in both cases and it can be particularly serious for unshielded equipment…It is recommended that the dose-equivalent rate 5 cm from the surface of the enclosure should not exceed 5 μSv h^{-1} at the maximum operating conditions of the set. This may be achieved by shielding in the manner described elsewhere by the Commission… Any device in which electrons are accelerated by a potential difference greater than 5 kV should be regarded as a possible source of unwanted x rays. Such sources should therefore be carefully examined, and when required the recommendations made [by the Commission] for x-ray apparatus should be applied with any necessary adaptations."* [50]

(82) These recommendations were, in essence, adopted in international standards as exemption criteria. The BSS establish that, under the general criteria for exemption, *"the following sources within practices are automatically exempted without further consideration from the requirements of the* [BSS], *including those for notification, registration or licensing:… any electronic tube, such as a cathode ray tube for the display of visual images, provided that they do not cause in normal operating conditions an ambient dose equivalent rate or a directional dose equivalent rate, as appropriate, exceeding 1 μSv h^{-1} at a distance of 0.1 m from any accessible surface of the apparatus or the maximum energy of the radiation produced is no greater than 5 keV."*[51] These criteria were naturally extended to apparatuses and devices containing radioactive substances not otherwise exempted, provided that: they were of a type approved by the Regulatory Authority, the radioactive substances were in the form of sealed sources that effectively prevent any contact with radioactive substances or their leakage, and in normal operating conditions they would not cause an ambient dose equivalent rate or a directional dose equivalent rate, as appropriate, exceeding around 1 μSv h^{-1} at a distance of 0.1 m from any accessible surface of the apparatus.

(83) The Commission continues to reaffirm that apparatuses and devices that generate adventitious ionizing radiation under the conditions described in the current international standards should be exempted from radiological protection controls.

6.2. Cosmic Rays

(84) In ICRP Publication 60 [ICRP, 1991], the Commission recommended that cosmic rays at the earth's surface should be excluded from regulations. The recommendation was followed by international standards, which identified exposure '*from cosmic radiation at*

[50] ICRP Publication 36, paragraphs 61, 62 and 67.
[51] See BSS, Schedule 1, I-4 (b)

the surface of the earth' as an example of excluded exposures[52]. In this report, the Commission confirms this position.

(85) The international approach to exposures to cosmic rays above the earth's surface has been more ambiguous. The most common situation is added exposure of passengers and aircrew while flying; the exceptional situation is exposure of astronauts in space flights. The typical radiation level at flying altitude is around 5μSv h^{-1} for flights over polar latitudes and around half that on equatorial flights. With these levels of exposure it is estimated that frequent flyers and crew would incur an annual mean doses of 4-5 mSv to 1-2 mSv depending whether they are long-haul or short-haul [Maxwell 2006]. The levels of exposure in space are very high and irregular.

(86) The regulatory approach to these cosmic ray exposure situations has been uneven. In ICRP Publication 60 [ICRP, 1991], the Commission recommended that exposures to cosmic rays be part of occupational exposure in the operation of jet aircraft and space flight. Thus, it recommended that all flying individuals who are likely to cross the 1 mSv threshold should be classified as occupationally exposed. The Commission subsequently modified this recommendation in ICRP Publication 75 [ICRP, 1997], indicating that it is not necessary to treat the exposure of frequent-flyer business passengers as occupationally exposed for the purpose of control –essentially only aircrew should be considered. At that time, the Commission already noted that the only practical regulatory measures were controlling flying time and route selection. Some national regulations require monitoring of aircrew exposures and others set a limit of 6 mSv above which their work schedule must be adjusted, but they are generally mute for non-crew flyers.

(87) Regulation of cosmic ray exposure in air travel would necessitate important interferences, such as intrusion in life style and, for aircraft operation, restriction of the flying time and rostering of exposed people. These types of disruptions may possibly be considered of an infeasible nature. Flying time of aircrew and frequent flyers is already subject to control, among other motives for reasons of fatigue. Moreover, for reasons other than radiation exposure, it is common practice to transfer pregnant aircrew and business flyers to duties that do not require flying, which should ensure adequate protection of the foetus in pregnant flyers. The Commission considers, therefore, that there seems to be no obvious reason to introduce regulatory controls for common exposure situations to cosmic rays above the earth surface but recognizes that national authorities may wish to monitor these situations until more information becomes available. Exceptional cases of cosmic ray exposures, such as exposure in space travel, where doses may be significant and some type of control warranted, should be dealt with separately taking into account the special type of situations that can give rise to this type of exposure.

(88) The Commission, in summary, continues to recommend that cosmic radiation at ground level need not be included in radiological protection regulations and may therefore be considered by legislators for exclusion from relevant legislation. In addition, exposure to cosmic rays at altitudes above ground level may be considered as a candidate

[52] See BSS, footnote 2

for either exclusion from legislation or generic exemption from most regulatory requirements, depending on the legislative system and national arrangements in place.

6.3. Use of Materials Containing Radionuclides of Natural Origin

(89) As discussed in Section 3, radiological protection regulations have until now focused largely, if not exclusively, on exposures from human endeavours making use of artificial radiation sources. The concept of exemption in particular was mainly developed for those situations. Industrial activities involving bulk quantities of materials containing radionuclides of natural origin have been regulated unevenly. Some of these industries, such as the mining and milling of uranium and thorium, have generally been regulated with the systems used for artificial sources. Conversely, in others of these industries the presence of radiation exposure has been largely ignored. Examples include: the production of mineral sand products, phosphoric acid from phosphate rock, and some metals (e.g., tin); the oil industry, with its sub-product of radioactive scales; the use of natural building materials containing natural radionuclides; and, surprisingly, the generation of non-nuclear energy from combustibles such as coal that may leave radioactive ashes as a radioactive residue of environmental significance. It should be noted that the presence of radioactivity in these types of industry is adventitious, i.e., incidental to the use to which the material is being put.

(90) The Commission's recommendations strengthened the idea that, in principle, such industrial activities may be candidates for regulation. In some cases, the radiation doses attributable to these activities may be similar in magnitude to those attributable to normal operations of nuclear installations. Moreover, these industries may produce radioactive byproducts, waste and residues containing higher levels of radioactivity than those currently considered appropriate for exemption.

(91) These situations present differences from practices involving artificial radionuclides where the concept of dose triviality has mainly been used to decide on the extent of regulatory involvement. The industries and processes have often been operating for many years and may predate systems of radiological protection that were introduced, at least initially, for protection against artificial radionuclides. The possibility of significant changes in exposure rates, in particular, an increase, may be automatically limited by a number of factors including plant throughput, the natural upper bound on the activity concentration of the raw material, and conventional occupational standards controlling, for instance, the concentrations of airborne dusts.

