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International Developments on the Concepts of Exclusion, Exemption and Clearance

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1. INTRODUCTION

The concepts exclusion and exemption, as established in the International Basic Safety Standards [1] can be seen as scoping the applicability of the regulatory system used to control exposure to radiation sources. The concepts determine what should and what should not be subject to regulatory control (see Figure 1). This is an important matter since considerable regulatory and administrative resources could otherwise be expended if the scope is not properly defined. The issue has received increased attention of late, not least, because of the question of whether to regulate industries involving the use of materials containing naturally occurring radionuclides. (NORM).

The increasing number of nuclear facilities in the world undergoing decommissioning has brought recognition of the need to have well-established and internationally accepted policies for controlling the release of materials from decommissioned nuclear facilities for subsequent reuse, recycle or disposal. The concept of clearance is relevant in this context. It has also been suggested that rules for governing the international movement of materials containing trace amounts of radionuclides should be based on the clearance concept. Finally, the exemption and clearance concepts have been suggested as a basis for definitions of radioactive material in international standards and conventions.

It is clear, therefore, that these and related concepts are important in the fields of radiation protection and waste management. This paper summarises the current and developing international position with respect to the definition and application of the concepts. Many of the points and issues raised have been emerged from the recent series of meetings in Vienna concerned with revising basic international guidance on these concepts.

2. INTERNATIONAL STANDARDS

The International Basic Safety Standards (BSS) set down requirements for protection against the risks associated with exposure to ionising radiation [1]. These requirements are based, amongst other things, on the recommendations of the International Commission on Radiological Protection (ICRP) [2]. The Standards address **practices** which are human activities that add radiation exposure to that which people normally incur due to background radiation, and **interventions** which are human activities that seek to reduce radiation exposure that is not part of a controlled practice.

*These notes have been developed from the paper presented by John Cooper, of the UK National Radiological Protection Board and presented at the recent IAEA Conference on the Safety of Radioactive Waste Management, Cordoba, Spain (2000).

The BSS are implemented in Member States by a regulatory system that will have limited resources. In order to achieve appropriate use of resources, the scope of application of regulatory systems needs to be defined. Is it reasonable, for example, to control all practices with the same rigour irrespective of the hazard posed and should all discharges of radionuclides be subject to the same requirements irrespective of the risks to man and the environment? Furthermore, to what extent should steps be taken to reduce exposures that are not part of a controlled practice?

3. TERMINOLOGY

Three terms are used in the BSS to describe situations where regulatory controls are unwarranted or futile. These are exemption, exclusion and clearance.

Exemption and clearance are used in the context of practices whereas exclusion is more appropriately linked to interventions [3].

The terms are described in the BSS as follows:

Exemption —Schedule I to the BSS provides the following description of exemption 'Practices and sources within practices may be exempted from the requirements of the BSS, including those for notification, registration or licensing ..... Exemption should not be granted to permit practices that would otherwise not be justified'. Generally, in using the term 'exemption' it is important to state from what the practice, *etc*, is being exempted. In this paper, unless otherwise stated, the term exemption refers to exemption from all of the BSS' requirements except justification. The term exemption itself is not defined in the glossary to the Standards.

Clearance —This is defined in the glossary to the BSS as 'Removal of radioactive materials or radioactive objects within authorised practices from any further control by the Regulatory Authority'. Furthermore, the BSS state that clearance is subject to clearance levels which are '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'.

Exclusion —Any exposure whose magnitude or likelihood is essentially unamenable to control through the requirements of the BSS is deemed to be excluded from the BSS.

4. EXCLUSION

Some exposures to radiation are part of the natural human environment. Examples include exposures from cosmic radiation at sea level and exposures from potassium-40 in the body. Exposures of this kind are unavoidable and, most importantly, it is not practicable to control them through regulation: they would be excluded.

Exposure, rather than the source of exposure, is excluded because a source can produce various magnitudes of exposure in a variety of situations, some of which may be amenable to control and others unamenable to control. Furthermore, it may be the case that exposures that would otherwise have been excluded reach such levels in particular situations that action to reduce them may be required on the grounds of health considerations. The way such situations are identified is usually through the use of an action level. If an action level is exceeded, or for whatever other reason action to reduce exposures is deemed necessary, the principles of protection for intervention would be invoked. The most well known example of the application of exclusion and of the use of an action level is to radon gas in the home. In relation to other exposures to radiation from natural sources, the BSS are less precise - they refer to exposure from unmodified concentrations of radionuclides in most raw materials as an example of an excluded exposure. Thus, industries in which such material is being used could, by this interpretation, be excluded from the requirements of the BSS. The approach to be adopted when there is some enhancement in concentration due to the industrial process is not so clear.

