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NUCLEAR REGULATORY COMMISSION
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MEMORANDUM FOR: Hugh L. Thompson, Director
Office of Nuclear Material
Safety and Safeguards

FROM: Richard E. Cunningham, Director
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: INTERNATIONAL GUIDANCE ON THE DE MINIMIS ISSUE

A joint IAEA/NEA expert group met during March 21-25, 1988 in Vienna to prepare a guidance document on the de minimis issue. The enclosed draft represents the final markup on the last dayof the meeting. The document needs editing and to be cleared through various approval groups within IAEA and NEA before publication. Based on the broad representation within the expert group, I believe it will be approved without significant problem. EPA as well as NRC was represented at the meeting. A list of participants is enclosed.

The document uses the term "exemption rules" which means exemption from the basic radiation safety standards adopted by IAEA and NEA. These radiation safety standards are consistent with ICRP recommendations. The document provides the analytical approach to granting exemptions, i.e., "below regulatory concern." Within that framework it also establishes a level of trivial individual and collective dose and describes the conditions for its use. The document also provides in the Annex criteria by which a "practice" and "source" can be defined.

Unless unforeseen problems arise during the final approval process, I believe the international guidance will now provide a solid basis for preparing broad NRC policy on "below regulatory concern" and trivial dose.

Richard E. Cunningham, Director
Division of Industrial and
Medical Nuclear Safety, NMSS

Enclosures: As stated

cc: w/enclosures
R. Bernero, NMSS
G. Sjoblom, NMSS
J. Hickey, NMSS
B. Cool, NMSS
H. Denton, GPA
R. Hauber, GPA
M. Congdon, GPA
L. Roche, EDO
B. Morris, RES
B. Lahs, RES
R. Browning, NMSS
M. Knapp, NMSS

DRAFT

EXEMPTION OF RADIATION SOURCES AND PRACTICES FROM REGULATORY CONTROL

IAEA/NEA Expert Group

March 21-25, 1988

1. INTRODUCTION

1. The IAEA/ILO/NEA(OECD)/WHO Basic Safety Standards for Radiation Protection (BSS) [1], published in IAEA Safety Series No.9, provide guidance on regulations for radiation protection, based on the recommendations of the International Commission on Radiological Protection (ICRP) [2]. These include a system of dose limitation which contains three basic principles, namely, justification of a practice, optimization of protection and limitation of individual risk.

2. The basis of regulatory control* in the BSS is a system of notification, registration and licensing, which makes it possible for the competent authority to impose appropriate requirements for protection. The BSS envisage varying degrees of regulatory control. The highest of these is the full system of licensing of the the operations involving radiation. Below that is a system of general authorization, in which the precise details of where all radioactive material is, or even how many users exist at one time, may be lost, but in which the competent authority still has a means of knowing more generic information through notification and possibly registration, such as the total amount of material in the country, the design of devices approved for distribution, and the users remain subject to certain aspects of regulatory control, e.g. disposal in an approved waste disposal facility. In some cases, even this level of control is not required, and there are then reasons for exemption from all the controls recommended in the BSS.

3. Exemptions may be either generic or specific to one application by one proponent. In either case exemptions may be granted at levels above those that could be regarded as being intrinsically negligible.

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* The term "control" is used in this document to mean "exercising restraint" rather than "checking or verifying" (viz-a-viz applicable to all derivations from the term such as "controllable", "controlled", etc.).

4. The scope of this document is to recommend a policy on exemptions from the BSS system of notification, registration and licensing.

5. Virtually all materials are radioactive, because they contain natural radionuclides or are contaminated with artificial radionuclides, usually at very low levels. The nature of some of these materials and some other sources of exposure is such that control by competent authorities is not practicable or perhaps not possible. An example of that is the potassium-40 in the human body. Therefore, such sources are by their nature excluded from regulatory control. However, when technological enhancement occurs, there may be reason to institute a system of control. For example, the competent authority might decide to control radon levels inside buildings, while it is obviously impracticable to control the levels of naturally-occurring radon outdoor.

6. When reaching decisions about exempting sources of radiation or practices involving radiation exposure, the competent authority should be assured that the risk and detriment* connected with the use of the sources or performance of the practices will be so small as not to warrant the application of the system of notification, registration, and licensing.

7. The formulation of exemptions from regulatory control should not allow the circumvention of controls that would otherwise be applicable by such means as deliberate dilution of material or fractionation of a practice.

8. The authority will also need to take account of the probability and severity of possible consequences of accidents or misuse. Such consideration may contra-indicate the exemption of a practice, even if it gives rise to very small doses under normal conditions.

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* risk and detriment are defined in the Radiation Protection Glossary (SS No._?)

9. Competent authorities may have reasons different from those concerned with radiation protection for either exempting or not exempting particular sources or practices from regulatory control. Moreover, bearing in mind the principle of justification, they may want to prohibit ~~frivolous~~ use of radioactive materials even if the associated doses are trivial, e.g. frivolous items.

10. It is expected that recommendations regarding application of the exemption policy in this document will be issued by the appropriate international bodies and that the competent national authorities will formulate explicit rules and guidance for application.