(92) One approach for dealing with radiological protection regulations for these industries would be to exclude some level of naturally radioactive materials from regulation on the basis of unamenability to control. Another approach follows from a decision that specified industries, based on the nature of the process or the activity concentration of the material that they use or produce, should be subject to regulation, i.e. that they constitute a *practice* proper in the context of the Commission's system of protection. In such cases, a provision for generic exemption from regulatory requirements may be useful, but the conditions for such exemption would need to be defined on the

basis that no control is the optimum radiological protection solution rather than the concept of triviality of additional individual dose, i.e., the 10 μSv in a year criterion that is used for exemption of 'artificial' practices. In cases where regulation is considered necessary, a graded approach should be used, taking account of the potential risks to people. For example, where the risks due to radiation are low and where the source or practice is inherently safe, a notification by the operator or owner to the regulatory body that the practice exists might be sufficient.

(93) In ICRP Publication 75 [ICRP, 1997], the Commission provided some guidance on exposure to naturally occurring radionuclides. Noting that levels of uranium-238 and thorium-232 in the environment are generally of the order of 40 Bq kg^{-1} with a variation of an order of magnitude or so higher, the Commission felt that it would be reasonable to consider that such materials might be excluded from control. It recommended that regulatory agencies choose activity concentrations of parent radionuclides within the range of 1000-10000 Bq kg^{-1} to determine whether the exposures from these materials should be subjected to regulatory control.

(94) As discussed before, the Commission feels that national regulators may profit from the recent international agreements on radiological criteria on commodities. Thus, they might consider establishing either exclusion levels or generic exemption levels for naturally occurring non-edible materials of around 1000 Bq kg^{-1} for materials containing radionuclides from the primordial chains and of around 10000 Bq kg^{-1} for materials containing potassium-40. Industries handling naturally occurring radioactive materials with activities (in all the processes) not higher than these values could be either excluded by the legislator from the radiological protection legislation or exempted by the regulator from the regulatory requirements of notification and authorization. It should be noted that such levels would be coherent with the 1mSv in a year criterion discussed before. An exception to these generic criteria should be made for naturally occurring radioactive materials that are used as building materials, an issue that is discussed in the following section.

(95) Exclusion or generic exemption of situations involving naturally occurring radioactive material on the basis of activity concentration (1000 or 10 000 Bq·kg^{-1}, as appropriate), while being a useful approach for eliminating a large number of practices from unnecessary regulation, will not in itself identify all situations for which regulatory control is not warranted. For some practices involving materials with activity concentrations exceeding these values, even by large amounts, the optimum regulatory option may still be not to apply regulatory requirements to the legal person responsible for the material. In situations where the activity concentration values are exceeded, therefore, the regulatory body, before automatically imposing regulatory requirements, needs to decide whether to exempt on a case-by-case basis. The most appropriate basis for such a decision would be an approach based on dose. From the foregoing discussion, it is evident that a dose of 1 mSv per annum could serve as a suitable criterion for case by case exemption in such situations (and has indeed already received a substantial degree of international acceptance), especially as this also happens to be the maximum dose likely

to be received as a consequence of the above-mentioned activity concentration values for exclusion or generic exemption [IAEA, 2004 (b)].

6.3.1. Building Materials

(96) The use of building materials rich in gamma-emitting primordial radionuclides may cause substantial exposures to those inhabiting dwellings built with these products. In many parts of world, this type of building material has been used over generations. The main products of concern are building stones, concrete, plaster and industrial by-products and residues used as ballast in building materials. The background levels in rocks from the ^{238}U and ^{232}Th series and ^{40}K make similar contributions to the externally incident gamma radiation as the median concentrations of ^{238}U, ^{232}Th and ^{40}K in the earth's crust, and are typically around 35, 30 and 400 Bq/kg respectively. Typical activity concentrations in other building material such as concrete are also relatively close to those of the earth's crust with values of about 40, 30, and 400 for ^{226}Ra[53], ^{232}Th and ^{40}K respectively [EU 1999].

(97) Natural building stones are made from different types of material. The radionuclide content is lowest in basic rocks of magmatic origin. Also marbles, limestone and various detrital sedimentary rocks contain only small amounts of natural radionuclides. Higher concentrations are generally found in acid magmatic rocks, especially in late-magmatic granites, and in some metamorphic rocks. The use of these building materials is mostly used for floors and therefore assessment of exposure should be based on scenarios where the material is used in a typical way.

(98) Concrete is one of the most commonly used building materials. The variation of natural radionuclide concentrations in concrete depends on ballast materials and additives. Commonly used ballast materials are sand, gravel, macadam and shingle, which normally do not enhance the radioactive content of the concrete. There are, however, also other ballast materials used, such as pumice stone with a high ^{226}Ra concentration, and granite with a high ^{40}K concentration, and these ballast materials do enhance the radioactive content of the concrete. Aerated, or lightweight, concrete consists mainly of the same materials as ordinary concrete, but a small quantity of aluminum powder is added in order to create the cell structure in the final product. Alum-shale, which has been used in the past as ballast material in ordinary and aerated concrete, has a particularly high ^{226}Ra concentration (up to 4500 Bq/kg).

(99) The use of industrial by-products and residues as ballast for building material is increasing for economical and environmental reasons. Most commonly used materials are fly-ash (from coal and peat burning), blast furnace slag and phosphogypsum. These materials may have enhanced concentrations of natural radionuclides, because of concentration during the manufacturing process. For instance, coal ash from coal-fired power stations (both, fly ash and bottom ash combined), which is radioactive because of the presence of primordial radionuclides in the coal, has been used widely around the

[53] In the uranium-238 series, the decay chain segment starting from radium-226 is radiologically the most important and, therefore, reference is often made to radium instead of uranium.

world. More than 280 million tonnes of coal ash are produced annually, of which about 40 million tonnes are used in the production of bricks and cement and a great deal as floor-materials stabilizer and asphalt mix. Some large users of coal ash as filling materials are not included in these figures: for instance, it is reported that in China, in 1996, when the raw coal output was about 1400 million tonnes, the production of coal ash amounted 329.6 million tonnes of which 141 million tonnes were used in the production of building materials including cement [Pan 1999].

(100) Although the radiation doses attributable to the use of materials containing radionuclides of natural origin in building construction are not well known, the average worldwide exposure for this cause has been estimated to be around 0.4 mSv/y, with a typical range of 0.3-0.6 mSv/y [UNSCEAR 2000], while it is recognised that residents can incur annual doses of up to several mSv. Annual doses approaching 10 mSv have been reported in houses in Europe with outside walls containing uraniferous alum shale and also coal slag. In at least one major Asian city, exposures due to the use in house construction of shine-bottom deposits collected from areas through which underground water from hot springs in travertine is flowing is reported to deliver annual doses up to well above 100 mSv.

