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Practical Applications of Exemption

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Abstract. The concept of exemption has been widely used in radiological protection. It is part of the regulator's arsenal for applying legislative requirements in a graded fashion, to avoid the expenditure of effort on situations where the return in terms of improvement in protection would otherwise be trivial. Nevertheless, it still remains a controversial matter. Perhaps somewhat surprisingly, it is not so much the dosimetric criteria for exemption that cause debate; it is more the way in which the concept is used; the scenarios employed to calculate derived activity concentrations, and its relationship to the somewhat analogous concept of exclusion. Much of the debate regarding the use of the concept and its relationship with exclusion finds its origin in the national legislative culture that has developed over the years in various countries and the inevitable resistance to keep pace with the evolution of the system of radiological protection as recommended by the International Commission on Radiological Protection and implemented through the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources. A particular problem has been the full integration into the legislative system of protection of exposures to radiation from sources of natural origin and the degree to which exemption is a relevant concept for dealing with such situations. The purpose of this paper is to attempt to provide some clarity on the two concepts and their practical implementation with a view to encouraging international harmonization and avoiding further unnecessary debate.

1. Introduction

The concept of exemption is invaluable in the legislation or regulation of exposure to ionizing radiation. Its overall purpose is to avoid regulatory attention being given to certain 'practices', when such attention would produce little or no benefit in terms of protection. A related concept is that of exclusion, from which the concept of exemption should be clearly distinguished. It is however related to it in the sense that its purpose is also to avoid unnecessary regulatory attention and it is often a matter of national choice over which is the more appropriate concept to use in any particular circumstance. Nevertheless, it is important to retain the distinction because the concepts operate in fundamentally different ways. Exclusion generally operates *a priori*; it provides an input in determining the scope of any particular set of legislative requirements, but once the scope has been defined and the legislative requirements made, it serves no further purpose[1]. Exemptions may also be established *a priori* and defined in a particular set of legislative requirements. However, provided there is provision for the regulator to grant exemptions in the legislation, they may also be issued *a posteriori*. But in both cases, they are part of the regulator's arsenal for implementing the regulatory requirements in a graded sense.

In the next few paragraphs, these differences between the two concepts are described in fuller detail. The paper then discusses the scope of legislative or regulatory control and the practical application of the concept of exemption within the legislative framework. While it is recognized that other approaches to regulating exposures to radiation may be feasible and are being discussed, the approach followed here will be based on the system of radiological protection as recommended by the

[1] There are even exceptions to this in that the regulator may be given discretionary powers to exclude particular exposures or situations. An example of this is the Euratom Directive [1], which defines radioactive substance as '*any substance that contains one or more radionuclides the activity or concentration of which cannot be disregarded as far as radiation protection is concerned*'. Those countries that have adopted this formulation into their legislative requirements have, in relation to radioactive substances, effectively given the regulator the ability to define the boundaries of those requirements.

International Commission on Radiological Protection given in Publication 60 [2] and further explained in Publication 82 [3] and implemented through the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources [4].

2. The concepts

2.1. Exemption

Exempt means to release or excuse from an obligation. It has no value unless it is clear to whom the exemption applies and the obligation from which the person is exempted. Often, the term is used in the context of a legal or administrative obligation - for example, an obligation to pay a certain tax or to undertake military service – and, only then is it useful to me personally if I know that I satisfy whatever conditions apply.

In radiological protection, exemption is a term that is widely used in a legislative or regulatory context and relates to the exemption of a person or organization from the legislative or regulatory obligations[2] that would otherwise apply. As with taxes or military service, the exemption only applies to me if I meet the specified conditions, and, by implication, if I break or no longer meet those conditions, I will no longer be exempt from the obligations. So there is a need to comply with certain requirements, and, in principle, the regulator may well wish to check and enforce compliance with those requirements.

The fact that exemption applies to persons is often overlooked; for example, the term 'exempt product' can result in confusion, when what is meant, in fact, is that persons otherwise affected by the legislation are exempt from the specified requirements with respect to that product.

There may be various legitimate reasons why a regulator would wish to exempt someone from one or more legislative requirement. In radiological protection, exemption is usually used in the context of regulated 'practices'[3] and, it is in that context that the term will be used here. Such exemptions relate to situations where the administrative requirements of the legislation - particularly notification and authorization - would achieve little in terms of protection, or put another way, when, without provision for them, the amount of regulatory attention might well be out of proportion to what might otherwise be achieved. Exemption thus provides benefit for the regulator and the regulated since both are released from unnecessary administrative burden. In a world with limited resources, provision for exemption within the legislative arrangements is clearly sensible, not only in radiological protection, but also in many other situations. These days, there is some reluctance to talk about balancing of costs and benefits of particular actions, but in the context of legislative control, this is entirely reasonable. In that sense, exemption is then simply a mechanism for reflecting whether through any reasonable regulatory action the exposure from a particular practice is amenable[4] to control. Amenability to control in this context should therefore be regarded as a relative, rather than an absolute, matter and one involving judgement.

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[2] In the rest of this paper, the word 'legislation' will be used to means laws, regulations, etc., as appropriate. 'Legislative' will be used as the corresponding adjective.

[3] The word 'practice' is used with the meaning given to it by the International Commission on Radiological Protection (ICRP) [2] and adopted by the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources [3], i.e. '*any human activity that introduces additional sources of exposure or exposure pathways or extends exposure to additional people or modifies the network of exposure pathways from existing sources, so as to increase the exposure or the likelihood of exposure of people or the number of people exposed*'.

[4] The phrase 'amenable to control' or 'amenability to control' has sometimes been misunderstood. Amenable means in this context responsive – responding readily to - or tractable – easily handled, manageable. Decisions as to what is amenable to control therefore require judgement since 'readily' and 'easily' are relative concepts. Similarly, unamenability to control is also a relative matter. Amenability to control should also be equated to 'controllability'.

The obvious criterion for permitting exemption in radiological protection legislation is on the basis of the magnitude of the expected doses from the practice, including those that might be received from accidents and misuse. When the risk can be regarded as trivial, then exemption would be appropriate. It is this criterion, which makes it difficult to apply to natural sources of exposure.

2.2. Exclusion

Exclusion, put in its bluntest form, means 'shut out'. It can relate to a person or a thing, but the matter from which the person or thing is excluded needs to be specified. For example, I may be excluded from a particular meeting; alternatively, a certain topic may be excluded from the agenda of that meeting. Usually, the reason for the exclusion will be apparent; for example, the meeting may be confidential in nature or the topic may not be pertinent to the main theme of the meeting, that is, it would be out of the scope of that meeting.

Scope however is a broader matter than exclusion, although exclusion should be regarded as *one mechanism*, although not a necessary one, for defining the boundaries of legislation. Such boundaries can also be established in a more positive fashion by defining what is actually within the scope of the legislation. Often the choice of mechanism for defining scope will depend on the approach adopted by the lawyers and the national legislative culture that exists.

As a simple example in radiological protection, the protection of workers would be out of scope of legislation that is specifically aimed at the protection of patients, because, presumably that particular area of protection is covered in some separate piece of legislation. Similarly, the legislation may be specifically concerned with placing obligations on persons responsible for businesses rather than on members of the public. The way this scope is expressed is often a matter of choice by the drafting lawyers.

The 'things' that come within scope of legislation are generally covered by the term 'practice' as defined by the International Commission on Radiological Protection (ICRP) [2], although there is no obligation as such for those drafting the legislation to use that term. This term is simply defined as human activities that increase the overall exposure to radiation. The origin of the concept of 'practice' can be traced back to earlier ICRP recommendations [5,6], although Publication 60 [2] was the first occasion when it was explicitly used.

In the early days of radiological protection, the focus of attention was essentially on man's activities; uses of extracted radium and x-rays. The advent of nuclear power and the ready availability of radionuclides of artificial origin for a wide range of activities in the middle part of the last century caused attention to encompass the production and use of these radionuclides as well. Indeed, the extracted radionuclides of natural origin and x-rays, radionuclides of artificial origin became the main focus of attention.

When I first entered radiological protection in the 1970s, there was considerable debate as to whether adventitious exposures from radiation of natural origin should be the focus of any attention other than for the purpose of providing a useful yardstick for comparison with exposures from sources that were subject to regulatory control. It was only when the high exposures from radon in some buildings were found and there was a realization that something could be done relatively easily to reduce them that a progressive change in this thinking occurred and a questioning attitude developed regarding the possibility of affecting the exposures from other sources of natural origin [see, for example, 7]. The concept of controllability of the exposure being the motivation behind the introduction of controls with respect to natural sources of exposure can be found in earlier publications of the Commission [see for example, 8].

There also was recognition that it was not entirely logical to focus on 'practices'[5], given the assumption of linearity of dose and effect used as the basis for radiological protection [3]. This progression in thinking – from controlling what clearly fell under the definition of a practice, to controlling what was controllable - however has not taken place uniformly throughout the world, and, as a consequence, unlike the situation with exemption, international agreement has been hard to achieve, because it is a relative rather than an absolute matter (i.e. no single value of risk or dose can be used). In particular, there is so far no unequivocal numerical international guidance on exclusion, although, amenability to control was established as the basis for exclusion [4].

Thus, there has been this overall increasing recognition during the last two decades or so that radiological protection should consider all sources of exposure and focus protective actions on all those that are amenable to control, not just those resulting from deliberate acts of man where exposure to radiation is an integral part. However, while it is relatively straightforward to draft legislative requirements that are directed at controlling exposures from x-rays, extracted radionuclides such as the isotopes of radium, uranium and thorium, and radionuclides of artificial origin – all of which involve deliberate human acts of which exposure is an integral part and also are generally regarded as 'practices' - it is less straightforward to define when adventitious exposures to radiation of natural origin should be subject to control, or put the other way round, when such exposures should be excluded from the system of control.

