

Protection of the environment from the effects of ionizing radiation

A report for discussion



INTERNATIONAL ATOMIC ENERGY AGENCY



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FOREWORD

The acceptability of practices which involve the release of radionuclides into the environment, and of situations where residual radionuclides from accidents or improperly controlled practices exist in the environment, are generally assessed on the basis of implied radiation doses to humans. This approach is consistent with the recommendations of the International Commission on Radiological Protection (ICRP), which include the statement that "the standard of environmental control needed to protect man to the degree currently thought desirable will ensure that other species are not put at risk". The general applicability of this statement has been explored in previous IAEA and other publications. These concluded that the statement is generally valid but that reliance upon human based radiological protection criteria may not be adequate for all possible space or time scales.

In recent years awareness of the vulnerability of the environment has increased and the need to protect it against the effects of industrial pollutants has been recognized. This trend is reflected in new and developing international policies for environmental protection. In the context of protection of the environment against ionizing radiation, the existing international approach is being challenged in some IAEA Member States and proposals are being made for strategies which provide for explicit protection of the environment.

The present publication represents a first step towards establishing an internationally accepted philosophy and associated methodology for protecting the environment against ionizing radiations. The report reviews the various related issues and examines possible approaches to establishing criteria. It is intended for use in stimulating discussion on the subject in Member States. For its part, the IAEA intends to continue a programme of work in this area with the long term objective of providing specific recommendations on primary protection criteria and methods for demonstrating compliance with such criteria.

The report was developed with the assistance of consultants under the leadership of W. Whicker, USA, and reviewed at a Technical Committee meeting in January 1999. K.-L. Sjoeblom of the Division of Radiation and Waste Safety was the responsible officer at the IAEA.

EDITORIAL NOTE

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1. INTRODUCTION

1.1. BACKGROUND

As the world population grows in size, it is coming to be recognized that a healthy environment¹ is essential to the well-being of humans. Among other things, healthy ecosystems maintain the quality of air, water and soil; and they provide food, fibre, energy, recreation, and cultural and psychological benefits to people.

Protection of the environment from human activities is provided for in many national regulations. However, few deal specifically with standards or criteria relating to the effects of ionizing radiation on the non-human components of the environment. In other areas of environmental protection, examples exist of national and international legislation developed to protect either individual species or specific groups of animals or plants.

In the case of radionuclides entering the environment, however, controls have been based on limiting the risk of harm to humans alone. Indeed, it has been stated by the International Commission on Radiological Protection (ICRP) that:

"Although the principal objective of radiation protection is the achievement and maintenance of appropriately safe conditions for activities involving human exposure, the level of safety required for the protection of all human individuals is thought likely to be adequate to protect other species, although not necessarily individual members of those species. The Commission therefore believes that if man is adequately protected then other living things are also likely to be sufficiently protected." [1]

The ICRP statements on this subject have changed slightly over time, resulting in the following statement in ICRP Publication 60:

"The Commission believes that the standard of environmental control needed to protect man to the degree currently thought desirable will ensure that other species are not put at risk. Occasionally, individual members of non-human species might be harmed, but not to the extent of endangering whole species or creating imbalance between species." [2]

These statements are consistent with, and support the long standing practice applied in many countries, of using human protection criteria and practices to infer protection of the environment from effects of ionizing radiation. The extent to which such statements apply has been discussed in several publications, e.g. [3, 4]. In particular, it has been pointed out that reliance upon human radiological protection criteria may not be adequate for all possible space or time scales, nor for all circumstances. For example, in an intervention situation involving the management of a contaminated area from which the people have already been removed, the protection of the environment itself may be a significant concern [5].

Furthermore, there is a growing need to examine methods to explicitly address the protection of the environment from radiation. The concept of sustainable development² places environmental protection on an equal footing with human protection, on the basis that it is necessary first to protect the environment in order to protect human populations. It is therefore necessary to demonstrate protection of the environment explicitly. Another concern is that, without specific criteria or standards, it may become difficult to gain public acceptance of any activity involving possible releases of radionuclides. The lack of specific criteria or standards may also lead eventually to legal difficulties. International and national policy commitments

For the definition of the environment as used in this report, see Definitions.

² See Definitions

have been made to protect the environment but there is no generally accepted method of demonstrating how the policy commitment can be met.

Thus, in summary, although the ICRP's radiation protection framework is currently the normal basis for controlling environmental releases of radionuclides, the need to examine further the subject of radiological protection for the environment is recognized for the following reasons:

- the ICRP statements might not apply to all time and space scales or under all conditions such as situations where humans, or pathways to them, are absent;
- the lack of specific environmental protection criteria or standards, and guidance to support their implementation, may undermine public confidence in decisions made with regard to various nuclear issues, such as waste disposal options and assessment of their impacts;
- approaches to assessing the environmental impact of radionuclides (protection of the public) differ from those used to assess the impact of other pollutants (protection of biota), thereby creating inconsistency in the underlying bases of standards applied to the radioactive and non-radioactive materials of authorized discharges from licensed nuclear sites;
- there is no internationally endorsed method of providing explicit assurance that measures presently taken to protect the environment against ionizing radiation are adequate.

A framework for protecting the environment must deal with many issues. A fundamental issue is the 'endpoint' or the measurable objectives of the framework. For human radiological protection the endpoints are clear, and relate to the protection of individuals from specific expressions of harm and at numerically defined levels of risk. Should this be done for other species? This problem is not materially different from that pertaining to the protection of fauna and flora from other pollutants. Numerous 'endpoints' have been considered: harm to individuals or populations; to embryos or adults; stochastic or deterministic effects; physiological, genetic, mutagenic effects and so on. The issue of the appropriate definition of 'harm' is not unique to radiological protection. There is now sufficient literature on this topic [4] to move ahead and a consensus on this issue is needed.

Demonstration of compliance with any set of criteria or standards that may ultimately arise is also an important issue. The approach would depend on the precise nature of the criteria or standards. For the majority of potential environmental pollutants, standards are usually set in terms of chemical concentrations in specified materials, although other 'environmental' criteria and targets are used to demonstrate compliance with specific policy decisions and regulatory frameworks for human and non-human species. For humans, radiation standards are expressed in terms of effective dose, and compliance is assessed by direct dosimetric measurement and/or by rigorous modelling. Both techniques are also being developed and used in the field of environmental protection. However, present uncertainties in models for ecological dosimetry could be reduced considerably with more knowledge.

1.2. OBJECTIVE

The objective of this report is to examine the need for the development of criteria and approaches for protection of the environment from the effects of ionizing radiation in different situations, such as, the controlled discharge of radioactive materials, the disposal of solid radioactive wastes, and the aftermath of accidental releases of radioactive materials. The

present report is intended to promote discussion which might eventually lead to the development of an IAEA Safety Standard providing specific recommendations on primary protection criteria as well as methods for demonstrating compliance with such criteria.

1.3. SCOPE

The report examines the subject of protection of the environment from the effects of ionizing radiation (hereafter referred to as 'radiation') as broadly as possible. It does not restrict itself to any one section of the environment, nor to controlled releases, nor to environments that contain human populations or sources of food. Reference is primarily made to the effects of radiation on fauna and flora. The extensive literature describing the effects of radiation on plants and animals was reviewed quite recently by UNSCEAR [4], and this information is not repeated here.

A number of relevant multilateral commitments have been made to protect the environment from the effects of radioactive substances and various approaches are already being adopted in some countries. Some of the existing commitments are outlined and, although a comprehensive review of current international practice has not been undertaken, information on the situation in various countries is given in an appendix and an annex hereto.

1.4. STRUCTURE

Following this Introduction, Section 2 describes some of the existing principles and policies relevant to protecting the environment. Section 3 briefly reviews a number of relevant regulatory approaches, and Section 4 addresses the concepts of ecological risk assessment that could be considered in the development of standards, criteria and guidance for protection of the environment from ionizing radiation. Section 5 provides conclusions.

2. RELEVANT PRINCIPLES AND POLICIES FOR ENVIRONMENTAL PROTECTION

Numerous principles and policies have been established by international bodies, organizations and governments which are directly or indirectly relevant to this discussion paper. Such *principles* usually represent a very broad consensus on goals which, in this case, often relate to the present and future welfare of mankind, and the quality of the environment. *Policies* usually represent formal statements from governing bodies which are intended to influence human activities and actions. Such policies often result from, and relate to, consensus-driven principles.

A number of principles relevant to environmental protection from ionizing radiation have been developed over the years by the IAEA. Examples include the Safety Fundamentals on Radioactive Waste Management [6] and on Nuclear Installations [7]. Several of the fundamental principles of radioactive waste management [6] apply directly or indirectly to environmental protection. Principle 2 states that "Radioactive waste shall be managed in such a way as to provide an acceptable level of environmental protection". In elaborating on this principle, mention is made of the fact that, as part of radioactive waste management, radioactive substances may be released within authorized discharge limits. Discharges would potentially have an effect on organisms other than humans, thus impacts of exposure to non-human organisms should be taken into consideration.

On the subject of protection beyond national borders (Principle 3 in the Safety Fundamentals [6]), it is stated that any detrimental effects imposed by environmental radioactivity on other countries should be kept as low or lower than that which is regarded as acceptable within the country that is in control of these discharges. Principle 4, dealing with protection of future generations, has relevance from the general point of view that detrimental effects occurring in the future should be of no less concern than such effects occurring today.

As part of the development of an IAEA Technical Report on the effects of ionizing radiation on plants and animals [3], an effort was made to assess the likely dose rates to fauna and flora, from controlled discharges of radionuclides to the atmosphere, to surface waters, and into waste repositories. It was concluded that, at discharge rates which would not give rise to doses to members of the public in excess of 1 mSv/a (the ICRP dose limit for members of the public), doses to fauna and flora in the pathways leading to human exposure would generally be less than those likely to harm them. The study did, however, conclude that the presence of rare or endangered species or combined stresses, at any particular site, might require specific assessments of environmental effects.

A somewhat different case in which the IAEA has been involved is related to the former practice of deep sea disposal of radioactive waste [8]. It was shown that the radiation dose rates to deep sea fauna likely to cause environmental harm could occur without the dose limit of 1 mSv/a to humans being exceeded [9].

The general scope of environmental protection has widened in recent years, mainly as a result of the United Nations Conference on Environment and Development (UNCED) Earth Summit in Rio de Janeiro in 1992. The Rio Declaration on Environment and Development [10] emphasizes the issue of sustainable development, implying that development should only take place with proper consideration of the use and maintenance of natural resources. It was agreed that "environmental protection shall constitute an integral part of the development process and cannot be considered in isolation from it" (Principle 4). The Convention on Biological Diversity³ [11] addresses the issue of protection of the environment specifically in terms of preserving genetic and biological diversity, biological resources, and habitats.

Agenda 21 of the report of the UNCED also contains specific recommendations concerning radioactive wastes and the environment. It is recommended that States should:

- "Support efforts within IAEA to develop and promulgate radioactive waste safety standards or guidelines and codes of practice as an internationally accepted basis for the safe and environmentally sound management and disposal of radioactive wastes."
- "Promote proper planning, including environmental impact assessment where appropriate, for safe and environmentally sound management of radioactive waste, including emergency procedures, storage, transportation and disposal, prior to and after activities that generate such waste."

It would therefore seem necessary that these points be considered and elaborated in further detail in connection with radioactive contamination of the environment.

Another relevant document is the Convention on Environmental Impact Assessment in a Transboundary Context (a regional convention for Europe) which was agreed in 1991 and came into effect in 1997 [12]. The list of activities to which this Convention's requirements apply include nuclear power stations and other nuclear reactors, production and enrichment of nuclear fuels, reprocessing of irradiated nuclear fuels, and the storage, processing and disposal of radioactive waste.