5. APPLICATION TO PRACTICES

5.1 Exemption

Historically, in this context, the area where most work has been done is exemption. It was established early on in the development of the Standards that some practices do not warrant full imposition of the regulatory system. Over ten years ago, the IAEA, jointly with the Nuclear Energy Agency (NEA) of the OECD, set out the following general principles for exemption [5]:

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

These principles were further developed by IAEA/NEA. The first principle was interpreted as meaning that situations involving trivial risks would not warrant regulatory control (the other conditions being satisfied of course). Comparison with society's response to, and perception of risks from, other activities led to the conclusion that annual risks of death of the order of 10^{-6} to 10^{-7} are generally not of concern to individuals. Using the then current risk factor for fatal cancer of $1^{\circ}10^{-2\circ}Sv^{-1}$, this could be converted to an annual dose of around 10° Sv to 100° Sv.

Considerations of doses from natural background radiation and of their natural variations supported the idea that doses in this range could be regarded as trivial. From this range, a value of about 10° Sv per year was proposed on the basis that an individual could be significantly exposed to more than one exempt source. Knowledge of radiation risks has advanced since this IAEA/NEA study in 1988 and it is now believed that the risk to health is greater per unit dose. However, as it is now considered unlikely that an individual would be significantly exposed to more than one exempt source at a time, the conclusion stands that a level of individual dose, regardless of origin, may be regarded as trivial if it is of the order of 10° Sv per year or less.

Turning to the optimisation principle, IAEA/NEA made the point that a practice could be considered as a candidate for granting exemption if the result of the assessment of optimisation showed that exemption is the optimum radiological protection option. Furthermore, the resources required for regulation were a factor that needed to be considered in the optimisation of protection. IAEA/NEA suggested on cost-benefit grounds, that if the collective dose committed by one year of the unregulated practice was less than around 1°manSv, the total detriment would be low enough to permit exemption 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; rather it would have to be shown in such cases that exemption is the optimum solution in radiological protection terms. However, the 1°manSv collective dose criterion has, in general, not been a determining factor in the exemption of practices [6].

The dose criteria, together with the requirement for inherent safety, have been accepted internationally as a basis for the exemption of practices from regulatory control. Schedule I of the BSS allows a practice or a source within a practice to be exempted from the requirements of the BSS, except justification, 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 10 Sv 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 manSv or an assessment for the optimisation of protection shows that exemption is the optimum option.

These dose criteria, however, may not have immediate practical value; their application would entail an assessment of each candidate practice. The criteria have, however, been turned into radionuclide-specific levels which can be applied directly [6]. In doing so, the concept of exemption was further refined as follows:

- a practice is taken to be a use of radionuclides for a specific purpose [industries where large quantities of naturally radioactive ores or materials were being processed but not for their radioactive properties were not considered].

- candidate practices involve small-scale usage of radionuclides, *eg*, medical research, *etc* [practices involving large quantities of radionuclides, *eg*, nuclear installations, may not be 'inherently safe'].
- the dose criteria apply to individuals working in the practice as well as to members of the public exposed incidentally to discharges (this is implied in the IAEA/NEA document).

On the basis of these assumptions, a set of exposure scenarios was constructed and used to derive radionuclide-specific concentrations and total quantities that corresponded to the dose criteria. These derived radionuclide-specific levels are included in Schedule I of the BSS (the same values are also given in Annex I of the Euratom Basic Safety Standards [7]). Their use allows automatic exemption from the requirements of the BSS except that the practice should be justified; exemption should not be invoked to allow frivolous or unwarranted usage of radionuclides. Thus, a practice that is so exempted is not outside the system of radiological protection nor is it outside the scope of a regulatory system. Rather the exemption is from the bureaucratic aspects of a regulatory system. Furthermore, such regulatory involvement should not be required at any stage and this includes the disposal of resulting wastes.