CHAPTER 2: Basic Concepts

2.1 Excluded Sources and Practices

In the B.S.S. (Annex I, para. A.I.3), it is suggested that competent authorities do not regulate the following: -

"(a) Devices producing x rays of quantum energy not exceeding 5 keV;

(b) Radioactive substances in the form in which they occur in nature without preparation intended to increase the concentration of radioactive nuclides."

The phrase "in the form in which they occur in nature without preparation" is subject to various interpretations. The control of exposures from these substances is not always practicable and they are therefore excluded from the whole system of control specified in the B.S.S. Examples of these are exposures resulting from potassium-40 in the human body, cosmic rays, and radon in the open air.

Although many naturally-occuring sources are excluded from regulatory control, certain practices result in the inadvertent mobilization and/or concentration of the radionuclides, such that workers or the public might receive doses high enough to warrant regulatory control of the practices. For example, radon daughters can concentrate in the air inside houses built on radium-rich soil, leading to high doses to the occupants breathing that air. Other examples are concentration of nuclides of the uranium series in phosphate fertilizers, or in building materials, mineral water factories, thermal spas, industrial uses of zircon sands, and coal fired power plants.

Specific guidance for controlling practices that result in enhanced exposures to naturally-occuring radionuclides is being considered internationally [BSS, ICRP 39], and should also be considered by the national competent authorities.

2.2. The concepts of Practice and Source

2.2.1 Introduction

The term "practice", usually associated with such terms as "operation" and "source" has been used very frequently in the last few years in radiation protection recommendations and regulations to characterise the object of specific guidance or assessment. Examples of this are the definition of "justification of an operation or a practice", the concept of "collective dose per unit practice", the "exemption of sources and practices from regulatory control", etc.

The guidance given in this report on the principles and criteria to be applied to exemption from regulatory control would be ambiguous and difficult to apply if a definition of what should constitute a "practice" and a "source" in the concrete situations for which exemption is considered were not given.

The exemption principles recommended in this report may be expected to find use in a variety of applications. These include, for example, the exemption from notification, registration and licensing of the disposal of certain types of low-level radioactive wastes in terrestrial and aquatic environments and the recycle of slightly contaminated materials from the nuclear industry. Also, in some applications the practice being considered for exemption may involve the whole cycle comprising the use and disposal of a source. In other cases, it may be appropriate to consider the disposal process itself as a separate practice.

It is clear, therefore, that the sources or practices may be of a widely varying nature; however they should all correspond to the following general definitions.

2.2.2 Practice

A practice may be defined as

"a set of co-ordinated and continuing activities involving radiation exposure which are aimed at a given purpose, or the combination of a number of similar such sets".

The size, scope and time duration of a practice can be different, depending on the purpose and the intended impact of the radiation protection assessment or regulatory action addressing the practice. For example, these three features can be different in the case of justification of the practice, or optimization of protection or licensing or exemption of a given activity.

In any event, when exemption from regulatory control is considered, the following features should characterise any identified specific practice:

a) the activities composing the practices must be co-ordinated and aimed at a common objective;

b) the sources which are the object of the practice should be clearly identified;

c) it should be possible to identify a specific critical group (or groups) uniquely linked to the practice;

d) the dose to the individuals of the critical group(s) and the dose to the whole population exposed by the practice should not be significantly affected by other similar (or identical) practices (e.g., several waste disposal sites in a same region).

e) the activities composing the practice must be easy to identify and describe, both in spatial and temporal terms, and be sufficiently well defined to facilitate impact analysis and regulatory assessments and to minimise the complexity of the procedures required for exemption from regulatory control.

2.2.3 Source

The "source" can be defined as "the physical entity whose use, manipulation, operation, decommissioning and/or disposal, constitutes the co-ordinated set of activities defined as "practice" in para 2.2.2". In other words, the "source" is not equivalent to the "practice", but is simply the radioactive material, the equipment emitting radiation or containing radioactive material or the installation (or group of installations) producing or using radioactive material, which is the object of the practice.

Specific features to be used to characterise a source include the possibility of distinguishing it from other sources not only in terms of its physical characteristics and location, but also in terms of different environmental pathways, critical group, etc.

2.2.4 Application

The application of all the above considerations to the field of exemption is liable to be different for the different practices. A few major cases are currently of primary interest. They include the use of consumer products, the disposal of very low level solid radioactive wastes, the recycle and reuse of materials resulting from decommissioning of nuclear facilities, and the discharge of very small quantities of radioactive effluents. [The proposed ~~definitions~~ of "practice" and "source" for these cases are discussed in Annex x.

Balance of Chapter 2

Applicable principles of radiation protection

1. The system of dose limitation, which is applied in the BSS to the regulation of practices involving exposure to ionizing radiation that are subject to control by a competent authority, must, of necessity, also be considered in exempting practices from such control. This system is comprised of three basic elements: justification of a practice, optimization of protection, and limitation of individual risk.

2. We consider here only those practices which have, in some manner, been justified, since this decision may be made outside the context of regulatory control (or exemption from such control, in the present case).