³ See Definitions hereto for definitions of biological diversity and biological resources.

3. EXISTING REGULATORY APPROACHES FOR ENVIRONMENTAL PROTECTION

There are many policies and principles relating to nuclear safety and radioactive waste management which have the stated objective of protecting the environment against radiological hazards. Until recently most national regulatory agencies discharged their environmental protection mandate within the ICRP framework of limiting radiation doses to members of the public. However, in the context of environmental protection policies and regulations currently enacted (e.g. the European Union's Directive 97/11/EC [13], the Canadian Environmental Assessment Act [14], Canada's Nuclear Safety and Control Act [15], the USA's CERCLA regulations [16]), or in the process of being enacted, (e.g. within the OSPAR Convention for the Protection of the Marine Environment of the North-East Atlantic [17]), activities which may give rise to radiation impacts on the environment are becoming subject to requirements for both human radiation protection and environmental protection.

In some countries, standards already exist for the protection of fauna and flora against the effects of chemicals. Nuclear sites are large and complex, and handle many chemicals that are controlled within an environmental protection framework. It would, therefore, be advantageous if criteria developed for protection of the environment from radioactive substances were compatible with those developed for other substances likely to be released from the same site. An environmental radiation protection framework consistent with current approaches for non-radioactive substances is therefore needed to assess a site's total impact on the environment. Furthermore, it is stated in the IAEA Safety Fundamentals that:

"radioactive waste management should be undertaken with a level of environmental protection at least as good as that required of similar industrial activities." [6]

implying that radiation protection standards or criteria should reflect at least the same level of protection as those adopted for chemicals.

There are several instances where regulatory standards are in the process of being developed for protection of the environment from ionizing radiation. For example, in the United States, the Department of Energy (DOE) currently has in place a dose rate standard (10 mGy/d) for the protection of aquatic organisms [18] and is considering inclusion of primary dose rate standards for the protection of both aquatic and terrestrial biota in a proposed rule [19]. The DOE has decided not to promulgate these criteria until guidance for demonstrating compliance with the standards has been developed. In this regard, DOE is currently developing screening methods for evaluating doses to biota for comparison with those standards and for conducting ecological assessment of radiological impacts. These dose standards are based on conclusions of an IAEA report [3] and a DOE workshop [20] which independently examined these conclusions and relevant scientific data. A similar effort is under way within Canada's Atomic Energy Control Board (AECB) and Department of the Environment, and by Sweden's Radiation Protection Institute.

In the context of the OSPAR Convention for the Protection of the Marine Environment of the North-East Atlantic, the OSPAR Commission will:

"undertake the development of environmental quality criteria for the protection of the marine environment from adverse effects of radioactive substances and report on progress by the year 2003." [24]

Other nations are also beginning to develop, or are contemplating development of, relevant regulatory standards.

3.1. ENVIRONMENTAL IMPACT ASSESSMENT

Virtually all countries that engage in activities that might give rise to radiation impacts on the environment now have environmental impact assessment (EIA) regulations and have developed procedures and assessment methods for implementing these regulations. Although these differ in detail from country to country, the basic features of the EIA systems are essentially similar, and these are well illustrated by the European Union regulations [13, 21]. These requirements are mandatory for numerous types of nuclear projects, including:

- (a) installations for the reprocessing of irradiated nuclear fuel;
- (b) installations designed:
 - for the production or enrichment of nuclear fuel,
 - for the processing of irradiated nuclear fuel or high-level radioactive waste,
 - for the final disposal of irradiated nuclear fuel,
 - solely for the final disposal of radioactive waste,
 - solely for the storage (planned for more than ten years) of irradiated nuclear fuels or radioactive waste in a different site than the production site.

Additionally, any changes or extensions to existing projects are, according to certain criteria, subject to these same requirements by the EU Member States.

The provisions contained in these Directives, as subsequently applied in EU Member State legislation, regulate the coverage of environmental assessments for the types of projects listed above and the process and procedural requirements they must satisfy.

Based upon these provisions, or similar ones in legislation applicable to other countries (e.g. Canadian Environmental Assessment Act [14]), procedural arrangements covering each of the stages in the EIA process have evolved and assessment methods have been developed to assist in undertaking the different tasks at each of these stages. To meet the requirements of the EIA regulations, procedures and assessment methods are being developed for radiation protection of the environment by various national agencies.

Numerous other legislative mandates also exist that automatically require environmental impact analysis of proposed actions or management strategies. One example in the USA is the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) [16]. Often referred to as 'Superfund', this legislation deals with alternative management strategies for historically contaminated sites. Under this legislation, assessments of the human health and ecological risk implications for all reasonable management alternatives are required. This legislation applies to all stressors present at the contaminated site, including radionuclides. In response to these regulations, many assessments of potential radiation impacts on contaminated ecosystems are currently under way in the USA.

4. FACTORS AFFECTING THE FUTURE DEVELOPMENT OF SPECIFIC CRITERIA FOR ENVIRONMENTAL PROTECTION

It is important to consider the factors and issues that may need to be addressed in developing radiological protection criteria for the environment, based on the concepts of risk and harm.

4.1. TARGETS AND ENDPOINTS OF CONCERN

The general target for radiation protection considered in this report is that of the Earth's biosphere and its inherent interacting components (air, water, soils, sediments, plants, animals

and human beings). In practice, the spatial extent of the actual target is limited to a particular geographic area of potential impact. Focus is generally, though not always, placed on potential radiation impacts on the living components of the environment (i.e. plants and animals), rather than the abiotic components (air, water and soil). Of course, abiotic media may be affected indirectly if plants and animals are affected, and at sufficient doses, these media may be directly affected. Focus in this report is nevertheless placed on the protection of plants and animals.

There are numerous biological endpoints that might be theoretically considered for radiation protection of the environment. These can range from molecular changes (e.g. DNA damage) in individual cells, to complete devastation of the ecosystem. Some example endpoints that have received scientific study in relation to radiation effects include chromosome mutation frequency, reduced repair enzyme capability, effects on immune systems, physiological change, productivity reduction, reproductive impairment, life span shortening, lethality, community diversity reduction and alteration of community structure.

The question then arises whether, for species other than man, one should be concerned primarily about 'harm' to the individual, or 'harm' expressed at a population level. This is still an area open to discussion. In some countries, special protection is given in law to individuals of certain species, for example, those that are threatened or endangered, or that have particular economic or cultural value. In such cases, harm to an individual may be a relevant endpoint. However, the traditional view is that, for most species, it is protection from harm at the population level which is the principal focus of concern [3, 4, 9, 22]. Indeed environmental protection criteria or standards derived for non-radioactive chemicals are usually intended to protect populations.

If criteria were established on the basis of protection of the population, the appropriate definition of a population may need to be considered in detail in applying the criteria. For example, in many regulatory settings a population is defined as the group of individuals of a particular species in an exposed habitat. The spatial boundaries of the habitat would need to be defined to take account of the spatial extent of radioactive contamination and the mobility or breeding range of the species.

The biosphere is composed of many different habitats each having rather distinct physical characteristics and unique assemblages of plant and animal communities, and with different species that may have extremely varied exposure pathways and vulnerabilities to radiation stress. There are an almost infinite variety of shapes, sizes, and types of fauna and flora such that it would be impossible to develop models, and to obtain data for all of them. In some areas, scientific knowledge and data may permit the development of protection criteria for major taxonomic groups (e.g. mammals, birds, fish and so on).

In general terms, there are two possibly complementary approaches to selecting targets for assessment purposes. One is the use of *reference* types of fauna and flora for which data bases of dose models could be derived. The other is to identify, if possible, *critical species* for a given situation [23]. A *critical species* would be defined as that which is thought to be the most vulnerable biological component of a given ecosystem such that, if adequately protected, would provide assurance that all other species in the community were also protected. The demonstrated lack of detrimental effects on the most vulnerable component(s) of a community would ensure that there were no harmful effects on the community as a whole, or on the ecosystem in general. Identification of the critical species should consider several factors, including:

— exposure potential (e.g. dose rate to vulnerable tissues per unit of contamination density);

- radiosensitivity (e.g. effect per unit dose rate);
- reproductive strategy, including age when reproductive;
- importance to the structure and function of the biological community; and
- genetic isolation.

In principle, identification of reference or critical fauna or flora is similar to the assessment endpoint identification step found in numerous existing ecological risk assessment frameworks, e.g. [24, 25]. The lack of specific knowledge and scientific data can be a problem for projections over very long time frames, where the composition of ecosystems may change. In such cases, the weight of evidence from the general scientific literature and expert judgement may be needed to identify the organisms likely to be the most vulnerable to radiation effects for particular ecosystems.

Most research has shown that the most radiosensitive stages of the life cycle are those associated with reproduction (i.e. the effects on gametes and embryos, rather than on the life expectancy of juveniles and adults). This is obviously of relevance when considering the potential effects of radiation on populations; if recruitment to a population exceeds mortality, a population should be able to maintain itself, and even expand, if available resources permit. Recruitment might be realized either through reproduction within the exposed group of individuals, or from immigration of unexposed individuals from surrounding or adjacent areas. Community and ecosystem level changes require changes in at least the more sensitive populations.

Another ecologically relevant endpoint, at least on a limited time-, and spatial scale, is growth and productivity of longer-lived plant tissues. For example, coniferous forests can die at relatively low radiation dose rates because of reductions in photosynthetic production and growth. This can lead to a slow death of the forest cover, as was observed following the Chernobyl accident. Following such losses of the coniferous forest cover, more radiation-resistant plants, including grasses, shrubs and deciduous trees, may appear. This would constitute a significant change in the structure of the biological community. This endpoint may be of particular relevance for a period of the order of years, if the loss of forest cover leads to deleterious changes to the ecosystem. If viable seeds or other easily-dispersible propagules that can colonize impacted areas are not available, then long term ecosystem changes in the local environment can be expected.

Genetic damage can be measured in organisms at dose rates well below those known to impair reproduction. The ecological and evolutionary consequences of such damage are uncertain because of repair and selection processes. The study of genotoxins and their influence on populations is an emerging discipline. Some studies show that effects expressed at the population level from genetic changes are far more complex than would be suggested by the simple loss of deleterious genes through natural selection [26, 27]. Hence, genetic damage may need to be kept under review at radiation dose rates less than those needed to cause significant reproductive changes. This consideration is not specific to radiation but also applies to other genotoxic agents. It is, therefore, important to consider pollutant-induced genetic damage in the perspective of the natural frequency of mutations.

4.2. DEVELOPMENT OF PROTECTION CRITERIA

Environmental protection criteria derived for non-radioactive substances often represent concentrations at which no effects on the most sensitive species and the most sensitive stage of its life cycle are expected to be observed. This concentration is then considered to protect the entire ecosystem from which this critical species is derived.

Although a significant body of scientific information exists on the effects of ionizing radiation at high doses and dose rates, there are limited data available on the effects of exposure to the low radiation doses. This information is mainly based on laboratory experiments on individual organisms. Most of the data were developed from designed experiments, in which X ray or sealed gamma radiation sources were used to irradiate individual plants and animals. There is, however, also some information related to the effects of radiation on populations and communities in natural settings, where intact ecosystems were irradiated with large gamma radiation sources. In addition, the nuclear accidents at Kyshtym and Chernobyl produced measurable impacts on plant and animal populations. Experimental data were reviewed in an IAEA report in 1992 [3] and more recently by UNSCEAR [4].