The essential criterion for determining whether such exposures should be excluded from or included within the legislative system is their amenability to control, or controllability. This concept of controllability has come to the fore during the discussions that have taken place over the review and revision of ICRP's recommendations as ICRP has attempted to rationalize further its system of radiological protection [10]. While amenability to control is also behind the concept of exemption, it operates in a somewhat different way in the case of radiation exposures of natural origin. Here, consideration has to be given to the magnitude of the problem and the ease with which exposures can be reduced. Certainly, trivial risk or dose can no longer be the basis for decision.

It is perhaps less well recognized that exclusion may also be a concept that needs to be applied to radionuclides of artificial origin. Due to past practices, such radionuclides are widespread in the environment, albeit generally at very low levels, as a consequence of past practices or accidents. Such low levels should also be excluded from the scope of legislative requirements.

2.3. Overview

The ICRP has used both terms 'exemption' and 'exclusion' in its Publication 60 [2]. However, these terms were not fully defined until Publication 82 [3]. In this document, exemption '*refers to exempting [sources] from compliance with some specific regulatory requirement, such as the requirement to notify, register or license a source*'. It applies to persons undertaking 'practices' that are covered by radiological protection legislation. It is used with this meaning in the International Basic Safety Standards for the Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS) [4]. Exclusion as used by ICRP [3] '*refers to [exposures] not being regulated because they are either uncontrollable or unamenable to control*'. It is also used with this meaning in the BSS, which specifically defines the word 'excluded' as 'outside the scope of the Standards' [4]. A useful collation of ICRP statements taken from Publication 82 [3] is given in the Annex.

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[5] ICRP Publication 60 seems to require a binary decision – either practice or intervention – in order to determine which protection measures apply. The problem has to be solved at its roots by not requiring a separation into practice and intervention [9]. As recognized in ICRP Publication 65 with radon exposure in the workplace, although an action level implies intervention, in practice, workplaces with levels above should be treated under the principles of protection for practices. This clearly indicated the limitations of the term 'practice' to describe all situations that should be subject to routine legislative control.

The BSS also state ‘any exposure whose magnitude or likelihood is essentially unamenable to control through the requirements of the Standards is deemed to be excluded from the Standards. But the fact that there has not been total clarity regarding these terms earlier has meant that the different approaches have been established in many countries, which had made the achievement of consensus now very difficult.

Both terms – exemption and exclusion – have a similar objective, which is to avoid unnecessary attention by the regulator, or rather to limit his/her attention to those areas where something might be achieved through regulatory control. But they function at different stages and the basic criteria to be used to determine what should be exempt or excluded will not be the same. The former operates within the legislative arrangement, although some of the situations that may be exempted may well be defined *a priori*. The latter, on the other hand, can be fundamental to the definition of the scope of the legislative requirements.

While recognizing that exempt strictly relates to people subject to the legislative requirements and also the term exclusion can be related to people, I will focus in this paper on the application of the concepts to ‘things’ – sources and exposures - that should be subject to regulatory control. It is first necessary though to discuss the scope of legislative controls, which may involve the use of the concept of exclusion.

Figure 1 illustrates the overall process in which these concepts contribute.

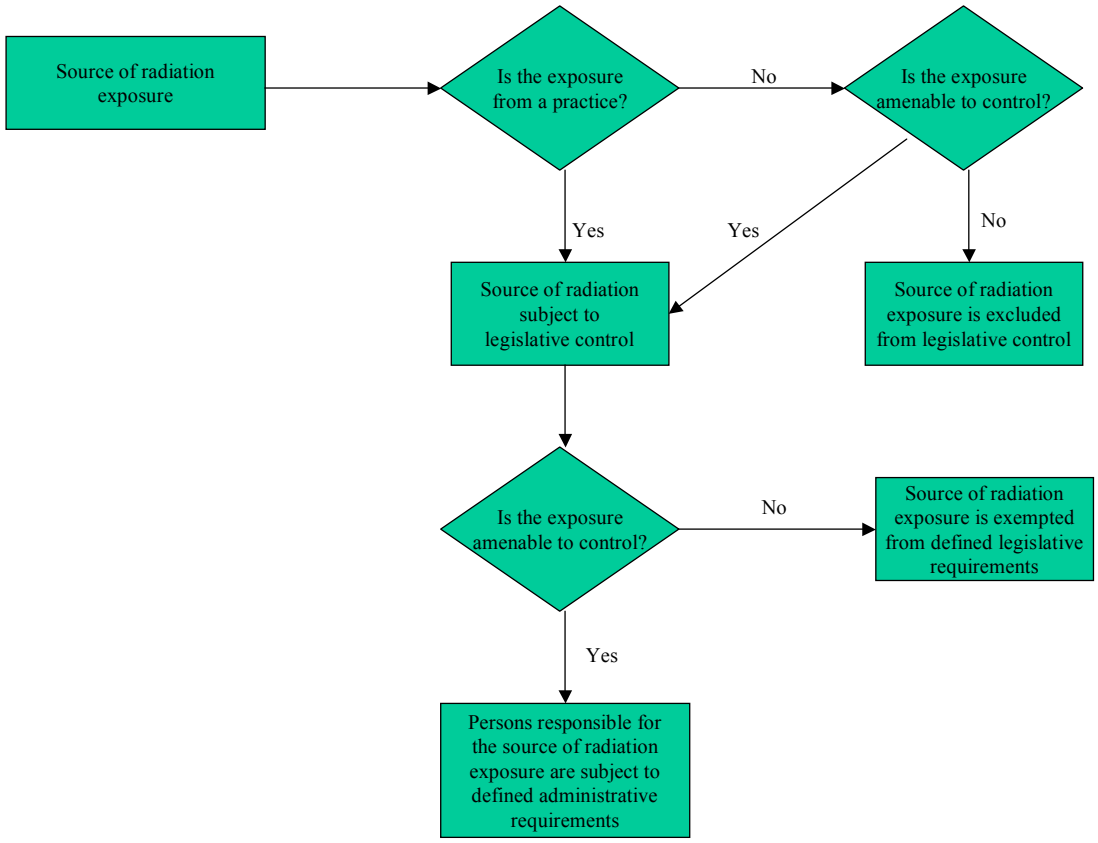

FIG.1. *Application of the concepts of exclusion and exemption*.

3. Scope of legislative controls

One approach to regulatory control is to make the legislation all encompassing, explicitly or implicitly. An advantage is that the regulator then has wide powers to deal with any situation to which he/she feels that attention should be directed. Furthermore, there would be no need for a priori decisions regarding what should be excluded.

This all-encompassing approach would appear, at least at first sight to be the approach is used the Euratom Directive laying down the basic safety standards for the protection of the health of workers and the general public against the dangers of ionizing radiation [1][6]. The first IAEA Basic Safety Standards published in 1962 [11], also does not make explicit use of the concept of exclusion. It states, under scope, that '*these standards shall be applied to the production, processing, handling, use, storage and transport of natural and artificially produced sources*'. However, it states, also under scope, that '*these standards shall not be applied to operations exempted from notification, registration or licensing under 5.1.14.*' One of the provisions of paragraph 5.1.1.4. relates to '*operations which do not involve the use of radioactive substances at a concentration exceeding 0.002 μCi* g^{-1} *or solid natural radioactive substances at a concentration exceeding 0.01 μCi* g^{-1}. So, even though the term 'exclusion' is not used in either of these documents, the concept, as it is understood above, was used in both; the former, implicitly, because it leaves the matter to the regulator to determine what activity concentration '*cannot be disregarded as far as radiation protection is concerned*'; the second more explicitly since the standards indicate that they do not apply to what is exempted from the administrative requirements. Clearly the scope for confusion is great and it is no wonder that it has been difficult to reach consensus on the matter.

In this paper, however, use will be made of the concept of exclusion consistent with the approach contained in the BSS [4] and given in ICRP Publication 82 [3].

The term 'practice', as introduced in ICRP Publication 60 [2] and used in the BSS [4], covered those areas of primary concern – the extraction and use of radionuclides of natural origin, activities involving radionuclides of artificial origin and activities resulting in exposure to x-rays. It is generally accepted that these should fall within the scope of legislative controls and therefore they will not be discussed further here. As we have seen, practices are however only one type of situation that is amenable to control; some exposures particularly from natural sources of radiation are amenable to control and, when this is the case, they should come within the scope of legislative requirements. Exclusion is a concept that is used for identifying those exposures that are not amenable to control, and conversely identify those exposures that should come within the scope of legislative requirements.

3.1. Natural sources of exposure

In the context of occupational protection, ICRP recommended that the principles of protection for practices might also be applied to those situations involving exposure to natural sources of radiation that could reasonably be regarded as the responsibility of the operating management [2]. It identified four situations where there should be a requirement to include exposures to natural sources as part of occupational exposures, namely:

(a) Operations in workplaces where the regulatory agency has declared that radon needs attention and have identified the relevant workplaces;
(b) Operations with and storage of materials not usually regarded as radioactive, but which contain significant traces of natural radionuclides and which have been identified by the regulatory agency;
(c) Operations of jet aircraft;
(d) Space flight.

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[6] See footnote 1.

Specifically in the context of exposure to radon in the workplace (case (a)), ICRP recommended that, because there is some exposure in all workplaces, it would not be appropriate to require the use of a formal system of separate decisions to exempt each individual workplace where controls are not needed. Rather, it would be appropriate to make use of a general system of exclusion. At the time, ICRP did not give any quantified specifications for this, recognising that considerable knowledge and judgement would be required to define such a system. However, it subsequently developed quantitative guidance to help in making that judgement [12].

The BSS [4] only explicitly cover occupational exposure to radon, although there is provision for the regulator to specify other exposures it considers should be subject to control.

Apart from space flight which only affects a very few individuals, each one of the categories of exposure identified by ICRP will be discussed in turn below.

3.1.1. The case of radon

The naturally radioactive noble gas radon (^{222}Rn)[7] is present in the air outdoors and in all buildings, including workplaces. It is thus an inescapable source of radiation exposure both at home and at work. High levels in air can occur in buildings, including workplaces, in some geographical locations. This applies particularly in workplaces such as underground mines, natural caves, tunnels, medical treatment areas in spa, and water supply facilities where ground water with high radon concentrations is treated or stored. In guidance given by ICRP in its Publication 65 [12], controllability of exposure is the underlying theme. It uses the concept of 'action level' to define both when a particular situation should be considered for intervention and when it should be treated under the requirements for practices.