(101) The Commission would therefore wish to take some exception on the suggested exemption levels for controlling naturally occurring radioactive material if they can be used as a building product. It recommends that building components containing naturally occurring radioactive materials should not be excluded from the legislation nor granted a generic exemption without a careful analysis of the radiological implications of such decision. The issue has been recently discussed at an international consultancy to draft an international safety guide [IAEA 2005]. The consultancy, comprising of experts from a number of countries that are deeply involved in this matter, concluded that regulatory authorities should ensure that annual doses are restricted to a few mSv in the worst-case scenarios. The internationally agreed exemption levels for radionuclides in non-edible commodities (in IAEA Safety Guide RS-G-1.7) taken individually would meet such criteria[54], provided that the following activity concentration equation is used to ensure that the annual dose criteria is met:

$$\frac{C_{K}}{10Bq/g}+\frac{C_{Ra}}{1Bq/g}+\frac{C_{Th}}{1Bq/g}\leq 1$$

where C_K, C_{Ra} and C_{Th} are the concentrations in Bq/g of potassium-40, radium-226 and thorium-232[55]. However it is warned that, in applying this condition, the regulatory authority should consider whether additional restrictions need to be placed on the activity concentration of Ra-226 in order to control the dose from radon[56] (see next section).

[54] Although some situations especially in the case of building materials having a high concentration of several natural radionuclides (not restricted by [IAEA 2004b] may result in doses up to 15 mSv.

[55] The proposed approach does not deviate significantly from the values in [EU 1999], in the case where activity concentrations presented in the index are accepted independently. Fluctuations in dose calculation of the most stringent scenario are related to the subtraction of background and redistribution of the fractions of the three radionuclides.

[56] The exhalation rate of radon from building materials will be influenced not only by the physical characteristics of the material itself but also by national building practices. As a general guideline, the indoor concentration of radon derived from building materials should not exceed the national action level set for radon in indoor air in homes.

(102) The Commission is following with interest all these new developments on the crucial issue of controlling building goods containing natural occurring radioactive materials. It continues to encourage the collection of factual information of the levels of exposure at dwellings built with this type of product. Given the information available, it provisionally endorses the calculation of exemption levels on the base of a weighted summation the activity concentrations of ^{226}Ra, ^{232}Th and ^{40}K with a formula such as the inequality above.

6.4. Radon

6.4.1. A Significant Radiation Source

(103) The naturally radioactive noble gas radon is ubiquitous in all terrestrial materials. Three radioactive isotopes of radon occur naturally in the environment: radon-222, radon-220 and radon-219. Radon-219 has a half-life of 4 seconds and is derived from the natural radioactive series headed by uranium-235. Radon-220, more normally referred to as *thoron*, has a half-life of 55 seconds and is derived from the natural radioactive series headed by thorium-232. Radon-222, more generally referred to as *radon*, has a half-life of 3.82 days and is derived from the natural radioactive series headed by uranium-238. Because of its short half-life and the normally low concentrations of uranium-235 in soils, the radiation dose from exposure to radon-219 is negligible and therefore not of radiological concern. The same applies to thoron, with the exception of situations where buildings are constructed using materials with a high concentration of thorium-232 (see previous section). Radon, because its half-life is long enough to allow it to accumulate in the environment and as uranium-238 can be present in relatively high concentrations in soils, is potentially a source of significant radiation exposure. Radon atoms are released (by recoil when they decay) from the solid matrix of natural materials and migrate into the air. They decay into isotopes of other elements, the atoms of which attach themselves to the condensation nuclei and dust particles present in air.

(104) Confined spaces selected by humans as dwellings, especially those bound by radon-emitting materials and/or located on radon emitting ground, are prone to having enhanced concentrations of radon in the air; examples range from the caves used by primitive humans to the stone and brick dwellings of modern humans. The use of natural gas for cooking has also enhanced exposure to radon in homes, because natural gas may contain significant amounts of radon. More recently, the insulation of houses to improve the efficiency of heating has exacerbated the problem. Extreme concentrations of radon and its progeny in buildings have been reported as locally occurring maximum values in several countries, with levels as high as 100,000 Bq/m^3. These levels can cause exposures up to two orders of magnitude higher than those in areas with ‘typically elevated exposures’, leading to annual doses of up to several hundred millisieverts.

(105) While these extreme radon concentrations are in most cases being reduced by remediation, it is indisputable that high levels of radon can occur in dwellings and workplaces making it a significant source of human exposure. In fact, UNSCEAR has

estimated that radon is the most important contributor to human exposure – which is mainly caused by inhalation of the short-lived decay products, and their subsequent deposition along the walls of the various airways of the bronchial tree of the lungs [UNSCEAR, 2000]. Because of its significance, the Commission has given great attention to the issue of human exposure to radon and provided detailed advice on protection against radon exposure in ICRP Publication 65 [ICRP, 1993].

6.4.2. The Development of Recommendations on Radon

(106) The underlying theme of the Commission's recommendations on radon is the controllability of exposure. They identify the circumstances under which exposure to radon in workplaces may need to be subject to the Commission's system of protection for practices and where the need for action against exposure to radon in dwellings should be considered. Already in ICRP Publication 60 [ICRP, 1991], the Commission had recommended the use of *action levels* for initiating intervention "*…to help in deciding when to require or advise remedial action in existing dwellings*"[57]. In ICRP Publication 65 [ICRP, 1993], the Commission further refined the concept of action levels for radon in dwellings and indicated that *"an action level is needed to define workplaces…in which intervention should be undertaken to reduce radon exposures*"[58], where such action level will define "*the workplaces in which the Commission's system of protection for practices should be applied to radon exposures, with other workplace not being subject to this system*" [i.e., being exempted from it][59]. Thus, the Commission recommended: "*It seems clear that some remedial measures against radon in dwellings are almost always justified above a continued annual effective dose of 10 mSv. For simple remedial measures, a somewhat lower figure could be considered, but a reduction by a factor of five or ten would reduce the action level to a value below the dose from natural background sources. The choice of action level for annual effective dose is thus limited to the range of about 3-10 mSv. The Commission recommends that the action level should be set within this range by the appropriate authorities. The corresponding rounded value of radon concentration is about 200-600 Bq* m^{-3}*, with an annual occupancy of 7000 hours and an equilibrium factor of 0.4. Continuous domestic exposures at average concentrations of 200 Bq* m^{-3} *and 600 Bq* m^{-3} *would imply annual exposures [to radon gas of 1.4 MBq h* m^{-3} *and 4.2 MBq h* m^{-3}*, respectively, and to radon progeny of 3.11 mJ h* m^{-3} *and 9.33 mJ h* m^{-3}*, respectively]…Workers who are not regarded as being occupationally exposed to radiation are usually treated in the same way as members of the public. It is then logical to adopt an action level for intervention in workplaces at the same level of effective dose as the action level for dwellings. The action levels for intervention in workplaces can be most easily derived from the range of action levels for dwellings by multiplying by 7000/2000 (the ratio of the occupancy) and by 3.88/5.06 (the ratio of the dose conversion coefficients). The resulting range (rounded) is 500-1500 Bq per* m^3*. When selecting action levels for dwellings and workplaces, authorities should choose values that are similarly located within the two ranges. In some mines, the equilibrium factor may be significantly different from 0.4. National authorities may then wish to use a different*

