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Background of Values Used for Exclusion, Exemption and Clearance of Practices and Sources from Regulatory Control

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ABSTRACT

In this article, we explain the need for the exclusion, exemption and clearance of different sources and practices. We also explain the approach and list the criteria that were (and are) used for the implementation of these principles. For practical implementation, radiation protection legislation contains levels of specific activity concentration (Bq / g) and activities (Bq) for materials and sources which are used as exemption and clearance levels. The background and procedure of levels calculation are explained and also the benefits of knowing and comprehending these procedures for radiation protection experts dealing with different sources.

1 INTRODUCTION

During the licensing or registration process and also during the use of radioactive sources officials, applicants, and later licensees or registrants, meet with some kind of classification method when a practice or radioactive source is categorised. The purpose of this approach is to simplify the legal decision process and to optimise requirements regarding required documentation and requests for safety measures and emergency preparedness.

For practically all radionuclides these levels are conveniently listed in relevant regulations and available to all users. But the real background of the values is not evident to the majority of people involved in the authorisation process and use of sources. Therefore, we have decided to review and explain the logic behind exemption from regulatory control and the background of criteria and scenarios that were used to develop and calculate the exemption and clearance levels. We hope that these explanations could be of practical value for professionals dealing with the assessment of exposures of members of the public and professionals from sources of ionising radiation.

2 THE NEED FOR EXEMPTION OF SOURCES AND PRACTICES

Legislation in all European countries requires the introduction of measures for the protection of the health of workers and the general public against dangers arising from ionising radiation.

This requirement was formally introduced in the Treaty establishing the European Community (EURATOM) [1]. Article 30 of the Treaty requires that Basic standards must be laid down. The expression 'basic standards' means the definitions of:

a. maximum permissible doses compatible with adequate safety;
b. maximum permissible levels of exposure and contamination;
c. the fundamental principles governing the health surveillance of workers.

As a result of this requirement, the Basic Safety Standards Directive [2] was introduced practically immediately after the ratification of the Treaty. Provisions of the directive were incorporated into the national radiation protection legislation and regulatory measures.

Since an essential requirement for any regulatory structure is to present a clear definition of its scope, i.e. which sources or practices may be excluded from regulatory requirements or exempted from regulatory supervision, the first Basic Safety Standards Directive [2] comprised instructions on how to decide whether some source or practice should be controlled or supervised. These instructions were relatively simple and contained simple criteria for deciding, and also accompanied by a suggestion that regulatory body in a particular country can use the instructions as a basis and define their version. Instructions and criteria in succeeding versions of Basic Safety Standards are much more comprehensive and elaborated and are based on common bases suggested by ICRP.

Regulatory supervision in the field of ionising radiation is based on the following principles: reporting, prior authorisation, prohibition (of unjustified practices), exemption and exclusion.

The exemption is a relief from the obligation to comply with a condition imposed by law or authorities. The word exemption should never stand alone and one should always specify from which requirements or provisions there is an exemption. **Exclusion** is the acknowledgement of limits beyond which the law cannot apply and consequently cannot regulate. It can also be defined as a social decision to refrain from including within the scope of the regulation subjects and situations where regulatory control would prove difficult or even unrealistic to apply.

The reason for exclusion and exemption is the primary need to avoid excessive regulatory procedures. Therefore, the legislation includes provisions for granting exemptions in cases where it is clear that practice is justified, but where regulatory provisions are unnecessary. Provision may also be made for the complete exclusion of some situations from the scope of any regulatory instruments.

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.

Although these criteria look trivial, in reality, it is not simple to establish a practical basis for exemption. For example, if we consider a single smoke detector both the individual and the collective doses from that source may well be trivial, but the individual may be exposed to

many other sources. But if we consider smoke detectors in general, the individual doses will still be small, but the collective dose may be substantial (e. g. NUREG-1717, [3]). We can see that exemption is a source-related process, while the triviality of the dose is primarily individual-related.