Optimization of Protection

3. A quantity used in the optimisation of radiation protection is the health detriment. It is defined as the expectation of deleterious consequences to health as a result of exposure to radiation, weighted according to their severity. In the consideration of exempt practices, these consequences will be limited to stochastic effects (cancer deaths and serious genetic effects) (ref. BSS). The health detriment is assumed, for the purpose of radiation protection, to be proportional to the collective effective dose equivalent commitment (ref. BSS). We will refer to this quantity henceforth, as the collective dose commitment.

4. The collective dose commitment, rather than simply the collective dose, is the appropriate quantity since the operation of a practice in a given year may produce doses in the future. Further, since incremental costs for regulation will be incurred on an annual basis, we use the collective dose commitment per year of practice. The size of a practice may also vary in time. For the purpose of making decisions about optimization, the year of relevance is that in which the practice reaches its maximum size.

5. The collective dose commitment is assessed ~~in terms of exposed~~ using average behaviour of radionuclide ~~transport~~ transfer and exposure of individuals. The unit of collective dose commitment is the man sievert (man Sv)**.

Limitation of Individual Risk

6. In the case of exemptions, the limitation of individual risk** is carried out by controlling the radiation doses in a group of individuals most likely to receive the highest doses from the practice. For this purpose, the concept of the critical group is introduced. This group is chosen to be representative of individuals receiving the highest levels of dose from the particular practice, and is defined so that it is reasonably homogeneous with respect to factors that affect the dose received. It is also necessary to choose that time when these doses are at their maximum value. The assessment then proceeds in terms of the average dose in the critical group.

7. Unless otherwise stated, throughout this document the term "dose" refers to the sum of the effective dose equivalent from external exposure in a given period and the committed effective dose equivalent from radionuclides taken into the body in the same period.

Additional considerations

8. Under the assumption of proportionality between dose and risk, a given increment in the individual dose or collective dose will always result in the same increment in the individual risk or in the collective health detriment independent of other contributions to individual or collective dose. This makes it possible to assess the consequences of the exposure from any arbitrary group of radiation sources, such as the group of radiation sources subject to exemption from regulatory control, and to limit these consequences without consideration of other sources.

** The proportionality factor, ~~for~~ between detriment and the probability of radiation-induced lethal cancers and serious hereditary effects is taken to be of the order of magnitude 10^{-2} per sievert.

9. However, In some instances the benefits derived from an exempt practice and the collective dose will be directly proportional to the number of sources used within a practice.

10. In considering the exemption of a particular practice, from the radiological point of view either the a) optimization of practice or b) limitation of individual risk may turn out to be a more restrictive factor, depending upon the nature of the practice.

CHAPTER 3 Principles for Exemption

There are two basic criteria for determining whether or not a practice is a candidate for an exemption from BSS: radiation protection must be optimized and individual risks must be sufficiently low. The [illegible] question is usually answered through a cost benefit analysis, intuitive or formal, or some other similar form of analysis. Nevertheless, it is useful for authorities to have guidelines about typical exemption levels which are commonly believed to be trivial and acceptable without a great deal of detailed analysis. That which follows is a derivation of those guidelines.

3.1 INDIVIDUAL-RELATED TRIVIAL RISK

In the case of individual members of the public, the concern is over the risk to which the individuals will be exposed. There appears to be agreement from many authors, that it is appropriate to apply the concept of a trivial level of dose, or risk, in a purely individual-related assessment: very small doses and the corresponding minute risk should not be of any concern, either for the regulator or for the individual himself [1,2,3].

For the individual there are two main considerations to deciding upon a trivial level of dose: firstly choosing a level of risk which is of no significance to individuals thence a level of dose; secondly to use the existence of the natural background or radiation exposure, to the extent that it is normal and difficult to avoid, as a relevant reference level.

3.1.1 The Risk-Based Considerations

In the first consideration it is widely recognised that levels of individual risk, which can be treated as insignificant by the decision-maker, can be judged as the point at which individuals who are aware of the risks they run would not commit significant resources of their own to reduce them [4]. This is a difficult point to judge because few people are conscious of the magnitude of small risks and have little opportunity to demonstrate their preferences. There is likely to be a wide range of individual views on this subject and any decision is likely to leave some people feeling that they are exposed to risks calling for further control.

although speculative,

There is a widely held view, ~~though better described as speculation~~ that few people would commit their own resources to reduce an annual risk of death of 10^{-5} and that even fewer would take action at an annual level of 10^{-6} [4]. Most authors proposing values of trivial individual dose ~~for radiation protection~~ have set the level of annual ~~radiation~~ risk of death which is held to be of no concern to the individual at 10^{-6} to 10^{-7} [5,6,7]. Taking a rounded risk factor of 10^{-2} Sv^{-1} for whole body exposure as a broad average over age and sex [8], the level of trivial individual effective dose equivalent would be in the range 10-100 μSv per year.

3.4.2 Natural Background Radiation Considerations

The level of natural background radiation has been judged to give a dose of about 2 mSV per year [9]. This average conceals a wide variation due to different concentrations of radioactive materials in the ground and in building materials, as well as differences due to living at different altitudes. About half of this dose is due to radon exposure, a source for which controls are suggested. The other half comes from exposure to cosmic rays, terrestrial gamma rays and radionuclides in the body for which control is impractical.