[57] ICRP Publication 60, paragraphs 216-218.
[58] The Commission defined *action level* for radon as *the concentration of radon at which intervention is recommended to reduce the exposure in a dwelling or workplace*. (see ICRP Publication 65 – Definitions)
[59] ICRP Publication 65, paragraph 83

action level in terms of radon concentration in such mines."[60] The international standards generally followed these Commission recommendations and established that "*Optimized action levels relating to chronic exposure involving radon in dwellings should, in most situations, fall within a yearly average concentration of 200 to 600 Bq/m^3 of 222Rn in air… The action level for remedial action relating to chronic exposure situations involving radon in workplaces is a yearly average concentration of 1000 Bq of 222Rn per cubic meter of air*"[61]. Since the Commission's latest recommendations on radon, several epidemiological studies have confirmed the risk of radon exposure even at relatively moderate concentrations. These studied have generally validated the Commission recommendations on protection against radon. However, UNSCEAR is currently reassessing its estimates on radon [UNSCEAR, 2005]. The Commission is following the issue of protection to radon closely and eventually could revisit its recommendations and if justifiable suggest changes in the range of action levels. This may influence, but not substantially, the quantitative recommendations on regulatory scope for radon described hereinafter.

6.4.3. The Controllability of Radon Exposures

(107) Exposure to radon is usually controllable and new isolation techniques have made radon control even simpler. Impermeable barriers beneath the floor slab of dwellings have been used to diminish radon entrance. Construction of a radon sump that could be activated if radon levels are found is another common technique for controlling radon concentration indoors. The incorporation of radon control requirements into national building and construction codes is becoming a common practice.

(108) However, while the control of radon is normally straightforward, in practice situations arise involving low radon concentrations that are less amenable to control. It is not clear that any universal concentration value could be considered as indicating a level below which control is unwarranted. Radon concentrations in dwellings and workplaces differ widely around the world, *inter alia* because of differences in geology and climate, in construction materials and techniques, and – significantly – in domestic customs. This situation makes difficult international harmonization of regulatory approaches for defining amenability of control of radon, as it depends so much on local circumstances: sometimes radon is easy to control, sometimes control is practically unfeasible. Perhaps because of all these reasons the Commission did not address in the past explicitly the issue of whether exposure to radon below a given concentration has to be considered unamenable to control, and therefore subject to exclusion from radiological protection legislation.

6.4.4. Excluding Radon Exposures Situations

(109) The Commission now considers that it would be convenient to define some concentration value of radon below which the exposure could be internationally considered to be excluded from legislation. While, as indicated above, this definition is

[60] ICRP Publication 65, paragraphs 72, 73 and 86

[61] See BSS, Schedule VI

not simple, it is recalled that typical outdoor radon long-term average concentrations have been reported to be 1 to 100 Bq m^{-3} [UNSCEAR 1993]. Typical concentrations are several tens of Bq m^{-3}, with an arithmetic mean of the worldwide distribution of 10 Bq m^{-3} outdoors and 40 Bq m^{-3} indoors [UNSCEAR, 2000]. As for the case of cosmic rays at ground level, it would seem to be impractical to consider controlling exposure to radon at these normal ambient levels.

Kommentar [AM2]: The text is inconsistent throughout on the format of units, should it be Bq/m^3 or Bq m^{-3} ?

(110) Therefore, following a reasoning parallel to the case of cosmic rays at ground level, the Commission recommends that an activity concentration of radon below 40 Bq/m^3 may be regarded as unamenable to control and could therefore be used as an exclusion level specific for situations of ambient exposure to this radionuclide. This level could therefore be considered for exclusion from legislation or, according to the national arrangements, granted a generic exemption from regulatory requirements.

6.4.5. Exempting Radon Exposure Situations

(111) Once the legislator has established the levels of radon that are not excluded from legislation, it still remains for the regulator to decide whether it is warranted to control radon exposure in a particular situation or whether it is more convenient to exempt the situation from regulatory requirements. Again this would depend very much on local situations including the applicable social and economic conditions. It will very much depend also on whether the situation is subject to regulatory action or not. If the radon situation is not regulated, there is no identifiable person to whom the exemption may apply. Many occupational exposure situations to radon are subject to regulations, e.g. mining activities, but many others are not, for instance domestic workers in houses are generally not subject to occupational radiological protection regulations even if the house environment is rich in radon. Regulation of public exposure to radon is even more rare. Few countries have enforced building codes where radon concentration is considered but even this cannot be considered a radiological protection regulation *per se* as there is not a registrant or licensee to whom exemption could apply.

(112) As indicated before, however, regulatory authorities are expected to select 'action levels', for both dwellings and workplaces, from ranges recommended by the Commission. At such action level the undertaking of remedial measures for radon in dwellings and workplaces should be considered to be generically warranted. The lower value in the range could be considered a *de facto* exemption level, because below this value protective measures were not considered to be warranted in a generic sense.

(113) ***The case of Dwellings*:** The range of 200-600 Bq m^{-3} for selecting 'action levels' for radon in dwellings recommended in ICRP Publication 65 [ICRP, 1993] was adopted in the BSS [IAEA 1996]. The upper-bound value of 600 Bq m^{-3} is expected to be used by national authorities as an upper-bound for selecting an action level at which remedial action should be taken under any circumstances. Conversely, the lower-bound value of 200 Bq m^{-3} defines the lower level for the national action level. Below this level therefore any situation of exposure to radon in dwellings can be expected to be a candidate for a *de facto* exemption. Under the current standardized conversion factor this level would

correspond to an individual dose of few mSv per annum, a level compatible with the l mSv criterion suggested for naturally occurring radioactive material. It is emphasized that the level of 600 Bq m^{-3} is the international upper bound for the selection of an optimized national rather than international action level. Thus, the national action level is expected to be between 200 Bq m^{-3} and 600 Bq m^{-3}, and national authorities may monitor to find homes above the action level and eventually to require remedial actions. Below the national action level the authorities are not expected to intervene. Thus the establishment of a lower number has little practical significance, except that, depending of national practice, an exclusion level of 40 Bq m^{-3} could be established to keep radon exposure situations out from legislation and an international minimum exemption level of 200 Bq m^{-3} could also be referenced as the lower level for which control deems to be internationally warranted. This lower exemption number would become a *de facto* exclusion level and would only be useful as an international reference. Therefore, there is little practical use for levels lower than the national action level other that perhaps to screen homes; but, it should be underlined that the exclusion concept is not related with screening areas and a value of 40 Bq m^{-3} as a basis for screening would be impractical, and that usually here are national criteria to determine 'radon prone' areas. Under the above provisos, the Commission recommends, in addition to the exclusion level of 40 Bq m^{-3}, a minimum exemption level of 200 Bq m^{-3} for exposure situations to radon in dwellings.