However, the exposure scenarios used in calculating the radionuclide-specific levels all assumed small scale usage of radionuclides; situations involving large volumes of materials with very low activity concentrations, such as can arise during decommissioning of nuclear installations, were not explicitly considered. If the radionuclide-specific exemption levels are used in these types of situations, doses in excess of trivial levels could theoretically be received (although probably not in excess of the dose limit for members of the public). This fact has provided support for the establishment of the concept of 'clearance' as a separate entity with its own derived radionuclide-specific levels.

5.2 Clearance

Clearance applies in the case of practices that have not been exempted as described above. Initially, at least, the term was considered to apply to solid materials but recently it has also been used in the context of liquid and gaseous effluents [8].

The historical development of the concept of clearance is covered elsewhere [9]. Essentially, clearance is the release of materials (wastes, *etc*) from a regulated practice, with the minimum of regulatory involvement.

Practices involving radioactive materials may generate wastes ranging from those that have no additional radioactive content to those that have activity levels so high that special precautions are required for protection. Some of the wastes may be candidates for release to the environment, while others will require isolation in an appropriate facility. Generally, controlled releases of radioactive materials from authorised practices are governed by an authorisation. Such authorisations may have conditions attached to them including, for example in the case of effluent discharges, requirements for environmental monitoring, retrospective assessment of critical group doses, *etc*. The greater the assessed dose to members of the public, the more stringent can be the requirements [see reference 10 for examples]. It makes sense to define some point on this spectrum where there are no such requirements. This point defines clearance. 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. This regulatory involvement could be a requirement for monitoring of the environment or, in the case of solid material, specification of the destination for the discharged material or of the use to which it should be put. Thus, clearance is analogous to the exemption of practices with the difference that clearance only applies to the materials being released by practices. Thus, the dose criteria developed for exemption could equally be applied to clearance.

An alternative interpretation of clearance is that it represents a 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 materials with activity levels at or below, would not be regarded as being radioactive for regulatory purposes.

Clearance levels have now been developed for a number of materials. 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 [11]. IAEA has developed clearance levels for release of materials from medicine, industry and research [8] and is also developing

clearance levels for general application to any solid material [12]. All of these studies applied the quantitative dose criteria developed for exemption, in particular, the 10^{-5} Sv individual dose criterion.

Taking all of these studies into account, for any particular radionuclide, a range of derived values for radionuclide concentrations in materials is often obtained. When compared with the values derived for exemption, the clearance values tend to be the lower. One reason is that much larger quantities of materials are generally taken into account in calculating clearance levels than in deriving exemption levels. There have been some discussions as to whether one set of radionuclide-specific values should be used to allow both exemption of practices and clearance of materials from regulated practices. 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 for regulatory purposes. There are, however, counter arguments. The values for exemption were derived on the basis of different assumptions and for a different purpose from those derived for clearance. A consequence of choosing one set of values is likely to be selection of the lowest of those available. This may in turn limit their utility for exemption of practices with limited radiological risks. 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. One possibility is to use a specified fraction of the published exemption levels as proposed in reference 8.

One area in which agreement is developing, is that for any radionuclide, clearance levels should not exceed exemption levels for, if they do, there is the possibility that cleared materials could re-enter the regulatory system at a later stage.

Returning specifically to the issue of solid material within the authorisation process, there are possibilities other than clearance for releasing material from authorised practices. Material could be released for restricted uses. A requirement would be that the critical group dose arising from the proposed use should be within the appropriate constraint. If other uses of the material could give rise to higher doses, then some form of institutional control would be required in order to ensure compliance with the restricted use.(see Figure 2). An often quoted, but perhaps theoretical, example is the use of slightly contaminated steel from, say, the decommissioning of a nuclear installation, in bridge construction. The resulting doses to workers and members of the public could be above the trivial levels considered for clearance, but provided the doses were within the appropriate constraints, this could represent a radiologically acceptable option for using the steel. Clearly, depending upon the radionuclides and materials involved, it may also be necessary to ensure adequate control over the materials beyond, in this case, the design lifetime of the bridge in order to ensure that unacceptable doses do not arise in the future. Such restricted uses for material are becoming referred to as authorised use. This is different to clearance. However, it is not clear whether the concept of authorised use has ever been applied; there is likely to be public resistance to the idea. However, it remains a theoretical possibility.