Individual members of the public do not generally take account of this variation in whole body natural background radiation when considering moving from one part of a country to another, or when going on holiday. It can therefore be judged that a level of dose which is small in comparison with the variation in natural background radiation, can be regarded as trivial. The figure of whole body or effective dose equivalent suggested by authors is of the order of one to a few percent of natural background [6,7], i.e. 20-100 μSv per year.

3.1.3 ~~Summary~~ Conclusions

The conclusion to be drawn is that a level of individual radiation dose, regardless of its source, is likely to ~~legitimately~~ be regarded as trivial if it is of the order of some 10's of μSv in a year.

It is noted that this level of dose corresponds to a few percent of the annual dose limit for members of the public and is much smaller than any upper bound set by regulatory authorities. recommended by the ICRP

The trivial individual risk level is most helpful in putting radiation risks to individuals into perspective. In most practical situations however, the regulatory need for an exemption arises in consideration of source-related assessments, where the total detriment, is the primary parameter of interest.

3.2 SOURCE-RELATED RADIATION PROTECTION CRITERIA

Doses resulting from sources or practices involving exposure to ionising radiation or to radioactive substances shall, according to the Basic Safety Standards (para 401), be restricted by a system of dose limitation which shall include justification of the practice, optimization of radiation protection, and annual dose limits. Acceptance of a practice will depend on many factors, mainly unrelated to radiation protection. For this reason justification is not discussed further.

Once a practice has been justified, it is necessary to design, plan and subsequently use the sources of exposure involved in the practice to ensure that "exposures are as low as reasonably achievable, economic and social factors being taken into account". This means that although the doses to the most exposed individuals, as a result of introducing a source of exposure, are below the relevant dose limits, it is still necessary to "optimize", that is, reduce the doses to as low as reasonably achievable. One of the techniques to carry out this optimization introduced by ICRP is the use of differential cost-benefit analysis [10].

In differential cost-benefit analysis, the cost of radiation health detriment saved, i.e. by reducing the doses, is compared with the cost of increasing the level of protection. The optimum level of protection is achieved when the next level spent on protection exceeds the value of health detriment thereby averted. This technique therefore provides a mechanism for deciding on the correct allocation of resources in protection against ionizing radiation.

For source-related assessments to be carried out, the IAEA recommends a procedure of assigning a cost for unit health detriment so that detriment can be "costed" and compared with costs of protection [1]. The International Atomic Energy Agency has developed guidance on the minimum value to be assigned to unit collective dose [11] and has proposed US$ 3000 per man-Sv in 1983 prices.

3.3 ~~4.~~ "Source/Practice-Related" Exemptions

3.3.1 ~~5.1~~ Individual Dose Considerations

For the purpose of exemption, it was concluded that a level of individual effective dose equivalent of some 10's of μSv in a year could reasonably be regarded as trivial by regulatory authorities.

Because an individual may be exposed to radiation doses, each of which is from a source or practice that may have been judged exempt, in order to ensure his total dose does not rise above the individual exemption dose criterion, each exempt source can only utilize a part of that criterion. If it is possible that an individual might be significantly exposed to doses from several exempt sources or practices, it may be reasonable for national authorities to apportion a fraction of the upper bound to each. This fraction could lead to critical group doses of the order of 10 μSv in a year from each exempt source.

3.3.2 ~~3.2~~ Collective dose considerations

It has to be recognized that the undertaking of optimization studies and their implementation may be costly in terms of regulatory time and resources. It can therefore be argued that where, in the absence of further protection measures, the residual individual doses and the collective dose commitment are sufficiently small, the cost of performing the optimization may in itself outweigh the savings in the cost of the potential reduction in health detriment. In such situations the rigorous use of cost-benefit analysis would not be justified and the initial assessment of levels of exposure may lead to a decision to exempt the material or source. This is not because the levels of dose and health detriment are of no concern per se, but because they are already optimal

A primary implication of this approach is that each source must initially be assessed as if it were to be formally subjected to an optimization procedure. Practical experience suggests that the cost of formal optimization procedures will be at least several thousand dollars [2,6]. The use of the IAEA minimum value of the man Sv of [11], would lead to a source-related Collective Exemption Level of the order of a few man Sv. For continuing practices this can be interpreted as a commitment of about 1 man Sv per year of practice.

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Chapter 4 Preparation and Administration of Exemptions

. Derivation of exempt quantities

In general, the methodologies to derive exemptions will be based on assessments of individual and collective doses that may arise from the exempt practice. These assessments should be appropriate to the practice under examination and as comprehensive and reliable as to satisfy the authorities that respect of the radiological protection criteria will be ensured. Other factors which may bear on the final decision to exempt a practice must also be considered, in particular relevant national provisions (e.g. conservation laws) and social and economic factors.

If a generic assessment, at its early stages, indicates that the likely consequences of exemption, in terms of dose, are below the chosen criteria, the authorities may well decide to lay down the quantities thus derived for immediate use. There may be cases, however, where such simplified procedure will be not satisfactory and more detailed assessments, including comparisons with other available alternative options, will be required.