(114) ***The case of Workplaces*:** For radon in workplaces, the range recommended in ICRP Publication 65 [ICRP, 1993] within which the national action level could be selected is 500-1500 Bq m^{-3}. For any situation, the value of 1500 Bq m^{-3} recommended by the Commission is an upper-bound for selecting an occupational action level for radon. Conversely, the lower-value of 500 Bq m^{-3}, which corresponds to the same levels of dose as the 200 Bq m^{-3} for dwellings, could be considered as a *de facto* exemption level because below that level no protective actions are required. However, it is to be noted that, in the interest of international harmonization of occupational safety standards, a single value of 1000 Bq m^{-3} was established in the BSS. For the same reasons, the Commission considers that this internationally established value might be used globally to define the action level for occupational exposure situations to radon. In fact, this international action level of 1000 Bq m^{-3} serves *interalia* for a much needed globally harmonized monitoring and record-keeping system. This is relevant for determining when the occupational radiological protection requirements apply - i.e. what is actually included within the system of regulatory control. Thus, in international practice the workplace has to be monitored to find whether it is over 1000 Bq m^{-3}. As in the case of dwellings, below the national action level the authorities are not expected to intervene. Thus the establishment of a lower number has little practical significance, except that, depending of national practice, an exclusion level of 40 Bq m^{-3} could be established to keep radon exposure situations out from legislation and an international minimum exemption level of 500 Bq m^{-3} could also be referenced as the lower level for which control deems to be internationally warranted. This lower exemption number would become a *de facto* exclusion level and would only be useful as an international reference. Under the above provisos, the Commission recommends, in addition to the exclusion

level of 40 Bq m^{-3}, a minimum exemption level of 500 Bq m^{-3} for exposure situations to radon in underlying that the international standardized value is 1000 Bq m^{-3}.

(115) In summary, depending on the diverse national legal and regulatory practices for controlling radon, either the Commission's recommended exclusion level of 40 Bq m^{-3} and minimum exemption levels of 200 Bq m^{-3} (dwellings) and 500 Bq m^{-3} (workplace) are used (with action levels being chosen at some value equal to or higher than the exemption levels), or the national action levels or the internationally standarized occupational action level of 1000 Bq m^{-3} are treated as *de facto* exclusion levels or generic exemption levels.

6.5. Commodities

(116) Produce that can generally be used or consumed by the public, such as foodstuffs, building materials, as well as other consumer products, can have incorporated radioactive materials. How to regulate these products, which would be generally termed *commodities* in this report, has become an international challenge. The Commission considered the issue of regulating commodities in ICRP Publication 60 [ICRP, 1991].[62]

(117) Usually, natural radionuclides are present in commodities as a result of natural processes and deliver exposures that are essentially unamenable to control. However, radionuclides from both natural and artificial origins may also be present in commodities as a direct result of human activities. For instance, they may have been incorporated as a result of the operation of practices, or as result of radioactive residues from the decommissioning of the practice or, from exempted materials that are cleared for recycling and released into the market. The levels of radionuclides in commodities attributable to the operation of practices should conceptually be controlled through the principles of the *system of radiological protection for practices*, including the criteria for exemption of practices. However, as described previously, radionuclides may also be incorporated into commodities from an environment with a high contect of natural radionuclides or which is contaminated with radioactive residues from past activities or events, or even from accidents. This is the more pervasive process of incorporation of radioactivity into commodities and the method of control should be through the *system of radiological protection for intervention*. But the Commission's system of radiological protection for practices and interventions may be unsuitable in practice to help in solving practical situations of radionuclides in commodities: in fact, mainly due to the globalisation of markets, intervention exemption levels of radionuclides in commodities cannot be established on a case-by-case basis; rather, they need to be standardised.

(118) In ICRP Publication 82 [ICRP, 1999], the Commission recommended,…"*a generic intervention exemption level of around 1 mSv…for the* [maximum] *individual*

[62] In ICRP Publication 60, paragraph 284, the Commission stated that: *'To avoid unnecessary restrictions in international trade, especially in foodstuffs, it may be necessary, in this context, to apply derived intervention levels [that] indicate a line of demarcation between freely permitted exports or imports and those that should be the subject of special decisions. Any restrictions applied to goods below the intervention levels, better called intervention exemption levels for this purpose, should be regarded as artificial barriers to trade. Trade in materials above an intervention exemption level should not automatically be prohibited, but such materials might be subject to temporary controls. Intervention exemption levels used in this way in international trade should not necessarily have the same quantitative values as the intervention levels used for initiating action in other circumstances.'*

annual dose expected from a dominant type of commodity amenable to intervention, such as some building materials...". The Commission also stated that "*concerned national and, as appropriate, relevant international organizations should derive generic, and radionuclide-specific, intervention exemption levels for individual commodities."* The Commission however cautioned, "*The recommended generic intervention exemption level should be used with care. For instance, there are commodities that are, in given situations, irreplaceable and essential for materials containing radionuclides of natural original living, such as some basic building materials and foodstuffs. Other commodities, such as a number of consumer products, may be considered superfluous. It is not appropriate to use the same criteria for these different situations. In addition, it should be recalled that international and national guidance exists on exemption for individual consumer products, usually expressed in terms of an annual dose of a few hundredths of a millisievert.*" Moreover, the Commission underlined that: "*Intervention exemption levels should not be used, either explicitly or implicitly, for relaxing the limits imposed on the activity of radionuclides that may be released from practices. In particular, they should not be used for clearing the recycling of materials resulting from the decommissioning of practices (these situations are better handled with the criteria of exemption for practices)* [63].

(119) Legislators and regulators could judge trade in commodities containing small amounts of radionuclides as a 'practice' or as an 'intervention'. Trade is a human activity that may cause an increase exposure, so it fits the usual regulatory definition of a practice to be regulated. However, trade is not conventionally thought of as a practice, and indeed the Commission has treated it in the context of intervention. If regulators treat the problem as an intervention they may wish to drop the term exemption from 'intervention exemption level' and just use 'intervention level'. In this case it is the regulatory body that is intervening and without its intervention the trade would continue without any regulatory requirements being applied. Obviously, the regulatory body cannot exempt itself from intervening. Therefore, there seems to have been a degeneracy of concept in the use of the term intervention exemption level, rather like a double negative. If there is just one boundary in the 'regulation space' – below it no restrictions, above it specified controls – then this double-barrelled label that seems to come at the one level from opposite directions is probably not needed. Intervention level may be sufficient because it defines the level above which intervention takes place; that is, above which requirements may be placed on the trader. Regulatory concepts and terminology are difficult enough without making them unnecessarily tortuous and complex, but some regulators may wish to continue to use the term 'intervention exemption level', while clearly explaining that it is a level below which the person responsible for the trade is exempted from applying any controls otherwise required by the regulatory body following its intervention. As it can be seen below, the term preferred internationally has been simply '*radiological criteria in commodities*'.

