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A New Approach to Authorisation in the Field of Radiological Protection

The Road Test Report

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Consultants to NEA

NUCLEAR ENERGY AGENCY
ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

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NUCLEAR ENERGY AGENCY

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The mission of the NEA is:

- to assist its Member countries in maintaining and further developing, through international co-operation, the scientific, technological and legal bases required for a safe, environmentally friendly and economical use of nuclear energy for peaceful purposes, as well as
- to provide authoritative assessments and to forge common understandings on key issues, as input to government decisions on nuclear energy policy and to broader OECD policy analyses in areas such as energy and sustainable development.

Specific areas of competence of the NEA include safety and regulation of nuclear activities, radioactive waste management, radiological protection, nuclear science, economic and technical analyses of the nuclear fuel cycle, nuclear law and liability, and public information. The NEA Data Bank provides nuclear data and computer program services for participating countries.

In these and related tasks, the NEA works in close collaboration with the International Atomic Energy Agency in Vienna, with which it has a Co-operation Agreement, as well as with other international organisations in the nuclear field.

FOREWORD

The most significant challenge currently facing the radiation protection community is how to better reflect modern concepts of and approaches to risk governance in the system of radiological protection. This issue is manifest in the growing stakeholder involvement in decision-making processes addressing human health and environmental risks. In radiological protection, these trends, as well as interpretation and application difficulties with the current system of radiological protection, have led to a general review of the system's foundations.

The NEA Committee on Radiation Protection and Public Health (CRPPH) has been concerned with the evolution of the system of radiological protection for several years, in particular since 1999. The Committee's goal is to ensure that consensus on directions for improvement is reached among radiation protection experts from national regulatory authorities, and that this consensus is taken into account during the development of new approaches and international recommendations. To achieve this goal the CRPPH has established a series of expert groups to develop and diffuse its views. The Expert Group on Controllable Dose published, in 2000, the first CRPPH report in this area: *A Critical Review of the System of Radiation Protection: First Reflections of the OECD Nuclear Energy Agency's Committee on Radiation Protection and Public Health.*

This review identified key areas where the current system of radiological protection, as described in the Publication 60 Recommendations of the International Commission on Radiological Protection (ICRP), could be improved. Taking this work a step further, the NEA Expert Group on the Evolution of the System of Radiological Protection developed a second report, providing concrete suggestions for improvement. These suggestions were published in 2002 under the title *The Way Forward in Radiological Protection: An Expert Group Report.*

As part of the mandate of the Expert Group, the CRPPH requested that any new suggestions be "road tested", that is, critically tested against practical problems to see whether they would truly bring an improvement in the

radiological protection afforded by the system. Specifically, the mandate of the Expert Group included the following charge:

> *The Expert Group should use a case-study approach to "road test" its proposed changes, to assure that the changes move the system of radiological protection towards a more understandable, easy to apply, and acceptable system.*

To achieve this, the NEA contracted two consultants – Dr. Richard Osborne and Dr. Frank Turvey – to work with the Expert Group, and to critically test key ideas from the Group's report. The consultants presented the results of their work in September 2002, at which point it was approved by the Group for presentation at the Asian Regional Conference on the Evolution of the System of Radiological Protection, held on 24-25 October 2002 in Tokyo. Based on discussions during the conference, the consultants finalised their report, which was subsequently presented to the CRPPH at its annual meeting in March 2003.

The CRPPH agreed that the consultants' work on the concept of comprehensive authorisation, and on source and dose characterisation, was a useful validation of the work of the Expert Group, and would be of great use to the ongoing discussions on the evolution of the system of radiological protection. The Committee thus approved the consultants' report for publication as its views, and for submission, on the part of the CRPPH, to the broader radiation protection community.

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EXECUTIVE SUMMARY

The NEA Committee on Radiation Protection and Public Health (CRPPH) has been investigating ways of improving the existing system of radiological protection so that it would be simpler yet no less effective, more understandable, and more transparent; it would also be one in which the interested and, potentially or actually, affected parties could participate. Two of the possible improvements suggested by the CRPPH in its report of that investigation* were the characterisation of sources and exposures in order to facilitate the identification and social acceptance of possible radiological protection actions, and a coherent process of authorisation of all justified exposures.

This report is a review of these two possible improvements. It has involved:

- the development of "source and exposure characteristics" that could be used to identify, in advance, those situations that could best be addressed (or could only be addressed) through stakeholder involvement processes;
- an analysis of the concept of the process of authorisation; and
- tests of the characterisation and process of authorisation with a set of sources and exposures.

In devising a system for characterisation, some 50 to 60 apposite characteristics were identified. These were divided into two lots, one for sources and the other for exposures. Each of these was further divided into 9 groups for sources and 8 groups for exposures. There is an average of three related characteristics in each group, e.g. in the source group called physical state these are gas, liquid and solid. Usually, but not always, the characteristics in a group are mutually exclusive. Each is given a value on the scale of 0 to 5 so that the sum of all in a group is 5. Again, taking the above example, gas is given a value of 3, liquid 2 and solid 0.

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* NEA, *The Way Forward in Radiological Protection: An Expert Group Report*, Nuclear Energy Agency (OECD), Paris (2002).

When characterising a source and exposure to it, one fitting characteristic is chosen from each of the 17 groups and their values contribute to a total score for the source and again for the exposure. These are expressed as a percentage of the maximum possible scores in each case: thus the exposure and source characteristics are expressed in percentage terms. The characterisation of the combination of source and exposure can now be expressed by calculating the mean value of the two percentages.

In some instances there may be no characteristic in the group that fits, or describes well, the source or exposure under consideration. In such instances the group is ignored and the maximum score used in the percentage calculation is reduced by the highest valued characteristic in that group.

A combined percentage rating above 65% indicates the need for the regulator to consult with stakeholders. A rating of less than 35% indicates to the regulator that no protective measures are needed but stakeholders may need to be consulted. An intermediate score usually means that the regulator must evaluate the situation in the traditional manner. However, if the combined source and exposure percentage rating is close to the 65% or the 35% borders then the source and exposure may be re-evaluated using the double counting system, which is aimed to give a refined result that anticipates the expected difference between the regulators technical judgement, including social and economic considerations, and those of the possible stakeholders. The idea is that regulators may find this refined result useful in making judgements in borderline cases.

Characterisation can be seen as the first step in the process of authorisation. The process itself can be seen as a particular application of the general approach taken in assessing and managing health risks of all kinds. Such an approach is to define the problem and put it in context; to analyse the risks; to examine the options for addressing the risk; to decide which option to implement – i.e. the optimum solution; to implement the decision; and to evaluate the results. The concepts developed in the EGRP report cover the first four steps.

The first step is realised by characterising, as described above, and screening the particular case taken from the “world of sources and exposures”. The decision made as a result of the screening may be that the source and exposure being considered can be excused from protective actions. In effect, the source and exposure are returned to the world of radiation sources and exposures. Alternatively, the screening may lead to the realisation that further analysis is needed, possibly with input being sought from stakeholders, according to the criteria noted above. The “further analysis” corresponds to the next three steps of the general approach and can here be called an optimisation

of protection under dose constraints. The initial question asked at this stage is whether the exposures are justified. If so, then the optimisation would entail considering, *inter alia*, the characteristics of the source and exposures in more detail, any relevant dose constraints or quantitative guidelines, the feasibility and cost of protective actions, any other related impacts on health and the environment, stakeholder views and the societal context of the exposures. For all but the last two considerations, specific recommendations from international agencies would be helpful, particularly in encouraging the application of a common set of quantitative criteria. For the last two considerations, given differing national practices, only general recommendations from international agencies might be expected.

On the basis of further analysis, the regulatory authority may decide that the optimum outcome is to excuse the sources and exposures from protective actions, or to authorise them subject to some conditions. The process as described so far has, in effect, covered the mechanisms in the current system of exclusion, exemption and regulatory control. Reconsideration by the same process of a source and exposure that is currently under regulatory control may lead to a change in the level of control and, in particular, may prompt the regulator to decide that that particular source and exposure no longer warrant control; they can be excused. The latter decision is equivalent to implementing the process for clearance in the current system.

In the review, the complete process of characterisation, screening, and optimisation – called here "comprehensive authorisation" – was tested on a variety of sources and exposures, ranging from cosmic ray exposures of the public to radioactive releases from nuclear facilities. The scores obtained in the characterisation range from less than 35% to more than 65%, the two values suggested as the criteria for excusing from regulatory action on the one hand and for indicating the need for stakeholder involvement on the other.

The comprehensive authorisation process would appear to lead to the same general outcomes as does the present system but in a more unified way without some of the confusing terminology. Characterisation looks to be a helpful way of triggering stakeholder involvement, though there may be some difficulty in arriving at a common set of attributes – some "tuning" is needed. There is still a need for international recommendations on dose constraints and other quantitative guidelines for consideration in the optimisation process. The process of comprehensive authorisation appears to be an evolution of the present system, able to take advantage of those parts of the current system that work well. With the comprehensive authorisation process, there would appear to be a potential for improved coherence with the approaches in health risk assessment in general as well as with environmental risk assessment.

AUTHORS' PREFACE

Dr. R.V. Osborne (Canada) and Dr. F.J. Turvey (Ireland)

In 2002, the CRPPH invited us, as consultants, to:

- analyse "authorised release" from regulatory control as part of a comprehensive system of authorisation that addresses all exposures;
- develop "source and exposure characteristics" that could be used to identify, in advance, those situations that could best be addressed (or could only be addressed) through stakeholder involvement processes.

We were also entrusted with:

- collecting detailed base information and analysing it, and
- drafting a report with annexes of supporting material.

While clarifying the task, the following points were agreed:

- The characterisation should be of sources and exposures separately and not, for example, of exposures with the source of exposure as a co-ordinate of the characteristic.
- The characteristics may be given values to assist in determining the need to discuss protective measures with stakeholders and in making other regulatory decisions.
- Using the values the regulation of those exposures and sources that definitely do not need stakeholder involvement can be identified as also can those that definitely do.
- A third category comprises the remaining items that have to be further scrutinised by the regulator in order to decide into which of the other two groups they should go.

- The two tasks of characterisation (Turvey) and authorisation (Osborne) should be combined as the first is the precursor of the second in the regulatory process.
- Characterisation of sources and exposures not only helps in identifying the need for stakeholder involvement but could also be a very useful step in the authorisation of releases. Hence, this might also be examined.

1. INTRODUCTION

The practice of radiological protection in recent times has been based on the recommendations of the International Commission on Radiological Protection that were issued in Publication 60 of the ICRP [IC91]. The system of protection, which has been followed in most parts of the world, has provided a high level of protection to the public and to workers but it has been found to be both complex and somewhat incoherent.

These shortcomings among others, such as an arcane terminology and difficulties in application of the concept of collective dose when individual doses are low, have been recognised widely. In addition there has been a feeling that the recommendations encouraged too prescriptive an approach to regulation; one that tended to preclude the participation of parties likely to be affected by regulatory decisions. Professor Roger Clarke, Chairman of the ICRP, therefore initiated in 1999 a general discussion of a different and less complex system of protection based on the new concept of *controllable dose.*

The Nuclear Energy Agency of the OECD while acknowledging the need to improve on ICRP Publication 60 felt that such a radical change might not be appropriate. The reasons for this included the absence of new scientific information as a basis for change, the need for legislative stability in member states over a further significant period of time, and the feeling that the cure might be worse than the disease.

The NEA Committee on Radiation Protection and Public Health (CRPPH) was therefore charged with investigating ways of improving the existing system of radiological protection to one that would be simpler yet no less effective, more understandable, and more transparent, in which the interested and, potentially or actually, affected parties could participate. Two of the possible improvements suggested by the CRPPH in its report of that investigation were the characterisation of sources and exposures in order to facilitate the identification and social acceptance of possible radiological protection actions, and a coherent process of authorisation of all justified exposures.

It was agreed that an attempt to develop and test these suggested improvements should be initiated with the help of consultants.

2. OBJECTIVES, SCOPE AND CRITERIA FOR SUCCESS

2.1 Objectives of the review

- To support the Expert Group on the Evolution of the System of Radiological Protection (EGRP) by examining the ideas, developed by the EGRP, of using characterisation of sources and exposures, and the process of authorisation as parts of a comprehensive approach to the regulation of radiological protection.
- To provide the EGRP with conclusions about the feasibility of this approach and any pertinent recommendations.

2.2 Scope of the review

The review is based on the report by the Expert Group on the Evaluation of the System of Radiation Protection (ERGP), *The Way Forward in Radiological Protection* [NE02].