Thus ICRP has already taken a position with respect to the amenability to control of radon in workplaces; a range of activity concentrations of 500-1500 Bq m^{-3} was selected for workplaces within which national authorities should select an action level. This activity concentration range implies annual effective doses in the range of 3-10 mSv. A single activity concentration of 1000 Bq m^{-3} is given in the BSS [4], which is approximately equivalent to an annual effective dose of 6 mSv. In this context, it is noted that the worldwide average radon concentration indoors is of the order of a tenth or less of these values, so clearly, the levels have been selected at the upper end of the distribution of indoor activity concentrations of radon.

Some confusion can arise because of the use of the term 'action level'. In reality, if intervention is unsuccessful in reducing the levels below the selected action level, this level then serves as a means of defining the scope of the requirements, and, for this purpose, the term 'action level' would no longer be appropriate; it has a conceptually different purpose from that of intervention[8].

The application of the requirements of the BSS to occupational exposure situations where the presence of radon is adventious has been further discussed in an international Safety Guide [13].

3.1.2. The case of cosmic rays

ICRP has already recommended that cosmic rays at the earth's surface should be excluded [2,3]. Exposures from this source are also given as an example of what should be excluded in the BSS [4]. ICRP has further recommended that exposures to cosmic rays be part of occupational exposure in the operation of jet aircraft and space flight, although in subsequent guidance [14], it indicated that it does

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[7] Another isotope of radon, ^{220}Rn, commonly known as thoron because of its presence in the thorium-232 decay chain, is present in air. Levels of exposure are less significant and much less variable than with radon and consequently, the control of adventious thoron would not appear necessary.

[8] See footnote 5.

not consider it necessary to treat the exposure of business passengers as occupational for the purpose of control; essentially only aircrew should be considered. It noted that the only practical measures were over flying time and route selection.

The dose rates due to cosmic rays at the altitude of jet aircraft flight are of the order of a hundred times those at ground level and are dependent on altitude and latitude [15]. Annual effective doses to the aircrew of such aircraft are of the order of a few mSv. Any variation about this number will depend on the flying time and the route taken, but unlike the situation with radon, exposures of an order of magnitude or more above the average for this group of workers would not normally be expected. The amenability to control of exposures from cosmic rays in aircraft is therefore less clear than it is with radon. Indeed, it could be argued that there is relatively little that can reasonably be done to affect such exposures short of substantially limiting flying time and controlling the routes travelled. This debate is reflected in the fact that the Euratom Directive [1] specifies requirements relating to the exposure of aircrew; the BSS [4], on the other hand, makes no explicit reference to aircrew. In view of the relationship with international travel, a common position on the matter would appear desirable, specifically whether the exposure of aircrew should be excluded from the legislative requirements.

3.1.3. The case of materials

As with radon, radionuclides of natural origin are ubiquitous; they have always been a feature of the natural environment. Little would be achieved by including them in their totality within the scope of legislative control apart from providing the regulator with the freedom to determine for himself when such control should be applied[9].

The principal radionuclides of natural origin are potassium-40, and uranium-238 and thorium-232, and their respective radioactive decay products. They are a source of both external and internal radiation exposure, the actual dose to persons varying depending on the circumstances including the activity concentrations of these radionuclides in the human habitat, foodstuffs and atmosphere. However, potassium, which is itself an essential element of diet and contains the naturally occurring radioactive isotope, potassium-40, in a fixed concentration, is under homeostatic control within the body and hence the actual dose is dependent on human biology related principally to age and sex. So, only external radiation from this radionuclide need be considered.

Historically, controls have been exercised over the mining, milling and processing of ores from which naturally radioactive elements are extracted, namely uranium, radium and thorium, and as indicated above, these activities are generally considered as coming under the requirements for practices. However, material mined for other purposes may also contain elevated levels of these elements, albeit possibly not to the same extent, but the exposure of workers and the public may be significant and worthy of consideration of control. In addition, radionuclides of natural origin can build up in plant, for example, as scales, even when the feed materials possess relatively normal levels of activity. This has been recognized by some authorities, but by no means by all. Thus, in some countries, such materials come within the scope of regulatory control; in others, the materials are not regarded as radioactive. International consensus however is desirable because of the important international trade in some of the materials. Examples of these materials are zircon, baddeleyite, rare earth ores and some phosphates, as well as the scales of from such industries as those associated with the extraction of oil and gas.

In Publication 60 [2], ICRP recommended that the exposures from such materials should be excluded from occupational exposure, unless the regulatory agency has ruled otherwise, either in a defined geographical area or for defined practices. It subsequently developed further guidance on the matter in ICRP Publication 75 [14]. It noted that the principal radionuclides of interest are those in the decay chains headed by uranium-238 and thorium-232 and components of those decay chains, particularly

[9] See footnote 1.

those headed by the isotopes of radium and lead-210. Levels of these radionuclides in the environment are generally of the order of 0.04 Bq g^{-1} with normal variations being up to an order of magnitude or so higher. It would be reasonable to consider that such normal levels should be excluded from control; indeed, ICRP [14] recommended that regulatory agencies choose activity concentrations of parent radionuclides within the range of 1-10 Bq g^{-1} to determine whether the exposures from these materials should be regarded as occupational for the purpose of regulatory control. A similar range is given in an international Safety Guide [13]. Others have suggested slightly lower levels, 0.5-5 Bq g^{-1}, which is simply indicative of the subjective nature of the judgement involved in selecting an appropriate levels [16]. It is perhaps interesting to note that the activity concentrations that may be used for the exemption of practices involving these radionuclides are also in the range of 1-10 Bq g^{-1}[1,4][10].

Since the external exposures from ^{40}K for a given activity concentration, are an order of magnitude lower than those from exposures from the decay chains of uranium-238 and thorium-232, a range of values of about 10 times higher might be used for this radionuclide.

The actual implied doses depend very much on the situation, but experience has shown that effective doses to workers can be of the order of a few mSv in a year from materials containing naturally occurring radionuclides with these activity concentrations [13,14].

As with radon, in the context of occupational protection, the activity concentrations for the various radionuclides of interest, selected within these ranges, effectively define the levels above which the legislative requirements for practices should apply. Or, put another way, they provide the lines of demarcation between what might be excluded from regulatory requirements and what should be included within the application of the system of protection for practices. The selected levels can be applied to materials containing naturally occurring radionuclides, irrespective of their origin – whether as extracted from the ground or as a consequence of some industrial process.

Above the selected values, regulatory agencies should give consideration to the exposures of both workers and members of the public, in the latter case, for example, as a consequence of any discharge or release of material to the environment. As far as worker exposure is concerned, only relatively simple measures, such as dust suppression, may be necessary to optimize their protection.

4. Legislative requirements

The form of legislative requirements varies widely, but there are some generally agreed approaches. A fundamental need of the regulator is to obtain information on those situations, including practices that may need to be subject to his oversight. Notification is the basic mechanism generally used for this purpose, which involves the person responsible simply informing the regulator of his intentions. The conditions under which such notification should be given will normally be laid down in the legislative requirements. For practices where the exposures in normal use are expected to be very small and the likelihood and magnitude of potential exposures are negligible, this may be sufficient. It would, for example, provide enough information for the regulator to be able to undertake any inspection that he felt was necessary. However, frequently, the regulator would wish to be able to issue an authorization to the person to undertake the particular activity, before it is started. This is a mechanism that provides

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[10] It is also perhaps interesting to note that the BSS [4] gives exposure from 'unmodified concentrations of radionuclides in most raw materials' as an example of an excluded exposure. The reference-unmodified concentrations have caused some to focus only on situations where the concentrations have been modified by some activity of man. The reason why they should think that exposures from modified concentrations are amenable to control while those from unmodified concentrations are not is unclear. Furthermore, this interpretation of the BSS is in itself flawed. The reference to 'most raw materials' indicates that may well be a few industries where the activity concentrations of the raw materials are high enough to warrant control. In addition, the reference to 'unmodified concentrations' is intended to draw attention to the fact that processing of raw materials, which have relatively normal concentrations, may lead to products or wastes that have much higher levels [17].

the regulator with the opportunity to review the proposed practice and to place conditions on how operations should be carried out in a safe manner. The approach to authorization should be graded according to the normal exposures that are expected to be received and the likelihood and magnitude of potential exposures.

In some cases, different terms are used to reflect this graded approach. Registration may be used in situations where radiological protection is largely ensured by the design of the facilities and equipment, the training requirements are minimal, and there is a history of few safety problems during operation. Licensing may be used for the higher risk or more complex practices, including those in which the protection depends largely on human performance, such as industrial radiography on site. In general, this type of authorization is a more resource intensive process because it requires a careful case-by-case evaluation by the regulator. This graded approach to the application of administrative requirements for practices is reflected in the BSS [4], and has been in existence since the earlier times [11].

For practices and other sources of exposure to which the requirements for practices are to be applied, whether those sources contain radionuclides of natural or artificial origin, the system should be able to operate with an appropriate degree of flexibility. As already indicated, exemption is a mechanism whereby the responsible person may be released from some or all of these legislative requirements, including those of an administrative nature in order to avoid excessive regulatory procedures. In essence, it completes the lower end of the graded approach to regulation and helps to ensure that the regulator's focus is on those situations that warrant attention particularly from the point of view of ensuring that protection is optimal.

4.1. Criteria for exemption

For practices, a fundamental principle is that of justification. It therefore follows that only justified practices should be exempted, which in principle, implies that exemption should not be granted without reference to the thing that is being exempted. However, sometimes clear evidence for justification does not appear to have been sought (for example through the generic use of activity concentrations); in such cases, one might then argue that exclusion would be the more appropriate mechanism for avoiding unnecessary regulatory attention.

The level of risk, and hence dose, that is trivial as far as the individual is concerned is a relative matter. The approach used by an IAEA Expert Group [18] was to choose a level of risk that increases the overall risk to an individual to a negligible or marginal amount. This was done with respect to the totality of risks to which humans are subjected, and to the total risks to which individuals are normally subjected from natural sources of radiation.

