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# INTERNATIONAL GUIDANCE ON CLEARANCE CRITERIA FOR APPLICATION TO MATERIALS CONTAINING RADIONUCLIDES

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## 1. Introduction

The International Basic Safety Standards (BSS) [1] establish requirements for protection against the risks associated with exposure to ionizing radiation. Radiation occurs everywhere in the environment and radiation which cannot be attributed to current human activities is known as background radiation. Human activities that add radiation exposure to that which people normally incur due to background radiation, or that increase the likelihood of their incurring exposure, are termed 'practices' in the BSS. Human activities that seek to reduce the existing radiation exposure, or the existing likelihood of incurring exposure, which is not part of a controlled practice, are termed 'interventions'. The BSS provide the basis for a regulatory system for the control of radiation: one part of the system applies to practices, another to interventions.

One purpose of a regulatory system is to ensure appropriate implementation of protection requirements. Some practices require a greater degree of regulatory control than others in order to achieve an appropriate level of protection, that is to keep the increase in exposure within acceptable bounds. Some situations of existing radiation exposure require more extensive intervention action than others in order to reduce doses to an acceptable level. Regulatory effort should be tailored to the circumstances by focusing on areas where real benefits can be obtained.

The full regulatory system does not need to be applied to practices that give rise to radiological risks that are not of regulatory concern. Similarly, it is clearly not efficient or desirable for the scope of regulations to cover situations of existing exposure where it would be impracticable to reduce doses. There are two regulatory concepts and related procedures for deciding when the requirements of the Standards need not be applied: 'exclusion ' and 'exemption'. These terms are concerned with leaving things outside the requirements of regulations; that is, with not bringing them under regulatory control. A further terms - 'clearance' - is closely related to exemption and is concerned with releasing things from regulatory control. These and other related concepts are illustrated in Figure 1.

At the IAEA Specialists Meeting [2] held in 1997, attention was drawn to the confusion which is resulting from the variety of different terms being used internationally and nationally to describe these and related concepts. Since then, IAEA working groups have made proposals for

a consistent terminology in this area and these are also presented in the paper.

## 2. Intervention and Exclusion

Actions intended to reduce or avert exposure, or the likelihood of exposure, to sources that are not part of a practice or which are out of control as a consequence of an accident are termed interventions. However, some exposures to radiation are part of the natural human environment and it is not practicable to reduce them. Examples include exposures from cosmic radiation at the earth's surface and exposures from potassium-40 in the body. Exposures of this kind are regarded as unavoidable and, most importantly, it is usually not practicable to control them through regulation. The deliberate omission by a Regulatory Authority of a particular category of exposures (including potential exposures) from regulatory control on the grounds that they are not considered amenable to control through regulation is termed exclusion in the BSS. Such exposures are termed excluded exposures.

People may receive exposures from several different sources, both natural and manmade. The regulatory system may need to be applied differently to each component of exposure. If the exposure is being caused by a certain human activity that lies within legal jurisdiction, in such a way that it adds to the exposure that would otherwise have been received, it should be dealt with as arising from a practice. That is, regulatory controls should be applied to the practice that causes it. Note that inhabiting the natural environment is not considered a practice, so that, for example, moving from a region of low natural background radiation to a higher background area is not a practice.

If the exposure is not treated as arising from a practice, it may be excluded from regulatory requirements or dealt with by intervention. This is the case, for example, when the exposure already exists and cannot be attributed to an identifiable practice. The key to determining whether a component of exposure may be excluded is whether or not it is amenable to control. If there are no reasonably practical means of reducing it, it may be excluded from the regulatory system. The borderline between what may be regarded as amenable to control and what is not is not clear cut. There will be cases in which it may be physically possible to reduce exposures, but cause unreasonable costs.

When radiation exposures in situations which are generally excluded rise to unacceptable levels, perhaps as a result of enhanced natural radionuclide concentrations at a particular location, then intervention may be appropriate. Action levels for intervention in the case of radon exposure are specified in the BSS.