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[63] In ICRP Publication 82 [ICRP, 1999], the Commission then stated… [thus]…"*it would be illogical to allow the annual dose components attributable to commodities and amenable to intervention even to approach* [the recommended] *level. Natural background exposure causes annual doses of at least a few millisieverts per annum and, taking account of possible annual doses from authorized practices, this leaves an upper bound of the order of a few millisieverts per annum for the annual doses from all commodities to be exempted from intervention. It is not likely that several types of commodities would be simultaneous sources of high exposure to any given individual."*

(120) Following the Commission's advice on commodities, the policy-making organs of the IAEA tackled the issue. The IAEA General Conference decided that the IAEA, in collaboration with the competent organs of the United Nations and with the specialized agencies concerned, should develop *"radiological criteria for long-lived radionuclides in commodities, particularly foodstuffs and wood"*[64]. After a large number of consultations, which included consultations with the Commission, in September 2004 the IAEA policy-making organs [IAEA, 2004 (a)] approved a final resolution on radiological criteria for radionuclides in commodities. The established levels for non-edibles commodities were issued in an international safety guide on the application of the concepts of exclusion, exemption and clearance [IAEA, 2004 (b)], which provides values of activity concentration of radionuclides (both natural and artificial) in bulk amounts of materials that would be applicable to international trade.[65] They can also be used for the purposes of exclusion[66]; exemption[67]; and clearance[68]. A graded approach consistent with the requirement of optimization of protection would be applied[69] in the event of values exceeding the values prescribed. It is to be noted that the values for activity concentration in non-edible commodities, which have been agreed internationally, are not limited to 'artificial' radionuclides but include 'natural' radionuclides as well. The value for the radionuclides in the primordial chains (headed by ^{238}U, ^{235}U and ^{232}Th) is l000 Bq kg^{-1} and for potassium-40 is 10000 Bq kg^{-1}.

(121) Similarly, the FAO/WHO Codex Alimentarius Commission[70] (CAC) has developed levels for artificial and natural radionuclides in foodstuffs. [Codex Alimentarius, 1991] [Codex Alimentarius, 2004]

(122) At the same time the World Health Organization (WHO), has developed specific guidance levels for radionuclides in drinking-water. The levels have been established in the third edition of the WHO's Guidelines for Drinking-Water Quality[71] [WHO, 2004].

(123) The Commission has been following the above-described developments of international radiological criteria on commodities, noting that they establish *de facto* exclusion levels of activity or radionuclide concentration for any material at about 1 Bq kg^{-1} for α emitting radionuclides and at about 10 Bq kg^{-1} for β and γ emitting radionuclides. Observing that such levels are minute and difficult to monitor, the Commission consider that they can therefore be taken to be unamenable to control in

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[64] Resolution GC(44)/RES/15.
[65] IAEA Safety Standards: Safety Guide RS-G-1.7 (http://www-ns.iaea.org/downloads/drafts/ds161.pdf).
[66] See BSS, paragraph 1.4.
[67] See BSS, paragraphs 2.17 and 2.18, and Schedule I – particularly sentence (d) in footnote 36
[68] See BSS, paragraph 2.19
[69] See BSS, paragraph 2.8
[70] The Codex Alimentarius Commmission is a body of the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) charged with developing the *Codex Alimentarius*, or the food code, which has become the seminal global reference point for consumers, food producers and processors, national food control agencies and the international food trade. Both FAO and WHO cosponsor the BSS. The Codex Alimentarius provides the basis for the BSS generic action levels of radioactivity for foodstuffs.
[71] WHO published the first edition of *Guidelines for drinking-water quality* in 1984 and 1985. In 1993, a second edition was published. The third edition of the Guidelines has been recently approved. (See http://www.who.int/water_sanitation_health/dwq/gdwq3_9.pdf)

practice. The Commission also notes that the international agreements establish much higher values, which are radionuclide-related, for generic and universal exemption.

(124) Furthermore, the Commission notes that according to these international agreements, non-edible naturally occurring radioactive materials may be generically exempted when the activities are as high as l000 Bq kg^{-1} for any of the radionuclides of the primordial chains and 10000 Bq kg^{-1} for potassium-40, in spite of the fact that under some hypothetical scenarios relatively high individual doses can be attributable to exposure to those materials. These levels may in fact be considered to be excluded from legislation for any practical purpose, except in the case of building materials that may require special treatment (see earlier).

(125) The Commission now considers that these international agreements provide a good basis of a generic and universal nature for recommending exemption levels for radionucleides in commodities. They are applicable for radioactivity concentration in non-edible materials, in foodstuff and in drinking water, for both artificial and natural radionuclides.

6.5.1. Exempting Commodities in the Aftermath of an Emergency

(126) In its recommendations on radiological protection in prolonged exposure situations in ICRP Publication 82 [ICRP, 1999] and in the aftermath of a terrorist attack in ICRP Publication 96 [ICRP, 2005], the Commission addressed the issue of large amount of materials, including foodstuff and water, remaining contaminated in the event of a radiological emergency. The Commission recognized that the internationally agreed radiological criteria for commodities described above would provide an adequate level of protection in such event. Furthermore, in ICRP Publication 82 [ICRP, 1999], the Commission recommended how to deal with commodities that are produced in an area affected by the emergency, which present a particularly difficult situation. If the corresponding activity levels are higher than those in produce from neighboring areas, issues of market acceptance could arise, particularly if there are trans-boundary movements of the commodities. The Commission continues to consider that if the annual doses in the area affected by the accident are acceptable because the intervention strategy has been optimized, the situation outside the affected area will also be acceptable because the individual annual doses elsewhere from the use of commodities produced in the affected area would materials containing radionuclides of natural originally not be higher than those in the affected area. However, the production of commodities in areas affected by an emergency could commence some years after the event; this possibility should be considered in any intervention strategy applied after the event. If the restrictions on commodities produced in the area affected by an emergency have not been lifted, production of the restricted commodities should not be restarted; conversely, if the restrictions have been lifted, production can be restarted. If an increase in production is proposed, it could proceed subject to appropriate justification. In circumstances where restrictions have been lifted as part of a decision to return to normal living, the resumption and potential increase of production in the affected area should have been considered as part of that decision and should not require further consideration.

