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he Process of Regulatory Authorisation

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The Process of Regulatory Authorisation

A Report by the CRPPH Expert Group on the Regulatory Application of Authorisation (EGRA)

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FOREWORD

During the past several years, the NEA Committee on Radiation Protection and Public Health (CRPPH) has been actively contributing to the international dialogue on the development of new International Commission on Radiological Protection (ICRP) general recommendations. This has included the publication of several reports on the subject, most recently the following two:

- *The Way Forward in Radiological Protection: An Expert Group Report* (NEA, 2002).

- *A New Approach to Authorisation in the Field of Radiological Protection: The Road Test Report* (NEA, 2003).

A key concept that was developed in *The Way Forward in Radiological Protection* is that of "authorisation", which is described in the report as follows:

The current system of radiological protection as recommended in ICRP Publication 60 is comprehensive. In discussing how this system could evolve, the EGRP felt that an "ideal" system of radiological protection should provide guidance on virtually all types of exposure. Initially, all known radiation sources and exposures would be considered to be included within the system of radiological protection. This would give the positive message that the regulatory control flowing from an inter-nationally agreed-upon system of radiological protection considers all sources, and then regulates them in a logical fashion. From this starting point, some exposures could then be excluded, based on the fact that they are not amenable/possible to control, control would not improve the situation, or based on some other clearly explained rationale. Some sources could be authorised for release from some or all regulatory control, through a process of constrained optimisation based on clearly explained and, where appropriate, internationally agreed-upon criteria. All remaining exposures and sources would be subject to regulatory control. (NEA, 2002)

To test whether the ideas and concepts developed in *The Way Forward in Radiological Protection* would, if implemented, result in an improved system of

radiological protection, the CRPPH Expert Group commissioned two consultants to "road test" these ideas. With respect to authorisation, the consultant's report, *A New Approach to Authorisation in the Field of Radiological Protection*, suggests the following:

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. […] 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 an improved coherence with the approaches in health risk assessment in general as well as with environmental risk assessment. (NEA, 2003)

The concept of authorisation as discussed by the CRPPH Expert Group was communicated to the ICRP, and to the broader radiation protection community, for consideration. In response, the ICRP took up the concept of authorisation in its latest draft recommendations (RP05 – ICRP 2004), but in a more narrow context. In addition, the ICRP continues to maintain the position that its recommendations are guidance rather than regulatory text. As such, the concept of authorisation was introduced, but details were not provided by the ICRP.

Given this approach by the ICRP, the CRPPH felt that a detailed and wide-ranging discussion of the concept of authorisation would be useful. Further, the CRPPH considered it appropriate to provide such an elaboration given that it had been at the forefront of developing this concept, and that the CRPPH approach was somewhat broader than that of the ICRP.

To accomplish this task, the CRPPH created the Expert Group on the Regulatory Application of Authorisation (EGRA) to further explore the nature and use of authorisation in a regulatory and practical context. The objective of the Group's work was to develop a more detailed understanding of the regulatory concept of authorisation, from a conceptual and practical standpoint, to clarify for radiological protection regulatory authorities and practitioners how such a concept could be applied. This would also help the "translation" of ICRP recommendations into practical application.

The work of the EGRA was widely presented internationally (for example at the IRPA-11 Congress in May 2004; and at the 1st and 2nd NEA Asian Regional Workshops on the Evolution of the System of Radiological Protection held in October 2002 and July 2004 respectively), and improved as a result of comments. The deliberations of the ICRP regarding the development of new

recommendations were also taken into account in preparing this work, which was provided to the ICRP for consideration in finalising its recommendations. In this way, it is hoped that this work will help ensure a seamless application of the new ICRP recommendations in practice.

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EXECUTIVE SUMMARY

Governments and/or regulatory authorities are responsible for, among other things, the definition of regulatory controls or conditions, if any, that should be applied to radioactive sources or radiation exposure situations in order to appropriately protect the public, workers and the environment. Countries use different policy and structural approaches to fulfil this responsibility. Generally, the recommendations of the International Commission on Radiological Protection (ICRP) are used as at least part of the basis for protection. Now, with the evolution of recommendations from the ICRP, a single, conceptually simple, and self-coherent approach can be used by governments and regulatory authorities to define appropriate protection under all circumstances. This report describes this process.

Previously, the ICRP recommended the use of various approaches to protection. For what were called *practices*; exposures were subject to limits. *Optimisation of protection* was required to maintain exposures below these limits. What were called *interventions* were subject to *intervention levels*, above which some action could be considered *justified*, and actions should be optimised based on consideration of how much dose could be averted by the countermeasure considered. Radon in homes was subject to action levels, above which some sort of countermeasure could be recommended.