# 3. Practices and Exemption

Some practices cause greater exposures than others. Clearly, there is some point towards the lower end of the spectrum of doses caused by practices below which it makes no sense to apply regulatory requirements. The cost of regulation would exceed any benefit from a marginal reduction in doses. The point at which practices, or sources within practices, could be left outside the regulatory requirements, through 'exemption' corresponds to a level of radiation risk that is considered trivial.

Practices or sources within practices may be exempted from the requirement of the BSS [4] with the exception of the requirement for 'Justification', provided the Regulatory Authority is satisfied that the practices or sources meet the principles and criteria for exemption specified in the BSS. Maintaining the requirement for 'Justification' is important; exemption should not be used to allow unwarranted or frivolous use of radionuclides. Furthermore, the fact that an exempt source or practice still has to be justified means that it is within regulatory purview. The exemption is from the procedural aspects of regulatory control.

The general principles for exemption provided by the BSS are:

- 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).

Taking the concept of trivial risk into account, the BSS further state that

'A practice or a 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 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 man.Sv or an assessment for the optimization of protection shows that exemption is the optimum option'.

The BSS includes in its Schedule 1, levels of activity and activity concentration such that sources at or below such levels - or practices using only such sources - can be granted exemption. These levels are termed exemption levels and are derived using the criteria described above.

## 4. Practices and Clearance

Sources, including substances, materials and objects, within notified or authorized practices may be released from further requirements of the BSS, subject to complying with clearance levels approved by the Regulatory Authority. A clearance level is a level of activity or activity concentration such that materials at or below such levels can be granted clearance. The clearance concept is different from the exemption concept, since the materials subject to clearance are already under regulatory control until the Regulatory Authority clears them. It is the responsibility of the Regulatory Authority to establish requirements for clearance and to verify compliance with the requirement.

Cleared sources and materials have no further regulatory controls applying to them; they are outside the regulatory system. Thus, the doses or risks associated with the subsequent use or disposal of the materials should be 'sufficiently low to be of no regulatory concern' which, in this context, should be taken to mean that they should be trivial. In this sense, clearance is the inverse of exemption. It follows that clearance levels should take account of the exemption criteria specified in the BSS.

In establishing requirements for clearance, the Regulatory Authority should not only take account of the exemption criteria specified in the Standards but also of the exemption levels specified in Schedule 1 of the BSS or as described by the Regulatory Authority on the basis of the criteria specified in Schedule 1. This latter requirement is intended to avoid situations where material is released from regulatory requirements at one point only to re-enter at another due to exemption levels being exceeded. The IAEA and CEC have proposed generic clearance levels [3, 4, 5].

# 5. Other Mechanisms for Release of Materials Containing Radionuclides

When dealing with release of radioactive materials, clearance is just one of the possibilities. Material may be discharged into the environment, within a management system which includes the concept of authorized release, or the material may be dealt with through the process of authorization for further use or recycling, or where no further use is foreseen, authorization for disposal. In these cases, the risk is not necessarily trivial, whereas the concept of clearance applies when the risk is trivial. These terms are described further here only in order to clarify their usage and avoid confusion with the concept of clearance.

Radioactive wastes in liquid or gaseous form may be released to the environment through authorized discharge. While direct control over the discharged material is lost, the process of release to the environment is kept under regulatory control. Control is carried out at the point of discharge and surveillance may be performed in the environment depending upon the assessed level of risk. Under the terms of the authorization, conditions may be imposed on the form of the material, the rate at which it may be released, the ambient meteorological and environmental conditions required for discharge, and so on. For example, it may be possible to release liquid material to sewage or local waterways under controlled conditions of concentration and release rate; environmental monitoring can confirm that any possible radiological consequences continue to be acceptably small.