6.6. Low-level Radioactive Waste

(127) Any beneficial practices involving the use of radioactive materials obviously give rise to *radioactive waste* that, by definition, should be viewed as one aspect of the practice. Radioactive waste is the term formally used to mean radioactive material in gaseous, liquid or solid form for which no further use is foreseen. Waste disposal is the term used to describe the discarding of waste with no intention of retrieval, which usually covers the discharge of effluents and the disposal of solid waste. The whole sequence of operations starting with the generation of waste and ending with disposal is usually termed waste management. Radioactive waste management should be placed in the context of the management of society's waste in general. The Joint Convention for the Safety of Spent Fuel Management and Radioactive Waste Management provide the international regulatory framework for safe waste management that has been accepted by the parties to that convention [IAEA, 2003].

(128) The management and disposal of low-level radioactive waste has been linked to the issue of the scope of radiological protection regulations for the simple reason exempted wastes and residues cannot have a regulated management and disposal. The Commission continues to believe that controlled releases of radioactive materials from approved practices are governed by authorization of discharges and the overall management of radioactive waste should be governed by specific regulations following the specific Commission recommendations [ICRP, 1985 (b) and 1998]. However, the Commission also believe that when the condition for exemption within the system, or clearance, has been achieved, the materials for which control can be relinquished should not be considered for radioactive waste management anymore. They can be either recycled or treated as conventional wastes.

7. DEFINING RADIOLOGICAL PROTECTION REGULATIONS

(129) Within the context described in the previous Sections, the Commission has re-examined both of its previous recommendations related to the scope of regulatory instruments for radiological protection. Furthermore, the Commission has reviewed the fundamental principles of exclusion and exemption and the international agreements reached on this subject under the aegis of international intergovernmental organizations. On the basis of the discussion in this report, the Commission provides below its recommendations for defining the scope of radiological protection regulations.

(130) The Commission’s overall position on the issue of regulatory scope continues to be that radiological protection regulations need not be established to cover exposure situations that are deemed to be unamenable to control. Moreover, provided that every individual is afforded an acceptable level of protection, regulatory requirements may be relinquished if they are unwarranted because the societal efforts needed for their application are deemed to be disproportionate to the saving in radiation detriment they

would achieve[72]. Such regulations and requirements would be deemed to be unjustified and the protection provided by them would probably not be optimal.

(131) The main concepts for achieving the above position continue to be the *exclusion* from radiological protection legislation of those radiation exposure situations that *cannot* be regulated and the *exemption* from the full system of regulations of those non-excluded situations that *need not* be regulated. These concepts are ethically valid, as they are entirely consistent with principles of good governance: governments have obligations not to allow societal resources to be squandered on unproductive legislation and fruitless regulatory control and not to limit individual freedoms unnecessarily. The concepts can be considered a conceptual variant of the Commission's generic principle of justification – the continuing need to do more good than harm in decisions involving radiation exposures – and to support the principle of optimization of protection when applied to regulatory control.

(132) Thus the above-described Commission's position covers both the criterion of unamenability to control that has traditionally been used for *exclusion* from the legislation, and the criterion of unwarranted control that has usually been sought for *exemption* from regulatory requirements. While the Commission considers these criteria interlinked with the legal doctrine of *de minimis non curat lex* and *de minimis non curat praetor*, it prefers not to become involved in the legal mechanisms that jurisdictions employ to give effect to the intent of legislation. This is because diverse cultural approaches exist to regulatory control. Some national cultures are prone to include as many situations as possible within the scope of the legislation and even of regulatory control, perhaps because regulatory bodies may feel they might otherwise lack regulatory instruments to deal with situations that arise and they would like to control but that have been declared to be beyond the reach of the law. Conversely, other cultures seem more pragmatic about regulatory control and feel they could deal with situations as they arise, with provisions subject to a due process of appeal against flawed judgements by the regulatory body[73]. Thus, it is not the intention of the Commission to recommend to legislators and regulators how to phrase radiological protection legislation or regulations. Instead, its recommendations focus on the definition of technical boundaries between what should be regulated and what may not and leave to national preferences the mechanisms through which controls are applied or not applied.

(133) The determination of generic and universal technical boundaries for defining regulatory scope would involve societal value judgements of a universal nature and it is obvious that is difficult for the Commission to recommend absolute answers. However, where there is international consensus, such as those described in this report, it is useful to provide generic guidance for the purposes of international standardization. An indication of international consensus can be inferred from the global adoption by most

[72] In this context, 'societal efforts' includes all relevant efforts and expenditure of resources, both by the regulator and the regulated, together with any other burden borne by society or opportunity foregone in applying the controls; 'detriment' is a generic term meaning a composite of all measures of harm connected with the agent being regulated, such as exposure to radiation and risk of accidental exposure.

[73] One fairly common legal strategy in these cultures is the 'exception' or 'get-out' clause, which appears in a form similar to: 'Notwithstanding any of the above, (the regulator) may… if it has a need to do so'.

countries of the world not only of the current Commission's recommendations but also of international standards and other intergovernmental agreements derived from such recommendations. While this can be considered somewhat self-referential, it is nonetheless a fact that most national standards for regulatory control of radiation are essentially consistent with the Commission's recommendations and with the international requirements derived from them.

7.1. Exclusion from Legislation

(134) The Commission recommends that legislative systems for purposes of radiological protection may exclude situations of radiation exposure to:

- cosmic radiation at ground level;
- radionuclides that are natural constituents of the human body, such as potassium-40;
- substances containing an activity concentration of less than around 1 Bq per kilogram for α emitting radionuclides and around 10 Bq per kilogram for β and γ emitting radionuclides both of artificial origin;
- radon in ambient air with activity concentration below 40 Bq m^{-3}; and
- any other radiation exposure situations that be considered to be unamenable to control by any reasonable means.

7.2. Exemption from Regulatory Control

(135) The Commission also recommends that the legislative framework should in addition provide for exemption of radiation exposure situations for which regulation is considered unwarranted. However, exemption should not be granted to exposure situations that are deemed to be unjustifiable, such as the deliberate incorporation of radioactive substances in food, beverages, cosmetics or any other commodity or product intended for ingestion, inhalation or percutaneous intake by, or application to, a human being, and the frivolous use of radioactive substances in products such as toys and personal jewellery or adornments. Moreover, potential exposure situations where the exposure may be uncertain but, if it occurs, significant cannot be exempted.

(136) Exposure situations to cosmic radiation above ground level are obvious candidates for exemption. There are extraordinary situations, for instance in space travel, where cosmic radiation doses may be substantial. While these extreme situations may need to be covered by regulatory instruments it is not obvious what those instruments could effectively do to control the exposure.

(137) While the criteria for exemption are basically decisions of national regulators to be taken on a case-by-case basis, the Commission wishes to suggest the universal use of the generic criteria that have been developed by international intergovernmental organizations and which seem to be commonly accepted. This would promote a much-needed international consistency in matter of regulatory scope.