The second basis for exemption calls for a study similar to that needed in the optimisation of protection. It provides a logical basis for the exemption of sources that cannot be exempted solely on the grounds of trivial doses, but for which regulation on any reasonable scale will produce little or no improvement.

Essentially uncontrollable sources, such as cosmic radiation at ground level and ^{40}K in the body, can best be dealt with by the exclusion from the scope of the regulatory instruments, rather than by an exemption provision forming part of the regulatory instruments.

Close to the exemption concept is also the concept of clearance, but the two concepts relate to different stages in regulatory control. While exemption relates to practice and source, clearance relates only to sources. It is a procedure when authorities release from regulatory control certain sources, including materials and objects. This procedure requires the use of certain criteria, which are similar, but generally not the same as the criteria for exemption. The main difference is usually in the quantity of material, for example, if a source is material from decommissioning operation. However, sources that have been cleared from regulatory control mustn't again become subject to the requirements for reporting and authorisation.

In the next chapters, we will discuss criteria and methods that were used in the preparation of exemption levels, which are used as a practical tool for authorities to decide whether some practices and sources require regulatory control. These levels are nuclide specific and are a result of calculations of scenarios and models for sources with particular nuclides. Calculated doses are then used for the determination of activities and, in the case of bulk material, activity concentrations which are serving as a tool for the decision on a particular source or practice exemption.

3 EARLY DEFINITION OF EXEMPTION CRITERIA ([3], [4], [5])

Until 1996 (EU BSS 1996) exemption criteria in Basic safety standards were relatively simple and based on the relative radiotoxicity of radionuclides. In the first EU BSS [2] the limited number of radionuclides were divided into four groups: very high radiotoxicity (^{90}Sr+^{90}Y, ^{210}Po, ^{211}At, ^{226}Ra + daughter products, ^{227}Ac, ^{239}Pu, ^{241}Am, ^{242}Cm), high radiotoxicity, moderate radiotoxicity (most of the popular beta/gamma emitters) and slight radiotoxicity (^{3}H, ^{7}Be, ^{14}C, ^{18}F, ^{51}Cr,^{71}Ge, ^{201}Tl). Exemption levels were from 10^{-7} Ci (3.7 kBq, for radionuclides with very high radiotoxicity) to 10^{-3} Ci (37 MBq, for radionuclides with slight radiotoxicity)

Similar approach was used also in later documents. In the EU BSS from the year 1980 [5] the number of listed documents was extended but the division into four groups was preserved. The group 1 consisted of radionuclides with very high radiotoxicity (e.g. ^{241}Am, ^{238}Pu, ^{239}Pu, ^{252}Cf etc), and group 4 consisted of radionuclides with the low radiotoxicity (e. g. ^{3}H, ^{18}F, ^{40}K, ^{99m}Tc, ^{129}I, ^{135}Xe, ^{209}Pb, ^{235}U, ^{238}U, U_{nat}, etc). Exemption levels for these groups were as follows:

Group 1: nuclides of very high radiotoxicity: $5 \cdot 10^3$ Bq
Group 2: nuclides of high radiotoxicity: $5 \cdot 10^4$ Bq
Group 3: nuclides of moderate radiotoxicity: $5 \cdot 10^5$ Bq

Group 4: nuclides of low radiotoxicity: $5 \cdot 10^6$ Bq

Dose rates used for exemption of different X-ray generators and sources with radioactive sources were 1 μSv h^{-1} at the distance of 0,1 m from the surface and 5 μSv h^{-1} at the distance of 0,05m from the accessible surface for cathode ray tubes for the display of visual images.

4 DOSE CRITERIA FOR EXEMPTION ([6])

As we have just mentioned, exemption criteria are expressed in terms of activity concentration or activities of radionuclides which are related to the dose criteria by a set of defined models representing the practice being considered.

Dose criteria should represent “trivial” additional risk, which would be in the region of 10^{-5}, or even 10^{-6} per year if the vast array of potential sources of risk is considered.