Part of the review is the development of source and exposure characteristics that could be used to identify in advance those situations that could best be, or only, addressed through involvement of all those parties with valid interests (stakeholders) and to facilitate the process of authorisation.

A further part of the review is the examination of the process of authorisation that is keyed to source and exposure characterisation through various case studies.

2.3 Criteria for success

In order to judge whether the idea of a comprehensive authorization process, in which *ab initio* nothing is excluded or exempted, “holds up” when tested we need to ask the following questions:

- Does the recommended process help to resolve issues that have arisen under the current system of protection?

- Does the recommended process reinforce what already works well and is generally accepted?
- Is the recommended process helpful to and applicable in all countries, developed, developing and undeveloped?
- Is there sufficient guidance at the international level to meet the needs of national authorities who may have widely differing in house expertise but, at the same time, is there sufficient flexibility in what is recommended to allow national authorities to adapt recommendations to meet their own ambitions and cultures?
- Does the recommended process move radiological protection towards an improved coherence with approaches taken globally to the management of other carcinogenic risks, for example chemicals?
- Does the recommended process allow for a clear distinction between the scientific aspects of risk assessment, the social aspects of risk evaluation and management, and the regulatory aspects of risk management?

3. CHARACTERISATION AND AUTHORISATION IN THE SYSTEM OF RADIOLOGICAL PROTECTION

3.1 The general process of health risk assessment and management

In this report we are focusing on those aspects of a scheme involving the characterisation of sources and exposures and a comprehensive authorisation process that leads to unrestricted release; i.e., those situations that are currently addressed through mechanisms such as exclusion, exemption and clearance, and the concept of triviality. In doing this we need to examine the scheme not just with those sources and exposures that are now excluded, exempted and cleared but with a broader spectrum of sources and exposures that includes those that are currently subjected to regulatory control. By so doing we can examine whether the envisaged comprehensive process of authorisation can serve to simplify the current approaches.

The intention is to provide the EGRP with an evaluation of whether the suggestions in the EGRP report hold up when tested against real situations and, in particular, against situations that have been something of a challenge under the present radiation protection frameworks in the countries of the members of the NEA.

The system of radiological protection that has evolved over the last few decades has developed its own methodology and its own vocabulary and this has made it not readily understood by practitioners in health risk assessment and management in non-radiological fields. To some extent, the ideas of the EGRP appear to be bringing the system into a closer alignment with the more general approach.

The general process that a regulator is likely to follow in regulating risks to human health (and to the environment) has the following steps:

- define the problem and put it in context;
- analyse the risks, in context;

- examine the options for addressing the risks;
- make decisions about which option to implement;
- take actions to implement the decisions;
- evaluate the results.

The steps in this process would be iterative and in collaboration with stakeholders to varying extent. The iteration (with "stages" or "tiers", constituting a "graded" approach) can be structured so that the analytical effort expended towards making a decision is commensurate with the particular problem. For example, such processes usually encompass an initial "screening" stage that enables a regulator to decide very quickly whether a particular risk actually needs any regulatory action, whether it quite clearly does need control or action, or whether further analysis is needed to decide one way or the other.

This is a very general framework that is common in its essentials to many regulatory frameworks. For radiological protection, the ICRP interprets the scientific knowledge relating to radiological protection, recommends the principles, and indicates the practical implications for implementation of the principles. It calls this package its "system of radiological protection".

Such a system of radiological protection serves to guide international agencies such as the International Atomic Energy Agency and the World Health Organisation in developing international standards and to help national regulators in developing the details of their particular national regulatory frameworks.

3.2 The ideas of the EGRP in the context of a general health risk assessment and management framework

The EGRP report discusses aspects of both the ICRP system and possible regulatory frameworks. That is, it has a broad scope for what it calls the "system of radiological protection". The wording of the recommendations of the EGRP is to the effect that the "system of radiological protection" should have various features (not explicitly what might be desirable in recommendations from the ICRP). The desirable features recommended by the EGRP for the "system" therefore seem to be partly directed to new ICRP recommendations and partly to features of a regulatory framework.

The analysis below is in the context of this duality. In the conclusions, we consider the extent to which international organisations such as the ICRP in

their recommendations and standards can facilitate the regulatory implementation of the EGRP ideas.

An initial task here is to link the radiological protection vocabulary to the more general risk assessment and management vocabulary, which is itself, varied. Below we outline the connection between the steps in regulating risks that we list above to current mechanisms and concepts in radiological protection and to the ideas of the EGRP.

Define the problem and put it in context

Sometimes called "hazard analysis", this step is where the sources of exposure are identified and there is an initial estimation of the likely temporal and spatial ranges of exposures and doses. The context of the exposures is developed; i.e., which is exposed, the role of those exposed, perceptions of the exposures and risks, and any other features of the source and exposures that might bear on decisions about its regulation. In radiological protection vocabulary the definition part of this step can be termed "source and exposure characterisation".

Those responsible for managing any risk are identified at this step as well as a process for engaging stakeholders.

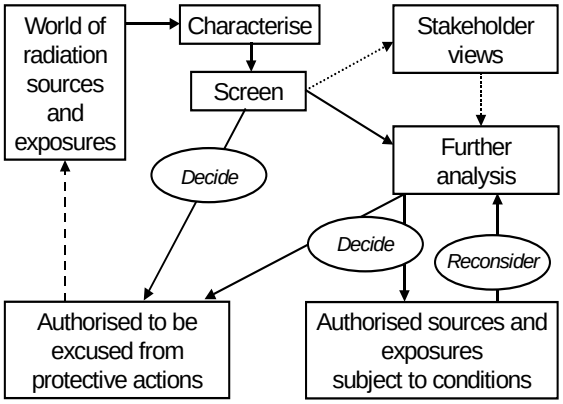
At this stage, it may be clear (possibly on the basis of pre-determined criteria) that the assessment need continue no further and the source or exposures (the "problem") does not need to be further considered and controlled by the regulatory authority. The decision may amount to no more than verifying that, on the basis of prior assessments or on the basis of being listed as needing no regulatory protective action, the source as characterised does not, indeed, need any regulatory action.

This step can be considered as equivalent to a "screening" step in a process of risk assessment and management. Characterising sources and exposures, and screening are shown in Figure 1, which is the authors' interpretation of the comprehensive process of authorisation as described by the EGRP.

Criteria for deciding that the assessment need proceed no further may be numerical criteria, clearly applicable to the source or exposures being considered, that have been developed by a national or international consensus process. They may also be qualitative such as there being a consensus that the source or exposures are trivial. A decision to proceed no further may be based

on a precedent to which there is sufficient similarity. Such a step is shown by the "decide" arrow in Figure 1 that leads from the screening box to authorisation that the source or exposure is "excused" from any further protective action.*

Figure 1. **The authors' interpretation of the comprehensive process of authorisation as described by the EGRP**



Such a decision to proceed no further with any regulatory action is equivalent to actions in current radiological protection termed "exemption "and "exclusion". Once this decision has been made, then the source and exposure to it being considered are, in effect, back in the world of sources and exposures, illustrated by the dashed arrow in Figure 1. At any time they could be re-analysed if any concern were to be expressed about their being excused from regulatory control; there is no rule to the effect, once excused, always excused as one seems to have with the current ideas of exclusion and exemption.

Although the EGRP's recommended system of protection ostensibly includes all sources of exposure, (the "World of radiation sources and

* In the treatment of the set of exposures and sources that does not come into this category of "not needing regulatory control" *ab initio* there needs to be some flexibility for the decision to be that nothing actually needs to be done – though the regulator might keep a watching brief. It is not clear how that might be captured. The phrase "no regulatory action" may be better – and there is some flavour of "protective action levels. More explicit would be "no regulatory action currently" Other possibilities are "accepted without regulation", "without regulatory objection", or simply "venial exposures" meaning that they are easily excused. The last possibility leads to the terms "excused" or "currently excused".

exposures" box of Figure 1) this initial screening step, based on the source characterisation, immediately narrows down to a range of sources and exposures that need be subject to further consideration (assessment) and possible management.

The distinction between a system of protection that applies only to defined sources and exposures (start with finite number and add as the need arises; the exclusive approach) and one that applies to all sources and exposures from which exceptions are immediately determined (start with an infinite number and immediately limit on the basis of clear criteria; the inclusive approach) therefore becomes more a philosophical issue than a practical one. Although the system of protection includes all sources, regulatory control (and hence the regulatory system as such) is exercised only on some.

- Analyse the risks, in context.
- Examine the options for addressing the risks.
- Make decisions about which option to implement.

If, after the initial screening step further consideration is seen to be needed, then a more detailed assessment of risks, in context, is carried out. This is indicated by the "Further analysis" box in Figure 1. The analysis may be an iterative process involving, first, verification that the exposure to the source is justified, and then a broadly-based optimisation of protection and the application of any limits or constraints that are applicable to sources and exposures of the particular character. The extent to which stakeholders are involved in this more detailed assessment would depend on national practice but an examination of the source and exposure characteristics could themselves provide an initial indication to the regulatory authority of whether such involvement would be appropriate. This involvement is illustrated in Figure 1 by the dashed pair of arrows, from the "Screen" box to the "Stakeholder views" box and then to the "Further analysis" box.

The outcome of the further analysis may be a decision that no regulatory control or protective action is needed, or that controls and protection appropriate to the particular circumstances are needed. If the assessment has been of a situation or operation that has been under some regulatory control but in which the hazard has changed, then the decision may be for more control or less control; the circumstances may even be such that controls can be withdrawn. In current radiological protection language, this withdrawal of the requirement for controls is termed "clearance". Figure 1 shows these parts of the process by the "decide" and "reconsider" arrows.

In the radiological protection vocabulary of the EGRP this overall process, from the initial hazard identification to a decision on whether and what protective actions are needed, if any, is termed the “process of comprehensive authorisation”.

- Take actions to implement the decisions.
- Evaluate the results.

This corresponds to the management of sources and exposures subject to regulatory control, and to the demonstration of compliance.

We now examine the EGRP’s ideas in the light of this background to see how well they fit into it.

4. SOURCE AND EXPOSURE CHARACTERISATION

4.1 The ideas of the EGRP

The first step in the process of comprehensive authorisation of practices involving some degree of risk is the assessment of the hazard and the starting point for this, in the case of exposure to ionising radiation, is the determination of the characteristics of the source of the radiation and of the resulting exposure. This was indicated in the report of the EGRP [NE02] where it is stated that:

- A modern system of radiological protection should fit within a common policy framework with the management of other carcinogenic risks.
- To assist in the development of guidance with regard to the appropriate protective action to take, exposures could be characterised in terms of their receptor/source and various aspects of the exposure.
- The system of radiological protection should characterise exposures to facilitate the identification of and social acceptance of radiological protection actions.

Also, it was noticed that throughout its report the EGRP stressed the need for numbers as benchmarks for regulators or, as the Group sometimes expressed it, the need for numerical guidance.

Further, in explaining the "road test" to which their ideas should be subjected, the EGRP clarified its ideas by saying that:

- A better understanding of the characteristics of an exposure or a source would be a useful regulatory tool to help identify, in advance, controversial situations. Once identified, the regulator could better address such situations, from the start, with processes of stakeholder involvement in radiological risk assessment and protection decision making.

4.2 Characterisation – its use and meaning

These ideas led us to start our work by looking at what already exists on this subject.

Sources of ionising radiation and exposures to them are identified in various ways in current systems of radiological protection. There is, generally but not always, agreement on how to identify them among the international bodies concerned with radiological protection. Most agree that exposures may be identified, or categorised, as being occupational, medical or public and sources as being sealed, unsealed radioactive substances and irradiating apparatus. At the same time they are categorised in other ways as well, for example, exposures are sometimes referred to as being normal and potential. So which context or aspect of radiological protection one is concerned about determines the categories used. At this point it is appropriate to ask the question, is there a difference between categorisation and characterisation?

Surely the answer is yes. A category is a group in which each member has a common quality whereas character is the sum of the traits, attributes, and or, qualities of a thing or person. Characterisation is the act of determining character by identifying and summing most or all of the traits, attributes and qualities – often referred to simply as characteristics. The important difference between the two is that characterisation tells us more about the thing – the exposure or source – than categorisation. For example in waste management, there are generally three categories (sometimes called types or classes) of waste: these are low level waste (LLW), intermediate level waste (ILW) and high level waste (HLW) but the first step in radioactive waste management is usually the characterisation of the waste no matter in which category it falls [Dz98]. Thus the biological, chemical, physical, radiological, thermal etc., characteristics must be identified at the outset of the waste management process; this allows a logical and thorough assessment of the hazardous nature of the waste and, ultimately, its safe disposal.