In both situations, the assessment will be carried out using calculational models which take account of:

- the characteristics of the practice to be exempted;

- the characteristics of the sources involved in the practice.

Sufficient flexibility should be allowed in the choice of models and in their sophistication in order to avoid the expenditure of resources out of proportion to the task involved. Thus, simple deterministic models may suffice for the purposes of a generic study addressing a well defined case for exemption. More elaborate models will be needed in other situations and these

can be deterministic, covering in detail a sufficient number of exposure scenarios, and/or probabilistic designed to provide a measure of the uncertainty inherent in the modelling and the database used.

The choice of scenarios should be such as to cover all the likely pathways and exposure situations that arise as a result of the decision to exempt the practice in question. The national authorities will have to exercise judgment in considering exposure situations, associated with low probability of occurrence, in which the chosen radiological protection criteria may be exceeded. In most cases, however, the adoption of suitably conservative assumptions would be sufficient to provide the desired degree of confidence in the results of the assessment. Otherwise, more realistic assumptions using more detailed models may be required.

In general the models will be required to provide estimates of doses to workers and to members of the public. Both normal and accidental exposure conditions should be covered; the latter, although unlikely, may have consequences serious enough to contra-indicate exemption. This conclusion may also apply to cases of misuse of sources involved in the exempted practice, and, therefore, the possibility of such misuse will have to be considered.

Approaches to setting the derived quantities using the models may involve either an iterative process whereby representative values of these quantities are selected and modelling carried out to demonstrate compliance with the criteria chosen, or a normalization process in which doses are computed corresponding to a unit exempt quantity, which subsequently leads to the evaluation of total amounts of sources that may be exempted in a given practice, which may continue for a well-defined time. In both cases the ultimate fate of the sources involved, and their likely re-utilization must be adequately covered.

In the calculation of individual and collective doses, particular attention should be paid to:

- type of materials involved, physical and chemical characteristics, isotopic composition, surface and mass activity concentrations;

- total mass(es) and activities involved.

. Specification for an exemption

Radiation sources involved in an exemption usually pass from a stage where they are regulated under a system of notification, registration or licensing to an exempt status. In other words there is a transfer from a controlled activity to an exempt activity.

It is important to clearly define the exemption so that persons making the transfer as well as regulatory authorities and persons in possession of exempt material have a common understanding about what is exempted. Exemptions are rarely, if ever, expressed in terms of individual or collective dose since these parameters are not practical to measure at the operational level. Rather, exemptions should be expressed in quantities that are measurable at the point of transfer so that compliance with the provisions of the exemption can be determined. A common method used to express the basic parameters of exemptions related to waste streams or recycle scrap are concentrations of specific radionuclides. In the case of consumer products containing radioactive materials, the exemptions are often in terms of total activity of a specific radioisotope in a source and product.

In addition to the basic parameters for the exemption, there can be additional provisions in the exemption which enhance the probability that the assumptions about individual and collective doses upon which the optimization study for the exemption is based will not be invalidated and minimize accidents as well as misuse. Examples of these additional provisions include:

a) a constraint on the total activity [illegible]r which may be released in a year from a regulated activity in an exempt waste stream;

b) the chemical and physical form of the radionuclides permitted in the exempt waste stream as well as a specification of the origin or the nature of the waste stream, e.g. cor aminated oil from reactor pumps;

c) the chemical and physical form of the radionuclides contained in sealed sources employed in consumer products as well as design of the source and quality assurance requirements.

d) the identification of the type of person to whom recycled scrap may be sold, e.g. an automobile parts manufacturer, in order to better assure that recycled scrap will not enter products giving rise to high individual exposures during the period of first recycle.

. Administering the transfer from control to exemption

Once the conditions of an exemption are clearly specified, the next step is to establish a method whereby the regulatory authority can determine compliance with the exemption conditions as transfers are made from a controlled status to an exempted status. One practical method to accomplish this objective is to include in the regulated user's licence, authorization to transfer the material to a recipient exempted from regulation. The application for a licence provides the regulatory authority an opportunity to review in advance the procedures and methods by which the licensee will assure compliance with the provisions of the exemption. The licence can contain specific provisions which also enhance compliance with the provisions of the exemption. For example the license can contain record keeping requirements which are subject to inspection. In the case of contaminated scrap to be recycled, the license can specify the person to whom the scrap can be sold. In the case of waste streams, the license can identify a specific land fill in which the exempt wastes can be placed. It can also contain reporting requirements regarding the amounts released under the exemption so that the regulatory authority can monitor the status of use of the exemption, thereby providing data for revalidation of the initial optimization study which formed the bases of the exemption. While not necessarily appropriate in all cases, these types of techniques can be used in the licensing process to better understand and control the ultimate impact of the exemption.

. Retrospective analysis

Finally, good radiation protection practice involves periodic reanalysis of the original optimization study which formed the basis of the exemption to determine if adjustments are appropriate. The foundation of such a reanalysis should include reports of quantities released under the exemption, the results of compliance inspections of licensees making the exempt transfers, reports of misadventures with exempt materials and environmental sampling where feasible as well as testing of radioactive consumer products purchased in the market place.