Based on a review of exemption criteria by the IAEA [7], it was agreed that an annual individual dose of a "few tens of μSv per year" or less provides a basis for exemption. Considering that a person could be exposed to more than one exempted source it was recommended that individual exposure should be of the order of 10 μSv per year.

The IAEA also require the collective dose to be ALARA and suggests that it may be assumed to be so if it is below 1 man-Sv per year of the practice. But exempt levels based on the individual dose criterion will for most situations ensure that the collective dose is well below 1 man-Sv per year.

To exclude the possibility of any deterministic effects, a limit on the annual dose to skin of 50 mSv has been adopted. This limit is applied to the area of skin in contact with the source, i.e., a few tens of square centimetres.

When accidents or misuse are considered, the probability that the exposure will occur is taken into account. It is done by comparing the probability-weighted dose with the dose criteria. The limit for weighted dose is 1 mSv per year.

5 DETERMINATION OF EXEMPTION LEVELS - SCENARIOS AND MODELS FOR EXPOSURE CALCULATIONS [6]

Calculation of exposures should consider different forms and quantities of radioactive materials. It can be in one or more physical forms: gas/vapour, liquid/solution, dispersible solid (e.g. powder), non-dispersible solid, thin film/foil and sealed source/capsule. The first models for calculation of exempted values were focused on radionuclides with potential uses in industry, science and medicine (about 100), and a moderate amount of material (not more than a tonne). Calculations were performed and limiting activity concentrations and limiting activities for sources were calculated.

Practical experience from decommissioning of nuclear facilities and handling of radioactive waste has shown, that in these conditions authorities have to decide on the fate of a much higher amount of material. Therefore, criteria were later developed (see e.g. European Commission documents related to derivation and practical use of the concepts of clearance and exemption: Radiation Protection 89, 113, 122) also for the clearance of bulk amounts of solid material which are also used as exemption criteria for large amounts of material. Current Basic Safety Standards (EU BSS [8] and also IAEA BSS [9]) have therefore different tables with exemption levels (activity concentrations and activities) for moderate amounts and exemption

and clearance levels for bulk amounts of material. Scenarios for bulk amounts are different from scenarios for a moderate amount and will not be discussed in detail here.

The scope of calculation was to study doses arising from the use, misuse and disposal of radioactive materials and then to compare the doses with dose criteria. For the dose calculation, 3 scenarios and 24 exposure pathways were identified as the most relevant. The scenarios were normal use (workplace), accidental (workplace) and disposal to landfill (exposure to public).

A brief description of scenarios is following:

1) The normal use (workplace) scenario represents the use of small amounts of radionuclides in industry etc, in the manner for which they are intended, and involves external exposure and inadvertent intakes of radioactive materials.
   Exposures to the public arising from normal releases of activity are adequately covered by this workplace scenario.
2) The accidental (workplace) scenario represents abnormal procedures or incidents that might occur during the routine use of small amounts of radionuclides. These situations may lead to exposures via a range of external, inhalation and ingestion pathways.
3) The disposal (public) scenario represents a member of the public becoming exposed after subsequent disposal of the source. This situation may lead to external, inhalation and ingestion pathways. Both normal and accidental situations are considered.

Exposure pathways considered in these scenarios are listed in Table 1.