The character of a source or exposure is the sum of its characteristics. It is not, therefore, sufficient to identify one characteristic only as is done at present in the act of categorisation of a source or exposure. To characterise it is necessary to go further and identify and recognise many, if not all, of the important characteristics. Thus a category of source widely known as a sealed source, besides being sealed, may have other important characteristics; gaseous and emitting gamma radiation, for example. It now has three identified traits that make up its character. Characterisation, in this way, is expected to help in the authorisation process within the system of radiological protection just as it does in the system of waste management.

It should be pointed out in passing that different terms are sometimes used, in existing radiological protection systems, to describe the same exposure or source category, for example, chronic and prolonged exposures are different terms used for the same exposure category and likewise open and unsealed sources are different terms used for the same source category. This often causes problems and should be borne in mind.

We see no evidence that any international or national organisation has tried to combine the characteristics of sources and exposures in a process of characterisation. They may have been typified/categorised/classified but they have not been characterised. For example, in one NEA member country sources are divided into two groups; those associated with the nuclear power industry (fissile materials, reactors and nuclear waste) and secondly those associated with non-nuclear power activities (irradiating apparatus, radioisotopes and the waste arising from their use). Exposures are categorised by their association with the aforementioned sources. In yet another member countries sources are divided into 7 groups. These are: exempted, insignificant, minor, simple, significant and very significant. Most member states use similar methods but a true system of characterisation of sources and exposures does not seem to exist in current national and international systems.

What we are seeking is a way of identifying the important characteristics of a source or exposure and describing them collectively, ideally using numbers, in a process of characterisation. This problem will be addressed in the next section where we review and develop the ideas of the EGRP and use a few simple examples to illustrate the possible usefulness of them.

4.3 Development of the ideas of the EGRP

> The use of characterisation as a first step, or prelude to, the process of authorisation within a system of radiological protection is to identify characteristics of the various exposures and sources that are the subject of an application for authorisation. This facilitates the identification of those that should, and those that need not be brought to the attention of parties with valid interests in the process of authorisation, i.e., stakeholders.

These were the words of guidance from the EGRP in setting out the first of two tasks aimed at testing their new ideas.

However, we felt that characterisation also serves the process of "comprehensive authorisation" in a more general way as explained in Section 3.2. As "authorisation" had been chosen by the EGRP for validation alongside that of "characterisation" we suggested that the two tasks might be combined. This was agreed; the overall concept is shown in Figure 1 where characterisation and screening are indicated by the boxes in the middle of the figure.

Important characteristics of sources and exposures

The essential characteristics of sources and exposures, namely those that are likely to give rise to public concern and are important to safety, are listed in Tables 1 and 2. These lists are not intended to be definitive but, containing most of these characteristics, they will be useful in testing the concepts of the EGRP, which is the goal of this exercise.

In Tables 1 and 2 the characteristics of sources and exposures are assembled in groups. In Table 1 each source group comprises characteristics that describe: radiotoxicity, security, size, origin, application, containment, dose rate, waste (meaning the method intended by the applicant for dealing with the source at the end of its life), and physical state.

Table 1. **Source characteristics for use in authorisation process**

Group	**Possible Options**				**Option Value Selected**
Radiotoxicity	Low = 1	High = 4			
Security	***Fissile = 4***	Other = 1			
****Size***	< 1 kBq = 0	>1 PBq =4	Other = 1		
Origin	Natural = 0	Artificial = 4	Other = 1		
Application	Medical = 0	Industrial =3	Research =1	Others = 1	
Containment	Sealed = 1	Unsealed =3	Machine = 1		
Dose rate @ 10 cm	< 1 μSv/h = 0	> 1 mSv/h = 4	Other = 1		
****Waste***	Dispersed =2	Stored = 1	Disposed = 2	Other = 0	
Physical State	Gaseous = 3	Liquid = 2	Solid = 0		

*To be double counted in Stakeholder calculation
Source Character Score = Score expressed as percentage of maximum (31) =

Likewise, in Table 2 the characteristics of exposures are in groups describing: choice, origin type, and comparison of benefit/detriment

distributions, duration, risk, receptor, and number of persons exposed. Note that there is a group of exposure characteristics entitled “duration”. Only two options are given “chronic” and “other”; acute exposure is omitted for the obvious reason that such an exposure would rule out its consideration for authorisation at the very outset. Therefore the option “other” excludes an acute exposure.

Within each group there are at least two choices of characteristics and at most four.

The characteristics are graded in importance within groups. For example, within the group of characteristics that describe the physical state of a source (Table 1), a gaseous source is considered more problematical, from the public perception and safety point of view, than if it were a liquid and even more so than a solid; therefore on a scale of 0 to 5 the gaseous source is given a value of 3, the liquid state 2 and solid 0 (the rule we have is that the total value must always be 5). There are nine groups of source characteristics and so there may be up to nine selected characteristics.

The source’s characteristics alone do not determine the grading process. Exposure must also be taken into consideration. The characterisation of exposures involves consideration, for example, of who is exposed, whether the resultant doses are high or low, received over an extended or other period of time etc. The characteristics are given values similar to those given to sources, i.e., on a scale of 0 to 5 with the total being 5. There are eight groups of exposure characteristics and so an exposure will have at most that many characteristics.

Table 2. **Exposure characteristics for use in authorisation process**

Group	**Options**				**Option Value Selected**
***Choice**	Voluntary = 0	Imposed = 4	Other = 1		
Origin	External = 1	Internal =4			
***Type**	Normal = 1	Potential = 4			
***Benefit/Detriment Distribution**	Poor = 4	Reasonable =1	Good =0		
Duration	Chronic = 4	Other = 1			
Risk	High = 4	Medium = 1	Low = 0		
***Receptor**	Worker =1	Patient =1	Public =3	Other =0	
Number Exposed	$>10^6$ = 4	<10 = 0	Other = 1		

*To be double counted in Stakeholder calculation.

Exposure Character Score = Score expressed as percentage of maximum (31) =

The addition of three other groups entitled “controllability”, predictability” and “inherently limited” to the above Table were considered but have not been adopted in this review for the reasons given below.

Controllability. In the context of cosmic radiation one could imagine giving a very low value, perhaps zero, to exposure to cosmic radiation at ground level because it is not amenable to control (high degree of uncontrollability) and not a concern to regulators or stakeholders. On the one hand, at 30 000 feet in an aircraft it is of concern to the regulator but probably not to stakeholders (note that at this altitude exposure cannot be controlled: it can only be avoided by not flying at this altitude.) On the other hand exposure to an anthropogenic source with a high propensity to accidents, i.e., having a degree of uncontrollability, would be of concern to the regulator and the stakeholder alike and thus would deserve a high value. In the Table we are not able to deal with this problem where the degree of controllability (or uncontrollability) in one context is seen to have a different value in another. However, the problem seems to be covered in Tables 1 and 2 to some extent by the groups called “exposure type” and “source origin”.

Predictability. This seems to be similar to “Potential Exposure” because if the behaviour of a source is unpredictable it may be less or more likely to give rise to an exposure depending upon its normal nature, i.e., it can be unpredictable in a good or bad direction. Potential exposure is a measure in the bad direction, which is the important direction for the regulator and the stakeholder; this is unambiguous and is thought to be sufficient.

Inherently Limiting Exposure. If an exposure is inherently limiting then surely it must be predictable. If it is predictable then it is covered in the already proposed system for the reasons given above against the introduction of a new group entitled “predictability”.

Finally, the inclusion of further groups tend to lessen the effect of the existing groups on the final outcome and also reduce the overall simplicity of the process**.**

Evaluation of characteristics for use in process of authorisation

Having allocated values to each source and exposure characteristic and determined the “character scores” (the sums of the values of each chosen characteristic from each group) for source and the exposure, the score may now be expressed as a percentage of the maximum possible scores. These may then be averaged to get a combined value for the subject source and exposure. This

numerical description of the character of a source and exposure to it allows screening of the applications for authorisation into either the “Excused” or “Further analysis” boxes, as shown in Figure 1. If the combined source and exposure percentage exceeds 65%, the application goes into the “Further analysis” box, meaning that it is submitted to the full authorising process by the regulatory authority, including referral to stakeholders.

If it is below 35% it goes into the “Excused” box, meaning that it may be authorised without any further consideration of protective actions or, in most cases, consultation with stakeholders.

Percentage ratings between 35% and 65% (“grey” items) also go for further analysis. These require examination by the regulator and a decision whether to send them to the excused box or onwards for authorisation in accordance with in-house quality assurance procedures and an optimisation process as described in the next section. During this examination, the characteristics of the grey items may be considered further, at the discretion of the regulator, by the “double counting” method. This is explained below. It is designed to indicate the interest of stakeholders. In this way all grey items should end up in the excused or authorised with control boxes.

Within a group, the characteristics are usually mutually excluding, i.e., it is a matter of one option or another. However, in some cases this ideal does not hold, for example, within the “waste” group of characteristics there will be occasions when the waste may be managed in several ways using storage, followed by disposal or dispersal into the environment. Likewise a liquid source may in some conditions become a gaseous one. In these and similar situations the value given must be the highest in the mixture

Between groups no such exclusivity is attempted. In fact every group should contribute to the overall character of the source or exposure. A source or exposure will have several characteristics, making up its total character, each coming from a different group.

Note that there is an obvious “horizontal hierarchy” of characteristics within each group indicated by the value given to each. Also between the groups, there is a subtle “vertical hierarchy”. Some groups are “weightier” than others and therefore have more influence on the outcome.

The system caters for the possibility that a group of characteristics in the tables may not be relevant. If this is so it may be ignored; this will not affect the combined rating of the exposure and source characterisation because it is

expressed as a percentage of the maximum score for the relevant groups as will be shown in the case of exposure of pilots to cosmic rays (see Section 6.2.1).

Of course, the system is not fool proof. The ignorant, inexperienced or the cheat can make it give the wrong answers by simply choosing the wrong options or claiming that groups are not relevant (but no regulator could have such characteristics!).

Example of retailing Ionisation Chamber Smoke Detectors

It may be useful at this stage to take a simple example. Assume there is a proposal/application from a retailer to store and sell 100 ionising chamber smoke detectors (ICSDs) each holding 37 kBq of ^{241}Am. Referring to Table 1 the sources might be characterised as follows:

- Radiotoxicity; low = 1
- Security; not fissile = 1
- Size; 100 x 3.7 kBq = 370 kBq = 1
- Origin; artificial = 4
- Application; other = 1
- Containment; sealed = 1
- Dose rate at 10 cm; low = 0
- Waste; dispersed = 2
- Physical state; solid = 0

Adding these values gives a source character score of 11. The maximum possible score is 31 so the percentage is 35.5%, a borderline situation which may be changed when the exposure calculation is taken into account.

The characteristics of exposure include:

- Choice; other = 1
- Origin; external = 1
- Exposure type; normal = 1
- Benefit/detriment profile; good = 0
- Duration; other = 1
- Risk; low = 0
- Receptor; public = 3
- No. exposed; other = 1

This gives an exposure character score of 8, the maximum being 31 and so the percentage is 25.8%.

Averaging these scores we get a value of (35.5% + 25.8%)/2 = 30.6% which puts this application into the excused box. A critical assumption in the processing of this case was that potential exposures were not possible. This was based on the smoke detector sources being solid sealed sources manufactured to the requirements of ISO Standard 2919 and consequently having good resistance to fire and mechanical damage and therefore most unlikely to give rise to a potential exposure. Also in the most exceptional scenario of ingestion of a source, the dose would not be significant. However, because it is close to the 35% border the regulator may wish to re-evaluate the characteristics by using the "double counting" method (as well he or she may do in any "border" case). This will either confirm the original decision or indicate the possible need to refer the application for further analysis by the regulators.

In the following section, after explaining the "double counting" system, we subject the above application to it by way of example.

Re-evaluation of characteristics when near the 35% and 65 % borders

The values given to characteristics and exposures in Tables 1 and 2 are more appropriate for the purpose of deciding on radiological protection actions than for deciding which applications should be referred for stakeholder opinion. This is because stakeholders may be more influenced by perceived rather than actual risk. However, the same characteristics are involved and it is only the values that need to be changed. This change can be achieved quite simply by "double counting" those groups of characteristics that are of greater concern to stakeholders such as the "waste" group, for example. These groups are indicated by asterisk in each of the Tables. The items near the 35% and 65% borders can now be re-evaluated using "double counting" which will push them further from, or nearer to, the borders and so help the regulator to make the necessary decision. The amount of movement is usually very slight and gives merely a hint to the regulator of the direction of the stakeholder thinking.