Using the first approach, the Group concluded that people would commit their own resources to reduce an annual risk of death of 10^{-5} and that only rarely people would take action at an annual level of 10^{-6} to 10^{-7}. On the basis of an aggregated detriment to the whole population of 7.3 10^{-2} per Sv (effective dose) [2], the level of trivial individual effective dose would then be of the order of 10 μSv in a year. This value has been adopted by ICRP [19] and would appear to have become generally accepted [1,4].

Radiation of natural origin gives, on average, an individual effective dose of about 2.4 mSv in a year [15], although the actual levels of individual exposure vary widely, being in some cases more than an order of magnitude higher than the average. About half of the average exposure is due to radon. The other half comes from cosmic rays, terrestrial gamma rays and radionuclides in the body, for which control is impractical. So, the figure of 10 μSv in a year is less than 1% of the annual effective dose received from those components of exposure to natural sources of radiation that are not amenable to control – this was the second approach of the IAEA Expert Group.

Some debate remains regarding the role of collective effective dose from sources that give very small individual effective doses but are widespread. The BSS specify a collective effective dose committed

by one year of performance of the practice of no more than about 1 manSv as a criterion for exemption; alternatively exemption may be granted if an assessment for the optimization of protection shows that exemption is the optimum option [4]. The role of collective dose in decision-making has recently been the subject of some debate in the development of the new ICRP recommendations [10]; furthermore, it is judged to be rarely limiting in the calculation of derived levels [20].

4.1.1. Derived quantities

Models of exposure pathways have been developed in order to derive generic exemption levels in terms of total quantities and activity concentrations based on the value of 10 μSv in a year [20]. These values are given in the international safety standards [1,4]. The values given represent the lowest values calculated in any scenario for a moderate quantity of material. More recently, work has been undertaken to develop levels for bulk quantities, which may also be used in the context of 'clearance', as discussed below [21].

The international safety standards [1,4] also provide for the exemption of radiation generators. These are required to be approved by the regulator, and any electronic tube, such as a cathode ray tube for the display of visual images subject to restrictions on dose rate and radiation energy. Exemption may also be granted for apparatus containing radioactive substances subject to conditions specified by the regulator, such as conditions relating to the physical or chemical form and to the use or disposal of the radioactive materials. In addition, the apparatus is required to be of a type approved by the regulator and the radioactive substances are required to be in the form of sealed sources. Again, there is a restriction on dose rate.

4.1.2. Consumer products

In general, it would be inappropriate to require members of the public to obtain an authorization to use a consumer product containing radioactive material or emitting ionising radiation. Indeed, the legislative arrangements in many countries are directed at controlling activities in business premises – worker exposure and discharges that could affect the public. The only reasonable form of control that can be exercised over the use of consumer products by the public is by authorization prior to their supply. It is prior to supply that consideration should be given to the justification for the practice and whether protection has been optimized and the regulator will therefore need to establish criteria for authorizing the supply.

The authorization of supply should be based on the criteria for exemption even though the public themselves may not be subject to the legislative requirements, since the products may actually be used in premises that are subject to the requirements. The implication is that such products should be subject to the derived criteria given in the previous subsection. In particular, in general, those devices containing sealed sources, such as smoke detectors should be subject to type approval by the regulator.

4.1.3. Application to waste

Exemption from authorization for release of radioactive material to the environment can be used by the regulator. It can be part of the overall exemption of the practice, or be given specifically in relation to the release of radioactive waste to the environment. Such an exemption from authorization to release radioactive material to the environment might therefore be better referred to as a generic authorization for that particular type of practice.

An exemption from authorization for the release of material to the environment from a particular type of practice should be based on the dose to the critical group. The criterion for exemption from authorization might then be 10 μSv in a year for the average effective dose to the critical group.

In the context of authorized releases of waste to the environment, there is another point to note. It would clearly be sensible from a legislative point of view to consider that any material contaminated as a consequence of an authorized release should not normally re-enter the system of regulatory

control. To prevent such materials from re-entering the regulatory system of control, national regulations should provide for their exclusion or exemption, according the legislative arrangements in place. This means that the principles of protection, including justification and optimisation of protection, should not need to be applied to any subsequent use of the material. The BSS deals with this in Schedule 1 as follows [4]: '*Radioactive substances from an authorized practice or source whose release to the environment has been authorized, are exempted from any new requirements of notification, registration or licensing unless otherwise specified by the Regulatory Authority'.*

4.1.4. Clearance

Clearance is a term that has entered the regulatory language of some countries; it also features in the international standards [1,4]. However, it has been a subject of some considerable debate. Usually the term is used to define a process to determine whether an article or substance is 'clean' or free from the radionuclides that have been used or produced in an authorize practice. But it is also used for situations involving radionuclides of natural origin that are subject to legislative control. Often it is used solely in the context of solid materials for disposal or subsequent reuse. It has arisen because in spite of attempts to decontaminate, some residual activity may remain.

The concept has some relationship with generic authorization or exemption. The dose criteria should therefore be the same as far as practices are concerned. Any activity concentrations based on these criteria should take account of possible exposure pathways, including reuse of the material through recycling. Large quantities may therefore be involved and the activity concentrations derived for the exemption of moderate quantities may not be appropriate. Although it is clearly a matter for national authorities to establish such activity concentrations, attempts are currently being made to establish internationally agreed values, as these would facilitate international trade [21].

In the calculation of derived levels for practical application of the criterion of 10 μSv in a year, unfortunately, there has been a temptation to use very pessimistic modelling such that the value of 10 μSv in a year is treated more as a limit than a guide to the regulator. To avoid the introduction of excessive pessimism, a value of 1 mSv has been introduced as an additional criterion against which to judge the significance of reasonably foreseeable events, including accidents and misuse, such as might occur with a frequency of once in a hundred years [21].

The clearance of materials containing radionuclides of natural origin presents a different problem. Here the criteria for exemption would lead to lower activity concentrations than were developed for defining the scope of the legislative requirements (or exclusion). It would appear illogical and confusing to use levels that are different from those used to define the scope of the legislative requirements.

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Annex 1

Text from ICRP Publication 82

Scope of the system of radiological protection

Exclusion: The Commission, recognising the necessary limitations in the scope of its system of radiological protection, has indicated that ([2], paragraph 99):

[as] '*everyone in the world is exposed to radiation from natural and artificial sources …, and any realistic system of radiological protection must therefore have a clearly defined scope if it is not to apply to the whole of mankind's activities. It also has to cover, in a consistent way, a very wide range of circumstances.*'

Therefore, although it is not wrong per se to extend the system to the whole of humankind's activities, its scope should be limited for practical reasons. The system can only deal with situations in which actions that influence the level of exposure of people are feasible, or at least worth considering, i.e. with situation where the exposure is *controllable*, or amenable to control. Some prolonged exposures are simply not controllable and others are essentially unamenable to control. The Commission has recommended that ([2], paragraph 291):

'*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 …*'.

The *exclusion* of some prolonged exposures from formal regulations is ultimately a matter of a regulatory decision on the amenability to control of the exposure[1]. such a decision must be made by competent authorities.

Exemption: The Commission has also provided recommendations on the *exemption* of sources from regulatory control as follows ([2], paragraphs 285-288):

'*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. It notes that the International Atomic Energy Agency and the Nuclear Energy Agency of OECD issue advice on this subject to their Member States. 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. The basis for exemption on the grounds of trivial dose is much sought after, but very difficult to establish. Apart from the difficulty 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*.'

The Commission has also indicated that ([2], paragraph 290):

'*The second basis for exemption calls for a study similar to that needed in the optimisation of protection. It provides a logical basis for exemption of sources that cannot be exempted solely on the*

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[1] Some exposures are obviously uncontrollable, such as the exposure caused by the homeostatically regulated levels of potassium-40 in the body; for others, the amenability to control depends on a regulatory definition. Many prolonged exposures caused by natural sources, such as exposure to cosmic radiation, are not amenable to control and are usually excluded from regulations.

grounds of trivial doses, but for which regulation on any reasonable scale will produce little or no improvement.'

Exemption levels for practices: In *Publication 64*, the Commission summarised the current criteria for exemption levels for practices as follows ([17], paragraph 86):

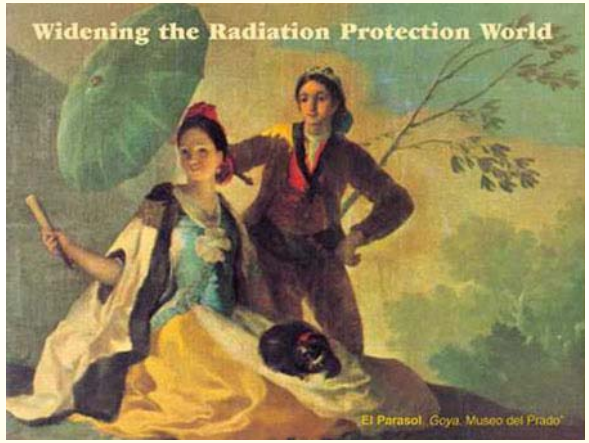
'*in the case of normal exposure, most regulatory systems include provisions for granting exemptions from the regulatory system where it is clear that a practice is justified but regulatory provisions are unnecessary. The grounds for exemption are that the source gives rise to small individual doses (of the order of 10 microsieverts per year) and the protection is optimized, 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 optimized).*'

Exemption levels for interventions: The Commission has considered the concept of exemption levels also within the context of interventions as follows ([2], paragraph 284):

'*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.*'

This important recommendation is applicable to prolonged exposure situations involving commodities for public use.

