Exemption from regulatory control: An international consensus

A summary of essential features and concepts

by G.S. Linsley and A.J. González

It has long been recognized that radiation sources, including equipment and installations, which emit ionizing radiations, are potentially harmful to health and that their use should therefore be regulated. The recommended regulatory approach is based on a system of notification, registration, and licensing.* Some types of radiation sources, however, do not need to be subject to regulatory control, either because they are not amenable to control (e.g. cosmic rays) and are therefore excluded from the regulatory process, or because they present such a low hazard that it would be a needless waste of time and effort to exercise control by a regulatory process. They can therefore be exempted from the regulatory process. National regulatory authorities have, in general, followed the approach outlined above of applying regulatory control only where it is needed. However, there is no internationally unified policy for excluding or exempting sources from regulatory control.

The need for a consistent international approach to exclusion and to exemption has become increasingly evident especially for sources which may be transported from one country to another; for example, consumer products containing very small amounts of radioactive material.

Background to international activities

The concepts of exclusion and exemption have been pursued in recent years through IAEA working groups under a general heading of "de minimis", mainly in relation to radioactive waste disposal in marine and terrestrial environments.** In 1984, a new programme was started with the specific objective of developing guidance on the principles for exemption of radiation sources and practices from regulatory control and on the application of the principles to practical problems. In 1985, two meetings were sponsored by the IAEA in co-operation with NEA and WHO on the subject of exemption principles. The text produced by the second of these groups was widely circulated and comments were received, *inter alia*, from NEA's Committee on Radiation Protection and Public Health, the European Communities' Article 31 Group, as well as from national organizations and individual experts. It was evident that further discussions would be necessary if a firm international consensus on exemption principles was to be achieved. Accordingly, an advisory group meeting was convened in Vienna in March 1988 sponsored jointly by IAEA and NEA. An IAEA Safety Series document is being published as a result of the advice received from the group.*

This paper presents a summary of what, in the opinion of the authors, are the essential features of the international consensus on exemption principles.

Concepts of exclusion and exemption

Virtually all materials are radioactive, either because they contain natural radionuclides or due to contamination with artificial radionuclides, usually at very low levels. For some of these materials, control by competent authorities is not always practicable or even possible. Examples of radiation sources for which control is not feasible are cosmic rays and radionuclides present in the human body (e.g., naturally radioactive potassium-40). Therefore, such sources are by their nature *excluded* from regulatory control.

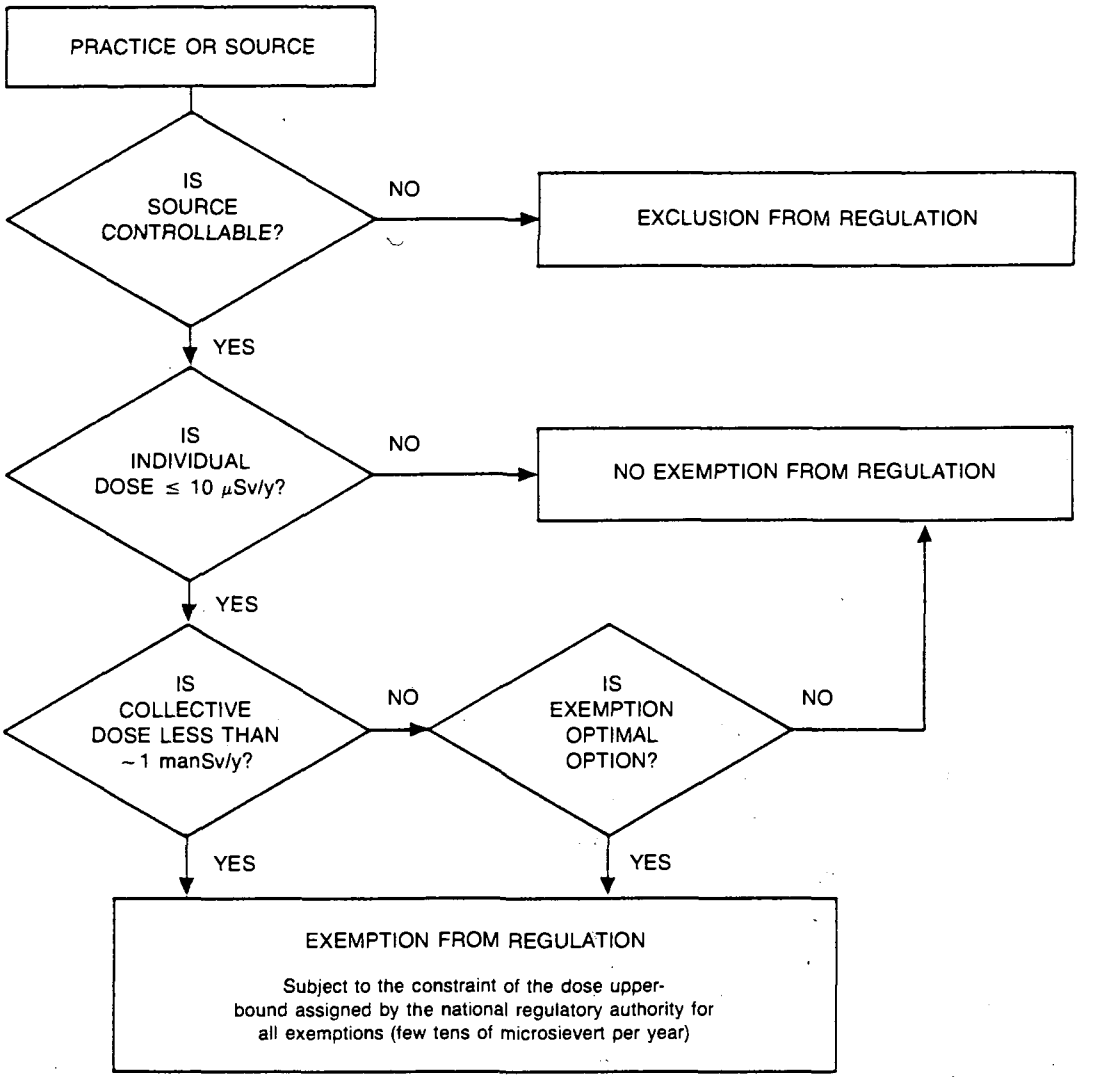
On the other hand, there are sources and practices involving radiation exposure which present such small risks to health that they do not warrant the application of the recommended systems of notification, registration, and licensing. These are candidates for *exemption* from regulatory control.