Table 1: List of scenarios and pathways

A ACTIVITY CONCENTRATION (1 Bq/g)
A1 Normal use (workplace) scenario:
A1.1 External exposure from handling a source
A1.2 External exposure from a 1 m^3 source
A1.3 External exposure from a gas bottle
A1.4 Inhalation of dusts
A1.5 Ingestion from contaminated hands
A2 Accidental (workplace) scenario:
This is covered by the normal use (workplace) scenario
A3 Disposal (public) scenario:
A3.1 External exposure from a landfill Site
A3.2 Inhalation of dust from a landfill site
A3.3 Ingestion of an object from a landfill site
B ACTIVITIES/QUANTITIES (1 Bq)
B1 Normal use (workplace) scenario:
B1.1 External exposure from a point source
B1.2 External exposure from handling a source
B2 Accidental (workplace) scenario:
B2.1 Spillage: External exposure from contaminated hands
B2.2 Spillage. External exposure from contaminated face
B2.3 Spillage: External exposure from contaminated surface
B2.4 Spillage Ingestion from hands
B2.5 Spillage: Inhalation of resuspended activity
B2.6 Spillage: External dose from an aerosol or dust cloud
B2.7 Fire Contamination of skin
B2.8 Fire Inhalation of dust or volatiles
B2.9 Fire External from combustion products

B3 Disposal (public) scenario: B3.1 External exposure from a landfill site B3.2 Inhalation from a landfill site B3.3 External exposure to the skin from handling an object from a landfill site B3.4 Ingestion of an object from a landfill site

Doses are calculated for sources with activity 1 Bq or activity concentration 1 Bq /g. The generic Formula used to calculate doses is as follows:

$$D = (A \; or \; C) \; f \; T \; R \; U \; s \qquad \text{Sv y}^{-1} \qquad (1)$$

Where the term D is an equivalent dose for skin doses, the effective dose for whole body doses or the committed effective dose for intakes of radionuclides.

Terms A and C are the activity (1 Bq) or activity concentration 1 Bq/g, respectively.

The terms f, T, U and s are all scenario-dependent parameters whose values are listed in a table.

The term R is the radionuclide-dependent dose factor, for a given pathway and the values are given in a table. This factor may be modified by a geometry factor if the size of the source is smaller than the geometry assumed when deriving the dose factors; for example, when calculating the external dose from a 0.1 m^3 gas bottle the dose factor for an infinite slab is modified to account for the size of the gas bottle by multiplying by a geometric factor.

The term f is the fraction of A or C which contributes to the dose D. This may be expressed, for example, as a fraction which contaminates the individual, eg, Accidental-spillage or Accidental-ingestion from contaminated hands.

The term T is the time for which an individual is exposed to the source, (h y^{-1}). The exposure time taken is generally realistic, for example, in the Accident (workplace) scenario, it is assumed that an individual is exposed for 10 minutes before decontamination takes place.

The factor U is intended to convert A or C into units consistent with those of the dose factor, R.

The term s represents the probability of an exposure occurring in a year. This is used in situations where it is not certain that a dose will occur in a year, ie, Accident (workplace) scenario and some Disposal (public) pathways. The probability chosen for all these situations was originally $1 \cdot 10^{-2}$ y^{-1}. The doses calculated for these accident situations are termed average annual doses and are the product of the dose if it occurs and the annual probability that it will occur.

The values of f, T, U and s are necessarily arbitrary to some degree, but in general realistic assumptions were made. The radionuclide-dependent data are largely standard dosimetric data from the literature.

5.1 Exemption level calculations

After the calculation of doses for different scenarios and radionuclides, the exemption levels were calculated by dividing dose criteria by the maximum doses obtained for each scenario and radionuclide:

$$\frac{Exempt\ level}{for\ each\ scenario} = \frac{Annual\ individual\ dose\ criteria}{Dose\ per\ unit\ activity\ (Bq)\ or\ activity\ concentration\ (Bq\ g^{-1})}$$

For the Normal use (workplace) scenario and Disposal (public) scenarios the dose was the sum of the doses from all pathways considered. For the Accident (workplace) scenario, the two basic types of accident (spillage and fire) were treated separately.

The smallest (most restrictive!) exempt level for each radionuclide and waste form was determined from the two workplace scenarios and the public scenario. It should be remembered that the exempt level for each scenario is based on the sum of doses from several exposure pathways.

For practical purposes (official tables) calculated values were rounded. Rounding uses the following algorithm: if the calculated value lies between $3 \cdot 10^x$ and $3 \cdot 10^{x+1}$, the rounded value is 10^{x+1}. This type of "near-logarithmic" rounding was preferred to err by the same factor rather than by a factor 2 upwards and 5 downwards in conventional rounding. Rounded values with critical (dominant) exposure pathways for some popular radionuclides are in Table 2.