International Radiation Protection Association
11th International Congress
Madrid, Spain - May 23-28, 2004



Refresher Course

Practical application of exemption

A. D. Wrixon, IAEA

(presented by Ches Mason)

Outline

Concepts

- Exemption
- Exclusion
- Clearance

International guidance

- ICRP
- IAEA

Regulatory application

- Regulatory styles
- Some examples

Difficult cases

- Discussion

Concepts: exemption

Evolution – 1900 - 1950

- Activities involving radiation mainly concerned with X rays and radium-226...
- but, an increasing awareness of stochastic effects

Exemption not an issue

Evolution – 1950s - 1970s

- Increasing use of artificial radionuclides
- LNT adopted as basis for radiation protection
- (by 1977) focus on ALARA

Exemption not explicit, but implied

Concepts: exemption

Evolution – 1980s - present

- Wide range of applications of ionizing radiation
- Focus on optimization of protection
- Elaboration of the concept of exemption
- Exemption used by ICRP and IAEA

Exemption widely accepted and applied as a useful regulatory tool

Concept

"*de minimis non curat lex*" - the law tends to exempt (from requirements that would otherwise apply) things that are not worth the effort and expense of applying the law

Concepts: exclusion

Evolution

- Until 1980s, regulations were often written to apply separately to X rays and to ‘radioactive material’ (defined in terms of activity concentration)
- This was effectively a form of exclusion – materials that are not ‘radioactive’ are outside the scope of regulation

Concept

Some things (as defined in law) simply do not fall within the scope of legal instruments for regulatory control

Concepts: clearance

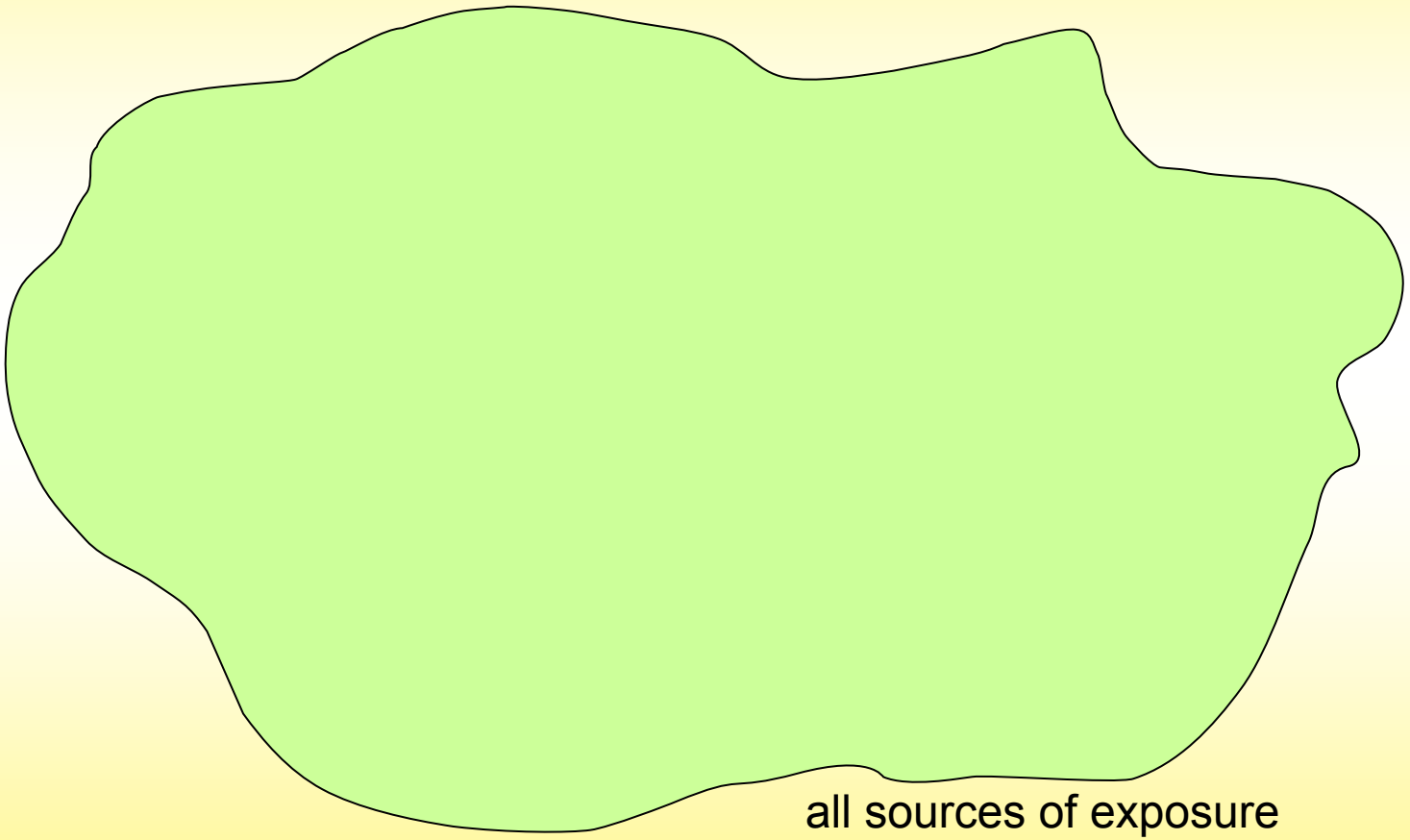
Evolution

- Clearance is essentially a renaming through common usage of a particular form of exemption

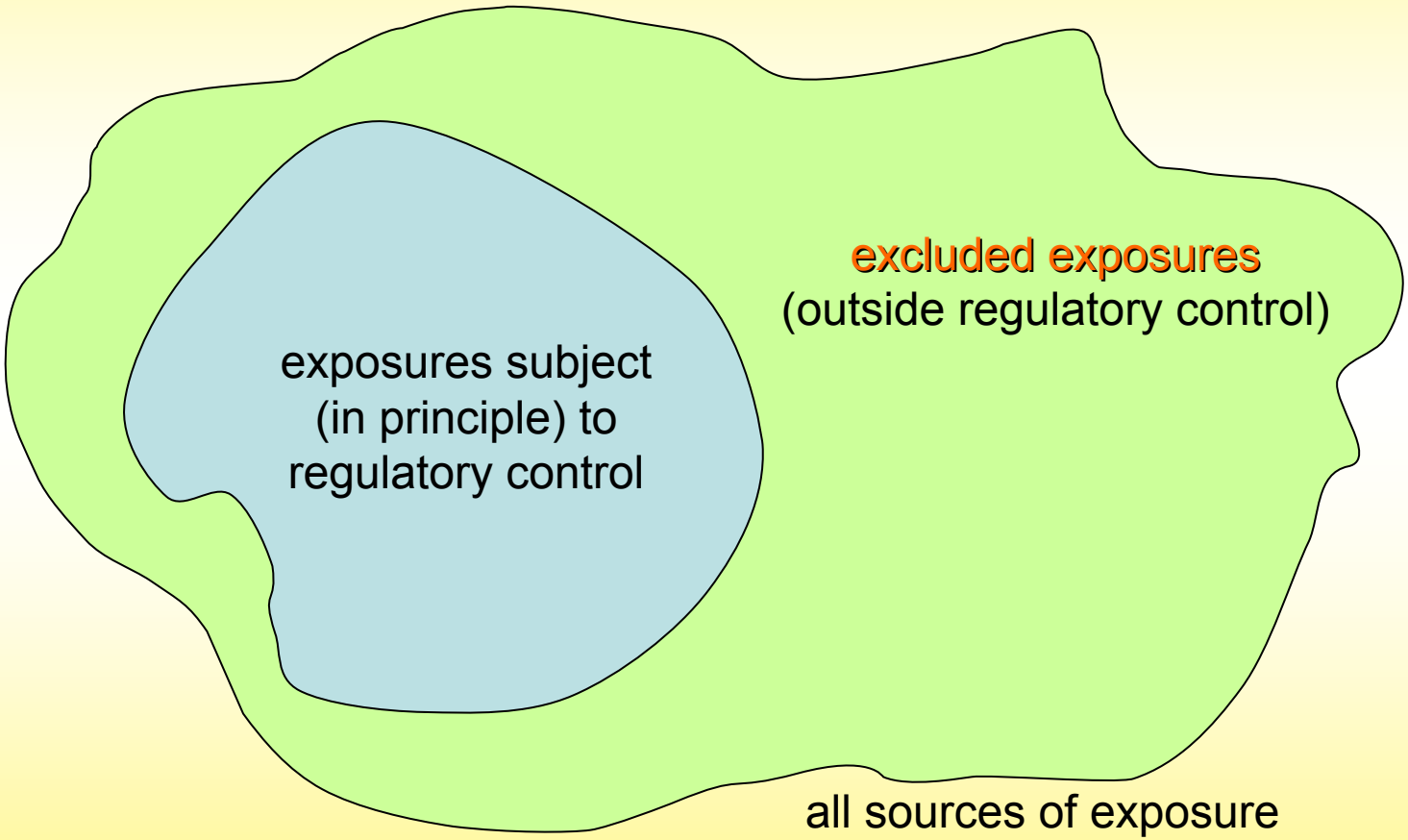
Concept

The release from regulatory control of materials that are found or that arise within regulated activities that can be exempted from further requirements