When calculating the combined percentage rating for the second time in this way there will be 12 rather than 9 for groups of source characteristics to be counted and 12 rather than 8 groups in the case of exposures.

Taking the above example of the retailing of 100 ICSDs again for the case of exposures: the original score was 8, to this is added the 3 for public receptor, 1 for normal exposure, 1 for voluntary choice, and 0 for good benefit/detriment distribution. This gives a new total of 13 out of a new maximum of 46. This, in turn, gives 28.2%.

In a similar calculation in the case for source characteristics, the result is 37%.

Thus the average is 32.4%, compared with 30.6% previously. This indicates a very slight increase in the value of the character when those characteristics likely to be of greatest concern to stakeholders are given the extra weight. This is probably not sufficiently significant to alter the initial indication that this application for the retailing of 100 ICSDs could be dispatched to the excused box with confidence.

Other examples

Does the system work for other sources of exposure, for example public exposures from the releases from a nuclear power reactor? Selecting options from the source and exposure groups in the usual way we get, firstly, for sources:

- Radiotoxicity; high = 4
- Security; fissile = 4
- Size; > 1 PBq = 4
- Origin; artificial = 4
- Application; industrial = 3
- Containment; sealed = 1
- Dose rate @10 cm; >1 mSv/h = 4
- Waste; mixed = 2
- Physical state; mixed = 3

Total score for source characteristics = 94%

And secondly, for exposures, we get:

- Choice; other = 4
- Origin; mixed = 4
- Exposure type; potential = 4
- Benefit/detriment profile; reasonable = 1
- Duration; other = 1
- Risk; high = 4
- Receptor; mixed = 3
- No. exposed; $>10^6$ = 4

Total score for exposure characteristics = 71%

The combined rating for the potential public exposures from nuclear power plant releases is therefore 82% indicating, as one would expect, that not

only are regulatory controls needed but that the case would need to be referred for stakeholder opinion.

Finally, let us a take an example of a ^{192}Ir source used in industrial radiography. It is assumed that the source is 740 GBq, transported in regular container with approved exposure mechanism, and the waste will be managed by decay storage. Going through the same process as demonstrated in the above examples one gets a combined character score of 48% that puts it into the "Further analysis" box as a grey item. Double counting to allow for stakeholder opinion does not change the percentage rating. The regulator must now decide but can be confident that it should not be excused and that it need not be referred to stakeholders.

4.4 Discussion of the tables of characteristics and their use

The seventeen groups of characteristics of sources of ionising radiation and exposures from them were chosen in the belief that they contain those that are most important to the regulator in the process of authorisation and particularly at the outset of the process when consideration must be given to the need to refer an application to stakeholders (over 65%) and to the need to authorise without a necessity for further radiological protection measures (under 35%).

There are many such groups used in existing regulatory systems in various ways but use of them in the above way seems to be unique. No similar system has been so successful that it has been adopted widely, probably because none has surmounted the problems of the many dimensions to, and the large scale (becquerels to petabecquerels and more) of the problem.

An attempt is made in the tables to simplify the problem, knowing that the result cannot be perfect but hoping that it may be practical in, at least, the more important and frequently used applications of ionisation radiation. The table is empirical. There is no sound basis for it in logic or theory. It is kept simple in the belief that the alternative would be unworkable, probably involving multicolumn and multirow matrices, for example. The justification for offering such a blatantly simple model is that it is useful in testing the validity of the ideas of the EGRP.

The groups of characteristics in the tables contain some terms that are not defined; for example, "low" and "high" in the "radiotoxicity" group (which could be simply "toxicity"). Others are described adequately like "size" (in terms of activity) of a source (in Bq), or "containment" of sources as "sealed" and "unsealed". Other groups may seem to be missing obvious terms like

TENORM in the source group named “origin”. We believe that this term is not helpful in deciding what should be referred to stakeholders and what may be authorised without need for protective measures and so it is omitted. More cogent reasons for this are given elsewhere in this report. “Tolerable” and “acceptable” were the terms used originally in the group of characteristics called “risk” but because of the difficulty in defining them they were replaced by multiples of background radiation. These in turn were dismissed mainly because exposure to background radiation is not typical of (and therefore not a useful yardstick for) the exposures that are of concern to regulators and stakeholders.

Although some other terms are not defined they are well understood and most professionals involved in radiological protection will have a good feeling for what they mean. We do not wish to be bogged down with discussion about the fineries of definitions at this stage of the testing of the EGRP ideas. The definitions may be revisited if and when it is shown that the ideas are practical and useful.

In Table 1 a group of source characteristics is called “waste”. This may seem to be an anomaly to many and so a word of explanation is needed. A source serving a purpose will eventually become a disused one for one reason or another. It is then likely to be declared as being waste. At the stage of initial authorisation it is necessary to know how its safety will be maintained after it becomes a waste and so some characteristics of the source at the end of its life, in its transformed state, are needed. A number of ways of doing this were considered including short, medium and long half-life, for example. Finally, “dispersal”, “disposal”, “storage” and “other” meaning decay storage, or maybe transmutation in the future, were thought to be appropriate. This is one of those cases where the given options are not mutually exclusive and the highest value of those applicable must be taken. There may be better solutions; this is an example where further “tuning” might be appropriate.

Another group has the unfamiliar title of “benefit/detriment distribution”; this is considered to be “good” when the distribution of benefits and detriment from exposures accrue to the same people and areas and it is “poor” when the distributions are dissimilar, i.e., when significant detriment is borne without benefit.

Finally, although this system of characterisation has been devised with the protection of humans in mind, it could also be used to assist in the protection of the environment. The first table on source characterisation needs no alteration and the second table could readily be modified to characterise exposures of all other organisms in the environment.

5. AUTHORISATION

5.1 The ideas of the EGRP

The overall regulatory process for assessing and managing risks was outlined in Chapter 3. The process for radiological risks as envisioned by the EGRP fits within this framework. We have discussed in Chapter 4 the initial step in this process, which is to establish the characteristics of sources and exposures. In this Chapter we discuss the ideas of the EGRP on the assessment and analysis that is needed to determine the appropriate level of regulatory control that may be need in any particular circumstance.

The EGRP recommendations are that a system of radiological protection (taken here as an including the recommendations of the ICRP and a regulatory process), pertaining to the process of authorisation, should have the following features:

- Provide for a process in which the need for protection and control can be assessed in a logical way, for any source of radiation exposure and any radiation exposure.
- Be consistent with the science underlying the risks to health of ionising radiation.
- Reflect the social aspects of risk evaluation and management.
- Be consonant with the regulatory aspects of risk management.
- Clearly identify international consensus as an important support for the social consent that is inherent in any numerical guidance provided (e.g. dose limits, dose constraints).
- Use a concept of comprehensive authorisation – a risk assessment and decision-making process as noted in Chapter 3 – by way of simplification, avoiding confusion with the mechanisms of exclusion, exemption and clearance.

Provide guidance on:

- making decisions about whether or not regulatory control might be needed for exposures identified in the future;
- making decisions about whether or not sources of radiation exposure need to be subject to regulatory control, possibly on the basis of internationally-agreed criteria;
- optimising radiological protection within the authorisation process, leading to the determination of the nature and extent of management and regulatory control in given circumstances, including authorising the release of source of radiation exposure from some or all regulatory control, assessing, making decisions about, and managing potential exposures;
- types and numerical values of dose constraints for which there is an international consensus; and
- criteria for the international trade in commodities for which there is an international consensus.

The concept of authorisation as developed by the EGRP is equivalent to the assessment and decision-making steps in a general scheme as outlined above. In this report we are examining whether the different detailed ways in which different kinds of sources and exposures are currently handled can be brought into this conceptual framework of authorisation with gain in consistency, understanding and acceptance, as well as in effectiveness of protection.

5.2 Developing the ideas of the EGRP

The key feature of the process as described by the EGRP is:

> All sources and exposures that are not immediately seen to be "excused from regulatory control" (our words) or "authorised" (EGRP term) with some specified level of control are considered in a process that is described as "optimisation of protection under dose constraints".

It should be noted that a discussion of the justification of exposures *per se* is outside our mandate for this review. Nevertheless, we see the need for a step in the comprehensive authorisation process in which the question is asked, "Is

the exposure from this particular source justified?" Such a step would be most appropriately after the initial screening on the basis of source and exposure characterisation and before the analysis is taken any further, as was shown in Figure 1 (Section 3.2).

Optimisation of protection under dose limits or constraints has been the cornerstone of radiological protection for many decades. The expression of the outcome of this process as "as low as reasonably achievable, economic and social factors being taken into account" well conveys the essence of the process, which can be as simple or as complicated, as informal or as formal, as narrow or as broad, as qualitative or as quantitative as is needed for a given case.

Many factors can be considered in the optimisation:

1. Characteristics of the source: natural, artificial; long-lived, short-lived; gaseous, solid, liquid; contained, open; etc. (At this stage these may be refinements of the basic source characteristics described earlier.)
2. Characteristics of the exposures: who; how many; when; where; what magnitude; for how long; inherent bound or unbound in magnitude, measurable or hypothetical; actual or potential; etc. (At this stage these may be refinements of the basic exposure characteristics described earlier.)
3. The risks to health of the exposures.
4. Relevant dose constraints on sources that have already been agreed internationally, nationally, or locally.
5. Relevant quantitative criteria (or guidelines) for radioactivities or radioactivity concentrations in materials that indicate values below which regulations need not apply, that have already been agreed internationally, nationally, or locally.
6. Relevant dose guidelines that have already been agreed that have already been agreed internationally, nationally, or locally. Such guidelines may be for values of individual doses that are intended to prompt regulatory authorities to examine the situations in which they arise or, conversely, they may be for values of individual doses that have been agreed as needing no regulatory control.
7. Other constraints or guidelines that may affect a decision – for example, requirements for the protection of biota.
8. Feasibility and cost of protective actions.

9. End results of applying protective options (radiological, economic, medical, etc.).

10. Impact on and consistency with protection from associated hazards.

11. Societal context in which exposures occur. This can include many parts reflecting culture and how lives might be affected etc.

12. Views of stakeholders.

Items 1-3 in the above list will have been largely taken into account in characterising the source and exposure. One or more of items 4-7 may be sufficient to drive a decision, if, for example, exposures are seen after some analysis to be below some pre-determined guideline or criterion for not needing regulatory control. Items 8-10 are additional items or attributes that would normally be considered in an optimisation of protection. Items 11 and 12 are less tangible attributes than the previous ten. The extent to which they are taken into account may well depend on national regulatory practice and culture. An important point is that the analysis involves considering all these items; the decision is not driven by just one characteristic such as dose. It is the outcome of what might be termed a "multi-attribute" analysis in which non-quantified factors are considered together with any relevant quantitative constraints. The analysis stops when the optimum is found, rather than when some single criterion is met.

Clearly, for such a process to work, the scientific basis for risk assessment needs to have been developed. Furthermore, there has to have been some agreement on how to handle the social aspects of risk evaluation and management, and the division between general aspects of a system of protection and the regulatory aspects of risk management needs to be clear.

Recommendations on those items 1-10 inclusive might be considered to be within the remit of international agencies. There is some blurring of the scientific aspects of risk assessment and the social aspects of risk evaluation and management but this is inevitable if there are going to be internationally recommended guidelines or constraints. One might see the ICRP developing the basis for risk estimation and principles for protection (as it does now), and recommending the adoption of a system of radiological protection that is in harmony with the general health risk assessment and management framework outlined in Chapter 3 (with which the recommended scheme of the EGRP is, by-and-large, consistent). The ICRP would continue to be the source of recommendations on dose constraints and other quantitative guidelines that it considers may be a basis for international consensus. The scheme of the EGRP

does not lead to new numerical values for guidelines or constraints – they are still needed from international agencies. International agencies (such as the NEA, IAEA, WHO), given that they have Member States as their constituents, are in a position to broker international agreements on the application and values of constraints and guidelines for doses and activities – as they do now. As will be seen in the discussion of test cases below, a more self-consistent set of such generic values is needed.

There are difficulties in providing, at the international level, firm advice on the last two items in the list. The extent to which societal context (item 11) and the views of stakeholders (item 12), however they are defined, are taken into account in decisions on risk management seems very much to be within the purview of any given national regulatory agency. There are two aspects to considering the views of stakeholders and societal context. One is the respect for human dignity, rights and self-determination that forms the basis for the Charter of the United Nations [UN45]. To the extent that respect for human dignity leads to direct involvement of affected individuals in decision making, then it is already incumbent upon regulatory authorities to include some consideration of items 11 and 12. The second aspect to considering the views of stakeholders and societal context is the more pragmatic one that such involvement is often key to obtaining societal (and hence, political) acceptance of the results of decisions.