A general conclusion of the 1992 IAEA Technical Report [3] was that there is no convincing evidence that chronic radiation dose rates below 1 mGy/d (0.1 rad/d) will harm animal or plant populations⁴. It was also stated that "in the aquatic environments, limiting chronic dose rates to 10 mGy/d (1 rad/d) or less to the maximally exposed individuals in the population would provide adequate protection for the population". The conclusions of this report were independently examined and endorsed at a US Department of Energy workshop on environmental protection [20]. The UNSCEAR report [4] concluded that detrimental effects on the most sensitive populations would not be expected at dose rates below 1–2 mGy/d for low-LET radiation.

The numerical value of a dose rate criterion will also be influenced by the nature of the discharge or contamination situation. The criteria applied to control discharges may differ from those used to determine cleanup objectives for intervention, or for assessing the significance of an accident. The choice of criteria will be affected by human value systems, legal questions, feasibility of attainment, adequacy of the science, and other factors.

Any future development of internationally accepted dose rate criteria for the protection of the environment will need to take account of the scientific data and uncertainties. For example, there is a scarcity of data on the effects of internally deposited alpha and beta emitters on flora and fauna, and the almost total lack of information on the combined effects of chemical and radiation stresses on the likely endpoints of concern. Significant areas of uncertainty surround the extrapolation of data from laboratory experiments to field conditions, and the effects of spatial scale.

The extent to which the absorbed dose calculated for specific radiations should be modified for other types of radiation is also uncertain. For example, the relative biological effectiveness (RBE) of alpha particles may range as high as 200–300 [28, 29] while RBE values of ³H beta particles may range from 1.8–3.8 [30, 31, 32]. Because the physical principles involved in producing RBE values in excess of 1.0 for densely ionizing radiations should apply to all organisms and most endpoints, doses to biota from alpha and very weak beta emitters might need to be modified in order to make useful comparisons; this might lead to the need for a new dosimetric quantity for organisms other than man.

These uncertainties suggest the need to introduce a certain margin of safety when setting numerical criteria, as discussed by Larsson et al. [33]. The appropriate magnitude of the margin of safety is worthy of further study and debate. Guidance on the use of safety factors

⁴ Environmental effects were discussed in Ref. [3] on the premise that the main concern for non-human species is focused at the population level of organization. Measured attributes at the population level mentioned are numbers of individuals, mortality rate, reproduction rate, mean growth rate, etc.

has been published by various organizations [24, 25, 34]. In other instances (e.g. Ref. [35]) a distribution of organism sensitivities in the field is assumed, and a criterion is set at a predetermined protection level from that distribution, for example contaminant concentrations that will protect 95% of the species.

4.3. DEMONSTRATING COMPLIANCE

Criteria or standards might specify the maximum acceptable dose rates to critical tissues of those organisms serving as *critical* or *reference species* for locations subject to radiation exposure. Direct measurements of such dose rates can sometimes, but not always, be carried out. Factors such as mobility (in the case of animals), complex geometries of critical and protective tissues, and the mix of photon and particulate radiations from many radionuclides, often make direct measurement difficult. In such cases, calculational models are necessary.

Routine monitoring programmes, involving measurements of radionuclides in air, water, soils and sediments, and sometimes biota, are common. In general, one would expect a reasonably strong relationship between ambient concentrations of radionuclides in environmental media, and calculated or measured absorbed dose rates in critical tissues. The relationship should be strongest for those species that are fixed in place, or for those with very limited mobility, so that equilibrium conditions are approached. The relationship may be weak or non-existent for highly mobile species.

The approaches for demonstrating compliance with dose rate criteria are likely to vary with the nature of the local ecosystem, the reference or critical species, release or contamination characteristics, and other circumstances such as the applicable regulatory framework. In general, however, routine measurements of radionuclide concentrations in air, water, soils, sediments and biota, in combination with appropriate models that account for the important transport pathways and dosimetric relationships, seem feasible and potentially robust as a tool for demonstrating compliance. Because all models are subject to uncertainty, arising from both inherent, natural variability and from imperfect knowledge, it is important to critically review and test transport and dosimetry models. This is essential in order to establish credibility in the assessment process. In some circumstances for example, model calculations can be verified by the use of thermoluminescent dosimeters (TLDs) attached to the organisms in the wild. This has been done, for example, with fish in the Irish Sea [36].

A possible companion to such assessments is biological surveillance. Here, the health and vitality of the environment is periodically assessed by making direct measurements and surveys of indicator species. Standardized methods can be used to assess population density, reproduction, mortality, body condition, productivity, etc. Comparisons with pre-release reference site conditions, when available, can reveal trends or differences. However, the occurrence of observed trends and differences can be difficult or impossible to interpret since they may occur naturally, for unknown reasons, or in response to non-radiological stresses. Therefore, reliance solely on biological surveillance is not recommended. As a companion to media monitoring and dose modelling, however, biological monitoring can be very useful, especially in ecosystems subject to simple point sources and when appropriate reference sites exist. This approach may not be useful in large ecosystems affected by multiple sources and types of stressors.

Environmental assessments of proposed activities or existing situations are usually carried out within well-defined, yet limited areas. The need to delineate an area and population for consideration arises automatically from the practical considerations and limitations of conducting site characterization, environmental monitoring and ecological risk assessment.

A multi-tiered screening approach is normally used in ecological risk assessments. Screening may also be a potentially cost-effective and easy way of demonstrating compliance with radiation criteria or standards for protection of the environment. For initial screening, a simplified, conservative ecological effects screening assessment could be conducted. Screening values should be used to identify radionuclides in situations of concern, and to determine whether these radionuclides warrant further assessment, or if they are at levels that require no further attention. In practice, this initial screening is expected to be sufficient in the majority of cases. When the initial screening fails, additional analysis or assessment may be needed. A two- or three-tiered scheme would help ensure that the magnitude of the assessment effort would be scaled to the likelihood and severity of environmental impacts.

Alternative approaches to comparisons with harm-based criteria may be considered. These include comparisons with variations in natural concentrations of certain radionuclides [37] or, alternatively, with spatio-temporal variations in dose rates experienced by organisms from natural background radiation. At such levels of exposure, detrimental effects on plants and animals are very difficult to detect or measure. The implicit assumption underlying such approaches is that exposures to radiation that are well within the magnitude of variations in natural levels may be acceptable for regulatory purposes.

5. CONCLUSIONS

The general conclusions to be drawn from this report are that:

- (1) Although the ICRP approach is used in many countries for protection of the environment, several countries recognize the need to develop guidance and criteria to explicitly demonstrate that the environment is protected;
- (2) There is, as yet, no clear consensus on what guidelines, endpoints or targets may be used as a basis for environmental protection, but a number of ideas have been put forward in this report;
- (3) The extent of knowledge on the effects of radiation on organisms other than man is considered to be sufficient to move forward on this subject;
- (4) Approaches and criteria for the protection of the environment from the effects of ionizing radiation should be developed to take account of approaches taken for other environmental pollutants;
- (5) In order to reduce uncertainties and achieve greater confidence that criteria will provide the desired level of protection, improved knowledge is required in certain areas.



Appendix

SUMMARY OF NATIONAL INFORMATION ON APPROACHES TO PROTECTION OF THE ENVIRONMENT FROM IONIZING RADIATION

Country	Approach to environmental protection	Status of criteria and dose calculation methods	Regulations
Canada	Developing dose rate guidelines for levels not expected to have a measurable effect on the environment.	Developing guidelines for inclusion in guidance.	NSC Act, March 1997 states that one of the objectives of the new Canadian Atomic Energy Control Board is: "to regulate the development, production, possession and use of nuclear substances, prescribed equipment and prescribed information in order to prevent unreasonable risk to the environment and to the health and safety of persons".
			Regulations under this Act require applicants for a licence to operate a nuclear facility to: "provide information on the effects on the environment and the health and safety of persons that may result from the operation and decommissioning of the nuclear facility, and the measures that will be taken to prevent or mitigate those effects".
China	The ICRP approach is applied with objective of managing radioactive waste to secure an acceptable level of protection for human health and the environment.	Specific criteria not being developed but calculation methods are a research topic.	Regulations (GB-8703) are developed to ensure the safety and health of radiation workers and public and to protect the environment.
Czech Republic	ICRP approach applied. (Densely and approximately homogeneously populated country — protection of man considered adequate.)	Specific criteria and calculation methods are not being developed.	Regulatory authority shared by the State Office for Nuclear Safety (SONS) as competent Radiation Protection Authority and the Ministry of the Environment (ME) as competent authority for regulation of environmental pollution. ME bodies issue all licenses, but in the area of radioactive materials SONS decisions, based on the ICRP approach, are both required and requested.

Country	Approach to environmental protection	Status of criteria and dose calculation methods	Regulations
Czech Republic (cont.)			ME has proposed that quantitative levels of radionuclides, resulting from discharges in different types of waters should be selected as indicators to be used by local administrative bodies for licensing purposes.
Finland	ICRP approach applied with some additional requirements.	Specific criteria and calculation methods are not being developed.	Finnish Nuclear Energy Legislation includes regulations for the protection of the environment. Regulations concerning the disposal of low level and intermediate wastes require that the increase in the total activity concentration of radioactive substances in the environment, arising from the disposed waste, shall remain insignificant in any part of the biosphere.
Norway	ICRP approach applied.	Specific criteria and calculation methods are not being developed.	Regulation is under consideration to integrate radioactivity into the Pollution Act (1981-03-13 No. 0006).
Philippines	ICRP approach applied.	Will be studying international developments and will select most appropriate methods for local conditions.	No formal regulations. USNRC's "Final Environmental Statement concerning proposed rule making conditions for operation to meet the criterion ALARP for radioactive material in Light Water Cooled Power Reactor effluents" (WASH-1258) applied to evaluate effects on biota for first nuclear reactor.
Russian Federation	ICRP approach applied with some additional proposals.	Dose rate criteria and calculation methods under development.	No formal regulations.
Slovenia	ICRP approach applied.	Specific criteria and calculation methods are not being developed.	No formal regulations.
Sweden	Developing an approach to protect the environment specifically.	In the process of developing dose rate criteria. Dose calculation methods not being developed at present.	Final management of spent nuclear fuel and nuclear waste (SSI FS 1998:1) states that "biodiversity and sustainable use of biological resources should be protected and biological effects in affected habitats and ecosystems shall be described".

Country	Approach to environmental protection	Status of criteria and dose calculation methods	Regulations
Ukraine	Currently using ICRP approach but a different approach is being considered.	Dose rate criteria and calculational methods subject of current research.	"Concept of ecological setting" by Ministry of Environmental Protection and Nuclear Safety of Ukraine contains the "Law of Ukraine on protection of natural environment", 25.06.91. Article 54. allows for "Protection of natural environment against ionizing and other deleterious impact of physical factors and radioactive pollution. Local Councils of peoples deputies, factories, institutions, organizations and citizens are obliged to realize necessary measures, under carrying out their duties, for prevention and non- admission of exceeding of accepted levels of ionizing and other deleterious physical impact upon natural environment"
United Kingdom	ICRP approach applied.	Dose rate criteria and calculational methods subject of current research.	Guidance to UK regulators set, out in "Review of Radioactive Waste Management Policy", requires safeguarding of the interests of existing and future generations and the wider environment.
United States of America	DOE adopts and implements radiation dose standards consistent with the recommendations of the ICRP. DOE has an explicit dose standard for protection of native aquatic organisms from ionizing radiation.	DOE Order 5400.5 requirements specify a dose standard of 10 mGy/d for native aquatic organisms. DOE is considering dose standards of 10 mGy/d for aquatic animals and terrestrial plants, and 1 mGy/d for terrestrial animals, for inclusion in Sub Part F of proposed rule 10 CFR Part 834.	Regulations for environmental protection exist: DOE Order 5400.5; Radiation protection of the Public and the Environment (1993). DOE Proposed Rule 10 CFR Part 834, Radation Protection of the Public and the Environment. Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). Ecological risk assessments at radioactivity contaminated CERCLA sites generally require an assessment of potential impacts of radiation as a stressor; which may include the estimation of radiation doses to aquatic and terrestrial organisms. Such

Country	Approach to environmental protection	Status of criteria and dose calculation methods	Regulations
United States of America (cont.)		DOE has prepared a draft DOE Technical Standard, "A Graded Approach for Evaluating Radiation Doses to Aquatic and Terrestrial Biota" (December 1998), which provides a screening methodology and technical guidance for demonstrating compliance with these existing and proposed dose standards, and for conducting ecological assessments of radiological impact.	assessments are mandated by Section 105 of CERCLA and its implementing regulations in the National Contingency Plan (NCP) of 40 CFR Part 300.