Annex X

Proposed Definitions of Some Practices and Sources

1. Consumer Products

The term consumer products covers a large variety of items of general use and emitting radiation or containing radioactive substances. They include, for example, smoke detectors, timepieces, static eliminators, optical lenses, glassware, electron tubes, etc.

In principle, the sale and distribution of a number of consumer products are subject in Member countries to notifiaction, registration and, often, licensing. There may be, however, some types of consumer products whose associated radiation risk and detriment are so small that their sale and distribution could be exempted from licensing and, perhaps, even from notification and registration. The general definitions and conditions given in sections are expressed in the following way for consumer products:

2.2.2 and 2.2.3

The "practice" is defined as the sale, distribution, use and disposal of a given type of consumer product on a national scale (the production of these items is considered as a separate practice, which is usually subject to regulatory control.

The "source" is defined as the whole of individual radioactive sources represented by the single items of the consumer product being considered.

As far as the correspondence to the features indicated in section 2.2.2 is concerned, the situation is the following:

- conditions a) and b) are obviously satisfied by the definition given here for the practice;

- condition c) can be fulfilled (the identified critical group can be a specific group of users, e.g. group of transport and distribution workers, or other;

- condition d) can be generally fulfilled. The "other similar practices" to be considered for the assessment of their fractional contribution to the doses associated with the practice under consideration are the sale and distribution of other types of consumer products;

- condition e) can be fulfilled without significant difficulties if the practice covers one type of consumer product. This would be more difficult from the technical viewpoint and complicated from the administrative viewpoint if the definition of the practice, in order to comply with condition d), had to cover several different types of consumer products.

2. Low Level Solid Radioactive Wastes

In principle, the practice being considered for exemption is the disposal of very low level solid radioactive wastes to municipal landfills, or incineration facilities, or into the sea at coastal disposal sites. However, it is appropriate, for practical reasons, to deal with exemption from each site at which the practice is carried out. Therefore, in this case the "practice" is defined as the disposal of very low level solid radioactive wastes at a given municipal landfill, or incinerator, or coastal disposal site. This includes the operation of the site and the period of its remaining in existence after discontinuation of disposal. However, if more than one disposal sites were located at a short distance from each other and gave comparable contributions to the dose of a same critical group, the practice should be defined to cover the combination of these disposal sites in order to satisfy condition d).

The "source" is defined as the complex of radioactive wastes disposed of in the considered site (or group of sites).

As far as the correspondence to the features indicated in section 2.2.2. is concerned, the situation is the following:

- condition a) is obviously satisfied by the definiton given here for the practice;

- condition b) may be less easy to fulfil. In fact, although the definition proposed above for the source refers to the whole of waste streams terminating in the disposal site, the regulatory authority could find it more practical to consider as the source the installation (or group of installation) from which the wastes are generated;

- condition c) can be fulfilled (the identified critical group can be the workers at the disposal site or a specific population group);

- condition d) can be satisfied by a judicious choice of the site (sites) to be included in a given practice and the installations from which the relevant wastes are generated;

- condition e) may be less easy to fulfil due to the potential complexity and the variability of the set of installations and waste streams composing the source.

It is to be noted that a practice defined as in this case would cover one disposal facility or a small group of such facilities out of a much greater total number of potential disposal facilities existing in a country. In this case, therefore, the national authority should apply the recommendation of section _____ and take due account of the potential impact of the totality of disposal facilities in the country when deciding on its exemption policy.

According to another proposal which suggests a full application of the above mentioned recommendation of section _____, the "practice" to be considered for exemption should encompass the whole of low level solid wastes disposal activities across a country. In this case, the "source" should be defined as the whole of radioactive wastes disposed of in the totality of ~~municipal landfill and incineration~~ sites in the country.

This definition of practice would certainly better comply with recommendations of section _____. However, its correspondence with the features indicated in section 2.2.2 would only be incomplete and the practical application of the regulatory assessment and procedures for exemption would be difficult.

In fact, as far as the above mentioned features are concerned:

- conditions a) and b) would, of course, continue to be fulfilled;
- condition c) would be very difficult to apply in practice. It is, in fact, unlikely that a unified critical group could be identified for the complex of disposal sites in the country;
- condition d) would not be relevant any further;
- condition e) would be very difficult to fulfil in practice.

3. Low Level Radioactive Effluents

In principle, the practice being considered for exemption is the discharge of very small quantities of airborne or liquid radioactive effluents from certain types of facilities where radioactive materials are produced or manipulated. Examples of such facilities may include some radiochemical laboratories, research and educational institution, hospitals, manufacturing or other industries, etc.

Therefore, in this case the "practice" is defined as the discharge of low level radioactive effluents into the atmosphere or the aquatic environment at a given site. This covers the whole duration of the discharge operations.

If more than one installations were discharging their effluents into the same environment and gave comparable contributions to the dose of a same critical group, the practice should be defined to cover the combination of the discharges from these installations in order to satisfy condition d).

The "source" is defined as the installation (or group of installations) discharging the effluents considered.