The outcome of the optimisation is an authorisation by the regulator of the particular exposure being considered, subject to whatever regulatory control appears to be appropriate on the basis of the optimisation of protection. The authorisation may be to the effect that no regulatory control is needed and that exposures from the particular source being considered are “excused” in the terminology here. Alternatively, the sources and exposures may be authorised to a magnitude and with a level of control that appears from the analysis to be the optimum.

We have therefore interpreted the emphasis that the EGRP places on including consideration of societal context and the views of stakeholders in the process of authorisation along the following lines. The essential thrust of the ideas of taking into account the societal context in which sources are present and exposure occur, and taking into account the views of stakeholders, is for there to be flexibility in decision making at the national and local levels. Accordingly, the recommendations from international agencies need to be sufficiently explicit for regulatory agencies to feel they have a solid base for their national regulations but, at the same time, there needs to be an acknowledgement that national or local input to decisions may be appropriate and helpful.

The recommendation sought from the ICRP or from international agencies could be along the lines that national regulatory agencies may note that in many instances when decisions involving risks or potential risks to health are of a nature that there has been public concern, then direct involvement to some extent of those concerned, or their representatives, in the process leading up to a decision has aided development of an accepted decision. For the process as it involves occupational exposures the situation is clearer because of the existence and involvement of the International Labour Organisation and other labour representatives.

Hence, with the caveat above on the inclusion of the views of stake-holders and of societal context in international recommendations, the ideas of the EGRP would appear to be a basis for the process of authorisation within a system of radiological protection. The next Chapter tests this conclusion against specific cases.

6. TESTING THE IDEAS OF THE EGRP

6.1 Selection of the test cases

Below, we examine how well the proposed new approach to source and exposure characterisation within a single process of comprehensive authorisation works with selected sources and exposures. The intention is to determine if the approach seems to be broadly applicable, leading to improvement in those cases where the current mechanisms have proved inadequate and not undermining in those cases that are seen as being well-handled by the current approach.

In the current system of protection, regulatory control is exercised to varying extents on many sources and exposures, some sources and exposures are declared free from regulatory control through the mechanisms of exclusion and exemption; and regulatory control can be withdrawn from some sources through the mechanism of clearance. The set of cases considered here has been selected and organised so that comparison can be made between the outcome of a comprehensive authorisation process with each of these existing mechanisms.

The scores assigned to the source and exposure characteristics for all the cases considered are tabulated in the Annex. We emphasise the point made in Section 4.4 that the tables of characteristics and the scores assigned are empirical. They are intended only to help in making decisions.

6.2 Cases relating to the current mechanism of exclusion

The recommendation of the ICRP in Publication 60 (para. 291 in [IC91]) is that "Sources that are essentially uncontrollable, such as cosmic radiation at ground level and ^{40}K in the body, can best be dealt with by the process of exclusion from the scope of regulatory instruments, rather than be an exemption provision forming part of the regulatory instruments." The IAEA's Basic Safety Standards (BSS,) reflect this idea, noting that the criterion for exclusion of exposures from regulatory control under the present system of protection is that the magnitude or likelihood of such exposures is essentially not amenable to control [IA96]. There does appear to be a distinction between excluding

sources, as in the ICRP publication, and excluding exposures, as in the BSS. This distinction seems not to be adhered to in practice but it is one of the arcane points that confusingly arises in discussions on the topics of exclusion and exemption. The key underlying idea is that regulatory control should only be introduced when there is some benefit from so doing.

There is a distinction made in the ICRP publication between exclusion, which is based on a criterion of controllability, and exemption, which is based on two criteria: one relating to the magnitude of doses and another relating to whether reasonable control procedures can achieve significant reductions in dose. This is a tenuous distinction since controllability and reasonableness are not really separable.

For some exposures there may be no debate on whether any consideration need be given to any form of control; for example, ^{40}K in the body. However, exclusion of a broad category of exposures such as those from unmodified concentrations of radionuclides in most raw materials is not so self-evident. Even for cosmic rays, the situation is far from clear. Although excluding public exposures from cosmic rays at ground level from any regulatory consideration seems to be generally acceptable, other exposures from cosmic rays (when flying for example, or when at work) may be considered as part of occupational exposures. Although this discrimination may be argued as justification for focussing the mechanism of exclusion on specific exposures, rather than on sources, this distinction is not particularly helpful when trying to decide whether a particular exposure from radionuclides in some material is definable as arising from an unmodified concentration of radionuclides and that the material is in the appropriate “raw” category.

Any risk assessment and management scheme needs to have some mechanism for narrowing the scope of active regulatory control. We referred to this in Chapter 3. Such a mechanism may be to define explicitly what is within the scope of regulatory control or it may be to take all risks as being potentially subject to regulatory control, with an initial, well-understood screening process that eliminates some risks from further consideration. The EGRP favours the latter approach, considering that all radiation exposures should be considered within the “system of radiological protection” and should be subject to authorisation. Further, the EGRP sees that the authorisation of some sources and exposures as not needing regulatory control would proceed on clearly explained grounds without the necessity for any further analysis.

Such sources and exposures would be “authorised”. Other sources and exposures would be subject to further consideration and might, as a result, be “authorised” as discussed below. Those not authorised would then be subject to

some graded regulatory control and “authorised with specific conditions” or, in the extreme, prohibited.

We add a cautionary note here on the terminology recommended by the EGRP. The term “authorised” means given official approval or given permission. That the ubiquitous radiation exposures from all natural sources need to be authorised may strike some as an unusual view. This potential issue arises from the use here of the term authorisation as a description of a process and authorised as a result of that process. Our understanding is that the intent of the EGRP is to eliminate the misunderstandings and difficulties that have arisen with the term “exclusion” (and also “exemption” and “clearance” – see below). With this in mind we have suggested (Chapter 3) that sources and exposures that are authorised in this sense might be better referred to simply as “not needing regulatory control” or, more simply, “no regulatory action” or “currently excused” or just “excused”. The role of the regulatory authority would be to give official acknowledgement (authorise) that such sources and exposures did not need regulatory control.

The EGRP argues for easily understood criteria as a basis for deciding that any particular exposure should be in the category of “no regulatory action” (our terminology) or “authorised” (EGRP terminology). The EGRP gives as an example that cosmic ray exposures at ground level cannot be controlled by reasonable protection actions and hence should not be subjected to radiological protective actions.

The extent of uncontrollability has been the main criterion for excluding (in the current terminology) exposures from regulatory control. In the EGRP scheme, there is no real distinction between whether an exposure is declared to be in the category “no regulatory action” *a priori* on the basis of its known characterisation and pre-determination that exposures of that kind are not subject to regulatory action (equivalent to the current exclusion) or on the basis of a more detailed assessment of the exposure (equivalent to the current exemption). (Both these end results are termed “authorised” in EGRP terms) Avoiding this distinction seems a helpful simplification and would appear to be eliminating one source of confusion.

Given that the most easily understood criteria are numerical values of dose, dose rate, activity or activity concentrations, the availability of such values should be helpful in establishing whether some particular kinds of source or exposure should be in the category of “excused” (i.e., authorised in EGRP terms).

The EGRP has suggested that such values need to be developed for international trade in commodities; values that have the imprimatur of the international agencies. For consistency in the process of authorisation as envisaged by the EGRP, such values that could be used as guides for deciding *a priori* that a particular exposure warrants no regulatory action could be the same as those that might be used as guidance for determining whether any other source or exposure should be treated in the same way; i.e., authorised or, in our terminology, declared to be excused from regulatory control. In making use of such values, regulators would not necessarily be slaves to the values; flexibility in decision making is important. This idea is consistent with the unifying approach of the EGRP ("optimisation under a constraint") for all decisions.

The assessment of all sources and exposures is not necessarily helped by a comparison with a single number though, and other characteristics that are not objectively quantifiable may be more pertinent. This is an area where international advice would be helpful.

As noted above, a decision to exclude (in the current terminology) a broad category of exposures such as those from "unmodified concentrations of radionuclides in most raw materials" is fraught with difficulty. What is meant by "unmodified"? What is included in "most raw"? A test of the system proposed by the EGRP is whether it can eliminate the need to try to decide what is meant by, or is included in, such terms, or others such as "technologically-enhanced".

One aspect of exclusion in current usage is exclusion from occupational exposure. The ICRP (in Publication 75) recommended that regulatory agencies, in considering exposures to natural radionuclides in ores, should choose a value of activity concentration of the parent nuclides in the range 1-10 Bq/g to determine whether exposures from these materials should be regarded as occupational exposures [IC97]. (The IAEA and ILO have followed this recommendation.) This aspect of exclusion can provide another test of the EGRP system.

With this as a preamble, we can ask how the EGRP system would work with exposures that are currently considered by some to be candidates for exclusion. Would they be "excused" in the terminology here?

6.2.1 Case: Exposures from cosmic rays – commercial pilots while flying

Suppose we characterise the exposure of a commercial pilot working the transatlantic route from Dublin to New York.

The assumptions are that the flight's maximum altitude is 39 000 feet, the solar radiation is minimum but the galactic is maximum, he or she flies 900 hours per year and the trip dose is 48 μSv, which equates to about 7 μSv/h. The annual dose is about 6.5 mSv [RP01]. Potential dose is accepted because of the very remote chance of being exposed to solar flares.

The source characteristics are assessed as follows:

- toxicity, not relevant;
- security, other (1);
- size, not relevant;
- origin, natural (0);
- application, industrial (3);
- containment, not relevant;
- dose rate, medium (1);
- waste, not relevant;
- physical state, not relevant.

Adding these values gives a source character score of 5 out of a possible maximum of 15. thus giving a percentage of 33%. Now going through the same procedure for exposure characteristics one gets:

- choice, other (1);
- origin, external (1);
- type, potential (4)
- benefit/detriment distribution, good (0);
- duration, other (1);
- risk, other (1);
- receptor, worker (1);
- number exposed, other (1).

This gives an exposure character score of 10 out of a possible maximum of 31 thus giving a percentage of 32%.

The combined rating for this case of a commercial pilot exposed to cosmic rays is therefore (32+33)/2= 33%.

Our suggestion was that an overall rating of less than 35% indicated that the source/exposure did not need to be subjected to any regulatory action and it could be excused. However, the closeness to the decision value of the combined rating for exposures of commercial pilots, and the recognition that the characterisation has a subjective element would prompt the regulator to look

more closely at the case. Stakeholder involvement would not appear to be warranted by the rating but the regulator, in considering the source and exposure characterisation may well note that the largest contributor to the rating is the "potential" attribute. Were it not for the chance of solar flares, the rating would be much lower. What is the effect of re-evaluating by the double counting method described in Section 4.2? The source rating does not change but the exposure rating increases slightly; the new combined rating is 34%.

The regulator may then decide, possibly in consultation with the stakeholders most involved (the pilots' representatives and the airlines) that, provided there is an adequate solar flare warning system and protocol for avoiding flares, exposures of commercial pilots cosmic rays could be authorised with this condition. The risk management that would follow from this authorisation would be solely one of assuring that the avoidance protocol was followed. In effect, the exposures would be acknowledged as being occupational exposures but with there being no need for on-going controls other than that noted and a review at intervals that flying times in general are not increasing substantially.

A point that can be made here is that at the screening stage there is no need to agonise over whether a particular exposure or source meets whatever the criterion was for excusing – i.e., for deciding "no regulatory action". If it is not clear, then the exposure or source goes into the next step of the authorisation process (i.e., the next level of assessment), which may or may not result in a decision to excuse. The idea of a single authorisation process facilitates this progression.

6.2.2 Case: Exposures from cosmic rays – public at ground level

For a member of the public exposed to cosmic rays at ground level, the overall rating is 29%, slightly lower than that obtained with commercial pilots. The source rating is lower that that for exposures of pilots while flying (13%, reflecting the lower score for "application" and dose rate). The exposure rating is higher (45%, the involvement of large numbers of the public out-weighing the absence of the potential for appreciable exposures from solar flares). The overall character score of 29% is well below the 35% screening level and a re-evaluation with the emphasis on attributes of stakeholder concern (the "double-counting" approach) decreases the score even more. Given that it is evident that control of exposures would be very difficult and that there is no strong indication from the characterisation for regulatory control, the optimum would appear to be to do nothing. The authorisation decision could then be that such exposures could be excused.