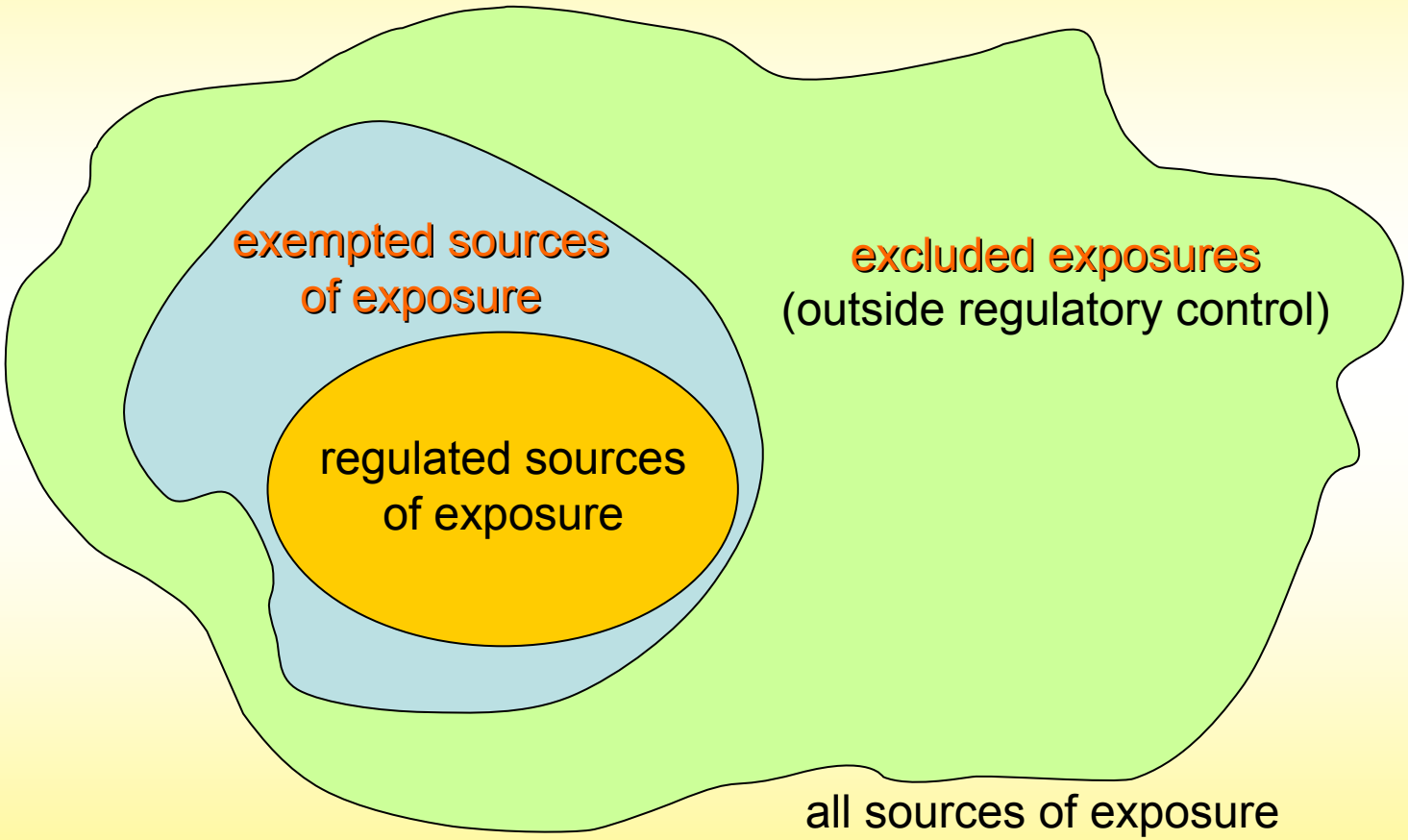
Concepts



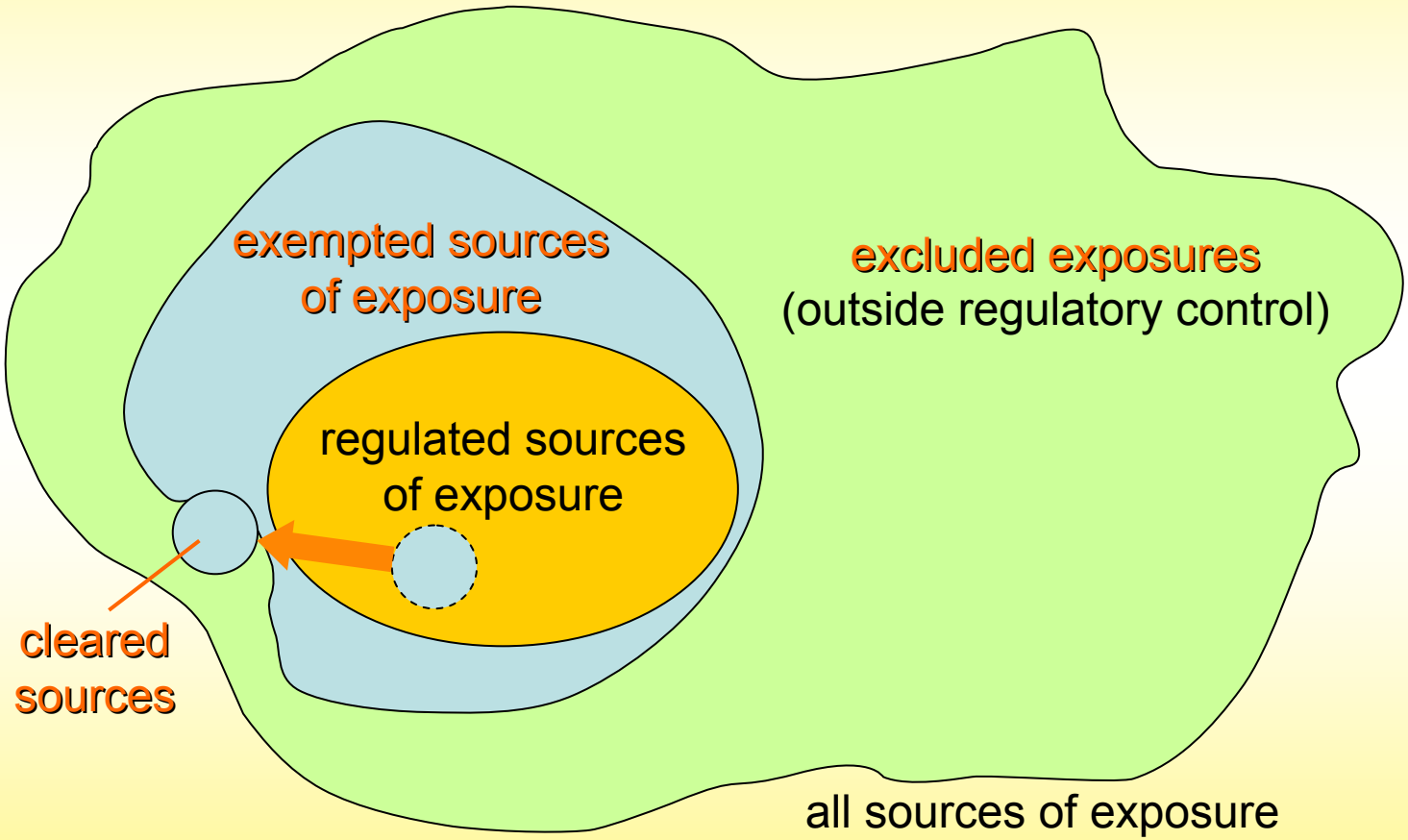
Exclusion


excluded exposures
(outside regulatory control)
exposures subject
(in principle) to
regulatory control
all sources of exposure

Exemption


exempted sources
of exposure
regulated sources
of exposure
excluded exposures
(outside regulatory control)
all sources of exposure

Clearance


exempted sources
of exposure
excluded exposures
(outside regulatory control)
regulated sources
of exposure
cleared
sources
all sources of exposure

International Guidance

ICRP

- ICRP39 – Principles for limiting exposure of the public to natural sources of radiation
  - guidance based on controllability
  - recommends use of action levels
- ICRP60 – 1990 Recommendations of the ICRP
  - introduces practices and interventions
  - some guidance on what activities should be treated as practices
  - for other activities, use intervention and action levels
- ICRP65 – Protection against radon-222 at home and at work
  - recommends action levels for radon

International Guidance

ICRP

- ICRP75 – General principles for the radiation protection of workers
  - guidance on when to treat activities that cause exposure of workers as practices
- ICRP82 – Protection of the public in situations of prolonged radiation exposure
  - most recent guidance of the ICRP
  - covers natural and artificial sources
  - exclusion based on unamenability to control
  - further guidance on exemption

ICRP on exemption

(ICRP60)

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.

ICRP on natural sources at work

(ICRP60)

...exposure to radon and the handling of materials containing traces of natural radionuclides should be regarded as excluded from occupational exposure...

Except:

...include exposures to natural sources in the case of

- operations where the regulatory agency has declared that radon needs attention and has identified the relevant workplaces,
- operations with and storage of materials not usually regarded as radioactive but which contain significant traces of natural radionuclides and which have been identified by the regulatory agency
- operation of jet aircraft, and space flight

International Guidance

IAEA

- SS89 – Principles for the exemption of radiation sources and practices from regulatory control
  - proposes exemption criteria
- SS115 – International Basic Safety Standards
  - detailed treatment of conditions for exemption
  - provides generic exemption levels for radionuclides in terms of activity and activity concentration
  - makes use of exclusion
  - notes the use of clearance

BSS on Exclusion

Basic Safety Standards:

"Any exposure whose magnitude or likelihood is essentially unamenable to control through the requirements of the Standards is deemed to be excluded from the Standards"

"unamenable": can be taken to mean that regulatory control is

- not possible (eg: K-40 in the body)
- not feasible (eg: cosmic rays at ground level)
- not warranted (eg: unmodified concentrations of radionuclides in most raw materials)

BSS on Exemption

Basic Safety Standards:

"The general principles for exemption are that:

(a) the radiation risks to individuals caused by the exempted practice or source be sufficiently low as to be of no regulatory concern;

(b) the collective radiological impact of the exempted practice or source be sufficiently low as not to warrant regulatory control under the prevailing circumstances; and

(c) the exempted practices and sources be inherently safe, with no appreciable likelihood of scenarios that could lead to a failure to meet the criteria in (a) and (b)."

BSS on Exemption

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

(a) the effective dose expected to be incurred by any member of the public due to the exempted practice or source is of the order of 10μSv or less in a year, and

(b) either the collective effective dose committed by one year of performance of the practice is no more than about 1 man.Sv or an assessment for the optimization of protection shows that exemption is the optimum option."