As far as the correspondence to the features indicated in section 2.2.2 is concerned, the following considerations apply:

- conditions a) and b) are satisfied by the definitions given here for the practice and the source;

- condition c) can be fulfilled (the critical group is usually a specific population group living in the surrounding of the installation or having particular living or dietary habits);

- condition d) can be satisfied by a judicious choice of the installation(s) to be defined as the "source";

- condition e) may be more or less easy to fulfil depending on the features of the environment receiving the discharges and of characteristics of the population exposed.

4. Recycle or Reuse of Materials

Activated or contaminated materials (steel, aluminum, concrete, etc.) resulting, for example, from decommissioning of nuclear facilities could be recycled or reused without radiological restrictions if a regime of exemption were applicable to them.

In this case, the "practice" is defined as the set of activities starting from the release of the material (or materials) out of the boundary of regulatory control (for example, the boundary of a nuclear site) and including all the operations, manipulations and uses which lead to exposure of a critical group (or groups).

The "source" can be defined as the radioactive material(s) to be recycled or reused or as the nuclear facility(ies) releasing the material for recycle or reuse.

The scope of the defined practice and the definition of souce depend on the features of these activities with reference to section 2.2.2 and on the particular exemption policy preferred by a national authority.

If it is preferred, for practical reasons, to deal with exemption from each site producing material for recycle or reuse (e.g., an exemption for each nuclear power station to be decommissioned), then the "practice" would be defined to cover only the material released from a given site and it should be made sure that the critical group and population doses relative to that practice are not significantly affected by the contribution of materials released (for the same kind of uses) from other nuclear sites in the country.

On the other hand, it could be considered that, because different materials (e.g. steel, concrete, aluminum) are likely to be used in largely different ways and expose different groups of workers and popuation, it may be sensible to define each material as a different "source". In this case, the recycle and reuse of each separate stream of materials could be defined as a separate practice, because it would have a different purpose and would involve different exposure pathways and critical groups.

Moreover, some material (i.e. steel) released one year could well add to the exposure of the same group(s) as the (same type of) material released in another year from a same site or group of sites, so the "source" could comprise all the material of one type from one site, irrespective of the time of its production and release, and the "practice" definition could refer to the recycle and reuse of all that material irrespective of the time of its production (i.e. all the steel from decommissioning of one or more power stations).

The correspondence to the features indicated in section 2.2.2 can be seen in the following way:

- condition a) can be fulfilled for any of the above-mentioned possible definitions of the source;

- condition b) can be more or less easy to fulfil, depending on the choice adopted for the definition of the source;

- condition c) can be fulfilled with different degrees of difficulty and specificity depending on the definition adopted for the source;

- condition d) can be fulfilled by a judicious choice of the material(s) and site(s) composing a practice;

- condition e) can be more or less easy and complex to satisfy depending on the choice of the material(s) and site(s) comprising a practice.

Once again as for example 2. of this Annex, another possible proposal would be to consider as the "practice" to be exempted the whole recycle or reuse of materials going on in a country.

In this case, the "source" would be the totality of radioactive materials being recycled or reused, or the totality of nuclear sites originating these materials.

Once again, as previously noted, such a broader definition of the practice would certainly satisfy to the recommendation of section _____, but it would partially fulfil the conditions of section 2.2.2 and introduce difficulties and complications in the practical implementation of the regulatory assessment and procedures required for the exemption.

5. In conclusion, although the general definitions and conditions suggested in this document should be applied, it is felt that national authorities will have, in practice, to define practices and sources taking into account their local situations. For example, if several neighbouring power stations were being decommissioned at the same time and all their steel was going to the same smelter, explicit consideration should be given to the "overlap" question [see condition d] with regard to the workers at the smelter. This situation would, of course, affect the definition of "practice" and "source" to be established in concrete.

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Department of Nuclear Energy and Safety
Division of Nuclear Fuel Cycle and
Division of Nuclear Safety

Issue No. 2
1988-03-23

NOTIFICATION OF AN AGENCY-SPONSORED MEETING

Title of meeting: AGM on "Principles for the Exemption of Radiation Sources and Practices from the Basic Safety Standards for Radiation Protection

Dates of meeting: 21-25 March 1988

Scientific Secretaries: Mr. G. S. Linsley, NENF
Room A-2656; Ext. 2666

Mr. A. J. González, NENS
Room A-2643; Ext. 2704

Mr. O. Ilari, OECD/NEA

Place of meeting: Meeting Room C07-IV, VIC

Secretary: Ms. N. Barrios
Room A-2661; Ext. 2667

PARTICIPANTS	ADDRESS ABROAD	ADDRESS IN VIENNA	PERIOD
ARGENTINA			
Mr. D. Beninson	CNEA Avenida del Libertador 8250 1429 Buenos Aires	Hotel Astoria 1010 Kärtner Strasse 32 Tel. 52 65 85-0	19-26 March
CANADA			
Mr. G. Jack	Atomic Energy Control Board Martel Building 270 Albert Street Ottawa, Ontario K1P 5S9	Hotel Wandl 1010, Petersplatz 9 Tel. 636317	20-26 March
CZECHOSLOVAKIA			
Mr. Z. Dlouhy	Nuclear Research Institute Rez 25068	Hotel Alte Donau Wagramerstrasse 51 1220 Vienna	21-25 March