Hence, as with the case of exposures of commercial pilots, the EGRP approach, as we have interpreted it, appears to lead to a pragmatic outcome for the case of exposure of the public to cosmic rays at ground level. Such exposures would be excused from regulatory action. This decision is arrived at though the comprehensive authorisation process without the need to invoke a special mechanism such as the current one of exclusion.

6.2.3 Case: Occupational exposure to natural radioactivity in ores

For the purposes of testing here, the materials for which numerical data are given in ICRP Publication 75 can be characterised [IC97]. For uranium and thorium ores with levels between 1 and 10 kBq/kg, annual occupational doses could be 1-2 mSv (~0.5-1 μSv/h). The ICRP report points out that similar values of dose arise from the exposure of workers to gamma radiation and dust from sedimentary phosphate ores containing about 1.5 kBq/kg of uranium.

The source characteristics of such ores can be taken as:

- toxicity, high (4);
- security, other (1);
- size, other (1);
- origin, natural (0);
- application, industrial (3);
- containment, unsealed (3);
- dose rate, other (1);
- waste, disposed (2);
- physical state, solid (0).

Adding these values gives a source character score of 15 out of a possible maximum of 31, a percentage of 48%. Going through the same procedure for exposure characteristics one gets:

- choice, other (1);
- origin, internal (4);
- type, normal (1);
- benefit/detriment distribution, reasonable (1);
- duration, chronic(4);
- risk, low (0);
- receptor, worker (1);
- number exposed, Other (1).

This gives an exposure character score of 13 out of a possible maximum of 31, a percentage of 42%. The total character score is 45%.

Hence, occupational exposures to natural radioactivity in ores in general would appear to warrant attention from regulators. The character score is above the "excuse" criterion. There is no change in the overall score when those characteristics that have been flagged as being of particular importance to stakeholders are double counted, though this is because an increase in the source character is balanced by a decrease in the exposure character.

In the further analysis, the process outlined in Section 5.2 would be followed. Provided the occupational work was justified, the regulator would need to look in greater detail, for example, at the doses that are likely to occur, the options for protection, and any numerical constraints that are relevant in deciding whether to bring the particular exposures being considered into program of occupational protection. Here, there is the helpful recommendation from the ICRP (in Publication 75, page 35), noted above, that regulatory agencies should choose a value of activity concentration of the parent nuclides in the range 1-10 Bq/g to determine whether exposures from these materials should be regarded as occupational exposures.

Hence, the EGRP's comprehensive authorisation process would again lead the regulator to a pragmatic operational decision without the need to invoke any special mechanism or concept.

6.3 Cases relating to the current mechanism of exemption

As noted in Section 6.2, the ICRP provides two criteria as a basis for exempting sources or exposures from regulatory control; one relating to the magnitude of doses and another relating to whether reasonable control procedures can achieve significant reductions in dose. This recommendation has subsequently been quantified to exemption being appropriate if individual doses are on the order of 10 μSv per year and if the collective dose is on the order of one man-sievert per year. The latter is seen as indicative that protection has been optimised (see ICRP Publication 64, paragraph 86, [IC93]). These values are included in the Basic Safety Standards of the IAEA, which also provides a table of exempt activity concentrations and exempt activities of radionuclides [IA96]. Not all countries use these values. There are, of course, difficulties in arriving at globally applicable values. The ICRP, in Publication 60, comments on the problem:

(288) The basis for exemption on the grounds of trivial dose is much sought after, but very difficult to establish. Apart from the difficulty of deciding when an individual or collective dose is small enough to be disregarded for regulatory purposes, there is considerable difficulty in defining the source ... The underlying problem is that exemption is necessarily a source-related process, while the triviality of the dose is primarily individual-related. [IC91].

Characterising sources and exposures separately as is suggested here may offer a way through this difficulty.

6.3.1 Case: Retailing of ionising chamber smoke detectors

This case was given as an example in Section 4.2. The combined rating was 31%, implying that this application falls into the excused box. Because the value is close to the decision value, the regulator may chose to re-evaluate, giving more prominence to the attributes that are seen as of particular importance to the public. The combined rating was determined to be 32%; only a slight increase. If the proposition is accepted that this re-evaluation of the characteristics emphasises stakeholder concerns, then the regulator could be confident that the distribution of these devices could be excused from any regulatory action.

A decision to excuse the retailing of ionising chamber smoke detectors from regulatory action would therefore appear to be easily made. The process of characterisation appears to solve the problem noted above when the current mechanism of exemption of a source is based only on the so-called triviality of dose.

6.4 Cases relating to the current mechanism of regulatory control

In these cases, the issues arise not in whether there should be regulatory action but rather what the extent of the regulatory action should be. The EGRP idea is that there should be flexibility in making decisions, the assessment or optimisation process being broadly based, as discussed in Section 5.2. The characterisation of the sources and exposures provides the initial indication of the extent to which stakeholders might be involved and their views reflected in the final authorised level of control. Other considerations that are suggested are the justification for the exposures, the societal context, the feasibility and cost of protective actions, the end result of applying protective options (these can be

radiological, sociological or economic), relevant criteria such as dose limits or constraints, and any other related impacts on health and the environment.

The extent to which stakeholders are involved in the regulatory process varies between countries, and within countries depending on the particular case. An example of the latter is the much greater involvement of stakeholders when radioactive releases from nuclear facilities are being considered than when radioactive releases from non-nuclear facilities (such as hospitals) are being considered. The experience has been mixed; sometimes the stakeholder involvement has led to consensus and acceptance; sometimes the involvement has been less successful.

One reason for the variability, not only in stakeholder involvement and its effectiveness, but also in other aspects of the system for protection, is the involvement in some countries of different agencies with responsibility for particular sets of sources and exposures. An increased flexibility in international recommendations on the authorisation process may lead to greater apparent inconsistency in decisions between such agencies. However, if there is consistency in the process followed by different regulatory agencies in making decisions, then such inconsistencies may well be just a reflection of local or national context and stakeholder input. One should therefore not expect that a regulatory agency in country A will adopt the same level of control as one in country B, even if they have adopted the same constraint under which to optimise and follow the same process as recommended by the EGRP. It is only when decisions have an impact internationally that greater harmony is needed. We shall come back to this in the discussion of the current process of clearance and intervention exemption.

6.4.1 Case: Radioactive releases from nuclear facilities

In Section 4.2, we considered the characterisation of the releases from a nuclear power reactor and take this as an example of what is clearly a source that will be under regulatory control. The total for the source characteristics was 94% and for exposure characteristics the total was 71%. The overall rating of 82% indicates, as one would expect, that it would need to be referred for stakeholder opinion and, indeed, a re-evaluation with an emphasis on the characteristics likely to be of concern to stakeholders increases the overall score.

Ideally, the authorisation process that would follow would be sufficiently broad and flexible to ensure that the protection overall was optimised, taking into account all the considerations noted above. That is, the appropriate trade-

offs would be made between, for example, occupational and public doses, between wastes concentrated and effluents released. We have not explored whether the EGRP authorisation process would have an impact here.

6.4.2 Case: Radioactive releases from a hospital incinerator

The hospital may be considered to be incinerating wastes containing medical radioisotopes such as ^{99m}Tc, ^{131}I, ^{125}I, ^{201}Tl, ^{75}Se, ^{111}In and ^{67}Ga. The score for the source character would be 61% and for the exposure character, 68%. The overall character score of 65% is increased to 68% when the characteristics that might be emphasised by stakeholders are double counted.

The regulator would conclude that stakeholder involvement is warranted and would proceed with the further analysis (optimisation under a dose constraint) with such input.

The EGRP process would therefore lead the regulator to seek stakeholders' views when carrying out the optimisation.

6.4.3 Case: Radioisotope therapy unit in a hospital

The unit considered has a source of 185 GBq ^{60}Co. The score for the source characteristic would be 55% and for the exposure characteristic, 29%. The overall character score of 42% increases slightly to 44% when the characteristics that might be emphasised by stakeholders are double counted.

As one might expect, the regulator would be led to ensure that the installation was under regulatory control with protection optimised but could be confident that there would be no need for stakeholder input.

6.4.4 Case: Application of depleted uranium

Depleted uranium metal has properties than make it attractive for shielding and for military applications. It is generally regarded as having low toxicity. For the particular case of the use of depleted uranium for shielding medical equipment, the source characteristics in the scheme proposed here is low (19%). The score for all the exposure characteristics is higher though (68%) and double counting of the exposure characteristics of particular interest to stakeholders takes this score to 80%. The overall total character score is 44%, going to 48% when the stakeholder adjustment is made.

Hence, the characterisation would alert a regulator to the need to undertake further analysis and to consider what regulatory action or controls might need be placed on the application of such material. In the current system of protection this need, driven by the character of the exposure, is not so apparent.

6.4.5 Case: Industrial radiography source

This case was considered in Section 4.2. The source was 740 GBq of ^{192}Ir. It was assumed that the source was transported in a regular container with an approved exposure mechanism, and that the waste would be managed by decay storage. The source character has a high score (58%) as expected, and with the worker exposure character of 39% the total character score is 48%.

There is therefore a clear indication of the need for regulatory control but there is no indication of any need for referral to stakeholders.

6.5 Cases relating to the current mechanism of clearance

The withdrawal of regulatory controls on radioactive materials used or produced in medical, industrial or research facilities has been termed clearance. In the terminology introduced here, it could be called “excused”. Criteria that have been developed by various international agencies for decisions on clearance are an interpretation of what constitutes a “trivial” dose. In the IAEA’s Basic Safety Standards, the criteria for the release from regulatory control of slightly contaminated materials are an individual dose of ~0.01 mSv/a and 1 man-Sv collective dose [IA96]. Levels for some radionuclides in metals from dismantling nuclear facilities have been recommended by the EU Article 31 Group and the IAEA is developing values for general application to any material. Values given for the process of clearance have also been taken to define the levels of activity below which waste is not deemed to be radioactive.

The appropriate relationship between numerical criteria for exemption and for clearance has not been established. The Basic Safety Standards requires clearance of materials to take account of exemption criteria. The volume of materials to be considered for clearance may be much larger than those considered for exemption and the numerical criteria may be correspondingly lower. One idea currently being explored in the IAEA is to use one set of values for purposes of:

- exclusion of exposure from materials containing radionuclides, primarily of natural origin;

- exemption of practices and sources within a practice;
- exemption of commodities containing radionuclides from intervention for the purposes of international trade; and
- clearance of radioactive materials from further control.

The comprehensive process of authorisation suggested by the EGRP would appear to lend itself to making use of such a single set of values. Taken as reference or guideline values rather than as prescriptive values, they could be the starting points in the broad optimisation that is recommended. The flexibility inherent in the process would allow the regulatory authority to reflect any particular national or local concerns (the context), and the views of stakeholders. An example would be the greater stringency that might be sought by stakeholders in the control of wastes from a nuclear facility compared with those from a medical facility. Another example might be the reflection and resolution of economic concerns in the scrap metal industry. Where such flexibility in decision making would be constrained would be when decisions might have an impact internationally. Here, clearly, there would need to be an adherence to internationally agreed values. When materials that have been excused (our terminology) do not move across national boarders, then the EGRP's authorisation process would appear to allow national authorities to set higher numerical values than recommended internationally as the excusing criteria.

6.5 1 Case: Storage of contaminated scrap metal

It is assumed in this case that some contaminated scrap metal has been in storage under licence in a scrap metal merchant's yard. Eventually it may be recycled in a smelter for re-use. The source is some old piping from an offshore oilrig. It weighs about 1 000 kg and is about 15 metres in length and about 300 mm in diameter. The inner surfaces are slightly radioactive. This is due to a thin adhering layer of radium containing some daughter products. The dose rate at 10 cm from a sample piece of pipe is 1.4 μSv/h. The question is whether continuing controls are needed during storage.

The source character score is 45% and the exposure character score is 35%. The total character score of 40% is increased to 43% when the stakeholder adjustment is made.

It should be noted that were recycling through the smelter to be considered, both the exposure and the source characters would increase in value.

The conclusion from this characteristic overall rating (which is > 35%), and from the above note, would be that a decision to excuse from regulatory control could not be made at that stage. The score is well below the criterion we are taking as an indicator for stakeholder involvement. The outcome of the more detailed assessment that the regulator would carry out may or may not result in storage of this particular scrap metal being excused from any regulatory control. The analysis of more detailed scenarios could make use of reference values, as discussed above.