6. APPLICATION TO NATURALLY OCCURRING RADIOACTIVE MATERIAL (NORM)

The developments described above have focused largely, if not exclusively, on man-made sources of activity. However, there is another area where arguments could be made for and against the need for regulatory involvement on radiological protection grounds: industries involving bulk quantities of natural radioactive materials but where the presence of radioactivity is often incidental to the use to which the material is being put. Examples of these industries include the production of phosphoric acid from phosphate rock, the production of some metals (*eg*, tin) and the use of natural building materials containing elevated levels of natural radionuclides. Historically, in many cases, such industries have not been regulated from a radiological protection perspective or, at least, have not been regulated to anything like the same extent as industries or processes using artificial radionuclides. The publication of ICRP's recommendations in 1991, prompted the idea that, in principle, such industries may be candidates for regulation; in some cases, doses to workers and members of the public were at least as high as those from nuclear installations, and in many cases they were significantly higher. The debate extended to consider whether, assuming these industries should, in principle, be regulated, there were grounds for exemption or exclusion from regulatory control.

These situations are different from those involving artificial radionuclides where the concept of triviality has been used to decide on the need for regulatory involvement. The differences are:

(i) 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.

(ii) the possibility of significant changes in exposure rates, in particular, an increase, is often automatically limited by a number of factors including plant throughput, the natural upper bound on the specific activity of the raw material and, for example, workplace legislation controlling concentrations of airborne dusts.

In such cases, it could be argued that provided the doses to individuals were within the appropriate constraints, the practice could be considered a candidate for exemption from some or all regulatory requirements provided that it is inherently safe. This could be viewed as interpretation of the three general principles of exemption set down in section 5. Essentially, it is exemption on the basis that it is the radiologically optimum option. Regulation does not add any 'value' if the situation is already acceptable and is very unlikely to change.

An alternative approach would be to exclude industries from regulations unless the activity levels in the materials used were such that the doses being received were sufficiently high to cause concern. The demarcation line between those materials requiring regulation and those that may not would be an appropriate action level.

In international discussions on this topic it has been pointed out that by following either of the approaches outlined in the preceding paragraphs, however reasonable from a theoretical perspective, it would be seen as applying different standards for situations involving artificial radionuclides as compared with naturally occurring radionuclides. For this reason it has also been proposed that the industries involved with natural radioactive materials should be regulated in the same way as for the nuclear related industries. The level of regulation could of course vary depending upon the potential risks to the workers and the public and for industries where the risks due to radiation are low and where the source or practice is inherently safe it might amount to little more than a notification by the operator or owner to the regulatory body that the practice exists (so called light regulation).

7. CONCLUSIONS

The principles for applying exemption in the case of practices where radionuclides are being used for their fissile, fertile or radioactive properties seem to be well established; the practice should be justified, inherently safe and doses in plausible exposure situations should be trivial. If the practice is exempt, discharges of materials are also exempted from regulatory requirements. In the case of practices that are not exempted, for whatever reason, it is possible, provided a specific criterion is met in advance, to discharge material without any subsequent regulatory requirements being enforced. This is clearance. The specific criterion is that the radiological risks from the discharged material are trivial in all plausible circumstances. Thus, the same dose criteria are used for establishing whether practices can be exempted and whether materials can be cleared.

Importantly, clearance is part of the general process of authorisation of discharges. Materials that could give rise to doses in excess of trivial levels can be discharged from regulated practices provided the assessed doses or risks are within the appropriate constraint. However, in this case, there may be, for example, requirements for retrospective assessment of critical group doses in order to verify that the public is being protected. One further point should be made about clearance. In the interests of clarifying the terminology, the term should not be used in circumstances where conditions have to be placed on, for example, the destination of the material being discharged in order to ensure doses are trivial. These types of situations should be covered by another form of authorisation.

In the case of artificial radionuclides, internationally agreed clearance levels could provide a useful role in facilitating international trade in most circumstances.

For NORM, an international consensus on the most appropriate approach for applying the concepts of exclusion, exemption and clearance has not yet been reached. The various propopsals currently being debated have been summarised in this paper.