These approaches are all conceptually distinct and logically constructed, but their differences, particularly the concepts of different numerical criteria used (limits, intervention levels, dose constraints, action levels, etc.) contributed to confusion and misunderstanding. As a result of many considerations such as these, in its new draft recommendations the ICRP is proposing the use of optimisation of individual protection below a pre-defined, source-related *dose constraint* for all types of situations. A parallel approach, which has not yet been fully elaborated by the Commission, will be developed for the radiological protection of the environment.

While the ICRP has been focusing on the basis for, and broad principles of protection, the CRPPH has been focusing its efforts on how radiological protection could be better implemented by governments and/or regulatory

authorities,* on the basis of what these authorities are already doing to respond to concerns regarding radiological protection. To this end, the CRPPH has developed a concept that it calls the process of regulatory authorisation. This is described in detail in this report, and is intended to help regulatory authorities to more transparently, coherently and simply apply the broad recommendations of the ICRP to the real-life business of radiological protection regulation and application. In developing this, the CRPPH recognises the importance of an appropriate level of stakeholder involvement in this process.

A new approach: The process of regulatory authorisation

International recommendations do not take the place of national legislation and regulation. Further, regulatory authorities generally have the national responsibility to address, in some fashion, any and all sources and exposure situations with which they are confronted. There is thus a need for a regulatory process that considers all sources (e.g.: cosmic, terrestrial, natural, artificial) and exposure situations (e.g. normal situations, accidents and emergencies, and controllable existing exposures) that are known by or brought to the attention of the regulatory authority. To address this need in a fashion that is as coherent and simple as possible, the Process of Regulatory Authorisation addresses all radiation sources and exposure situations in the same fashion (constrained, source-related optimisation of protection). In this way an answer, through appropriate statements and, if appropriate, actions, to the concern regarding the source or the exposition situation is, in any case, given. Through a series of conceptual steps, this process begins with the identification of a source or exposure situation, and ends with the definition of appropriate regulatory controls, if any are judged necessary. Three end points are possible. Analysis can result in sources or exposure situations that are:

- Not authorised, because they are not justified.
- Authorised and subject to regulatory controls.
- Authorised and not subject to regulatory controls.

Throughout this process, there is a need to make decisions. While the making of regulatory decisions is clearly the responsibility of regulatory authorities, the participation of stakeholders in decision-framing and decision-

* Different national approaches confide the responsibility for radiological protection decision making (laws, regulations, justification, etc.) in different bodies. To simplify terminology, this report will refer to the "regulatory authority", meaning the national governmental body or bodies in whom such radiological protection regulatory decision making has been confided.

making processes, at various levels, is increasingly recognised as a way to achieve sustainable and accepted protection solutions. This has been extensively documented and verified during the NEAs Villigen workshop series (NEA, 1998, 2001a,b, 2004a,b,c). Although in this context it is important to understand just what a stakeholder is, there is no single definition of a stakeholder. The stakeholder is typically felt to include those groups or individuals who bear the "costs", and those who receive the "benefits". However, even this definition is rather flexible. The stakeholders for a particular decision will not necessarily be the same stakeholders for another decision. Even for a single, specific decision, the stakeholders may change over time, with those initially involved not necessarily participating throughout the process. Although most cases will not require broad public involvement, the level of stakeholder involvement that is employed will be case dependent. With such flexibility, it is not surprising that governments have different approaches to the involvement of stakeholders in decision processes. The ICRP, in its latest draft recommendations, sees stakeholder involvement as a key to success, particularly in the optimisation of protection. Paragraph 196 of RP05 (ICRP, 2004) states:

"The involvement of stakeholders, a term which has been used by the Commission in Publication 82 to mean those parties who have interests in and concern about a situation, is an important input to optimisation. While the extent of stakeholder involvement will vary from one situation to another in the decision-making process, it is a proven means to achieve the incorporation of values into decisions, the improvement of the substantive quality of decisions, the resolution of conflicts among competing interests, the building of shared understanding with both workers and the public as well as trust in institutions. Furthermore, involving all parties affected by the decision reinforces the protection culture and introduces the necessary flexibility in the management of the radiological risk that is needed to achieve more effective and sustainable decisions."

Appendix 1 provides an overview of stakeholder involvement as it applies to radiological protection decision making in the context of the process of regulatory authorisation.

The first step of the process of regulatory authorisation begins when a source or exposure situation has been identified and brought to the attention of the regulatory authority. It should be noted that the regulatory authority will need to consider all such sources and exposure situations. The ICRP suggests that certain sources and exposure situations can be excluded from the scope of its recommendations. International recommendations are not intended, however, to take the place of national policy and regulations. National regulatory authorities may need to formally consider those sources and exposure situations

that would be excluded from the scope of the ICRP recommendations. While such consideration will most likely not entail significant regulatory effort or any regulatory controls, some sort of regulatory authority decision may be necessary. The fact that all situations are considered, however, provides a positive, proactive message that regulatory authorities are actively pursuing public, worker and environmental protection under any and all circumstances.