PARTICIPANTS	ADDRESS ABROAD	ADDRESS IN VIENNA	P É R I O D
FINLAND			
Ms. A. Salo	Finnish Centre for Radiation and Nuclear Safety P. O. Box 268 SF-00101 Helsinki	Hotel Wandl 1010, Petersplatz 9 Tel. 636317	20-26 March
FRANCE			
Mr. L. Fitoussi	Adjoint au Directeur des Recherches de Sécurité Nucléaire IPSN/DRSN Commissariat à l'Energie Atomique B. P. No. 6 92265 Fontenay-aix-Roses Cedex	Pension Pertschy 1010, Habsburgergasse 5 Tel. 533-70 94	20-25 March
GERMAN DEMOCRATIC REPUBLIC			
Ms. S. Przyborowski	Staatliches Amt für Atomsicherheit und Strahlenschutz der DDR Waldowallee 117 1157 Berlin		
HUNGARY			
Mr. L. B. Sztanyik	Frederic Joliot-Curie National Institute for Radiobiology and Radiation Hygiene P. O. Box 1010 H-1775 Budapest	Hotel Post 1010, Fleischmarkt 24 Tel. 51 583-0	20-25 March
ITALY			
Mr. M. Larsin	ENEA/DISP Via Vitaliano Brancati 48 I-00144 Rome	Hotel Nordbahn 1020, Praterstrasse 72 Tel. 24-54-33	
JAPAN			
Mr. Minoru Okoshi	Science and Technology Agency 2-2-1 Kasumigaske Chiyoda-ku Tokyo	Hotel Royal A-1010 Wien, Singerstrasse 3 Tel. 52-46-31	20-29 March

PARTICIPANTS	ADDRESS ABROAD	ADDRESS IN VIENNA	PERIOD
SWITZERLAND			
Mr. U. Niederer	Swiss Nuclear Safety Inspectorate CH-5303 Würenlingen	Hotel Kaiserin Elisabeth 1010, Weihburggasse 3 Tel. 51 526-0	20-26 March
UNITED KINGDOM			
Mr. R. H. Clarke	National Radiological Protection Board Chilton, Didcot Oxon OX11 ORQ	Pension Christina 1010, Hafnersteig 7 Tel. 5332961	20-25 March
U. S. A.			
Mr. A. Richardson	Office of Radiation Programs U. S. Environmental Protection Agency 401 M. Street S. W. Washington, D. C. 20460		
U. S. S. R.			
Mr. R. M. Barchudarov	Institute of Biophysics Moscow	Schiffmühlenstrasse 95 1220 Vienna	20-27 March
OBSERVERS:			
Mr. C. Pomroy	Atomic Energy Control Board Martel Building 270 Albert Street Ottawa, Ontario K1P-5S9 CANADA	Hotel Wandl 1010, Petersplatz 9 Tel. 636317	20-25 March
Mr. G. Gouvras	Health and Safety Directorate COMMISSION OF THE EUROPEAN COMMUNITIES Jean Monnet Building Rue Alcide de Gasperi L-2920 Luxembourg	Hotel Am Stephansplatz 1010 Stephansplatz 9 Tel. 534 05-0	20-25 March

PARTICIPANTS	ADDRESS ABROAD	ADDRESS IN VIENNA	P E R I O D
Mr. S. Benassai	ENEA Via Vitaliano Brancati 48 I-00144 Rome ITALY	Hotel Römischer Kaiser 1010, Annagasse 16 Tel. 512 77 51	21-25 March
Mr. Yoshikazu Yoshida	JAERI Tokai-mura, Naka-gun Ibaraki-ken JAPAN	Hotel Royal 1010, Singerstrasse 3	20-26 March
Mr. Shinichi Suga	JAERI Tokai-mura, Naka-gun Ibaraki-ken JAPAN	Hotel Royal 1010, Singerstrasse 3	20-29 March
Mr. F. Andaluz	Empresarios Agrupados C/Magallanes 3 28015 Madrid SPAIN	Erzherzog Rainer 1040, Mozartgasse (Wiedner Hauptstr. 27) Tel. 65-46-46	21-25 March
Mr. D. J. Tapia	Empresarios Agrupados C/Magallanes 3 28015 Madrid SPAIN	Erzherzog Rainer 1040, Mozartgasse (Wiedner Hauptstr. 27) Tel. 65-46-46	21-25 March
Ms. A. Hagen	UNITED NATIONS SCIENTIFIC COMMISSION ON EFFECTS OF ATOMIC RADIATION Rm. E0421, Vienna International Centre Vienna, Austria		
Mr. R. E. Cunningham	US Nuclear Regulatory Commission Washington, D. C. 20555 USA		
Ms. O. A.Zvetkova	All Union Scientific Center on Radiation Medicine Kiev USSR		

Department of Nuclear Energy and Safety
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Issue No. 2
1988-03-23

NOTIFICATION OF AN AGENCY-SPONSORED MEETING

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Dates of meeting: 21-25 March 1988

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Mr. R. E. Cunningham	US Nuclear Regulatory Commission Washington, D. C. 20555 USA		
Ms. O. A.Zvetkova	All Union Scientific Center on Radiation Medicine Kiev USSR		