6.5.2 Case: Wastes from a phosphate fertiliser plant

The wastes arise from the processing of phosphate rock for the production of fertiliser. The waste has ^{226}Ra at about 1 kBq/kg. The score for the source characteristics would be 48% and for the exposure characteristics, 42%. The score for the total character is 45%, increasing to 47% when the stakeholder adjustment is made.

The regulator would not be able to excuse the waste from regulatory control at this screening stage but would need to proceed with a more detailed analysis. There is not a strong indication for stakeholder involvement. In determining whether excusing from regulatory control would be the optimum outcome in this particular case, the regulator would be able to take into account current reference values for exemption levels such as those provided by the IAEA. However, the decision would not simply be a result of a comparison with a single criterion on concentration (or a total amount) but would be the result of considering the broad range of factors as discussed earlier.

6.6 Cases relating to the current mechanism of intervention

This is an area of protection where there is considerable confusion and disagreement. The recommendation in ICRP Publication 60 is that protective actions should be on the basis of averted doses, should be justified and the disadvantages that arise from any component of intervention should be more than offset by the advantages related to the reductions in dose that are likely to be achieved [IC91]. The generic guidance has been given (in ICRP Publication 82 [IC99]) to the effect that intervention in a situation in which doses will be above 100 mSv/a are almost always justified and that if doses are below about 10 mSv/a intervention is not likely to be justified. In reality, the idea of averted dose being the main criterion is often not readily accepted by those involved. The residual dose is seen as being important, with the values of 1 mSv/a (recommended by the ICRP as the dose limit for members of the public from

controlled facilities) or a lower value being somewhat arbitrarily applied as a decision criterion. A variant is that for decisions in the short-term (after an accident, say) avertable dose may be the appropriate criterion with residual dose being appropriate for decisions with long-term implications. Also, a decision that intervention is needed may be on the basis of existing dose although the actual optimised extent of the intervention may be determined more by the dose averted by the intervention.

There does not seem to be a consensus on whether pre-determined generic levels at which actions or interventions should be considered are helpful to decision makers; the suggestion that below some generic level, actions are unlikely to be justified seems to be even less accepted.

There are special recommendations for intervention to reduce the exposures to radon and progeny in homes and on the approach to be taken on radon exposures in the workplace (ICRP Publication 65 [IC94]). The recommendation is that the intervention level for the average annual concentration of radon in homes should be in the range 200-600 Bq/m^3. For workplaces, the recommendation is that the intervention level should be in the range 500-1 500 Bq/m^3. If concentrations remain above this, then the recommendation was that exposures should be treated as occupational exposures.

Other international bodies have followed ICRP's advice for radon in a general sense although there is variation in the actual intervention levels recommended. For example, the IAEA's Basic Safety Standards follows the ICRP as does the European Union for homes but recommends a slightly lower range (500-1 000 Bq/m^3) for the intervention level in workplaces. Some countries (for example, Sweden [Sw02]) have applied lower intervention values in homes.

How well the EGRP's idea of comprehensive authorisation help in situations where, in the current system of protection, issues of intervention arise are examined below for the cases of a contaminated site, for radon in homes and radon in the workplace.

6.6.1 Case: Contaminated site

The site is contaminated with ^{137}Cs such that annual dose to individuals living on the site and obtaining their food locally would be a few mSv. Several thousand people are involved. The score for the source characteristics would be 42% and for the exposure characteristic, 68%. The total character score would be 55%. Although there is no change in the total when the stakeholder

adjustment is made, there is a strong increase (to 80%) in the score for the exposure characteristics. The regulator would get the clear indication that regulatory action was needed and that there was a strong case for the involvement of stakeholders. Their involvement could be very influential in the determination of how and to what extent doses might be reduced, with generic guidelines on intervention or action levels being much less influential.

Were the situation to be one where estimated annual doses for people living on the site had dropped below 1 mSv and the removal of controls and re-population was being examined, then the character score would be different. The score for the source would be the same (42%) but the score for the exposure could be as low as 32% if the return was voluntary and food was mostly imported. Hence, with the total score at 37% the regulator would be prompted to excuse the site from any continuing controls at this screening stage but would be led to carry out a more detailed analysis. Here, the stakeholder effect overall is a decrease from 37% to 34% in the overall score and the regulator may well in these circumstances be influenced by the views and desires of the stakeholders and allow re-occupation of the site.

The EGRP process therefore appears to prompt the regulator to consider regulatory actions without needing to invoke generic intervention levels but with the strong indication to involve stakeholders in deciding on the actions that appear to be optimum.

6.6.2 Case: Radon in home

An existing home has an average annual concentration of ^{222}Rn of 450 Bq/m^3. What should the regulator recommend?

The score for the source characteristics is 50% and that for the exposure characteristic is 42%. The total character score is 46% which decreases to 45% when the stakeholder adjustment is made, the drive here being in the large decrease (from 42% to 37%) in the individual-related, exposure score. The regulator would therefore not be justified in excusing the case from any regulatory action. Given the nature of the case, the appropriate action would evidently be to recommend that the homeowner does take steps to reduce the radon levels. If the concentration had been 50 Bq/m^3, the total character score would have been 41%, which would still be indicating that the regulator would need to continue with the analysis. This is a concentration that can be considered well below where authorities generally consider that interventions are appropriate (see, for example, the Swedish study, [Sw02]). The characterisation in this case does not support excusing such cases from further regulatory interest at the screening step, which one might hope that it would. Of

course, the process of optimisation could lead to no action being identified as the optimum outcome.

6.6.3 Case: Radon in workplace

If a workplace has a ^{222}Rn concentration of 450 Bq/m^3, then the score for the source characteristics is 50% (the same as for the home, above), but the score for the exposure characteristics is only 29%, giving a total character score of 40% which drops to 38% when the stakeholder adjustment is made. The score is close to the decision criterion for excusing at this screening step. Note that if the concentration were to be substantially higher the score for the exposure characteristics would increase; an indication to the regulator at this screening stage that further analysis and possible regulatory action – which could be intervention or exposure – is needed. For a low concentration in the workplace, the total score could be as low as 34%.

As noted above, the recommended range for an intervention level in the workplace is 500-1 500 Bq/m^3. Application of the characterisation scheme in its present form does not lead directly at the screening step to a decision to recommend that intervention was not needed below 500 Bq/m^3, i.e., the case could be excused from regulatory action. Also, the application to homes did not lead to a decision at the screening step to recommend that intervention was not needed below a concentration in the range 200-600 Bq/m^3. Here, we have an indication that the scheme would benefit from some "tuning".

6.7 Cases relating to the current mechanism of intervention exemption

The ICRP, in Publication 60, has provided advice concerning restrictions on international trade as follows:

> (284) To avoid unnecessary restrictions in international trade. especially in foodstuffs, it may be necessary, in this context, to apply derived intervention levels that indicate a line of demarcation between freely permitted exports or imports and those that should be the subject of special decisions. Any restrictions applied to goods below the intervention, better called intervention exemption level, is for this purpose, should be regarded as artificial barriers to trade. Trade in materials above intervention exemption levels should not automatically be prohibited, but such materials might be subject to temporary controls. Intervention exemption levels used in this way in international trade should not necessarily have the same quantitative values as the intervention level used for initiating action in other circumstances [IC91].

There is no consensus yet on the criteria for intervention exemption levels. A variety of questions arise. Should there be the same criteria for irreplaceable and essential commodities and for superfluous consumer products? Should the origin of radioactivity in commodities determine the exemption level applied? Should there be intervention exemption levels for short-term contamination which are substantially greater than those applied when contamination is persisting over many years? For example, the WHO Codex Alimentarious Commission has adopted guideline levels for contamination in a commodities corresponding to a few mSv/a for individuals whose consumption of the commodities is entirely of those contaminated. For long term trade, much lower values would appear to be appropriate.

A multiplicity of sets of exemption levels corresponding to different situations can be confusing and the suggestion has been made that the ultimate objective should be a single set of activity concentration values that would define the scope of regulatory control of materials [IA01]. The extent of regulatory control would increase as the activity concentration involved increased; there would be a graded approach.

The ideas of the EGRP are consistent with this idea. The broadly based screening process and subsequent optimisation, possibly with stakeholder input would provide for the flexibility in regulatory action that is desirable.

6.7.1 Case: International trade in commodities

The case involves the export of ten tons of sheepmeat, contaminated with ^{134}Cs and ^{137}Cs at 600 Bq/kg. The score for the source characteristics is 56% and for the exposure characteristics, 48%. The score for the total character is 52%, which increases to 56% when the stakeholder adjustment is made. In this case of international trade, there would have to be screening on the basis of whatever intervention exemption concentrations has been agreed internationally for international trade. If the outcome of this screening were to be such that the concentrations of activities in this commodity (sheepmeat in this instance) were below the exemption concentrations then the regulator may have no grounds for not permitting the export. However, given the fairly high score on the exposure characteristics that are taken as being emphasised by stakeholders (60%), the regulator may be prompted to take steps to involve those most directly affected to assuage their possible concerns.

If the activity concentrations in the commodity (600 Bq/kg in this case) were to be above the activity concentrations established for intervention exemption, then a special case for trade would need to be made and further

analysis along the lines of the EGRP model could be undertaken, refining the source and exposure characteristics and involving stakeholders.

Note that if the contamination had been naturally occurring radioactivity, then the score for the total character would drop down to 39% which would indicate much less need for any stakeholder involvement.

Hence, the EGRP comprehensive authorisation approach could complement the application of a set of international exemption reference levels when the export of contaminated commodities is being considered, providing the framework for making decisions when flexibility with respect to the reference levels is sought.

6.8 Summary of cases

The test cases are listed in the Table 3 in order of the score for the total character. The higher the score the stronger is the signal to the regulator that stakeholder input should be sought. The lower the score, the lower should be the need for regulatory action. The two criterion levels, at 65% and 35%, are shown by the shaded rows. The right-hand column shows the effect on the total score of double counting the characteristics that are judged to be of most concern to stakeholders. The size and direction of the arrows indicate the “strength” of the influence of double counting on either the exposure or source characteristic or both and whether double counting tends to increase or decrease the score.

Table 3. **Summary of the test cases considered**

Test case	Character score	Stakeholder adjustment
Radioactive releases from nuclear facilities	82	↑
Radioactive releases from a hospital incinerator	65	↑
Public exposure on a contaminated site	55	-
International trade in a commodity, artificial activity	52	↑
Industrial radiography source	48	-
Radon in home, high concentration	46	↓
Exposure to natural radioactivity in ores in the workplace	45	-
Waste from a phosphate fertiliser plant	45	↑
Application of depleted uranium as medical shielding	44	↑
Radioisotope therapy unit in a hospital	42	↑
Radon in home, low concentration	41	↓
Radon in workplace, high concentration	40	↓
Storage of contaminated scrap metal, workplace exposure	40	↑
International trade in a commodity, natural activity	39	↑
Voluntary re-occupation of contaminated site	37	↓
Return to contaminated site	37	↓
Radon in workplace, low concentration	34	↓
Cosmic ray exposures of pilots when flying	33	↑
Retailing of ionising chamber smoke detectors	31	↑
Cosmic ray exposure of public at ground level	29	↓

7. CONCLUSIONS

In Section 2.3, a series of questions was presented as the criteria whereby the idea of comprehensive authorisation might be judged. Our conclusions from the review are presented as answers to these questions.

Does the recommended process help to resolve issues that have arisen under the current system of protection?

- The idea of source and exposure characterisation does serve as a tool for triggering the involvement of stakeholders.
- Decisions on whether to excuse particular sources and exposures from regulatory action or on the extent of any needed regulatory action can be made without having to decide whether one is dealing with a practice or an intervention and without needing to invoke concepts such as exemption and exclusion or specially-defined mechanisms such as clearance. Hence, the idea of comprehensive authorisation appears to remove some of the terminological confusion in the present system.
- For the purposes of this review, sets of characteristics for sources and for exposures were developed. The choice of these and the assignment of numerical values are necessarily subjective. There are many variables and, from our experience in this review, we can see that some "tuning" could be beneficial although there may be difficulty in arriving at a single set for which there is a consensus. Whether a single set for broad application in different countries is necessary could be debated. Characterisation is a tool to help regulators make decisions on stakeholder involvement and regulatory control. It may not be necessary for all to have the same sets – acceptance and application of the general approach is the key.

Does the recommended process reinforce what already works well and is generally accepted?

- The process of comprehensive authorisation, as interpreted here, does not lead to decisions about protection that are in conflict with those, made under the current system of protection, that are generally accepted.
- Numerical guidance that has been developed within the current system – such as dose constraints and exemption levels – are needed in the comprehensive authorisation process as a component of the optimisation. Comprehensive authorisation appears to offer the possibility of an evolution of the present system rather than a revolution to a completely different approach.