Thus, for any source or exposure situation, the regulatory authority will perform a preliminary characterisation of relevant attributes. This will provide a simple overview of the magnitude of any "costs" and "benefits" associated with the source or exposure situation, and will help the regulatory authority to better understand the level of stakeholder involvement that may be necessary in order to develop appropriate, sustainable and accepted decisions. Appendix 2 to this report provides a brief overview of this characterisation, as was developed in a previous NEA report (NEA, 2003h).

Based on this characterisation, a preliminary screening is performed to see whether the source or exposure situation is either clearly unjustified, or clearly should be authorised with no regulatory controls. If neither of these choices is obviously the case, further analysis and the development of an optimised protection solution will be needed.

It should be noted, however, that the appropriate final decision for some sources and exposure situations will be clear and obvious. For example, some sources and exposure situations will clearly not be amenable to dose reduction through regulatory controls (e.g. cosmic rays at the earth's surface). These unavoidable exposures would thus not be subject to any regulatory controls. Some sources and exposure situations will clearly not be justified (based on acknowledged social, political and scientific considerations) and will not be allowed by the regulatory authority (e.g. the deliberate use of radioactive material in toys). Most sources and exposure situations though, will require further analysis before a regulatory decision regarding any appropriate protection actions can be made.

The detailed analysis of these cases will include the optimisation of protection using an individual dose constraint as the upper bound. Regulatory controls, if any are warranted, will be imposed based on, among other considerations, the level of residual dose and/or radionuclide concentration remaining after protection has been optimised.

Based on this detailed analysis, some sources and exposure situations can be authorised, but only under certain regulatory controls. Authorised sources or exposure situations can include such things as the operation of facilities causing

public, worker and environmental exposures that are found to be justified. The ICRP has called these, in its latest draft recommendations, normal situations. Authorised sources or exposure situations can also include existing sources and exposure situations (to which the concept of justification does not apply), or justified protection actions in response to an accident, where actions would be authorised based on prescribed regulatory analyses and controls.

Detailed analysis can also result in sources and exposure situations that can be authorised by the regulatory authority with no need for regulatory controls. These may include existing exposure situations (e.g. radon in homes, or residual contamination long after an accidental release, that are below some numerical criteria fixed by the regulatory authority). This could also be normal, ongoing sources or exposure situations (e.g. the release of gaseous or liquid effluents from an operating nuclear facility, hospital or research laboratory) where regulatory controls are applied up to the point of release, but not with respect to released materials other than, for example, environmental monitoring or modelling. This would also be the case for the release of slightly contaminated solid materials from a decommissioning project. Some these situations would result in the release of radioactive materials into the environment in a practically irrecoverable fashion. While regulatory authorities will not try to "regain control" over these released materials, their existence will not be "forgotten", and may be considered when making future regulatory decisions regarding other sources and exposure situations that may expose the affected population to additional doses.

Finally, detailed analysis could result in the decision that a source or exposure situation can not be authorised because it is not justified. This could be the case, for example, when analysis reveals an alternative lower-risk method of achieving the same end without the need to cause radiation exposure.

The result of this process will be that any source or exposure situation considered by regulatory authorities will end up in one of the three cases cited above. However, views can evolve and change with time, such that the process of regulatory authorisation also takes into account the possibility of re-evaluation, motivated by changing technology and/or social norms. This could be the case for sources and exposure situations that have previously been declared unjustified, or for those for which protection measures have previously been optimised and regulatory controls imposed. This re-evaluation could lead to a new view of whether or not the source or exposure situation is or is not justified, or could result in a change in appropriate regulatory controls.

Again because of changing technology and/or social norms, concern may arise regarding sources or exposure situations that have been authorised and that

are not subject to regulatory controls. In such circumstances, the regulatory authority would be obliged to begin this process again in the new context, to explore again whether the concept of justification is applicable, and whether regulatory controls could be reasonably implemented to improve radiological protection.

Motivation for change: Simplicity, coherence, transparency

This approach is often already followed, in practice, by the regulatory authority that is called to give its judgement on radiological protection aspects, on request from many possible bodies or organisations. The value and innovation comes primarily from two aspects. First, all sources and exposure situations are treated in the same fashion, using optimisation of protection below a pre-determined dose constraint. This results in a system that is conceptually simple, consistent and coherent. It avoids the need to explain and justify, as previously necessary, why some regulatory "levels" were not to be passed (limits), and others required no actions until they were passed (action levels, intervention levels). This single approach is expected to be more easily and transparently applied, and by addressing all situations in the same conceptual framework it portrays a positive, proactive image of the government and regulatory authorities.

Second, this approach has tried to avoid the use of terminology that has been difficult to fully understand and explain to stakeholders in the past (e.g. *practice*, *intervention*, *exclusion*, and *exemption*). By concentrating only on the process aspects of radiological protection decision making, this approach emphasises the reasoning behind decision pathways rather than specific and narrowly-defined terms. This again leads to an approach that is more generally applicable and coherent.