Annex

EXAMPLES OF CURRENT AND DEVELOPING NATIONAL ARRANGEMENTS FOR PROTECTING THE ENVIRONMENT FROM THE EFFECTS OF IONIZING RADIATION



CANADA

Environmental protection program to be implemented to fulfill the mandate of the new Canadian Nuclear Safety Commission

Background

The Atomic Energy Control Board (AECB) is the Canadian federal nuclear control agency and exists under the Atomic Energy Control Act (AEC Act). Since the AEC Act was first adopted in 1946, the mandate of the AECB has evolved from one chiefly concerned with national security to one which focuses primarily on the control of the health, safety and environmental consequences of nuclear activities.

The AEC Act did not clearly establish the AECB's role in environmental protection. Instead, the AECB's regulatory approach to environmental protection issues evolved over the years, and was primarily based on the premise that "the degree of control necessary to limit exposure of the public to acceptable levels will ensure that other species are not put at risk". The validity of this premise has been questioned in recent years in light of the developments in ecological research and in policy approaches to environmental protection.

Developments in government policies and scientific approaches to environmental protection recognize the environment as a complex system and incorporate the objective of protecting all species, not just humans. Methods such as ecological risk assessment and environmental effects monitoring have been developed to assist in implementing this approach.

The AEC Act has been replaced with the Nuclear Safety and Control Act (NSC Act), promulgated in March 1997. The NSC Act establishes the Canadian Nuclear Safety Commission (the Commission), the successor of the AECB. Under the NSC Act one of the objects of the Commission is "to **regulate** the development, production, possession and use of nuclear substances, prescribed equipment and prescribed information in order to **prevent unreasonable risk** to the **environment** and to the health and safety of persons, associated with that development, production, possession of use, ...". The NSC Act, therefore, provides clearly for protection of the environment within the mandate of the Commission.

New regulations have been developed based on the powers of the new NSC Act. These are now undergoing public review. In terms of environmental protection regulatory requirements, applicants for a licence to operate a nuclear facility must, for example, provide information on "the effects on the environment and the health and safety of persons that may result from the operation and decommissioning of the nuclear facility, and the measures that will be taken to prevent or mitigate those effects" and on "The proposed measures to control releases of nuclear substances and hazardous substances into the environment", etc.

The new NSC Act makes no distinction between radiological and non-radiological environmental issues arising from nuclear facilities. This means that the scope of regulatory responsibility in the protection of the environment has been widened to include non-human species and non-radiological stressors.

Provided by: P. Thompson and L. Chamney Radiation & Environmental Protection Division Atomic Energy Control Board, Ottawa, Ontario, Canada

Implementation of the environmental protection program

In order to adequately fulfill its new environmental protection mandate, the AECB is in the process of developing an expanded environmental protection program. The basis for the expanded environmental protection program is the "Policy on Protection of the Environment" which establishes the approach that the Commission would take to fulfill this mandate. This regulatory policy, issued for public comment in November 1998, proposes that the decisions of the Commission be based on a consideration of the potential effects of licensed activities, the measure taken be licensees to control those effects, and the environmental performance of the licensed activities. The Policy also proposes that the environmental protection measures and programs developed by licensees be demonstrated to be effective in the control of risks to the environment. The Policy includes a definition of environment and of environmental effect:

Environment means components of the Earth, and includes:

- (a) land, water, and air, including all layers of the atmosphere;
- (b) all organic and inorganic matter and living organisms; and
- (c) the interacting natural systems that include components referred to in (a) and (b) above.

Environmental effect means:

- (a) any change that an activity, substance, equipment or facility that is regulated by the CNSC may cause in the environment, including any effect of such change:
 - -on health and socio-economic conditions;
 - --- on physical and cultural heritage;
 - —on the current use of lands and resources for traditional purposes by aboriginal persons;

or

- on any structure, site, or thing that is of historical, archeological, paleontological, or architectural significance; and
- (b) any change to any activity, substance, equipment or facility regulated by the CNSC that is caused by the environment.

This Policy will be the basis for the expanded environmental protection program which is a documented set of activities to be undertaken to fulfill the environmental mandate, including to confirm that licensees meet the AECB's environmental protection requirements. These activities range from regulations and regulatory procedures, standards and guides, to monitoring, assessment and analysis, and intergovernmental consultation, and stakeholder participation.

A key standard to be developed is that which identifies the regulatory criteria for the radiological protection of non-human species. These criteria would be complementary to regulatory criteria for the radiological protection of humans and are intended to be an equivalent to the criteria for the protection of the environment from non-radiological stressors (e.g. organic chemicals, metals).

Regulatory criteria for the radiological protection of non-human species

The regulatory mandate of the Commission is to prevent unreasonable risks to the environment. Any radiological protection criteria developed for the protection of non-human species must, therefore, be such that complying with them will provide assurance that regulated activities will not pose unreasonable risks to the environment. One key issue is the identification of what would constitute an "unreasonable" risk. The definitions provided below will aid in this determination, however, it should be recognized that social and economic considerations will also influence this determination.

The following definitions serve to describe the significance of potential effects on the environment and hence the potential risks associated with a licensed activity:

- **no effect** means that there is no interaction between the licensed activity (or substance, etc.) and the population or that the interaction has no effect.
- **negligible effect** is defined as one affecting the population or specific group of individuals at a localized area and/or over a short period in such a way as to be similar in effect to small random changes in the population due to natural environmental fluctuations, but having no measurable effect on the population as a whole.
- minor effect is defined as one affecting the population or specific group of individuals at a localized area and/or over a short period (one generation or less), but not affecting other trophic levels or the integrity of the population itself.
- **moderate effect** is defined as one affecting a portion of a population which may result in a change in abundance and/or distribution over one or more generations of that portion of the population or any population dependent on it, but does not change the integrity of any population as a whole. It may be localized.
- major effect is defined as one affecting a whole population or species in sufficient magnitude to cause a decline in abundance and/or a change in distribution beyond which natural recruitment (reproduction, immigration, to affected areas) would not return that population or species, or any population or species dependent on it, to its former level within several generations.

One the basis of these definitions, "no unreasonable risk" may be taken (as a first cut) to equate to **negligible** or **minor** effects. Demonstration that exposure to radionuclides released from nuclear facilities is having negligible or minor effects could be made using radiological protection criteria that equate to values that are "highly unlikely" to cause effects on exposed organisms. These radiological protection criteria would be used as screening values. In cases where these criteria are not met, a more detailed effects assessment would be conducted to estimate potential population effects from the operation of a licensed facility. These radiological "screening" criteria would be used in a similar manner to environmental protection guidelines developed for non-radiological substances. This would ensure that the bases for the assessment of radiological and non-radiological emissions from licensed facilities would be the same.

AECB staff have begun the review of the radiation effects literature using the methods developed by the Canadian Council of Ministers of the Environment and by Environment Canada. The criteria will be based on radiation effects data for the most sensitive species or life stage tested with the use of appropriate safety factors.

This preliminary work suggests that the following radiological dose criteria may be used for screening purposes:

Group of biota	Critical dose rate	Expected no effects dose rate
mammals	100 mGy/year	10 mGy/year
birds	500 mGy/year	50 mGy/year
amphibians/reptiles	100 mGy/year	10 mGy/year
benthic invertebrates	1000 mGy/year	100 mGy/year
fish	5000 mGy/year	

It should be noted that this work is not yet complete and has not been peer reviewed. It is expected that the draft guidance document produced in support of the radiological criteria for protection of non-human species will be ready for peer review in the fall of 1999.

Biota dosimetry issues are also the subject of ongoing work. More specifically, a working group is reviewing the available literature with the objective of recommending appropriate RBE factors for alpha and beta emitters for use in biota dose calculations. This report is also expected to be ready for peer review in the fall of 1999.

CHINA

Protection of the environment against ionizing radiation

In the Regulations for Radiation Protection (RRP) in enforcement in China, there are the following provisions dealing with the environment issue:

- 1.1 These Regulations are developed to ensure the safety and health of radiation workers and the public to protection the environment, and to promote the development of nuclear science and technology, nuclear power, and other applications of radiation.
- 4.4.3 Prior to low-level liquid waste being discharged into rivers and oceans, the location of discharge, and the total activity and concentration of effluent are subject to approval by environmental protection agencies concerned. The discharge region shall be kept away from laying zone for edible fishes, breeding zone for aquatic plant, salt field, seashore swimming and recreation places.
- 6.3.1 In siting of a nuclear facility, the possible impact on the public of radioactive material releases due to a nuclear accident shall be taken into consideration above all, and meanwhile the long-term impact of the facility shall be also considered.

In the Chinese Basic Safety Standards for Protection of Ionizing Radiation and for the Safety of Radiation Source to be issued in the forthcoming future (1999 or 2000), less provisions are made about the environment impact. There are only a provision "8.5.2 a) Radioactive waste shall be managed in such a way as to secure an acceptable level of protection for human health and of the environment". This is based on the following considerations:

- (1) In the RRP, the specific, but not quantitative, regulations are made about the environmental impact issue, but would be difficult to be put into enforcement in practices, instead causing confusion of thinking. Examples include the Provision "... The discharge region shall be kept away from laying zone for edible fishes, breeding zone for aquatic plant, salt field, and seashore swimming and recreation places".
- (2) The viewpoint of the ICRP on this issue is that "The Commission believes that the standard of environmental control needed to protection man to the degree currently thought desirable will ensure that other species are not put at risk".
- (3) Newly built nuclear power plant and other nuclear facilities release small quantity of radioactive materials into the environment, not creating the larger doses that poses significant biological impact than summarized in UNSCEAR 1996 Report.

Provided by: Ziqiang Pan

Science and Technology Commission

China National Nuclear Corporation, People's Republic of China

CZECH REPUBLIC

State environmental policy

Legal provisions

Between 1990–1995, 14 new acts of law, numerous amendments and dozens of other legal provisions were adopted and enacted to establish a system of normative, economic, institutional and informational instruments to protect the environment in the Czech Republic.

Act No. 17/1992 S.B. on environment protection, provides the basic notions and principles related to the protection of the environment. The act is formulated in general terms however it does not adequately define the responsibilities of the respective bodies with regard to the imposition of sanctions and the incorporation of the economically-related dimensions of environmental damage.

Obligations relating to EIA are provided in the Act of the Czech National Council No. 244/1992 S.B. regarding environmental impact assessments. The law provides obligations and procedures for buildings and structures but provisions relating to the assessment of products, concepts and transboundary impacts are not clearly defined, provisions relating to the binding nature of the law and certain elements of procedure are not provided.

Act of the Czech National Council No. 282/1992 S.B. regarding the responsibilities of the Czech Environmental Inspection and its jurisdiction in the protection of forest areas, to a large degree unifies the control activities in the sphere of the environment. Act of the Czech National Council No. 388/1991 S.B. regarding the State Environment Fund, unifies State funding of environmental protection. Both laws provide an adequate legal framework for those activities and responsibilities associated with the operation of these respective institutions.