Regulatory control of materials intended for re-use or recycling, but which do not meet the criteria for clearance, may be relinquished when such use is authorized by the Regulatory Authority and when the authorized use has been verified. That is, control of material is retained until it has been established that it has been used for the purpose for which the authorization was given. For example, it may be acceptable to use overburden from a uranium mine as construction material for road foundations. The road builder would be required to give an undertaking that the material would be used only for the approved purpose, and could, in principle, be subject to regulatory control until the road has been constructed and the authorized use verified. It is implicit in the concept of authorized use that, in making a decision, the Regulatory Authority will take into account the likelihood and implications of other uses being made on the material in the future. An example of authorized recycling might be the release for sale, on decommissioning, of cleaned and re-usable components of a uranium mill to another industrial application, such as a non-uranium mineral extraction plant.

Authorized discharge and authorized use require the optimization of protection, subject to dose and risk constraints. They also require *a priori* assessment of the scenarios of exposure. They allow the *a posteriori* verification of these assessments.

The relationships between clearance, authorized discharge, authorized use and retention of regulatory control are illustrated in Figure 2.

## 6. Clearance of Materials

#### 6.1 General

Clearance can apply both to materials that are intended to be disposed of and to materials intended for further use or recycling. In this context, the term 'material' covers bulk material as well as equipment, objects, solid wastes, collections of small sources, such as smoke detectors, etc. It is implicit in the concept of clearance that materials, once cleared, are subject to no further regulatory restriction or control for the purpose of radiation protection. It is important to be sure that no *a posteriori* conditions will imply a need for subsequent regulatory surveillance, as this cannot then be considered a true removal from regulatory control. Any conditions applied, such as, a specification on physical or chemical form should be aimed at ensuring *a priori* that the clearance criteria are and will continue to be met. Clearance occurs after the final control of the Regulatory Authority is performed at the point where the material leaves the controlled facility. Any *a priori* conditions attached to the clearance should be verified at this last control point.

## 6.2. Management of clearance

Clearance should be granted by the Regulatory Authority on the basis of:

- the triviality of the radiological impact due to the materials after clearance, and
- the ability of the operator to comply with the clearance requirements.

In granting clearance, the Regulatory Authority should take into account public acceptance.

Clearance requirements to be established by the Regulatory Authority should comprise the following:

- clearance levels derived from the radiological criteria for triviality (outlined in Section 3);
- a verification process to be implemented by the operator involving the use of measurement methods suitable for determining the levels of activity in the materials;
- a specific training programme to be implemented by the operator for those workers involved in the clearance process, and
- a QA programme to be implemented by the operator

#### 6.3. Establishment of derived clearance levels

Clearance requirements are rarely, if ever, expressed in terms of individual or collective dose, since it is not practical to measure these parameters at the operational level. Rather, they should be expressed in terms of derived quantities, established either generically or on a case by case basis, that are directly measurable so that compliance can be verified. The clearance requirements may relate to the total amount of material, to the total activity, to the radionuclide-specific total activity and concentrations, to the radionuclide-specific surface contamination, to the physical and chemical form of the material subject to clearance and to its origin.

The simplest regulatory mechanism is to establish generic clearance levels in terms of activity and activity concentration based on the criteria of Section 3, which are equivalent to the criteria for exemption. Generic radionuclide-specific clearance levels may be derived by the regulatory authority from the basic criteria, taking due consideration of all possible scenarios of exposure and the amount of material involved. If these clearance levels are met, the regulatory decision is straightforward.

The Regulatory Authority may also grant clearance on a case by case basis if it is satisfied that the dose criteria of Section 3 are met. The Regulatory Authority may thus consider approving specific clearance levels for clearly identified streams.

The derivation of these practical quantities, generic or specific, requires a thorough

examination of the possible routes by which humans could be exposed to radiation from the proposed cleared materials, irrespective of the use and destination intended. In considering the pathways by which humans may be exposed to radiation, it will always be possible to envisage some circumstances in which exposure may occur but is not certain to occur. These potential exposures should be considered as part of the assessment process, taking into account their likelihood.