Table 2: Rounded exemption values for selected radionuclides [6]

Radionuclide	Activity concentration (Bq/g)	Critical pathway for exempt activity concentration	Activity (Bq)	Critical pathway for exempt activity
^{60}Co	$1{,}00 \cdot 10^1$	EXT(W)	$1.00 \cdot 10^5$	SKIN(W)
^{63}Ni	$1.00 \cdot 10^5$	ING ACC(P)	$1.00 \cdot 10^8$	ING ACC(P)
^{131}I	$1.00 \cdot 10^2$	EXT(W)	$1.00 \cdot 10^6$	ING ACC(P)
^{137}Cs	$1.00 \cdot 10^1$	EXT(W)	$1.00 \cdot 10^4$	SKIN(W)
^{241}Am	$1.00 \cdot 10^0$	INH(W)	$1.00 \cdot 10^4$	INH ACC(P)

Meaning of abbreviations for critical pathways (also for other radionuclides, not listed here): **Activity concentrations**: EXT(W): External in a workplace from 1m cubed source; ING ACC(P): Accidental ingestion to the public from landfill; INH(W): Inhalation in the workplace; EXT(G): External in the workplace from a gas bottle. **Activities**: SKIN(W): Skin dose in the workplace; ING ACC(P): Accidental ingestion to the public from landfill; INH ACC(P): Accidental inhalation to the public from landfill; EXT(W): External in the workplace (effective skin + point source); INH ACCF(W): Inhalation in the workplace from fire; EXT ACCF(W): External in the workplace from fire; INH ACC(P): Accidental inhalation to the public from landfill.

We can see that the number of different critical pathways is limited, as we would expect. However, critical pathways for certain radionuclides are not as “expected”, e.g. for ^{60}Co or ^{137}Cs, where identified critical pathway for activity exemption is skin dose in the workplace and not exposure to point source.

6 EXEMPTION AND CLEARANCE VALUES IN THE CURRENT LEGISLATION [8]

In the current EU BSS from the year 2013 [8] separate tables are used for exemption values and clearance of bulk material and clearance levels (Annex VII, Table A Part 1: Activity concentration values for exemption or clearance of materials which can be applied by default to any amount and to any type of solid material) and activity concentration and activities for exemption of moderate amount of material (Annex VII, Table B, Total activity values for exemption and exemption values for the activity concentration in moderate amounts of any type of material). Table A is based on the IAEA document Application of the Concepts of Exclusion,

Exemption and Clearance [10]. Table B has not been changed from EU BSS from the year 1996 [11] and is based on the [6], where principles and methods for establishing exemption levels were established, as we have discussed.

Current EU BSS has more elaborated criteria for handling building materials with elevated natural radioactivity, elevated radioactivity and materials from the dismantling of nuclear and radiation facilities.

Dose criteria and exemption criteria for devices are practically the same as we have discussed in chapters 3 and 4. Exemption criteria for devices with sealed sources are still 1 $\mu Sv\ h^{-1}$ at the distance 0.1 m from any accessible surface. Exemption criteria have changed for the electrical device: now it applies to devices operating at less than 30 kV and does not cause a dose rate exceeding 1 $\mu Sv\ h^{-1}$ at the distance 0.1 m from any accessible surface.

7 CONCLUSIONS

We have seen that exemption values in Basic Safety Standards are built on rational and verified foundations. They are the result of extensive and elaborate work that has resulted in a solid and reliable basis for the decision-making of authorities.

Understanding the background of the exemption values development process (and evaluation) could be valuable for the authorities and qualified experts since it contains many details and values normally unreachable in normal textbooks and databases. It also enables a fast and competent comparison of exposure pathways and exposure situations for a source, which normally requires tedious and time-consuming calculations.

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