PLUS

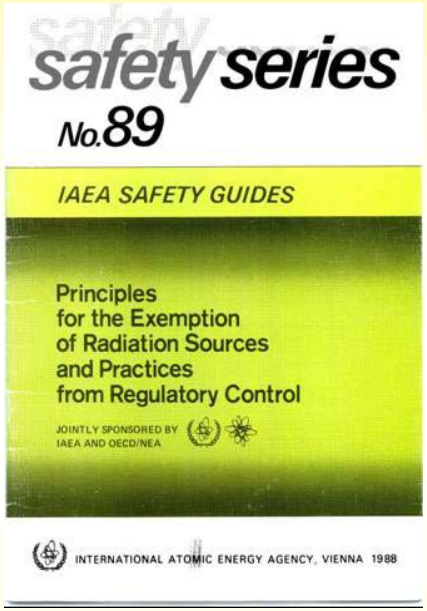
Table of exemption levels (activity and activity concentration)

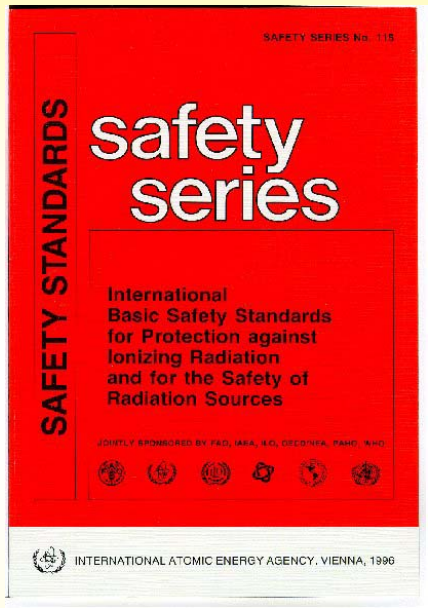
BSS on Clearance

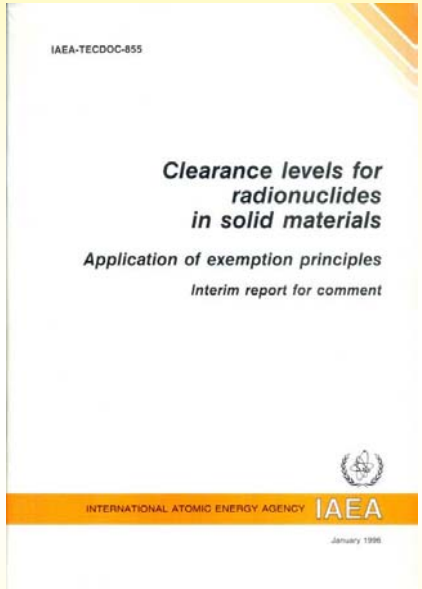
Basic Safety Standards:

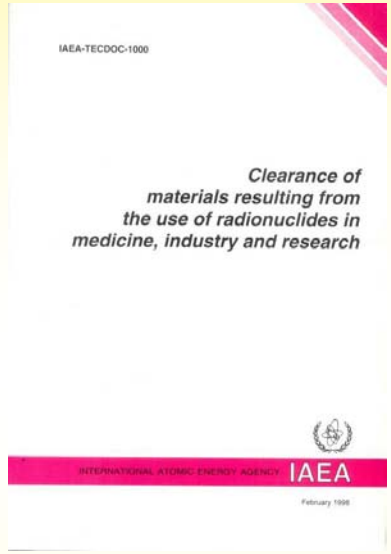
"Sources, including substances, materials and objects, within notified or authorized practices may be released from further requirements of the Standards subject to complying with clearance levels approved by the Regulatory Authority."

IAEA guidance









(+ DS161 around the corner?)

Exemption and clearance levels

Basic Safety Standards exemption levels are based on the dose criteria for exemption and modelling of a specific set of exposure scenarios involving 'moderate quantities' of material

whereas

clearance levels (eg: TECDOC-855), while based on the same dose criteria, are modelled on a broader range of exposure scenarios including bulk quantities of material

Clearance levels are therefore typically lower than exemption levels, often by an order of magnitude or more

Regulatory application

Regulatory styles*

- "Exempters" - retain as far as possible legal instruments for control of activities involving exposure to radiation. Minimal use of exclusion, preference for exemption (by regulatory decision).
- "Excluders" - only regulate activities that need to be brought into the scope of regulation. Preference for exclusion when appropriate, but also make full use of exemption.

[*The terms "exempters" and "excluders" were invented for this presentation only and have no other currency]

Regulatory application

Note on the application of exclusion and exemption

- Exclusion operates *a priori*. That is, regulatory instruments are written so as not to apply to the things excluded.
- The things excluded may be defined by any appropriate means, such as by activity concentration, or by identifying specific activities (eg: metalliferous mining)
- Where administrative decisions are made case-by-case on whether to apply regulatory controls, the concept of exemption applies
- Exemption may also operate *a priori*, through regulatory instruments that identify the things exempted

Regulatory application

Application of exclusion, exemption and clearance

- Although the concepts have been defined in terms of
  - exemption of practices
  - clearance of materials, and
  - exclusion of exposures

  all regulatory requirements apply to persons.
- Exemption may be granted (to the person responsible for a practice) from some or all of the requirements that would otherwise apply
- NB: exemption may be granted even when exemption *levels* are exceeded: the regulator may choose to make use of the underlying principles and criteria for exemption

Regulatory application: examples

Activities that should clearly be regulated as practices

- All nuclear power activities, including fuel cycle facilities
- Storage and waste management of spent nuclear fuel
- Operation of radioactive waste management facilities
- Operation of research reactors
- Uranium mining

- Operating irradiation facilities (sterilization plants)
- Industrial radiography
- Use of radiation gauges (eg: thickness gauges)

Exclusion and exemption do not apply

Regulatory application: examples

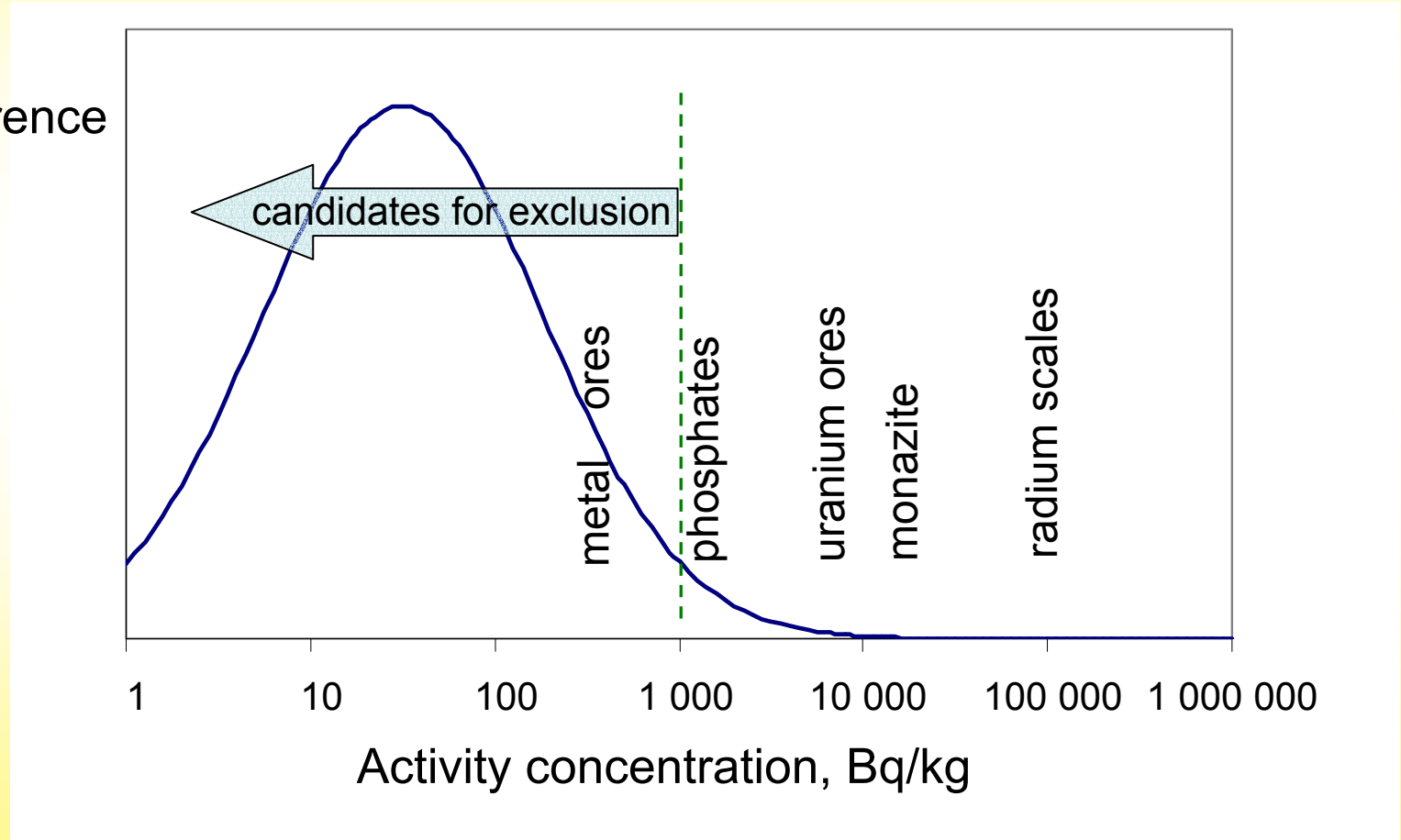
Activities that are usually exempted from regulatory controls

- Use of smoke detectors in private homes
- Sale and use of consumer products containing small quantities of radionuclides (eg: gas mantles)

(Manufacture is not exempted. The regulator can control the availablity of consumer products through authorization of supply)