This report describes how this umbrella concept, the process of regulatory authorisation, can be used by governments and regulatory authorities to address all radiological protection situations. It is felt that the use of this single, all-encompassing approach will facilitate the development of coherent regulatory decisions in a transparent fashion, and will probably be far easier to explain and defend than the current approaches flowing from the recommendations in ICRP Publication 60 (ICRP, 1991).

INTRODUCTION

There is a general consensus within the Committee on Radiation Protection and Public Health **(**CRPPH) that the public, workers and the environment are adequately protected by the current system of radiological protection, as recommended by the ICRP. There is also a general CRPPH consensus, however, that the current system is overly complicated and internally somewhat incoherent (NEA, 2000, 2002, 2003c, 2003h). This is most likely due to the way in which the current ICRP recommendations have evolved over the past 30 years, adding new recommendations as new circumstances have come to light, such as nuclear accidents and emergencies, radon, and other naturally occurring radioactive materials (NORM).

To address this complexity and incoherence, the ICRP is in the process of developing new recommendations that it hopes will be seen as simplified and more coherent. As part of this, the ICRP has more clearly defined its role, and focused its recommendations. Specifically, the ICRP has suggested that *justification* of activities causing dose is a social, political and scientific judgement, addressed by governments, in which radiation protection considerations may be but a small part. As such, the new ICRP recommendations will not discuss details of justification. The ICRP has also suggested that some radioactive material, radiation and exposure situations could be excluded from its recommended international system of radiological protection, and has given and will continue to give guidance for such exclusions. All sources and exposure situations that are justified and not excluded are then included in the ICRPs system of radiological protection, and should be under regulatory control. For these situations, the ICRP provides the broad principles of: source-related *dose constraints* for individuals; *dose limitation* for individuals in controlled situations and *optimisation of protection* under all circumstances. The Commission provides recommendations relating to the implementation of these principles. Finally, the ICRP suggests that some justified and regulated sources and exposure situations may be released from some or all regulatory control, calling these *exempted*, and has noted that this issue is a regulatory authority consideration, and will thus not be extensively addressed in detail by the ICRP. It should also be noted that the ICRP will be

developing recommendations on the radiological protection of non-human species.

A common element that runs through all of these ICRP concepts is that they each require governmental and/or regulatory judgements and/or actions for their implementation. This provides the opportunity to define a single, over-arching concept that can be used as a template for all regulatory actions in all radiological protection situations. In its publication *The Way Forward in Radiological Protection* (NEA, 2002), the NEA proposed this umbrella process, and called it the *process of regulatory authorisation*. This report develops this in more detail.

National regulatory authorities already use the process of regulatory authorisation to make social judgements, to assess risks, and to develop and enforce regulations. This report shows how this single, coherent process can be used, in principle, by regulatory authorities to address all radiological protection situations. These situations include, among others, the regulation of exposures from natural and artificial radionuclides caused by:

- existing exposure situations, such as caused by controlled, licensed operation of facilities using radioactive materials or generating radiation;
- newly proposed exposure situations, such as would be caused by new human activities being submitted for consideration of licensing;
- discovered exposure situations, such as could arise as the result of past, unregulated practices; or
- accident and emergency exposure situations, such as could arise as the result of a significant accident or incident at a facility using radiation or radioactive materials.

It is felt that the use of this single, all-encompassing approach will facilitate the transparent development of coherent regulatory decisions for all sources and exposure situations.

Operators, workers, the public and all interested groups are assured that each situation has been properly considered for the aspects regarding radiological protection, and a rational decision with a graded system of control has been taken, both in order that the appropriate standard of protection for man and environment is provided without unduly limiting the beneficial practices giving rise to radiation exposure.

THE PROCESS OF REGULATORY AUTHORISATION

One of the key national roles in radiological protection is the development and application of policies and regulations to ensure the safe use of radiation and radioactive materials, and the safety of radiation exposure situations, for the enhancement of our quality of life and of the human endeavour. In general, this role is accomplished through cost and benefit assessment, using stakeholder processes as appropriate (NEA, 1998, 2001a,b, 2004a,b,c), and by the use of regulatory judgement to determine the controls, if any, that are warranted for a given situation. National governments approach this role in different ways, confiding responsibilities in government itself, in single or multiple regulatory authorities, or in some combination of any or all of these.[1]

In this report, the word *control*, referring to regulatory controls, is used in its very broad form to mean any sort of regulatory conditions applied to a source or exposure situation. These regulatory controls will generally be applied in a graded fashion, to appropriately address the level of risk being considered. Controls can include simple actions, such as the requirement to notify the regulatory authority of the existence/purchase of a source, and more complex actions, such as periodic inspections, the requirement to measure occupational worker doses, to measure and model environmental contamination, to perform protection optimisation analyses, etc.