Two general approaches may be used:

- (a) the derivation of generic clearance levels through a systematic review of the possible routes of exposure and use of reasonably conservative assumptions and data, when appropriate, and
- (b) the derivation, on a case by case basis, of specific clearance levels using realistic scenarios and assumptions corresponding to likely situations owing to the properties of the materials and probable use.

The derivation of generic clearance levels requires consideration of a wide range of situations, including hypothetical situations, and may lead to very low clearance levels.

The case by case strategy for determining clearance may allow for a more realistic approach as regards the characteristics of the material considered for clearance and the possible pathways by which humans may be exposed to radiation. The practicability of control may also be adapted to the actual situation.

Clearance levels have been derived for international application, for example, in relation to the control of the transboundary movement of materials containing radionuclides [3, 4, 5]. Table I presents values of generic clearance levels for international application recently published by the IAEA.

TABLE I. GENERIC CLEARANCE LEVELS FOR SOLID WASTE (Bq/g) [5].

| Radio-  | Clearance level for     | Radio-  | Clearance level for     |
|---------|-------------------------|---------|-------------------------|
| nuclide | moderate quantities (a) | nuclide | moderate quantities (a) |
| H-3     | 1 x10 <sup>6</sup>      | Sr-89   | $1 \times 10^{3}$       |
| C-14    | $1 \times 10^4$         | Y-90    | $1 \times 10^{3}$       |
| Na-22   | 1 x 10 <sup>1</sup>     | Mo-99   | $1 \times 10^2$         |
| Na-24   | 1 x 10 <sup>1</sup>     | Tc-99   | $1 \times 10^4$         |
| P-32    | $1 \times 10^{3}$       | Tc-99m  | $1 \times 10^2$         |
| S-35    | $1 \times 10^{5}$       | In-111  | $1 \times 10^2$         |
| Cl-36   | $1 \times 10^4$         | I-123   | $1 \times 10^2$         |
| K-42    | $1 \times 10^{2}$       | I-125   | $1 \times 10^{3}$       |
| Ca-45   | $1 \times 10^4$         | I-131   | $1 \times 10^{2}$       |
| Ca-47   | $1 \times 10^{1}$       | Pm-147  | $1 \times 10^4$         |
| Cr-51   | $1 \times 10^{3}$       | Er-169  | $1 \times 10^4$         |
| Fe-59   | $1 \times 10^{1}$       | Au-198  | $1 \times 10^{2}$       |
| Co-57   | $1 \times 10^{2}$       | Hg-197  | $1 \times 10^{2}$       |
| Co-58   | $1 \times 10^{1}$       | Hg-203  | $1 \times 10^{2}$       |
| Ga-67   | $1 \times 10^{2}$       | Tl-201  | $1 \times 10^{2}$       |
| Se-75   | $1 \times 10^{2}$       | Ra-226  | 1 x 10 <sup>1</sup>     |
| Sr-85   | $1 \times 10^2$         | Th-232  | $1 \times 10^{0}$       |

<sup>(</sup>a) Moderate quantity means less than 3 tonnes per year and per facility. For larger quantities the clearance level is one tenth of the levels in Table I.

**Note**: The clearance levels for moderate quantities are identical to the BSS [1] exemption levels. The values in Table I take account of many possible exposure scenarios. Scenarios considered include the following:

| Landfill disposal | -   | transport workers                        |  |
|-------------------|-----|--|--|
|                   | -   | landfill site workers                    |  |
|                   | _   | disturbance of the site after closure    |  |
|                   | -   | radionuclide transfer via groundwater    |  |
| •                 | - , | fires in the landfill                    |  |
| Incineration      | -   | operators                                |  |
|                   | -   | emissions                                |  |
|                   |     | ash (to landfill)emissions               |  |
| Recycling (steel) | -   | scrap transport workers                  |  |
|                   | -   | scrap processing workers                 |  |
|                   | -   | workers at smelter and fabrication plant |  |
|                   | -   | consumer use                             |  |
|                   | -   | emissions                                |  |
|                   | -   | use of slag                              |  |

(Similar groups of scenarios are considered for non-ferrous metals and concrete).