Mr Linsley is a senior staff member of the IAEA Division of Nuclear Fuel Cycle, and Mr González is Head of the Radiation Protection Section of the IAEA Division of Nuclear Safety.

* This is exemplified by the *Basic safety standards for radiation protection* of the IAEA, International Labour Organisation (ILO), World Health Organization (WHO), and Nuclear Energy Agency of the Organisation for Economic Co-operation and Development (NEA/OECD), 1982 Edition, Safety Series No. 9, IAEA, Vienna, (1982).

** *Considerations concerning "de minimis" quantities of radioactive waste suitable for dumping at sea under a general permit*, IAEA-TECDOC-244, Vienna (1981); and *De minimis concepts in radioactive waste disposal — considerations in defining de minimis quantities of solid radioactive waste for uncontrolled disposal by incineration and landfill*, IAEA-TECDOC-282, Vienna (1983).

* *Principles for the exemption of radiation sources and practices from regulatory control*, Safety Series, IAEA, Vienna (in press).



A flow sheet may help to outline the procedure for making decisions on the exemption of sources and practices. As shown, the methodology to derive an exemption is based on the assessment of the individual and collective doses that may arise from the practice which is a candidate for exemption. If a generic assessment, at its early stages, indicates that the likely consequences of the exemption, in terms of radiation exposure, are below the chosen criteria, the authorities may well decide to grant the exemption. In cases where such a simplified procedure indicates that the collective dose is not below the criterion, more detailed assessments, including comparisons with other available options, will be required. (The flow sheet was developed by the joint IAEA/NEA secretariat of an advisory group meeting at the IAEA in March 1988.)

Concepts of practice and source

Some clarifications on the distinction between the terms "practice" and "source" are necessary for the purposes of exemption.

A practice may be considered to be "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".* A few major examples of practices are currently of primary interest in the context of exemption. 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 installations, and the discharge of very small quantities of radioactive effluents.

A "source" has been defined as "the physical entity whose use, manipulation, operation, decommissioning and/or disposal, constitutes the co-ordinated set of activities defined as 'practice'."* It 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.

* *Principles for the exemption of radiation sources and practices from regulatory control*, Safety Series, IAEA, Vienna (in press).

Principles for exclusion and exemption

Exclusion. A source has to be excluded from regulatory control whenever such control is not feasible.

Exemption. From a radiation protection standpoint, there are two basic criteria for determining whether or not a practice can be a candidate for an exemption from the system of notification, registration, and licensing: (1) individual doses must be sufficiently low as to be of no concern for the exposed individuals and not to warrant regulatory action; and, (2) further reductions by regulatory control must be shown not to be justified in terms of the regulatory effort needed to achieve such reductions.

The first aspect is addressed by defining a level of individual risk and consequently of dose that can be assumed to be "trivial" for the individuals. The second aspect is usually addressed by using optimization criteria, either intuitive or through formal techniques, such as cost-benefit analysis.

Defining an individual related trivial dose

Risk-based considerations. There is a widely held, although speculative view that few people would commit their own resources to reduce a risk rate of severe harm of 10^{-5} per annum and that even fewer would take action at an annual level of 10^{-6}. Most authors have set the level of annual risk of severe harm which is held to be of no concern to the individual at 10^{-6} to 10^{-7}. Taking a rounded risk factor of 10^{-2} Sv^{-1} for whole-body exposure as a broad average over age and sex, the level of individual effective dose equivalent considered to be trivial from the individual's point of view would be in the range of 10–100 microsievert per year.