(138) Taking into account the ubiquity of naturally occurring radioactive material and the international agreements reached on whether to control these materials, legislators may provide either for empowering regulators to establish a generic regulatory exemption for such materials, or depending of national practice for their straightforward exclusion from legislative instruments. The conditions for such generic exemption would be that the activity concentrations of the radionuclides in the primordial uranium and thorium series should be lower than around 1000 Bq kg^{-1} and of potassium-40 lower than around 10000 Bq kg^{-1}. However, building materials may warrant a more restrictive consideration of the sum of the activity concentrations of uranium-238, thorium-232 and potassium-40.

(139) While exposure situations to ambient radon are not generally subjected to a regulatory process, and the concept of exemption in this case is more elusive, the Commission suggests that exemption can be considered for ambient radon (i) in dwellings provided that the time-averaged radon concentration does not exceed a minimum value of 200 Bq m^{-3} and (ii) in workplaces provided that the time-averaged radon concentration does not exceed a minimum value of 500 Bq m^{-3}.

(140) The Commission notes the international agreements reached on radiological criteria for foodstuff and drinking water under the aegis ofthe Codex Alimentarious Commission [Codex Alimentarius, 2004] and the World Health Organization [WHO, 2004] and considers that foodstuff and drinking-water containing radionuclides in activity concentrations smaller than those specified in thise agreements may be considered as candidates for automatic exemption from regulatory requirements, including those for notification, registration or licensing and subsequent inspection.

(141) The Commission considers that exemption of situations involving exposure to non-edible radioactive materials can be established on the basis of the activity or activity concentration in these materials. The Commission notes the various international agreements reached on radiological criteria for these materials and consider that such situations may be considered as candidates for automatic exemption from regulatory requirements, including those for notification, registration or licensing and subsequent inspection, under the following conditions:

- the activity, at any one time, of material in a practice, should not exceed the values specified in the BSS (see [IAEA, 1996], Schedule 1, Table I-1), or
- the activity concentration in materials in a practice in amounts of 1 ton or less should not exceed the values specified in the BSS (see [IAEA, 1996] Schedule 1, Table I-1); while in transport, the activity of material should not exceed the values specified in the Transport Regulations [IAEA, 2004 (c)], or the radioactivity concentration of materials in transport irrespective of their amount should not exceed the values specified in the Transport Regulations [IAEA, 2004 (c)], or
- the activity concentration in materials, irrespective of their amount, in a practice or for unrestricted release from a practice shall not exceed the values specified in the guidance on *Application of the Concepts of Exclusion, Exemption and Clearance* [IAEA, 2004 (b)] and established in the Resolution GC(44)/RES/15 of the IAEA General Conference [IAEA, 2004 (a)].

(142) The necessary condition for exemption is that either the activity or the activity concentration in the materials does not exceed the applicable value. For mixtures of radionuclides other than ^{40}K and those in the decay chains headed by ^{238}U, ^{235}U or ^{232}Th, the applicable value of activity or activity concentration may be determined as follows:

$$X_m = \frac{1}{\sum_i \frac{f(i)}{X(i)}}$$

where *f(i)* is the fraction of activity or activity concentration of radionuclide *i* in the mixture, *X(i)* is the activity or activity concentration value for the radionuclide *i* given in the references in paraghraph (139), and X_m is the derived value of the activity or activity concentration for exemption. For mixtures of ^{40}K and/or radionuclides in the decay chains headed by ^{238}U, ^{235}U or ^{232}Th, the necessary condition for exemption is that, for each radionuclide, either the activity or activity concentration does not exceed the applicable value.

(143) Deliberate dilution of material (as opposed to the dilution that takes place in normal operations when radioactivity is not a consideration) to meet the recommended values of activity concentration given should not be permitted without the prior approval of the regulatory authorities. The Commission notes that while the recommended approach for management of radioactive waste is the treatment, reduction in volume, and containment of radionuclides, for some types of waste, however, dilution may be the optimum regulatory option. For instance, dilution of waste from minerals processing operations, in which the only radionuclides in significant concentrations are ^{40}K or those in the decay chains headed by ^{238}U, ^{235}U or ^{232}Th, may be permitted on the grounds that this is nothing more than re-establishing the original natural concentration of the ore.

(144) The Commission also recommends that the following sources of exposure may be considered as candidates for a generic exemption of universal application:

- Apparatuses and devices emitting adventitious radiation, which are of a type approved by the Regulatory Authority and which meet the following criteria: they do not cause in original operating conditions an ambient dose equivalent rate or a directional dose equivalent rate, as appropriate, exceeding around 1 μSv h^{-1}, at a distance of 0.1 m from any accessible surface of the apparatus; or, the maximum energy of the emitted radiation is no greater than around 5 keV.
- Apparatuses and devices containing radioactive substances, which are of a type approved by the Regulatory Authority and are not otherwise exempted provided that: the radioactive substances are in the form of sealed sources that effectively prevent any contact with radioactive substances or their leakage; and, in normal operating conditions, they do not cause an ambient dose equivalent rate or a directional dose equivalent rate, as appropriate, exceeding around 1 μSv h^{-1} at a distance of 0.1 m from any accessible surface of the apparatus.

(145) Regulatory authorities may wish still to keep in force some requirements for the notification, and in some cases even for the registration, of specific sources complying

with the criteria for exemption described in this report. Such decisions are a matter for national legal practice.

(146) Exposure to any discharge of radioactive material into the environment, if it is duly authorized by the competent authority and complies with the requirements of the Commission's system of radiological protection, need not be subject to further control.

(147) Separate recommendations may be needed for sources causing rare circumstances of exposure, such as from radioactive releases and residues in the aftermath of accidents or acts of war or terrorism involving radiation exposure. Moreover, the levels above may be unnecessarily restrictive in some situations. Regulators always have the option to exempt at higher levels if they judge that by exempting a source of exposure its radiological protection would be optimised.

7.3. Concluding Reflections

(148) Whether the legislative principles of *de minimis non curat lex* or 'exclusion', or *de minimis non curat prætor* or 'exemption' are used to give legal effect to the various components of the recommendations in this report depends on national regulatory and legal practice. The Commission is sensitive to the fact that throughout the world there are different legislative cultures that are the origin of diverse regulatory approaches. The concept of defining what is 'controllable' up front through a system of defined scope is certainly consistent with international standards, but it need not be the only approach, and indeed it may well be unacceptable to some countries. Thus, while the Commission recognises the mechanisms of exclusion and exemption for determining regulatory scope, it is careful about being categorical on their use by national authorities. The Commission wishes to stress that the controllability of radiation exposure is an issue that can be addressed on a situation-by-situation basis and through the principle of optimization of protection, but also points out that the quantitative recommendations in this report can be used to solve in practice the problem of defining the scope of radiological protection regulations.

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