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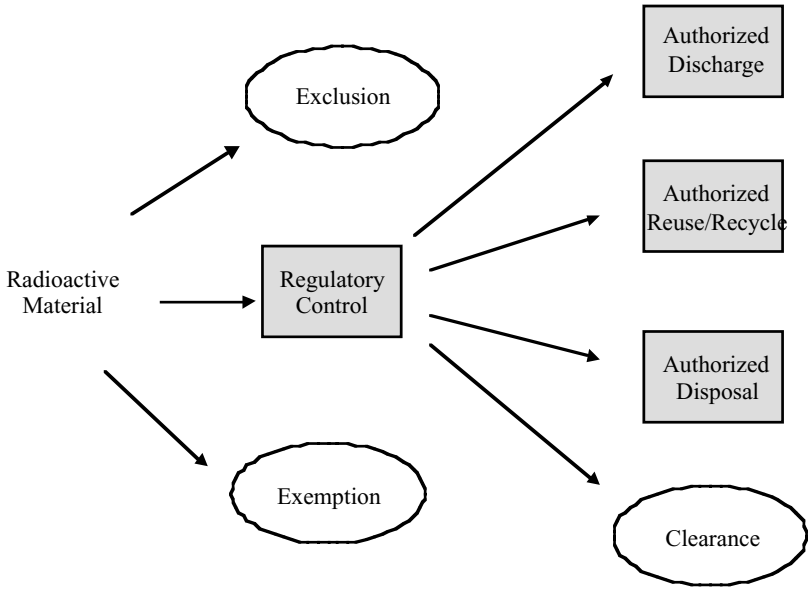

Figure 1 — Options for Radioactive Material Control

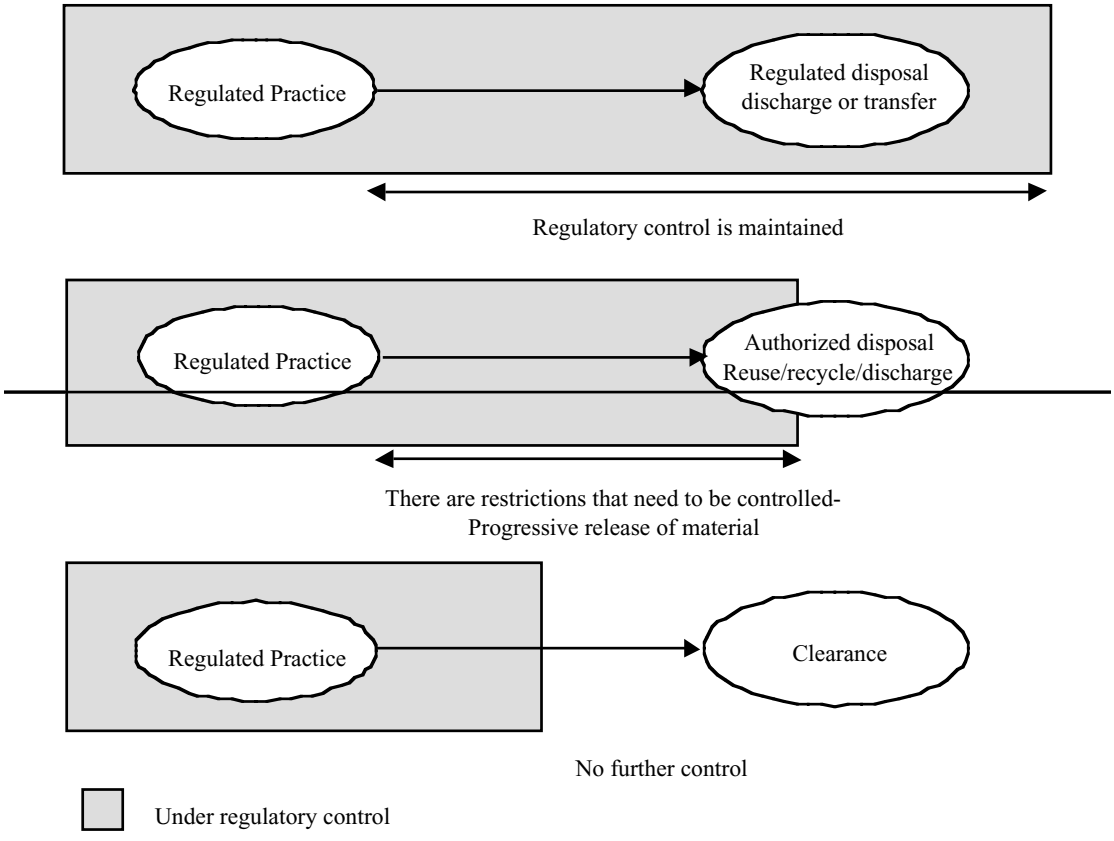

Figure 2 — Regulatory Processes