Regulatory application: difficult cases

Mining of ores other than uranium



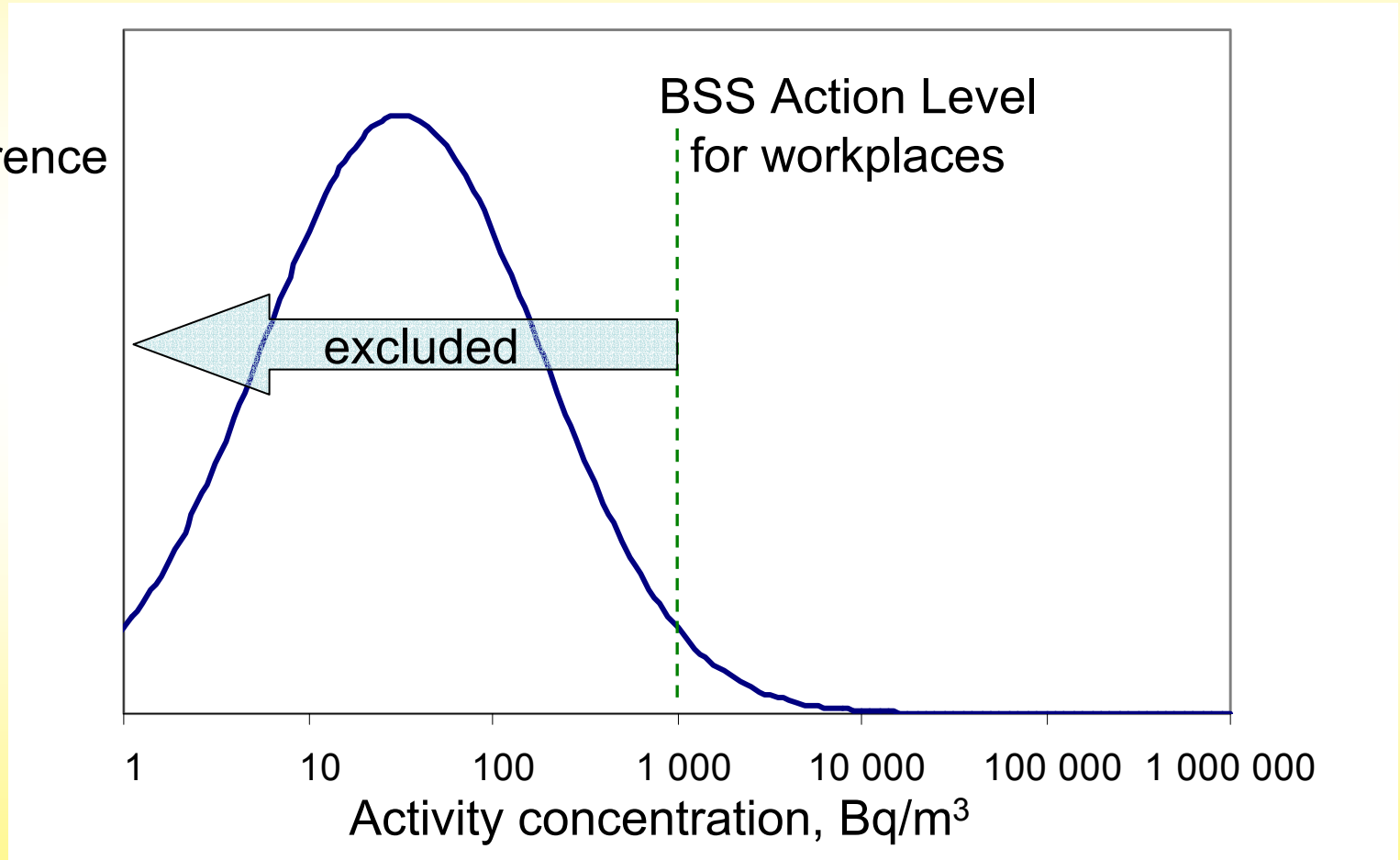
Regulatory application: difficult cases

Mining of ores other than uranium

- Assess exposure scenarios for each type of mining activity
- If activity concentrations are less than about 1 Bq/g (ICRP82 suggests doses up to 10 mSv/y), then regulatory controls may not be necessary
- Consider radon separately: if below the action level (1000 Bq/m^3), the radon exposure may be excluded
- If controls for practices are applied, use a graded approach: make the requirements consistent with the circumstances and scale of exposure

Regulatory application: difficult cases

Radon concentration in buildings



Regulatory application: difficult cases

Radon concentrations in buildings

- Make use of action levels
  - Workplaces: 1000 Bq/m^3
  - Dwellings: 200 to 600 Bq/m^3
- If average concentrations are below the action level, the exposure may be excluded
- If concentrations consistently exceed the action level, consider intervention to reduce exposures
- If concentrations cannot be reduced below the action level, may need to apply requirements for practices

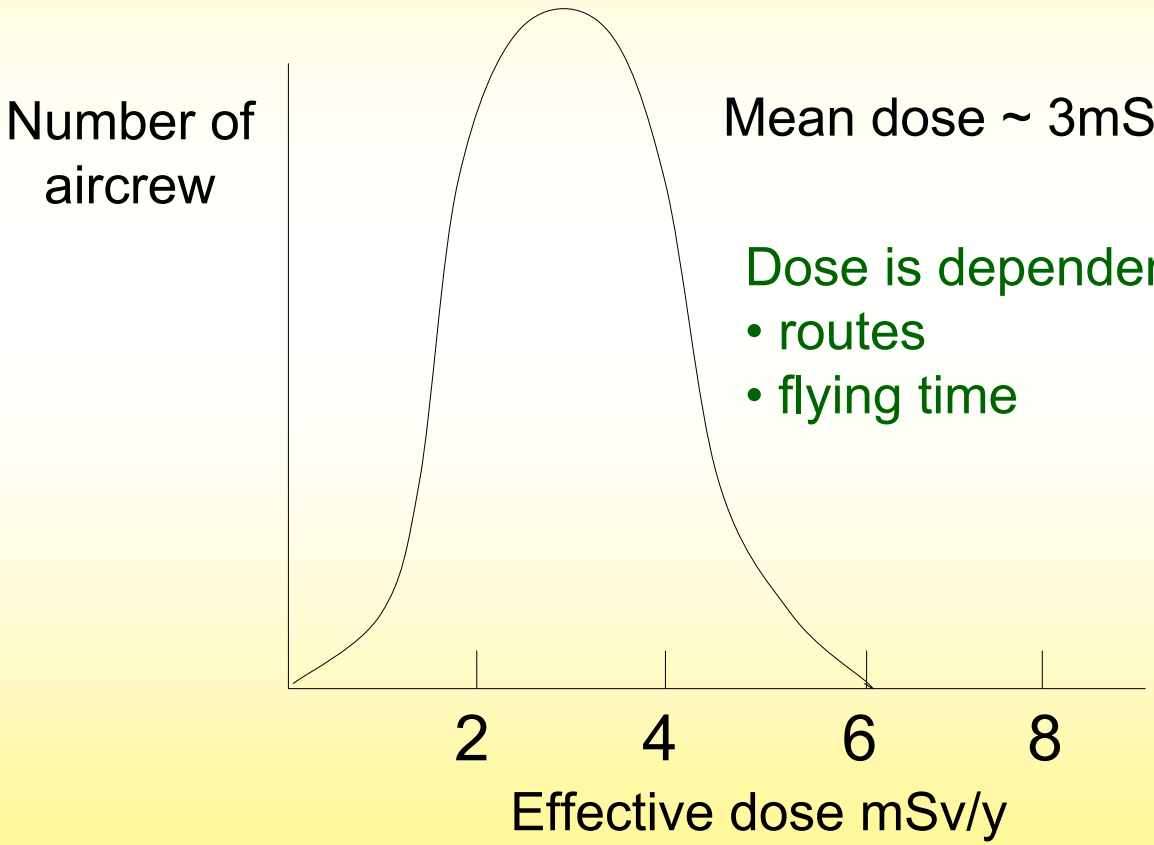
Regulatory application: difficult cases

Working with materials containing small quantities of natural radionclides

- Treat as for mining: assess exposure scenarios for each type of activity
- If activity concentrations are less than about 1 Bq/g, then regulatory controls may not be necessary
- Consider radon separately: if below the action level (1000 Bq/m^3), the radon exposure may be excluded
- If controls for practices are applied, use a graded approach: make the requirements consistent with the circumstances and scale of exposure

Regulatory application: difficult cases

Cosmic rays and aircrew



Discussion cases

Mining of mineral sands

- Usually need to apply regulatory controls for practices
- However, requirements for initial mining operations (raw mineral) may be minimal
- Requirements in separation plant will be more stringent (eg: access controls, exposure controls, dust controls, individual monitoring and dose assessment)
- Monazite product will need to be shipped according to the IAEA transport regulations; other products depending on activity concentration

Discussion cases

Other mining

eg: metalliferous ores, coal mining

- Regulatory controls usually not needed (exclusion concept)
- However, consider radon separately (especially deep underground mines)
- If radon action level consistently exceeded, intervention is required to reduce radon concentrations
- If concentrations cannot be reduced below the action level, the requirements for practices should apply

Discussion cases

Working in caves and spas

- Principal problem is radon: make use of the action level
- If action level is consistently exceeded, investigate possibility of reducing concentrations
- If reduction below the action level is not feasible, restrictions on working hours may need to be applied together with other requirements (eg: monitoring and dose assessment)

Offices and other common workplaces

- Radon may occasionally be a problem
- Remedial measures should almost always be able to reduce concentrations below the action level

Discussion cases

Building materials

- Make use of exemption levels
- However, consider carefully cases where large quantities of material are used as landfill, and especially cases where landfill or building materials contain uranium or radium, as indoor radon concentrations may become a problem
- One regulatory option is to prohibit the use of a material or a particular type of construction (justification)

Radon in dwellings

- Make use of action level
- If action level consistently exceeded, recommend remediation (legally enforceable requirements are not usually applied to homeowners, but may be applied to landlords in the case of rented accommodation)

Discussion cases

Foodstuffs and drinking water

- Make use of Codex Alimentarius levels
- Treat through intervention
- Different levels may be needed in an emergency situation!

Novel applications

eg: using uranium as a colorant

- Consider the issue of justification
- If not unjustified, make use of exemption levels

Discussion cases

Releases and clearance

- Clearance of materials implies no subsequent regulatory control
- Materials that do not meet the clearance criteria may be appropriate for authorized release

  eg: discharge to air or water, or disposal to an authorized waste site
- Recycled materials, if there is no subsequent control, must meet clearance criteria

Closing comment

Optimization of protection extends to regulatory control

- Ensure necessary controls are applied, but
- avoid an unwarranted regulatory burden.
- Make use of exclusion and exemption when appropriate.
- When controls are applied, use a graded approach.
- Finding the optimum regulatory solution is in the end a matter of judgement.