In order to fulfil its mandate, the regulatory authority will apply a regulatory process to all radiation sources and exposure situations of which it is aware, in order to identify any necessary regulatory controls. This includes those sources and exposure situations that already exist, that are newly proposed, that are discovered, or are the result of an accident.[2] Although this

1. Different national approaches confide the responsibility for radiological protection decision making (laws, regulations, justification, etc.) in different bodies. To simplify terminology, this report will refer to the "regulatory authority", meaning the national governmental body or bodies in whom such radiological protection regulatory decision making has been confided.

2. It should also be noted that, in general, it is individuals and/or corporate organisations that are subject to regulatory controls. That is, individuals and/or corporate organisations that use radioactive materials or generate radiation and put themselves or others in exposure

does not imply that all sources and exposure situations will be subject to regulatory controls, it does imply that some level of regulatory judgement is applied to all known sources and exposure situations.

The objective of this process is to assure the appropriate application of the rules and regulations that have been established, in a transparent and traceable fashion, to ensure the safe use of radiation and radioactive materials, and the safety of radiation exposure situations. In this report, this is being *called the process of regulatory authorisation.* Through this process, regulatory authorities implement government policy and decisions through the assessment of identified risks, making scientifically-informed regulatory judgements, allowing, or not, the use of radiation and radioactive materials under an appropriate level of regulatory control, and regulating appropriately radiation exposure situations.

An overview of regulatory authorisation

In normal practice, some sort of governmental and/or regulatory decision (e.g. "this is justified", "this is not justified", "do something", "don't do anything") is made regarding all radiation sources and radiation exposure situations known by or brought to the attention of the regulatory authority. The idea presented here of regulatory authorisation is simply to describe the process details that regulatory authorities already follow to carry out their mandate to judge, either specifically or generically, all radiation sources and radiation exposure situations of which they are aware.

In some legal systems, and in the International Basic Safety Standards, an *authorisation* is a license or a permit to carry out a specified human activity. In this document, the term authorisation is taken in its much broader form. The intent here is to describe the process that regulatory authorities follow when authorising, or not, known exposures to take place within their regulatory structures.

This process of regulatory authorisation embodies the regulatory authority's mandate to judge the "acceptability" of a source or exposure situation. The scientific assessment of risks will clearly be an input to this decision, however other aspects, such as political and social considerations, will also be of importance. The ICRP has called the judging of acceptability *justification*, has characterised it as a multi-dimensional decision, and has

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situations are required to follow regulations if there are any. Again, to simplify terminology, this report will refer to these regulations as regulatory controls on sources and exposure situations.

specified that only justified sources and exposure situations, and existing situations that are controllable will be addressed by the Commission's recommendations. The regulatory authority, however, is mandated to take a decision regarding whether a source or exposure situation is acceptable, in a broad social – political – scientific sense. As such this is a vital first step of the process of regulatory authorisation.

The process of regulatory authorisation also embodies the regulatory authority's mandate to develop regulations, and to make decisions regarding their application, that are informed by the assessment of the risks under consideration, and the benefits involved. This is thus the second broad step of the process of regulatory authorisation, the assessment of risks from authorised sources and exposure situations, and the development of regulatory controls appropriate for each such case. Regulatory authorities generally take a graded approach to regulation, and for this have many regulatory tools, including individual dose limits, source-related dose constraints, optimisation of protection, licenses, permits and inspections. The inclusion of stakeholders, beyond the regulatory authority and the licensee, in decision-aiding discussions is also useful in some cases.

Broadly, then, the process of regulatory authorisation begins when the regulatory authority becomes aware of a source or exposure situation, and involves judging its acceptability, and as necessary developing regulatory controls.

Because regulatory authorities are generally mandated to make decisions regarding public, worker and environmental protection, they are in a sense obliged to address, either explicitly (specifically, case by case) or implicitly (through generic judgements of broad classes of sources and/or exposure situations), all radiation sources and exposure situations of which they are aware. Initially then, the process of regulatory authorisation considers all radiation sources and exposure situations that are known by or proposed to the regulatory authority. This gives the positive message that the regulatory authority, drawing upon an internationally agreed-upon system of radiological protection, has transparently and openly taken into consideration all known sources and exposure situations, and applies regulatory controls, if any are warranted, at an appropriate level. This process encompasses, and rationalises for all sources and exposure situations, the concepts expressed in ICRP Publication 60, and perhaps in new ICRP recommendations, of *justification*, *dose limitation*, *dose constraints*, *optimisation of protection*, *ALARA*, *exclusion* and *exemption*. It should be noted that the terms *exclusion*, *exemption* and *clearance*, which have been the source of some controversy and confusion over the years, are not necessary to describe this approach, but are referred to here to

relate this approach to existing ICRP and IAEA recommendations and standards. From this starting point there are three possible results:

- Radiation sources or exposure situations may be found to be unjustified, and thus will not be authorised by regulatory authorities.

- Radiation sources or exposure situations may be authorised subject to regulatory controls.