The protection of air is provided in Act No. 309/1991 S.B. regarding the protection of the air from pollutants (amended by Act No. 211/1994 S.B.), in the follow-up Act No. 389/1991 S.B. regarding obligations for State administration of air protection and provisions for air pollution charges (amended by Act No. 212/1994 S.B.) and in other legal provisions. The laws provide legal provisions to stimulate the industrial sector to take remedial measures and undertake investments to make environmental improvements (these provisions have resulted in investments in order of dozens of billions of Czech crowns). It is also anticipated that the compliance schedules provided in these laws will result in fundamental improvements in air quality by requiring stringent reductions in emissions of harmful substances. Normative instruments (emission and immission limits) have been adequately established in these laws. However, the provisions concerning the air pollution charges only fulfil their fiscal function to a limited extent and as currently structured are inadequate in providing sufficient incentives to industry to reduce emissions and/or introduce pollution control technologies. Inadequacies in the structure of air pollution charges include low charge rates, difficulties in adjusting these rates to account for higher costs and limited possibilities for suspending the pollution charges. The 1998 deadline for compliance with the prescribed emission limits is projected to be met by approximately 75% of polluters.

Provided by: E. Kunz

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From a Document approved by the Government of the Czech Republic on August 23, 1995

The protection of the Earth's ozone layer is governed by the recent Act No. 86/1995 S.B. This act fully complies with international commitments for ozone protection which the Czech Republic has endorsed or will be endorsing within a prescribed time table.

The protection of water and the provisions related to water management are provided in Act No. 138/1973 S.B. and follow-up provisions. The legal norms provided in this act essentially fulfil its mandate for water protection and management as is evidenced by systematic improvements in water quality. However, this act does not adequately define existing property rights and ownership issues with regard to waters and their environment. The provisions regarding the use of economic instruments (charges for waste water discharges) fulfil their fiscal and incentive roles to a limited extent.

The geological and mining spheres are governed by Act No. 44/1988 S.B. on the protection and use of mineral wealth, by Act No. 61/1988 S.B. on mining activities, explosives and the State Mining Administration, and by Act No. 62/1988 S.B. on geological undertakings and the Czech Geological Office. These laws do not adequately define property rights and ownership with regard to raw minerals and mining activities not do they provide satisfactory support for the protection of irreplaceable natural resources.

Soil protection is governed by Act No. 334/1992 S.B. regarding the protection of the agricultural soil fund. This law concerns soil as a means of production but does not provide measures to address the environmental issues related to soil protection. In addition, in some instances, this act has hindered construction in urban areas.

Nature protection is governed by Act No. 114/1992 S.B. on nature and landscape protection and the follow-up provisions. Excluding some minor points, this act does not apply economic instruments to encourage protection and preservation of nature. The creation of the Czech Republic's national parks is provided by Government decrees. Accepted international commitments (e.g. CITES) are not endorsed under this legislation.

The protection of the forest and the principles of forest management are provided under Act No. 61/1977 S.B. (amended by Act No. 229/1991 S.B.) on forest management and the State administration of forests. Currently, no legislation is in place which adequately addresses the importance of forests in environmental protection, the appropriate economic use of forests and the non-productive function of forests in forest management.

The present legal norms regarding waste management proceed from Act No. 238/1991 S.B. on waste management and the follow-up provisions. At this time, these laws are insufficient and not address the current situation nor do they comply with the relevant standards issued by the EU and OECD. In addition, these laws do not provide adequate incentives to encourage waste minimization (especially in the area of hazardous waste). Existing economic instruments, such as charges for waste disposal, often encourage undesirable types of waste disposal (unsorted land filling) and not stimulate waste producers to collect, salvage, sort and recycle the waste. Many waste producers are unable to make the necessary investments in environmental technologies and their inability to make these investments is further hampered by their financial obligation to pay waste disposal charges. In addition, legislation regarding the transboundary movement of secondary raw materials is excessively stringent and incompatible European standards.

The existing legislation regarding the management of chemical substances and preparations is provided by Act No. 20/1996 S.B. on public health and follow-up legislation. This act of law inadequately defines properties of chemicals and chemical preparations with regard to environmental protection and the appropriate procedures for handling chemical substances which are hazardous to human health and the environment.

Currently legislation in this area does not provide necessary protection measures concerning the transboundary movement of chemical substances.

The current system of environmental legislation in the Czech Republic covers the most important areas of environmental protection more or less effectively. There are deficiencies in providing uniform terminology (for example, the terms position, decision, expert opinion, statement) and there are no provisions to address packaging requirements, the regulation of genetically modified organisms or accident prevention and response. In addition, the provisions addressing the remediation of old environmentally damaged sites are inadequate. However, an expedient and economically effective instruction has been the negotiation of voluntary agreements between the State administration and pollution producers. Voluntary agreements have proven to be advantageous in cases where there are a limited number of producers of a specific type of pollution and/or in those cases where the individual conditions provide mutual economic and environmental benefits for the State and the polluters. In 1995, the Ministry of the Environment of the Czech Republic concluded such an agreement with the Association of Manufacturers of Washing Powders for the gradual reduction of environmentally harmful substances in their products.

FINLAND

Legislative and policy measures for protection of the natural environment from adverse effects of ionizing radiation in Finland

The Finnish radiation protection regulations are based on the recommendations of the ICRP. The ICRP 60 recommendations (ICRP, 1991) are applied in the updated **Radiation Act** (529/91). Although the ICRP view on the protection of species other than man is not challenged, the need of protection of the environment by and large is recognised in the Finnish nuclear and radiation safety legislation.

In the Radiation Act (59/791) the protection of the environment is referred to in the context of discharges from a practice and radioactive waste management. Also the Nuclear Energy Act (990/87) and Nuclear Energy Decree (161/88) include provisions for protection of the environment. In order to apply the environmental impact assessment procedure in the nuclear energy legislation the Nuclear Energy Decree (161/88) was slightly amended (437/96).

The Convention of Biological Diversity (914/94) came into force in Finland in October 1994. The Council of State (Government of Finland) made a Decision in Principle in 1995, that each Ministry is responsible for protection of biological diversity and sustainable use if nature in its own area and can make proposals for action accordingly.

The objectives of the Act on Environmental Impact Assessment Procedure (486/94) and the Decree on Environmental Impact Assessment Procedure (792/94) are to further the assessment of environmental impact and the consistent consideration of it in planning and decision-making, and to increase the availability of information for the citizens and improve their possibilities to participate in decision-making. Concerning the natural environment, the assessment of impact of particular projects on soil, water, air, climate, organisms, interaction between them, natural diversity and utilisation of natural resources is required to be covered.

In the Finnish legislation neither numerical activity concentration nor dose limits are given for the protection of the environment against ionizing radiation. For protection of the members of the public the dose constraint for the critical group is 0.1 mSv for nuclear power generation and disposal of low and intermediate level reactor waste in the bedrock. Due to vigorous application of the ALARA principle the actual doses are substantially lower. In addition, the **Decision of the Council of State (398/91)** concerning the disposal of low and intermediate level waste provides that the increase in the total activity concentration of radioactive substances in the environment, arising from the disposed waste, shall remain insignificant in any part of the biosphere.

The **Decision of the Council of the State** concerning the safety of the final disposal of spent nuclear fuel was taken 25.3.1999. The decision provides that "in addition to effects on humans, possible effects on flora and fauna have to be considered".

Provided by: R. Saxén

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The status of the legislative and policy measures in Finland can be summarised as follows:

- The protection of the environment is by and large considered in the legislation but the desired level of protection is not specified.
- The requirements for maintaining the biodiversity and application of the principle of sustainable development in different fields of human activity provide for application of common principles in setting criteria both for radiological and non-radiological protection.
- Nationally and internationally accepted criteria for protection of the environment need to be established. A good starting point would be to find out the actual and potential, realistic situations where flora and/or fauna could be exposed to ionizing radiation more than humans and to identify the most sensitive species.

NORWAY

Radiological protection and the environment — The current status in Norway

In relation to radiological protection, the following legislation is currently (January 1999) in operation in Norway:

Act, of 18 June 1938, relating to the use of X-rays and radium, etc., The Ministry of Health and Social Affairs, Norway.

It should be noted that a new law is currently in the process of being introduced (at the hearing stage as of January 1999).

Both sets of legislation relate to the protection of man with no reference to the environment. The environment itself is considered in the Pollution Act of 1981:

1981-03-13 nr 0006: Lov om vern mot forurensninger og om avfall (Forurensningsloven).

This act provides a legal basis for the protection of the environment from all pollutants, but currently, this act has not been implemented for radioactivity. This is under consideration.

The Norwegian Radiation Protection Authority (NRPA) recognizes the limitations in relation to international guidelines with regards to the protection of the environment from ionizing radiation and therefore strongly welcomes the efforts of international organizations in relation to this subject. The NRPA have forged close links with the International Union of Radioecology to consider this matter.

The Norwegian governmental standpoint has for a considerable time highlighted the need for the protection of the environment from radioactivity through international forums. Examples include the London Convention, OSPAR and the General Assembly of the IAEA. Efforts to consider the effects of radioactivity on the environment have also been made through the Arctic Monitoring and Assessment Programme and through the joint Russian–Norwegian Commission which is currently developing criteria for impact assessment including the protection of the environment per se.

Provided by: J. Brown

Norwegian Radiation Protection Authority (NRPA)

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PHILIPPINES

Laws and policies for environmental protection in the Philippines

Presidential Decree 1151 otherwise known as the Philippine Environmental Policy and Presidential Decree 1586 known as "Environmental Impact Statement System" of the Environmental Management Bureau were promulgated by the President of the Philippines to integrate the national program of environmental protection. These decrees implicitly state that "public and environmental safety as a matter of government policy for all projects or undertakings both in the public or private sector.

During the construction of its first nuclear power plant, the Philippine Government through the Philippine Nuclear Research Institute (PNRI) recognizes the need to protect the environment from possible degradation in the operation of nuclear facilities. Cognizant of this importance, the Institute as mandated by Republic Act 5207 promulgated the Regulations for the Licensing of Atomic Energy Facilities and included in said regulations environmental concerns as one of the requirements for licensing of nuclear facilities.

In the nuclear field, the most critical facilities with potential environmental impacts are the nuclear power plant and any radioactive waste disposal and/or storage facility which may be set up in the Philippines. The practice that have been implemented for the environmental safety of these 2 facilities is to regulate and control the releases of potentially toxic materials to the environment and through constant and vigilant surveillance and monitoring for compliance with regulations. Environmental protection and regulation is controlled by Radiological Effluent Technical Specifications (RETS). The RETS was formulated to establish guidelines and criteria for the regulation and control of the radiological impacts of the nuclear power plant to the environment. The supporting document. Offsite Dose Calculation Manual (ODCM), was prepared using regulatory criteria and guidance given by the IAEA Safety Series 9, the US's 10 CFR20, Appendix D of Part 7 of the Code of PNRI Regulations, the US's Regulatory Guide 1.109. However, all these guidance and criteria don't give specific limits in terms of radiological dose, activity or concentration for the protection of the environment other than human. It is understood that the guidelines of the PNRI "Standards for Radiation Protection" which follows the ALARA concepts of the International Commission on Radiation Protection (ICRP 26) are being followed.

In line with the global environmental concerns on sustainable development, Republic Act 6969 also known as "Toxic Substances and Hazardous and Nuclear Wastes Control Act of 1990" was enacted into law with the Department of Environment and Natural Resources as the government implementing agency. The law mandates control and management of use, transport, treatment and disposal of toxic substances and hazardous and nuclear wastes in the country. It also seeks to protect the public health and the environment from unreasonable risks.