Natural background radiation considerations. The level of natural background radiation has been estimated to give, as an average, an individual dose of about 2 millisievert per year. 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 different altitudes and habits of living. On a global average, 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 not feasible. Individual members of the public do not generally take account of the variation in exposure to natural background radiation when considering moving from one part of the 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. A figure of whole-body or effective dose equivalent of the order of one to a few per cent of natural background (i.e., 20–100 microsievert per year) has been suggested.

Trivial dose. The conclusion to be drawn is that a level of individual radiation dose, regardless of its origin, is likely to be regarded as trivial by the individual concerned if it is of the order of some tens of microsievert per year. It is noted that this level of dose corresponds to a few per cent of the annual dose limit for members of the public recommended by the ICRP.*

Optimization of protection

Optimization of protection requires that protection be improved to reduce doses to levels such that further dose reductions do not warrant the efforts needed to achieve such reduction. This basic principle must also be considered in exempting practices from regulatory control. One of the techniques for implementing optimization is the use of differential cost-benefit analysis. In differential cost-benefit analysis, the value assigned to the radiation health detriment saved by reducing the doses is compared with the cost of increasing the level of protection in order to achieve such reduction. The optimum level of protection is obtained when the next level spent on protection exceeds the value of health detriment thereby averted.

A method of avoiding a full optimization analysis is to establish a trivial value of radiation health detriment for exemption purposes. Then, if the health detriment (expressed as collective dose) is less than this value, the protection may be considered to be already optimized.

Practical experience is said to suggest that the cost of any formal optimization procedure would be at least several thousand US dollars. For purposes of controlling transboundary releases, the IAEA has recommended a minimum value to be assigned to the unit collective dose in cost-benefit analysis assessments.** The recommended value is US $3000 per man-sievert in 1983 prices. If this value were used in a cost-benefit analysis for exemption, it would lead to a practice-related trivial collective dose for exemption purposes of the order of a few man-sievert. For continuing practices, this may be interpreted as a commitment of about 1 man-sievert per year of practice.

Application of the principles for exemption to a single practice

Individual dose considerations. It seems, therefore, that for the purpose of exemption a level of individual effective dose equivalent of some tens of microsievert in a year can be reasonably regarded as trivial by regulatory authorities. Because an individual may be exposed to radiation doses from several practices that may have been judged exempt, in order to ensure that his total dose does not rise above the individual exemption dose criterion, each exempt practice should only utilize a part of that criterion, and it may be reasonable for national

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* "Statement from the 1985 Paris Meeting of the ICRP", International Commission on Radiological Protection, Pergamon Press, Oxford, *Annals of the ICRP 15 3* (1985).

** *Assigning a value to transboundary radiation exposure*, Safety Series No. 67, IAEA, Vienna (1985).

authorities to apportion a fraction of that upper bound to each practice. This fractionation could lead to individual doses to the critical group of the order of 10 microsievert in a year from each exempt practice.

Collective dose considerations. Each practice should be initially assessed as if it were to be subjected to a formal optimization procedure. A generic study of the available options (including various kinds of regulatory action) should be made by the regulatory authority and the conclusion reached that exemption is the option that optimizes radiation protection. If this generic study, in its early stages, indicates that the collective dose commitment resulting from 1 year of the unregulated practice will be less than about 1 man-sievert, it may be concluded that the total detriment is low enough to permit exemption without more detailed examination of other options.

Other considerations. Exemption is intended for sources and practices which are inherently safe in the sense that there is no possibility of scenarios leading to radiation doses significantly higher than the ones assessed for the anticipated scenarios.

In considering the exemption of a practice, the regulatory authority should aim to exempt the practice as a whole. Where this is not feasible (as in defining exempt quantities of waste from one of many institutions) the authority should have regard to the implications of the total effect of these exemptions across the whole practice.

The formulation of an exemption should not allow the circumvention of controls, that would otherwise be applicable, by such means as deliberate dilution of material or fractionation of the practice.

Outlook

The international agreement on exemption principles is expected to lead to a more unified worldwide approach in exempting radiation sources and practices from regulatory control. Perhaps the most important feature of the work is that a logical procedure for establishing exemption criteria has been agreed internationally. Thus, although it is possible that the actual dose values used could change, because of different levels of ambition or because of changes in the associated dose/risk factors, the framework for arriving at the criteria should remain the same. The IAEA is continuing its work in this area by providing guidance to its Member States on how to use the exemption principles in some of the main application areas. Guidance on a methodology for deriving exempt concentrations of radionuclides in low-level wastes for disposal in municipal landfills or by incineration has already been prepared.*

Work is under way on the application of the principles to the use of consumer products, in the recycle and reuse of slightly contaminated materials from decommissioning nuclear facilities, and in the disposal of very low-level radioactive materials in the marine environment.**

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* *Exemption of radiation sources and practices from regulatory control: Interim report,* IAEA-TECDOC-401, Vienna (1987).

** *Code of practice on regulating the use of consumer products containing radioactive materials,* Safety Series, IAEA, Vienna (in preparation); and *Exemption principles applied to the recycling of materials from nuclear facilities,* Safety Series, IAEA, Vienna (in preparation).