Is the recommended process helpful to and applicable in all countries, developed, developing and undeveloped?

- There is flexibility in the process of comprehensive authorisation that allows the level of ambition for protection that is prevalent within any particular country to be reflected in decisions.

Is there sufficient guidance at the international level to meet the needs of national authorities who may have widely differing in house expertise but, at the same time, is there sufficient flexibility in what is recommended to allow national authorities to adapt recommendations to meet their own ambitions and cultures?

- Internationally recommended numerical guidance is applied as input in the optimisation carried out by the national regulator rather than as an inflexible standard. A variety of sets of dose constraints, exemption levels, intervention level currently exists. What would be helpful would be consolidation of them for application and interpretation as generic reference values in the comprehensive authorisation process as implemented by national regulators.
- There is flexibility inherent in the process of comprehensive authorisation that allows national or local needs to be reflected through the triggering of stakeholder involvement by the characterisation part of the process, and in the broad optimisation employed to arrive at decisions.

Does the recommended process move radiological protection towards an improved coherence with approaches taken globally to the management of other carcinogenic risks, for example chemicals?

- The steps within the process of comprehensive authorisation are those followed generally in the regulation of risks to health – hazard identification, analysis of risks, examination of the options for protection, decision making through some kind of multi-attribute analysis, with a flexibility for a "graded" approach that ensures most analytic effort and most resources are applied where protection is most needed. Terms peculiar to radiological protection are reduced in number and there is less need to agonise over the precise meaning of arcane terms. Comprehensive authorisation should therefore facilitate greater harmonisation of the management of radiological risks with that of other risks to human health.
- Characterisation of sources and exposures can, in principle, be easily extended to exposures of biota so that the process of comprehensive authorisation could facilitate the merging of a system for protecting human health from radiation with a system for protecting biota from radiation.

Does the recommended process allow for a clear distinction between the scientific aspects of risk assessment, the social aspects of risk evaluation and management, and the regulatory aspects of risk management?

- We have attempted in our interpretation and application of the comprehensive process to show the judgements that have been made. The characteristics of sources are clearly related to various physical, chemical, radiobiological properties but the numerical scores assigned to particular values of characteristics are necessarily subjective. The characteristics of exposures are, with three exceptions, objective measures (the exceptions are the voluntary/ involuntary; high. medium and low risk; and benefit/detriment distribution characteristics) with all the scores being subjectively assigned.
- One aspect of the characterisation is the determination of the effect on the total character score of emphasising those characteristics that are seen as being of particular interest to stakeholders. This is transparently bringing in social judgement, as is requesting input from stakeholders in the optimisation of protection.

- The optimisation of protection under constraints has to involve scientific and social judgements, just as in the initial characterisation, but the various factors involved should be able to be clearly identified.
- The decision making is part of the regulatory process, and the actual way in which a given level of protection is obtained would reflect the regulatory regime in any particular country.

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Annex

CHARACTERISATION OF TEST CASES

Table A1. **Summary of scores for characteristics**

Group	Options	Max. score	6.2.1 Cosmic rays; Pilots flying
Source			
***Radiotoxicity**	Low **1**; High **4**	4	x
Security	Fissile **4**; Other **1**	4	1
**Size*	< 1 kBq **0**; > 1 PBq **4**; Other **1**	4	x
Origin	Natural **0**; Artificial **4**; Other **1**	4	0
Application	Medical **0**; Industrial **3**; Research **1**; Other **1**	3	3
Containment	Sealed **1**; Unsealed **3**; Machine **1**	3	x
Dose rate @ 10 cm	< 1 µSv/h **0**; > 1 mSv/h **4**; Other **1**	4	1
***Waste**	Dispersed **2**; Stored **1**; Disposed **2**; Other **0**	2	x
Physical State	Gaseous **3**; Liquid **2**; Solid **0**	3	x
Source character; Score		31	5
Source character (percent of maximum)		100%	33%
Stakeholder source characteristics only items; Score		10	0
Stakeholder source characteristics only (percent of maximum)		100%	0%
Source character with stakeholder characteristics double counted		100%	33%
Exposure			
***Choice**	Voluntary **0**; Imposed **4**; Other **1**	4	1
Origin	External **1**; Internal **4**	4	1
***Type**	Normal **1**; Potential **4**	4	4
***Benefit/Detriment**	Poor **4**; Reasonable **1**; Good **0**	4	0
Duration	Chronic **4**; Other **1**	4	1
Risk	Low **0**; Medium **1**; High **4**;	4	1
***Receptor**	Worker **1**; Patient **1**; Public **3**; Other **0**	3	1
Number Exposed	> 10^6 **4**; < 10 **0**; Other **1**	4	1
Exposure character; Score		31	10
Exposure character (percent of maximum)		100%	32%
Stakeholder exposure characteristics only; Score		15	6
Stakeholder exposure characteristics only (percent of maximum)		100%	40%
Exposure character with stakeholder characteristics double counted		100%	35%
Total			
Total character score; Average (Source % + Exposure %)		**100%**	**33%**
Average Stakeholder only characteristics		**100%**	**20%**
Total character score with stakeholder characteristics double counted		**100%**	**34%**

* Double counted in determining stakeholder influence.
x Not applicable.

of the sources and exposures considered

6.2.2	6.2.3	6.3.1	6.4.1	6.4.2	6.4.3	6.4.4	6.4.5
Cosmic rays; Public ground level	**Natural radio-activity in ores; Occupa-tional**	**ICSD retail**	**Release from nuclear reactor**	**Release from hospital incinerator**	**Radio-isotope therapy unit in hospital**	**DU hospital shield**	**Industrial radiography source**
x	4	1	4	4	4	1	4
1	1	1	4	1	1	1	1
x	1	1	4	1	1	1	1
0	0	4	4	4	4	0	4
1	3	1	3	0	0	0	3
x	3	1	1	3	1	1	1
0	1	0	4	1	4	0	4
x	2	2	2	2	2	2	0
x	0	0	3	3	0	0	0
2	15	11	29	19	17	6	18
13%	48%	35%	94%	61%	55%	19%	58%
0	7	4	10	7	7	4	5
0%	70%	40%	100%	70%	70%	40%	50%
13%	54%	37%	95%	63%	59%	24%	56%
1	1	1	4	4	0	4	1
1	4	1	4	4	1	4	1
1	1	1	4	4	4	1	4
0	1	0	1	1	0	4	0
4	4	1	1	4	1	4	1
0	0	0	1	0	1	0	4
3	1	3	3	3	1	3	1
4	1	1	4	1	1	1	0
14	13	8	22	21	9	21	12
45%	42%	26%	71%	68%	29%	68%	39%
5	4	5	12	12	5	12	6
33%	27%	33%	80%	80%	33%	80%	40%
41%	37%	28%	74%	72%	30%	72%	39%
29%	**45%**	**31%**	**82%**	**65%**	**42%**	**44%**	**48%**
17%	**48%**	**37%**	**90%**	**75%**	**52%**	**60%**	**45%**
27%	**45%**	**32%**	**85%**	**68%**	**44%**	**48%**	**48%**

Table A1. **Summary of scores for characteristics**

Group	Options	6.5.1	6.5.2
		Storage scrap metal	**Fertiliser plant waste storage**
Source			
****Radiotoxicity***	Low **1**; High **4**	4	4
Security	Fissile **4**; Other **1**	1	1
**Size*	< 1 kBq **0**; > 1 PBq **4**; Other **1**	1	1
Origin	Natural **0**; Artificial **4**; Other **1**	0	0
Application	Medical **0**; Industrial **3**; Research **1**; Other **1**	3	3
Containment	Sealed **1**; Unsealed **3**; Machine **1**	3	3
Dose rate @ 10 cm	< 1 µSv/h **0**; > 1 mSv/h **4**; Other **1**	1	1
****Waste***	Dispersed **2**; Stored **1**; Disposed **2**; Other **0**	1	2
Physical State	Gaseous **3**; Liquid **2**; Solid **0**	0	0
Source character; Score		14	15
Source character (percent of maximum)		45%	48%
Stakeholder source characteristics only items; Score		6	7
Stakeholder source characteristics only (percent of maximum)		60%	70%
Source character with stakeholder characteristics double counted		49%	54%
Exposure			
****Choice***	Voluntary **0**; Imposed **4**; Other **1**	1	1
Origin	External **1**; Internal **4**	4	1
****Type***	Normal **1**; Potential **4**	4	4
****Benefit/Detriment***	Poor **4**; Reasonable **1**; Good **0**	0	0
Duration	Chronic **4**; Other **1**	1	4
Risk	Low **0**; Medium **1**; High **4**;	0	1
****Receptor***	Worker **1**; Patient **1**; Public **3**; Other **0**	1	1
Number Exposed	> 10^6 **4**; < 10 **0**; Other **1**	0	1
Exposure character; Score		11	13
Exposure character (percent of maximum)		35%	42%
Stakeholder exposure characteristics only; Score		6	6
Stakeholder exposure characteristics only (percent of maximum)		40%	40%
Exposure character with stakeholder characteristics double counted		37%	41%
Total			
Total character score; Average (Source % + Exposure %)		**40%**	**45%**
Average Stakeholder only characteristics		**50%**	**55%**
Total character score with stakeholder characteristics double counted		**43%**	**47%**

* Double counted in determining stakeholder influence

x Not applicable

of the sources and exposures considered (cont'd)

6.6.1		6.6.2		6.6.3		6.7.1	
Contam-inated site	**Return to contam-inated site**	**Radon in home (high concen-tration)**	**Radon in home (low concen-tration)**	**Radon in work-place (high concen-tration)**	**Radon in work-place (low concen-tration)**	**Interna-tional trade in commodity (artificial activity)**	**Interna-tional trade in commodity (natural activity)**
1	1	4	4	4	4	4	1
1	1	1	1	1	1	x	x
1	1	1	0	1	0	1	1
4	4	0	0	0	0	4	0
x	x	x	x	x	x	1	1
3	3	3	3	3	3	3	3
1	1	1	0	1	0	0	0
x	x	x	x	x	x	2	2
0	0	3	3	3	3	0	0
11	11	13	11	13	11	15	8
42%	42%	50%	42%	50%	42%	56%	30%
2	2	5	4	5	4	7	4
25%	25%	63%	50%	63%	50%	70%	40%
38%	38%	53%	44%	53%	44%	59%	32%
4	0	0	0	0	0	4	4
4	1	4	4	4	4	4	4
1	1	1	1	1	1	1	1
4	0	0	0	0	0	1	1
4	4	4	4	1	1	1	1
0	0	1	0	1	0	0	0
3	3	3	3	1	1	3	3
1	1	0	0	1	1	1	1
21	10	13	12	9	8	15	15
68%	32%	42%	39%	29%	26%	48%	48%
12	4	4	4	2	2	9	9
80%	27%	27%	27%	13%	13%	60%	60%
72%	30%	37%	35%	24%	22%	52%	52%
55.0%	**37%**	**46%**	**41%**	**40%**	**34%**	**52%**	**39%**
52.5%	**26%**	**45%**	**38%**	**38%**	**32%**	**65%**	**50%**
55.0%	**34%**	**45%**	**39%**	**38%**	**33%**	**56%**	**42%**

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A New Approach to Authorisation in the Field of Radiological Protection

Approaches to radiological protection have been evolving, particularly over the past several years. This has been driven by the emergence of modern concepts of and approaches to risk governance, and by calls from within the radiological protection community for the simplification and clarification of the existing system of protection, as based on the Recommendations of the International Commission on Radiological Protection (ICRP).

The NEA Committee on Radiation Protection and Public Health (CRPPH) has been very active in developing its own suggestions as to how the system of radiological protection should evolve to better meet the needs of policy makers, regulators and practitioners. One of those suggestions is that a generic concept of "regulatory authorisation" of certain levels and types of exposure to radiation should replace the current and somewhat complicated concepts of exclusion, exemption and clearance. It has also been suggested that by characterising emerging sources and exposures in a screening process leading into the authorisation process, regulatory authorities could develop a better feeling for the type and scale of stakeholder involvement that would be necessary to reach a widely accepted approach to radiological protection.

In order to verify that these suggestions would make the system of radiological protection more understandable, easy to apply, and acceptable, independent consultants have "road tested" the CRPPH concepts of authorisation and characterisation. Their findings, which show that applying these concepts would represent significant improvement, are reproduced herein. Specific approaches for the application of the new CRPPH ideas are also illustrated in this report.

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