- Radiation sources or exposure situations may be authorised but not subject to regulatory controls.

It is the responsibility of the regulatory authority to decide, for each source or exposure situation considered, which of the above categories is appropriate. Such decisions will generally be based on judgements, including such things as the social assessment of the costs and benefits of the human activity causing the exposure, and comparison with possible alternatives involving less or no exposure.

For those situations requiring some regulatory control, the choice of regulatory controls will be subject to judgement by regulatory authorities with respect to choices of protective actions, if any, that could be reasonably applied to manage exposures. Analyses of these situations will be necessary before regulatory actions, if any, can be developed. Regulatory controls or conditions are mandated for the protection of the public, workers and the environment, and include a wide range of possibilities, from simple notification of the regulatory authorities that the dose-causing process is ongoing, to requirements for intricate processes of dose measurement, recording, reporting and assessment. A graded approach will generally be taken, requiring an increasing degree of control with increasing residual exposures.

In general, it should be noted that the individual or the organisation authorised and responsible for causing, or proposing to cause a dose, is also responsible for submitting an exposure analysis to the regulatory authority in support of its proposal. Here, the regulatory authority will have to decide two things. First, through assessment, the regulatory authority will decide whether an optimised protection solution has been developed by the licensee. Second, what type of regulatory control, if any, should be mandated. Regulatory controls or conditions may be mandated in a generic sense, for example for all situations of a particular type, or may apply to specific situations.

In practice, regulatory authorities generally use dose as a quantity that is representative of risk. If this is not directly measurable, either in existing

situations, for planned activities or for emergency situations, corresponding radionuclide activities or activity concentrations derived from appropriate exposure scenarios are used as assessment quantities. Then an analysis of protection is performed to see whether it is optimised. This should include analyses of whether residual doses are as low as reasonably achievable (ALARA), re-calculating doses in a given context of protective actions, and if the use of the best available technology (BAT) is appropriate**.**

It should be noted that regulatory decisions are sometimes made in a blanket, generic fashion, should the regulatory authority decide that a specified class of sources or exposure situations (under a specified specific activity, under a specific dose rate, etc.) could all be addressed in the same fashion.

It is important to remember that radiation sources and exposure situations that are authorised without regulatory control are not "forgotten" by the regulatory authority. Materials that are released from control, such as gaseous and liquid discharges, or solid materials that are released, can not be reasonably collected or brought back under control. However, the regulatory authority may consider the doses caused by such materials in making further decisions, may require the monitoring of environmental radiation and radioactivity levels, and may at some point decide to reduce or forbid further discharges or releases. For example, when deciding whether to allow the release of solid materials from regulatory control, it is clear that once they are released they can not easily (or in some cases at all) be physically traced. As such, detailed modelling of possible exposure scenarios is used to demonstrate, or confirm, that the resulting risks will be outweighed by the resulting benefits. However, at some later time when making other regulatory decisions regarding other releases, the regulatory authority may consider the existence of previously released materials when assessing the optimised level for newly proposed releases. In this sense, released material is not controllable, but is not ignored by the regulatory authority in its decision-making processes.

A social framework to the process of regulatory authorisation

While the making of regulatory decisions is clearly the responsibility of regulatory authorities, the participation of stakeholders in decision-framing and decision-making processes, at various levels, is increasingly recognised as a way to achieve sustainable and accepted protection solutions. This has been extensively documented and verified during the NEAs Villigen workshop series (NEA, 1998, 2001a,b, 2004a,b,c). Although in this context it is important to understand just what a stakeholder is, there is no single definition of a stakeholder. The stakeholder is felt to typically include those groups or individuals who bear the "costs", and those who receive the "benefits".

However, even this definition is rather flexible. The stakeholders for a particular decision will not necessarily be the same stakeholders for another decision. Even for a single, specific decision, the stakeholders may change over time, with those initially involved not necessarily participating throughout the process. Although most cases will not require broad public involvement, the level of stakeholder involvement that is employed will be case dependent. With such flexibility, it is not surprising that governments have different approaches to the involvement of stakeholders in decision processes.

Decisions regarding radiation protection typically include consideration of justification and optimisation of protection. Both of these will take into account scientific as well as social aspects. In the context of decision-aiding discussions, which often include stakeholder involvement, it is useful to recognise the boundaries that exist between various justification and optimisation aspects of risk assessment and management. These boundaries help to define and explain the various aspects of the process of regulatory authorisation. First, the assessment of risks has a strong scientific component, particularly in terms of assessing the absolute and relative value of a risk, and associated uncertainties. Here, scientific, objective tools are used to measure, estimate, and model risks as best possible. This scientific assessment of risk, however, is distinctly different from the social aspects of risk evaluation and management. Here, social judgement assigns a social value to a given risk-causing situation in a given cost and benefit context, and identifies whether or not that particular risk is acceptable under the circumstances. Social judgement will also provide views on how such risks should be managed, particularly in terms of how much residual risk society is willing to accept for the given situation once regulatory controls have been implemented. Finally, given the decision aiding provided by scientific assessment and social judgement, the regulatory authority must regulate the uses of radiation and radioactive material, and radiation exposure situations, allocating regulatory and social resources to this task. These three aspects are distinctly different, but help to characterise aspects of the process that regulatory authorities follow in developing and applying regulations.