Provided by: M.V.B. Palattao Radiological Impact Assessment, Nuclear Regulations, Licensing and Safeguards Division, Philippine Nuclear Research Institute Manila, Philippines In summary, no numerical guidelines are explicitly stated in the Philippine regulations for the protection of non-human biota from ionizing radiation. However, the PNRI which is the sole government agency responsible for nuclear materials and facilities in the country has a continuing interest in environmental protection particularly in radiological environmental safety where its mandate lies. It has at its disposal expertise in nuclear techniques that can be utilized for environmental studies. Within the capabilities of its resources the Philippines through the PNRI stands ready to continue and enhance its environmental protection programs from ionizing radiation.

POLAND

Radiation protection policy in Poland

The Polish regulatory infrastructure on radiation protection of the natural environment is founded upon two legal Acts of Parliament:

- the Atomic Law (of 1986)
- the Act on Environmental Protection and Development of 1980 (as amended 1997), called also the Environment Protection Law.

In Poland the environment protection from ionizing radiation is subject to the Atomic Law, and it is based on recommendations of the ICRP 60. As a consequence, the protection against ionizing radiation is focussed on the man.

The protection of environment is mentioned in respect to the term of radiation protection itself, used in this act, which has meaning of action to prevent people and environment from ionizing radiation hazards and to keep such hazards as low as achievable. Also, the provisions of enacted regulation on radioactive waste management say that scientific and technical achievements should be applied to make radiation hazard to people and environment as low as reasonably achievable. However, the Atomic Law stipulates to impose radiological protection criteria only for humans. Thus, Poland has adopted permissible effective dose standards to determine ionizing radiation hazards.

The Environment Protection Law deals with the problems concerning the protection of the nature from adverse effects of many factors, including radiation with exception of ionizing radiation.

Poland has become a party to the Convention on Biological Diversity, ratifying it on 18 January 1996. The amended in 1997 Environmental Protection Law (the amendments entered into force on 1 January 1998) includes also the requirement of preserving biological diversity.

The Convention on Environmental Impact Assessment in a Transboundary Context was signed in 1991 and ratified in 1997 by Poland. The legal provisions, which form the basis for the Convention, have been revised in Poland. The legislation requires an impact assessment on the environment, at the project level of the proposed activities. The Minister of Environmental Protection, Natural Resources and Forestry determined the project types, which are exceptionally harmful to the environment and human health and also a category of developments, which may worsen the state of the environment. The relevant regulations were issued in 1998.

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SWEDEN

Proposed policy for protection of the natural environment from detrimental effects of radiation: considerations and decisions in Sweden

Summary

The environment comprises an interplay of biological and physical components of which one of the most important is human beings. The general objective for environmental protection is preservation of biological diversity and sustainable use of biological resources as stated in the new SSI regulations on spent fuel final management. This means that the focus for environmental protection is changed from only human beings, to the environment including human beings. The regulatory system for protection of biota should be based on similar principles as used in the protection of man, but due to lack of scientific data, the precautionary principle including the BAT concept seems at present to be most justifiable for the purpose. SSI has not, at present, provided quantitative criteria and standards for environmental protection, but effect-related criteria such as dose limits for reference species inhabiting different environmental media have to be established. Assessment guidelines could draw experiences from other disciplines such as chemical exposure situations where environmental monitoring and environmental impact assessments are relatively common.

Introduction

Protecting man and the environment today and in the future from detrimental effects of radiation is the ultimate goal of all radiation protection management. In accordance, the Swedish Radiation Protection Act from 1988 stipulates that man as well as animals and the environment shall be protected from the harmful effects of radiation. However environmental protection has not been defined in detail but in SSI's opinion it should be understood to comprise conditions for biological life in all of its forms and organisation levels, i.e., protection of the environment aims at the protection of organisms and their habitats which will allow future generations for a sustainable use of biological resources.

Radiation protection standards have traditionally been established for the purpose of protecting man, and ICRP [1] has assumed that this level of safety is probably adequate for protection of other species at a population level. According to ICRP's recommendations, radiation doses should be limited as far as reasonably achievable and an annual dose limit of 1 mSv to the public from radiation practices has been endorsed. The dose contribution from anthropogenically produced radionuclides in Sweden is estimated to be less than 0.1 mSv per year, thus corresponding to only a fraction of the current dose limit.

It has become increasingly apparent that the quality of human existence is directly or indirectly dependent on the health and vitality of the ecosystems. This has imposed a change in the focus within the area of environmental protection. This is mainly a result of the UNCED Earth Summit in Rio de Janeiro 1992 [2], where emphasis was put on sustainable development including concepts like biodiversity and biological resources. It was made clear that ecosystems should be protected to ensure resource savings for future generations.

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The central importance of biodiversity within the environmental area has been defined by the Swedish Government [Bill 1993/94:30] which states that action plans or measures for the conservation of biodiversity should be prepared by the Swedish Environmental Protection Agency for follow-up of environmental targets and for an overall assessment of the need for work within the entire field as well as by the competent authority in each sector as sector-specific concrete plans or programmes.

Biological resources are dependent on biodiversity and are discussed in terms of parameters such as quality and productivity. The presence of various contaminants may have an impact on the market value of these products even if the significance of deleterious effects is negligible. It is SSI's opinion that these aspects may have to be reflected in future considerations regarding releases from radiation practices.

Development of a regulatory framework

The development of a regulatory framework requires that an objective is set and that standards and indicators are derived in a multi-tiered approach. The standards and indicators may serve the purpose of allowing the regulator to assess whether the performance assessment contains the relevant data and whether the general objectives are being achieved. Standards and indicators may be identical in both prospective and retrospective regulation, either applied in the stage of design and planning or in assessments using data from environmental and/or biological monitoring.

Objective for environmental protection

The general objective for protection of the natural environment, as currently discussed by SSI and incorporating the prevailing decisions on environmental protection, can be formulated as below:

- Biological diversity shall be protected. In this regard, relationships between prolonged exposure and risk are less straightforward than in the case of effects on human health or in most cases insufficiently supported by science, as compared to effects on human health. Due to such shortcomings, decision-making or regulation will involve a large element of uncertainty. Proper consideration should thus be given not only to whether certain preventive measures are reasonable (which may be difficult to assess in quantitative terms) but also to the precautionary principle. The BAT (best available technique) approach may, under such circumstances, serve as a means for ensuring that the environmental objective is fulfilled. In principle, it should be possible to identify critical organisms real or generic inhabiting different ecosystems. A critical organism would normally be selected on the basis of radiosensitivity, but critical may also be defined on the basis of genetic distinction (e.g., endangered species, endemic species).
- Biological resources should be possible to exploit in a sustainable fashion. Thus, critical organisms may be identified on the basis of being important as a resource, i.e., economically important or vital for the culture and the life-style of communities. The economic value may be calculated with some certainty (i.e., market value), whereas the cultural and social values are essentially non-quantifiable factors.

Environmental risk management — guiding principles

Criteria and standards have to be derived that are measurable, predictable and ensure that the environmental objective is fulfilled. The basic principles that have been used in radiation protection for many years are well founded on the basis of scientific knowledge and experience. It seems therefore appropriate that the development of a regulatory system for protection of biota should be based on similar principles.

However, there are some problems that need to be highlighted. The ALARA principle stems from the risk scenario that ICRP has proposed, i.e., the probability of cancer resulting from radiation will be linear with dose, the linear no threshold model. This model has gained broad acceptance among scientists, regulators as well as the public and has been shown to be an efficient tool for managing human risks after low dose exposures, taking into account individual doses, number of exposed individuals, and the likelihood that an exposure situation should occur. The precautionary principle originating from the Rio-documents suggests that in order to protect the environment positive actions may be required before scientific proof of harm has been proposed [3]. The focus is more on methods that will eliminate or reduce the input of hazardous waste into the environment rather than determining the assimilative capacities.

The precautionary principle implies that concepts like BAT and BEP (best environmental practice) should be applied. The BAT approach has been used for more than a century in national legislation to reduce discharges from industrial activities, and it has also been included in a number of international conventions aimed at environmental protection. Various definitions exist, but, in summary, the BAT approach means that the technique used for limiting discharges should be proven state-of-the-art, or feasible to develop without compromising long-term reliability, and that it should be economically feasible. Moreover the benefit of measures taken to reduce discharges shall be judged against its cost (not always taken into account).

There are obvious similarities between the ALARA and the precautionary approach. Both strategies consider science, technology, and economics for the purpose to protect man and the environment. However, the risk scenario is less focused but more far-ranging for the precautionary principle since qualitative information becomes more important. Concomitantly, larger safety margins will be the result when quantitative scientific data are scarce.

It may be argued that for the present generation of people there are no differences between these two principles when applied to protection of humans from, e.g., outflow of radionuclides from a waste repository. A feature of the precautionary concept is, however, that it will enable both present and future generations to meet their sustainable needs by reducing the input of pollutants into the environment. This will become increasingly important due to a globally accelerated use and release of hazardous substances from an increasing population. In fact, effects on the natural environment from routine releases may in the future become more critical than estimated radiation risks for humans. Hence, the precautionary approach seems at present to be more efficient than ALARA to take actions to avoid any possible negative effects on the environment in the future.

Standards, etc.

The general target of concern for setting standards are, most likely, higher plants and animals. The standards that are developed for protection of the environment are supposed to be based on the dose approach but there are some general points which must be considered regarding the dosimetry. It is rarely feasible to measure dose-rates to a given organism directly. Part of the exposure may be due to α - and β - radiation from radionuclides that accumulate internally. Some important radionuclides, e.g. ¹²⁹I, may also lead to an inhomogenous energy deposition within the body of an organism. The sum of the uncertainties will be reflected in the safety factor, in accordance with the precautionary approach. There is

definitely a need to ultimately establish models for estimating the doses to target organisms, that could be used either retrospectively or prospectively in performance assessments.

To achieve this goal, biomarkers, indicators and indices need to be identified. They are defined as measurable parameters that provide information concerning the state of an organism or an ecosystem. Biomarkers are often referred to as specific molecular alterations at a cellular level while an indicator may be a 'critical' organism, defined by its radiosensitivity, genetic distinction, economic importance, or social/cultural value. An index may be regarded as a measure of a whole ecosystem.

Biological indicators could be established for different ecosystems to ensure that the standards are not exceeded. In order to select indicator species within an ecosystem an inventory analysis has to be performed for each ecosystem. Obviously, some of the organisms selected as indicators will be of 'higher' order with relatively low reproduction rate. Also species with high reproduction capabilities could be of importance provided that their distribution within the ecosystem is uneven. There is a general belief that reproduction is the critical end-point for the viability of the population. Yet genetic damages occur at much lower dose levels than those affecting reproduction and the long-term consequences of these damages are not very well understood.

Provisions in SSI's "Regulations on Protection of Public Health and the Environment in the Connection with Final Management of Spent Nuclear Fuel and Nuclear Waste"

In the new regulations on final management of spent nuclear fuel and nuclear waste [4], SSI has decided on general objectives for environmental protection that corroborate the principles laid down at the Rio-conference in 1992: The final management of spent nuclear fuel or nuclear waste shall be implemented so that biodiversity and the sustainable use of biological resources are protected against the harmful effects of ionising radiation [2]. The aim of this section is to minimise the effects of ionising radiation on organisms in the environment in the future and to allow for a sustainable use of biological resources. Regarding biodiversity, allowances had to be made in the regulations for changes with time due to natural reasons.

Furthermore the regulations say that: Biological effects of ionising radiation in habitats and ecosystems concerned shall be described. The report shall be based on available knowledge regarding the ecosystems concerned and shall take particular account of the existence of genetically distinctive populations such as isolated populations, endemic species and species threatened with extinction, and in general any organisms worth protecting. Protection cannot be ensured unless there is an evaluation of possible deleterious effects. This means that an estimate of the dose contribution to relevant organisms or groups of organisms must be made. It seems also obvious that some kind of response function is required that relates the probability of population survival to the dose-rate. There are however very few, if any, such dose response functions available, implying that effects at the individual level, that would be expected to contribute to radiation-induced damages at the population level, have to be examined in order to develop dose-response functions for critical species.