Reuse

- small tools and equipment
- large equipment
- buildings (use and renovation)

The evaluation of radiation exposure in each of the scenarios takes account, as necessary, of exposure due to external irradiation, and to inhalation and ingestion of radionuclides.

# 6.4. Examples of Application of the Clearance Concept

#### Recycling or reuse of materials

Activated or contaminated materials (steel, aluminium, concrete, etc.) resulting, for example, from decommissioning of nuclear facilities could be recycled or reused without radiological restrictions if they meet the clearance criteria.

#### Very low level solid radioactive waste

The management of very low level solid radioactive waste, e.g. disposal at a municipal landfill or incineration facility, may be dealt with either through an authorisation process for the disposal or incineration site or through the clearance of the waste. In the latter case, no conditions should apply to the disposal or incineration process. Conditions may apply to the waste streams before leaving the controlled facility, for example the amount of waste cleared in one year, and its radiological and physico-chemical characteristics.

#### References

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- [2] INTERNATIONAL ATOMIC ENERGY AGENCY, Application of the Concepts of Exclusion, Exemption and Clearance: Implications for the Management of Radioactive Materials, Proceedings of a Specialists Meeting, May 6 to 9, 1997, IAEA (Working Material).
- [3] INTERNATIONAL ATOMIC ENERGY AGENCY, Clearance levels for radionuclides in solid materials. Interim report for comment, IAEA-TECDOC-855, (1996).
- [4] EUROPEAN COMMISSION, Recommended radiological protection criteria for the recycling of metals from the dismantling of nuclear installations, Radiation Protection 89, Luxembourg (1988).
- [5] INTERNATIONAL ATOMIC ENERGY AGENCY, Clearance of materials resulting from the use of radionuclides in medicine, industry and research, IAEA-TECDOC-1000 (1998).

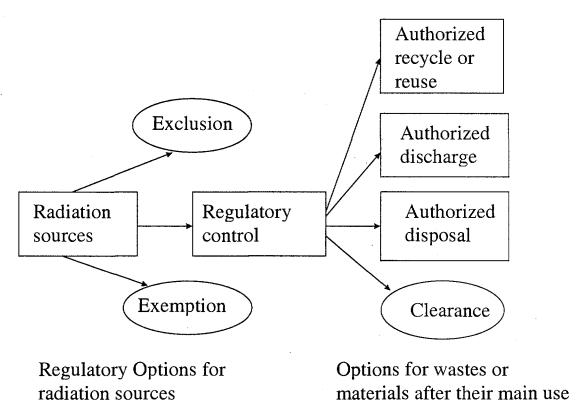


FIG. 1. Options for radiation source control

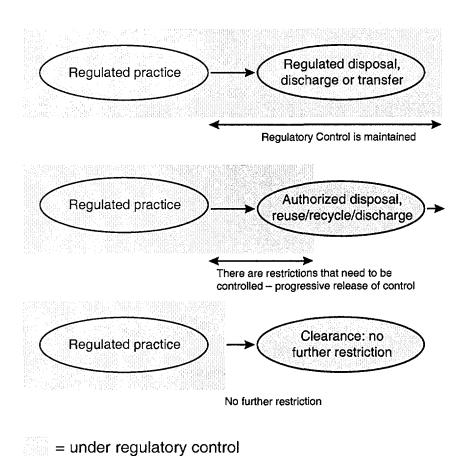


FIG. 2 Regulatory processes for dealing with relinquishment or transfer of regulatory responsibilities for radioactive materials.

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