In the framework of these boundaries, the process of regulatory authorisation can be conceptually described as a series of steps and decisions. These are described in this report as distinct pieces. In practice, these steps are often less precise than described, and may have some overlap with one or more of the other steps.

The results of regulatory authorisation

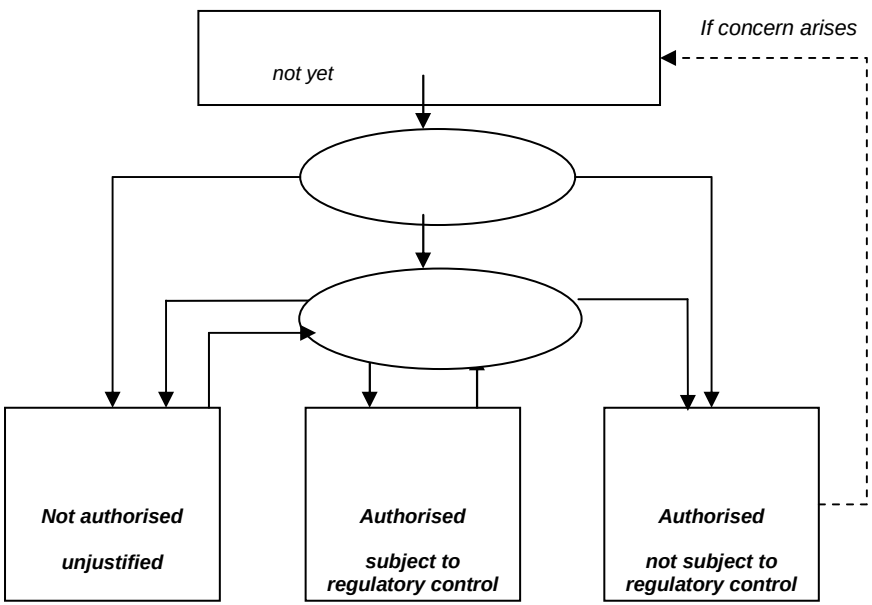
As a result of the process of regulatory authorisation, sources and exposure situations which are not unjustified will be allowed (or in the case of situations that are not amenable to control, will be acknowledged), resulting in some exposures. Any regulatory text associated with these authorisations can include a variety of radiological criteria, such as dose, dose rate, activity concentration, total allowable activity release, etc. These authorised levels can then be used, by the regulatory authority and by the operator, as reference values against which to check compliance with regulatory requirements or with the conditions associated with the regulatory authorisation. These levels have been called such things as dose limits, exemption levels, and exclusions levels. In accident and existing situations, intervention levels have been used. In the context of the latest draft ICRP recommendations, dose constraints, which apply in normal, accident and existing situations, have been established. All these are radiological criteria that are used to establish the conditions under which the regulatory authorisation will be valid.

Generally as a management tool, operators will establish action levels below the radiological criteria mandated by the regulatory authority to help ensure that regulatory levels are not breached.

THE STEPS OF THE PROCESS OF REGULATORY AUTHORISATION

Conceptually, the process of regulatory authorisation can be thought of as a series of analytical assessments leading to decision points. Decisions are made based on various criteria, and result in the identification of any regulatory actions warranted for the radioactive material, radiation exposure, or radiation exposure situation in the context being considered. This process can be iterative, and can be as detailed or as schematic as necessary depending upon the risks being considered. Figure 1 shows this process as conceived for this document. This structure is adapted from that presented in *A New Approach to Authorisation in the Field of Radiological Protection: The Road Test Report* (NEA, 2003h). The evaluations are shown as oval boxes, the starting point and the end points are shown as boxes, and the decision points are shown as arrows. Each box and arrow will be described.

Figure 1. Figure 1. The process of regulatory authorisation



Source: OECD/NEA.

A: The regulatory authority analyses a source or exposure situation.

B: The source or exposure situation should not be subject to regulatory controls.

C: The source or exposure situation is not justified.

D: Further analysis is needed.

E: After detailed analysis, the source or exposure situation is judged to be not subject to regulatory controls.

F: Optimised protection requirements are identified and implemented.

G: Review of existing, regulated sources or exposure situations.

H: After detailed analysis, a source or exposure situation is judged to be not or no longer justified.

I: Reconsideration of a source or exposure situation that has previously been declared unjustified.

Some sources or exposure situations that have been agreed to not warrant regulatory controls may, *if concern arises*, be reassessed by regulatory authorities. However, under normal circumstances the process in this diagram is not cyclical. (See box page 41 for further discussion).