The regulations apply to organisms in the habitats, i.e., the relevant environment for special organisms or groups of organisms and ecosystems concerned. Of special interest are organisms which are genetically distinctive and which are therefore of potential special importance for the ecological processes, biodiversity and biological resources. This includes populations at the margin of the species' distribution area, isolated populations with limited gene transfer within the main area where the species is found, endemic species (species found only in a geographically isolated area) and species threatened with extinction (i.e., where the number of individuals is a special genetic limitation). The concept of organisms worth

protecting also refers to organisms which, from a cultural or economic standpoint, require special treatment. Furthermore it is stated that the description must be based on available knowledge, i.e., existing documentation or documentation which can be prepared in connection with the siting. This means that a detailed analysis can only be carried out on the short term. For long time-scales after the closure of a repository, it is not possible to predict which genetically distinct organisms will occur. In such cases, an evaluation must be made in accordance with the general guidelines presented in the regulations.

SSI has not, at present, provided quantitative criteria and standards for environmental protection. Above all, this is due to gaps in scientific knowledge, with respect to the radiosensitivity of various organisms, ecological risk and synergetic effects. This means that the precautionary principle shall be applied, in accordance with the Rio-Declaration. Work is in progress within SSI to see what quantitative standards would apply in a regulatory framework. The establishment of a regulatory framework could draw experiences from other disciplines such as chemical exposure situations where environmental monitoring and environmental impact assessments are relatively common [5]. SSI intends to investigate whether evaluation criteria can be derived from existing documentation within this field.

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UKRAINE

National legislative policy measures taken or proposed for protection of the natural environment from adverse effects of ionizing radiation in Ukraine

- 1. One of the major national documents of Ukraine on protection of the natural environment from adverse effects of ionizing radiation is "Principles of Ecological [Environmental] Standardization" (1998, Ministry of Environmental Protection and Nuclear Safety, Kiev). The main content of it is that Ukraine intends to arrange (plus to existing hygienic standardization) also an ecological standardization for man-made ionizing radiation as well as for other anthropogenic factors, because ecological standardization is of not less importance than hygienic one.
- 2. Another national document of Ukraine related to radioprotection of the natural environment is called "Norms of Radiation Protection of Ukraine" (1997, Ministry of Health of Ukraine, Ministry of Extraordinary Situations, Kiev). This document is based on publication of ICRP Nos 63, 65–67, 69–71 (since 1991 up to 1995). Comparison of this document (1997) with the previous one (1987) shows the big difference in dose coefficients, maximum permissible concentrations and maximum permissible doses for man. For example, according to norms (1997) MPC of (and MPD from) ¹⁴C and ⁶⁰Co during inhalation exceed 3200 and 1000 times the previous norms (187). Respectively, from tritium 370 times, ¹³¹I 375 times, ⁹⁰Sr 87 times, ²³⁹Pu 85 times. The question is: "What is the position of IAEA re the ICRP publications Nos 86–89"?
- 3. The other national documents on this problem will be added in forms of a list of them and a review (as soon as possible).
 - 4. Ukraine is actively collaborating with both the IAEA and the IUR.

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UNITED KINGDOM

Legislative or policy measures taken, or proposed, for the protection of the natural environment from adverse effects of ionizing radiation in the UK

The most recent statement of overall UK policy relating to the protection of the natural environment from adverse effects of ionising radiation is set out in the 'Review of Radioactive Waste Management Policy', CM2919 which forms guidance to UK regulators. The UK government's policy is framed within the context of international guidelines and regulations. These include compliance with the European Atomic Energy Community's (EURATOM) Basic Safety Standards Directive by its transposition into UK law. The EURATOM Basic Safety Standards take account of recommendations from the International Commission on Radiological Protection (ICRP). The principles set out in International Atomic Energy Agency Safety Standards are also reflected in UK government policy.

UK regulators have a duty to ensure that the framework described in CM2919 is properly implemented in accordance with their statutory powers, including the safeguarding of the interests of existing and future generations and the wider environment, and in a manner that commands public confidence and takes due account of costs. Radioactive waste management policy is to be based on the same basic principles that apply more generally to environmental policy, and in particular to sustainable development.

The radiological protection principles underpinning the UK government's policy therefore take account of current ICRP recommendations and formal advice from the National Radiological Protection Board. Principles relating to optimisation and dose limitation are set primarily in relation to doses received by humans, with the assumption that if humans are protected then this will give adequate protection to the environment. There have however been cases where this assumption of protection of the environment by reference to protection of humans has been questioned, and the matter is being considered further. The UK has a distinguished record of research work into the effects of radiation on the environment, particularly the aquatic environment, and such research is continuing — funded both by Government Departments and its Environment Agencies — in order to inform both policy development and regulatory activities. In this capacity the UK has actively participated in IAEA, UNSCEAR, and other international reviews and discussions on this subject, and is keen to contribute further to its development.

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UNITED STATES OF AMERICA

Legislative and policy measures for protection of the natural environment from adverse effects of ionizing radiation in the USA

Summary

Requirements and guidance for the protection of the environment exist within several United States government agencies, primarily the US Department of Defense (DOD), the U.S Environmental Protection Agency (EPA), the US Nuclear Regulatory Commission (NRC), and the US Department of Energy (DOE). Requirements and guidance within DOD and EPA focus on the assessment of potential adverse environmental impacts and ecological risks from non-radiological contaminants or "stressors" to the environment. The NRC evaluates potential non-radiological and radiological impacts to the environment as part of their analysis for proposed commercial nuclear facilities, but has no explicit radiation dose standards for the protection of biota. The DOE currently has in place a radiation dose standard for the protection of aquatic organisms, and is considering proposing radiation dose standards for terrestrial biota. This overview centers on DOE policy, requirements, and guidance development initiatives regarding the protection of the environment from potential adverse effects of ionizing radiation.

DOE requirements and guidance for the protection of biota

The Atomic Energy Act of 1954 [1], as amended, authorizes DOE to protect the health and safety of the public against radiation in conducting the Department's programs. It is the policy of DOE to implement legally applicable radiation protection standards and to consider and adopt, as appropriate, recommendations by authoritative organizations, e.g., the National Council on Radiation Protection and Measurements (NCRP) and the International Commission on Radiological Protection (ICRP). Regarding environmental protection, the ICRP statement that "...if man is adequately protected then other living things are also likely to be sufficiently protected" [2, 3], uses human protection to infer environmental protection from the effects of ionizing radiation. This assumption is most appropriate in cases where humans and other biota inhabit the same environment and have common routes of exposure, and less appropriate in cases where human access is restricted to the contaminated area.

Accordingly, DOE, through Order DOE 5400.5 [4] currently has in place a dose standard of 1 rad/d (10 mGy/d) for the protection of aquatic organisms, and is considering inclusion of dose standards for the protection of terrestrial plants (1 rad/d; 10 mGy/d) and terrestrial animals (0.1 rad/d; 1 mGy/d) in Sub Part F of proposed rule 10 CFR 834, Radiation Protection of the Public and the Environment [5]. These dose standards are intended to ensure protection of populations of organisms. DOE has decided not to promulgate these criteria until guidance for demonstrating compliance with the standards has been developed. In this regard, DOE has developed a draft Technical Standard (i.e., guidance and methodology) which provides a graded approach for evaluating radiation doses to aquatic and terrestrial biota, to be used in demonstrating compliance with these dose standards [6].

Provided by: S.L. Domotor

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DOE's graded approach for evaluating radiation doses to aquatic and terrestrial biota

Guiding principles for methods development

The draft Technical Standard, referred to as the Biota Manual, was developed using an interdisciplinary team approach — with a guiding principle that both "developers" and "users" of the methodology be part of the process — through a DOE-sponsored *Biota Dose Assessment Committee* (BDAC). This committee was formed in June 1998 under the Department's Technical Standards Program. The BDAC Charter is provided as an attachment to this overview.

The following additional guiding principles were identified to focus the DOE methods development effort. The guidance should: (1) provide users with a "graded approach" for demonstrating compliance, which is cost-effective, easy to implement, and allows for the use of measured radionuclide concentrations in environmental media typically collected as part of routine environmental surveillance programs; (2) be applicable to demonstrate compliance with DOE dose standards for biota, and for use in ecological risk assessments of radiological impact; (3) provide a framework which supports the use of site-specific methods; (4) be technically sound and address gaps in previous approaches; (5) incorporate an ecological risk assessment framework as appropriate; and (6) provide leadership in methods development within the US and abroad.

A three-step process

The DOE graded approach for evaluating radiation doses to biota consists of an easy-toimplement three step process, which is designed to guide a user from an initial, prudently conservative set of screening values to, if needed, a more rigorous analysis using site-specific information. The three-step process includes: (1) data assembly, where measured maximum or mean radionuclide concentration data are assembled for subsequent screening. The most conservative approach would be to use maximum concentrations. However, use of mean values are appropriate in situations where time-series data are available and of sufficient quality; (2) a general screening phase, where measured radionuclide concentrations in environmental media (e.g., water, sediment, soil) are compared with a set of Biota Concentration Guides (BCGs). Each radionuclide-specific BCG represents the limiting radionuclide concentration in environmental media which would not cause DOE's existing and proposed dose standards for biota to be exceeded; and (3) an analysis phase, which consists of three increasingly more detailed steps of analysis: (3a) a site-specific screen, using site-representative parameters (e.g., distribution coefficients; bioconcentration factors) instead of default parameters, (3b) a site-specific analysis, employing a kinetic modeling tool provided as part of the graded approach methodology, and (3c) performing an actual sitespecific biota dose assessment within an ecological risk assessment framework, which would involve a problem formulation, analysis, and risk characterization protocol similar to that recommended by the US EPA [7].

The assumptions regarding sources, receptors, and routes of exposure used in the development of DOE's screening methodology provide for conservative screening values. Internal and external sources of dose (and their contributing exposure pathways) are incorporated in the derivation of the methodology. Four organism types (aquatic animal; riparian animal; terrestrial plant; terrestrial animal) were used to derive the screening biota concentration guides.

Biota manual and supporting resources

The draft Technical Standard is designed to be easy to use, with information on: (1) purpose and background; (2) applications and exclusions; (3) frequency of conducting evaluations; (4) interpretation of dose limits; and (5) step-by-step guidance for application. Detailed appendices provide information on: (1) use of time averaging and spatial variability considerations in applying dose limits; (2) biota sampling methods; (3) methods for selecting limiting concentrations; (4) default parameter values; (5) derivation of dose equations; and (6) radiation weighting factor for alpha particles. In addition to the Biota Manual, a set of electronic spreadsheets for performing the calculations is also provided on CD-ROM, and will be available through the Internet via the BDAC Web Site (http://tis.eh.doe.gov/oepa/public/bdac).

A biota dose assessment *environmental parameters database* is also being developed; a prototype is under review within the BDAC. The database is intended to support the DOE methodology, and all other dose assessment methods requiring environmental parameter data. A range of environmental parameter data (e.g., distribution coefficients; bioconcentration factors; biological uptake and elimination factors) and their reference sources (both published and grey literature) are available in the database. The database features the ability to add, edit and search for parameter data remotely via the Internet. There is the capability to search by multiple attributes (e.g., element/nuclide; parameter; taxonomic group; organism type; soil type; and reference).

Once finalized, the DOE Technical Standard should prove useful as a cost-effective tool for demonstrating compliance with dose limits for biota, and for conducting ecological assessments of radiological impact.

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Charter

Biota Dose Assessment Committee

PURPOSE -

The Biota Dose Assessment Committee (BDAC) is a topical committee within the Department of Energy (DOE) Technical Standards Program (TSP). The purpose of the BDAC is to:

- 1. Assist the Department in conceiving, developing, and promoting technical standards and associated guidance for DOE-wide application in assessing radiation doses to biota.
- 2. Serve as a major forum within DOE for obtaining technical assistance, discussing technical and policy issues, and sharing lessons learned regarding biota dose standards and assessment methods.

VALUE STATEMENT -

The Department needs a forum for sharing information on the development and application of easy, standardized methods for conducting preliminary assessments of doses to aquatic and terrestrial biota. The BDAC will provide a major forum within DOE for obtaining technical assistance, discussing and coordinating positions on technical and policy elements of biota dose standards and biota dose assessment methods. and sharing information and lessons learned from DOE site-specific biota dose assessment efforts.

The development of methods for evaluating radiation doses to biota and implementing site-specific biota dose assessments requires a diverse set of scientific disciplines. The BDAC brings together the expertise in health physics, ecology, radioecology, environmental monitoring, and risk assessment that is needed to serve the Department as an effective resource to meet the purpose and objectives identified in this Charter.

OBJECTIVES -

- 1. Serve as the DOE focal point for biota dose assessment technical standards issues.
- 2. Function as the Preparing Activity/Reviewing Activity for developing biota dose assessment technical standards. In this capacity the committee will provide assistance to the DOE Office with the primary interest for coordination of newly-published technical standards.
- 3. Provide review and comment, and help establish the DOE-wide position on DOE, non-DOE government, and non-government consensus biota dose assessment technical standards published or in comment coordination.
- Assist. consistent with DOE needs, in national or international biota dose assessment technical standards development.
- 5. The BDAC will assist in the Department's efforts to develop a cost-effective, easy-to-implement screening methodology for assessing radiation doses to biota which can be used in demonstrating compliance with DOE and internationally-recommended biota dose standards.
- 6. Serve as an advisory and technical assistance resource to DOE Program and Operations Offices in the application of biota dose assessment technical standards. and in the design and technical review of site-specific biota dose assessments.

- 7. Establish and maintain liaison with other DOE topical committees having mutual interests through the Technical Standards Program Office (TSPO). The committee shall advise all other DOE technical committees on the preparation of standards related in subject matter and the correlation and consolidations of similar standards prepared by these committees, and promote cooperation between these technical committees in areas of common interest.
- 8. Partner and interface with counterparts in standards development organizations (i.e., American National Standards Institute, American Nuclear Society) and other Federal agencies in the development and review of national and international technical standards.
- 9. Participate with representatives of other topical committees and the TSP manager to establish guidance and protocols for topical committee operations under the TSP.
- 10. Foster continuous improvement in biota dose assessment methods and guidance.
- 11. Share information and lessons learned from DOE site-specific biota dose assessment efforts.
- 12. Share and exchange information on technical, policy, and research needs for consideration by DOE when interacting with Federal and International Agencies on biota dose standards and assessment methods.

MEMBERSHIP -

Membership in the BDAC is open to DOE employees and DOE contractors who have interest in or responsibility for biota dose assessments through environmental and radiological protection programs and environmental risk assessment activities. Representation from each interested Program and Operations Office is a membership objective of the BDAC. The BDAC Steering Committee may set guidelines on the size of the BDAC to allow for work processes within the committee to be effective.

STEERING COMMITTEE -

The BDAC will be chaired by Mr. Stephen Domotor. DOE. Office of Environmental Policy and Assistance (EH-41), Air, Water and Radiation Division (EH-412). A Steering Committee, comprised of six representatives having the technical expertise needed for developing methods and guidance for biota dose assessment, has been established for the BDAC. The BDAC will be governed by the Steering Committee and the Chairperson (or a designated representative).

SPONSORSHIP -

The BDAC. formed in March 1998, is a technical standards topical committee organized under the DOE Technical Standards Program (TSP). The following principles will govern its operation:

Collaboration and Innovation: The BDAC will use and promote partnerships to leverage resources, expertise, and information on biota dose technical standards. The BDAC will use innovative tools and approaches to make biota dose assessment methods, guidance and expertise available to our customers.

Openness: The BDAC will take a consensus-based approach when developing technical standards for screening methodologies for biota dose assessment. The BDAC will be open to all persons who are directly and materially affected by the activity.

Balance of Interests: All technical standards development activities undertaken by the BDAC will include representatives of all categories of interest that relate to the subject matter. The composition of the BDAC Steering Committee reflects this principle.

Due Process: The BDAC will ensure that any individual or organization within DOE who believes that an action or inaction of the committee causes unreasonable hardship or potential harm is provided the opportunity to have a fair hearing of his/her concerns. A formal review process will be applied to all biota dose assessment standard methods and guidance developed through the BDAC.

Reporting: The BDAC Chair and/or Steering Committee will report on BDAC activities to the DOE TSPO on a regular basis. BDAC members will foster two-way communication within their organization by providing informal updates on the activities of the BDAC and bringing informal issues and recommendations back to the BDAC for consideration.

MEETINGS -

The BDAC Steering Committee will meet via teleconference as frequently as needed to complete work on specific tasks or milestones. The full BDAC will meet on an as-needed basis via teleconference and annually in-person at a formal meeting or workshop. The BDAC will seek to operate in a cost-effective and efficient manner, and will use innovative approaches to share information on issues, guidance and technical tools, and reviews of draft products through the BDAC Web Site.

This Charter was adopted on:

June 12, 1998

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Andrew Wallo III

Director

Air, Water and Radiation (EH-412)

Approved:

Steehen L. Domotor

Chairman

Biota Dose Assessment Committee

Approved by the DOE Technical Standards Program (TSP) Office:

Richard J. Serbu

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DEFINITIONS

The definitions below apply to terms used in this report, and may not necessarily conform to definitions adopted elsewhere for international use.

Biological diversity Variability among organisms from all sources including, inter alia,

terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within

species, between species and of ecosystems.

Biological resources The genetic resources, organisms or parts thereof, populations or

any other component of ecosystems with actual or potential use for

humanity.

Biosphere That portion of the Earth's environment normally inhabited by

living organisms. It comprises parts of the atmosphere, the hydrosphere (ocean, seas, inland waters and subsurface waters) and

the lithosphere (the solid portion of the Earth).

Community In the context of this report, a group of two or more different

species populations that coexist in a given geographic area. Members of the community have evolved functional interrelationships that permit a recognizable degree of stability in

the structural composition of the community.

Critical species That species that is thought to be the most *vulnerable* biological

component which, if adequately protected, would provide assurance that all other species in the community were also

protected.

Deterministic effects Radiation effects for which a threshold level of dose generally

exists, above which the severity of the effect increases with dose.

Ecological risk assessment The assessment of the risks to natural, semi-natural or managed

ecosystems, and their components, from one or more stressors.

Ecosystem The biological community together with the abiotic components

(air, water, soil, and nutrients) necessary for the continued existence of the community. Ecosystems have varied structures, depending on geographic locations, but they nearly always have similar functional groups such as nutrient pools, primary producers (plants), consumers (animals), and decomposers (micro-organisms,

etc.).

Environment The components of the Earth, including: land, water and air,

including all layers of the lithosphere, hydrosphere and

atmosphere containing life forms.

Environmental protection Protecting and preserving the inherent quality of natural and

managed ecosystems, as well as areas that have been developed for human occupancy and use. This implies protection of the quality of air, water, soils, and human structures; and preventing

harm to the health and vitality of plants, animals and people.

Genetic isolation Refers to a population in a given geographic area that is isolated

from individuals of the same species in other geographic areas. Therefore, interbreeding among such individuals is not possible.

Habitats Geographic areas which provide the biotic and abiotic

requirements for the continued existence of a particular species.

Intervention Any action intended to reduce or avert exposure or likelihood of

exposure to sources which are not part of a controlled practice or

which are out of control as a consequence of an accident.

Population A group of individuals of the same species, capable of

interbreeding, and thus maintaining the genome of the species through successive generations. In the context of this report, the "population" of relevance may be some fraction of the total population; for example, the exposed portion of the total

population.

Primary protection

criterion

A protection criterion usually given in terms of a dose and specified on the basis of a known or postulated relationship

between dose and risk.

Propagule Biological material, containing the genome of an organism, which

can be dispersed or spread geographically to permit colonization in

a new area. Examples are seeds, spores, eggs, larvae, etc.

Recruitment The replenishment of a local population either by reproduction or

by the immigration of members of the same species from other

areas.

Reference species Simplified quantitative description of a species, occurring in a

particular environment, defined for the purpose of assessing doses.

Risk A multiattribute quantity expressing hazard, danger or chance of

harmful or injurious consequences associated with actual or potential exposures. It relates to quantities such as the probability that specific deleterious consequences may arise and the magnitude

and character of such consequences.

Safety factor A factor by which a quantity such as a numerical standard is

multiplied to provide additional assurance of safety.

Stochastic effects Radiation effects, generally occurring without a threshold level of

dose, whose probability is proportional to the dose and whose

severity is independent of the dose.

Sustainable development Use of biological components of biological diversity in a way and

at a rate that does not lead to the long term decline in biological diversity, thereby maintaining its potential to meet the demands of

present and future generations.

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Consultants Meetings

Vienna, Austria: 27–30 May 1997 Vienna, Austria: 10–13 November 1997 Vienna, Austria: 7–11 September 1998

Technical Committee Meeting

Vienna, Austria: 11-15 January 1999

IAEA SAFETY RELATED PUBLICATIONS

IAEA SAFETY STANDARDS

Under the terms of Article III of its Statute, the IAEA is authorized to establish standards of safety for protection against ionizing radiation and to provide for the application of these standards to peaceful nuclear activities.

The regulatory related publications by means of which the IAEA establishes safety standards and measures are issued in the IAEA Safety Standards Series. This series covers nuclear safety, radiation safety, transport safety and waste safety, and also general safety (that is, of relevance in two or more of the four areas), and the categories within it are Safety Fundamentals, Safety Requirements and Safety Guides.

- Safety Fundamentals (silver lettering) present basic objectives, concepts and principles of safety and protection in the development and application of atomic energy for peaceful purposes.
- Safety Requirements (red lettering) establish the requirements that must be met to ensure safety. These requirements, which are expressed as 'shall' statements, are governed by the objectives and principles presented in the Safety Fundamentals.
- Safety Guides (green lettering) recommend actions, conditions or procedures for meeting safety requirements. Recommendations in Safety Guides are expressed as 'should' statements, with the implication that it is necessary to take the measures recommended or equivalent alternative measures to comply with the requirements.

The IAEA's safety standards are not legally binding on Member States but may be adopted by them, at their own discretion, for use in national regulations in respect of their own activities. The standards are binding on the IAEA for application in relation to its own operations and to operations assisted by the IAEA.

OTHER SAFETY RELATED PUBLICATIONS

Under the terms of Articles III and VIII.C of its Statute, the IAEA makes available and fosters the exchange of information relating to peaceful nuclear activities and serves as an intermediary among its members for this purpose.

Reports on safety and protection in nuclear activities are issued in other series, in particular the IAEA Safety Reports Series, as informational publications. Safety Reports may describe good practices and give practical examples and detailed methods that can be used to meet safety requirements. They do not establish requirements or make recommendations.

Other IAEA series that include safety related sales publications are the Technical Reports Series, the Radiological Assessment Reports Series and the INSAG Series. The IAEA also issues reports on radiological accidents and other special sales publications. Unpriced safety related publications are issued in the TECDOC Series, the Provisional Safety Standards Series, the Training Course Series, the IAEA Services Series and the Computer Manual Series, and as Practical Radiation Safety and Protection Manuals.

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