The world of radiation sources and exposure situations

There are many different types of radiation sources and exposure situations, and many different approaches to their categorisation. For the purposes of this report, "the world of radiation sources and exposure situations" refers to all sources and exposure situations in any and all of these categories. From the standpoint of the regulatory authority, "all sources and exposure situations" clearly refers only to those of which the regulatory authority is aware. This awareness can be because the source has been known for some time and in many cases has already been regulated in the past (e.g. emissions from nuclear power stations), because a new project is being proposed that will create a new source or exposure situation (e.g. a medical treatment facility), because of an emergency situation or because a previously unknown source or exposure situation is discovered and the authorities are alerted (e.g. discovery of an old mill-tailings pile). More specifically, sources and exposures situations can include:

- Radiation sources that are naturally occurring (e.g. the uranium series, the thorium series), artificially generated (e.g. ^{137}Cs, ^{90}Sr, ^{129}I, ^{85}Kr), or both (e.g. the plutonium series, tritium, ^{14}C).

- Radiation exposure situations that are caused by ongoing human activities where radioactive materials are used intentionally (e.g. the generation of electricity using nuclear power, scientific research activities involving radionuclides, mining of radioactive ores).

- Radiation exposure situations that are caused indirectly by ongoing human activities because of the ubiquitous nature of radiation and natural radioactive materials (e.g. the mining of non-radioactive ores, living in dwellings made with structural materials containing natural radioactive materials or located in radon-emanation areas, flying in aircraft at high altitudes).

- Radiation exposure situations resulting from planned human activities (e.g. new nuclear installations, new industrial activities using radiation or radioactive materials, new research or educational activities using radiation or radioactive materials).

- Radiation exposure situations caused as a result of an accident(e.g. accidental releases from a nuclear installation or industrial facility).

- Radiation exposure situations that are discovered (e.g. as the result of past, unregulated practices), or known sources or exposure situations that are not subject to regulatory control and for which concern arises (e.g. as the result of changes to regulations) thus requiring the reassessment of ongoing unregulated activities.

- Radiation exposure situations resulting from deliberate medical practices (e.g. diagnostic or therapeutic radiation causing exposures to patients, comforters and care givers, or professional health-care staff).

- Radiation exposures that are received by the public, by workers or by biota in the environment and are needed to be re-evaluated based on new concerns being raised.

Decision A: The regulatory authority analyses a source or exposure situation

Once regulatory authorities become aware of a source or radiation exposure situation, they will perform a preliminary characterisation to assist in more clearly defining the requirements in the next analytical step. Again, there are various reasons why the regulatory authorities would identify a particular source or exposure situation for analysis, including:

- The source or exposure situation is newly discovered.

- The source or exposure situation is proposed as a new use by a "licensee" or "potential licensee".
- The source or exposure situation is the result of an accident.
- The source or exposure situation has been previously known and was not previously deemed to need regulatory controls, but has been identified as needing to be re-evaluated.
- The source or exposure situation has been brought to the attention of the regulatory authorities as a result of stakeholder concerns.

Evaluation 1: Characterisation and screening

In a radiological protection system, as proposed here, all sources and exposure situations will need some level of assessment by the regulatory authority. Due to the ubiquitous character of ionising radiation, a quick and possibly automatic methodology must be found that can help regulators to choose the appropriate level of regulatory control in a graded fashion.

Thus, for those sources and exposure situations that are known by the regulatory authority, or have been brought to the attention of the regulatory authority by stakeholders, a preliminary assessment is performed that can be conceptually separated into two sequential parts: characterisation and screening.

The Characterisation of the source or exposure situation is made in order to decide whether further analysis is necessary, or whether a clear choice is possible immediately. Characterisation may be performed by the regulatory authorities alone, or stakeholders may be invited to provide input. The characterisation is only deep enough to allow the screening to be made in a transparent fashion. The aspects that can be developed here include such things as a rough assessment of the level of exposure and number of exposed individuals involved, of the nature of the source or exposure situation (e.g. fixed location or distributed source, natural or artificial radionuclides, benefits from the activity using the source), and the ability to affect exposures through regulatory control. At this level, the characterisation assessment will generally be more qualitative than quantitative. However, the significance of the source or exposure situation for stakeholders should be preliminarily assessed using a judgemental, quantitative technique that allows the identification of the level of stakeholder involvement that may be necessary in order to achieve a sustainable, agreed-upon decision regarding radiological protection options for the case in question. A detailed description of one possible approach to this has been described in a previous NEA publication (NEA, 2003h), and is briefly described in Appendix 2 to this report.

The screening of the source or exposure situation is to allow the regulatory authority to make a decision regarding regulatory control. At this stage there are three possible decisions: the source or exposure situation is clearly not subject to regulatory control; it is clearly unjustified and should not be allowed; or further analysis is needed before a decision can be reached. The types of rationales that can be used for these decisions are discussed below.

With regard to medical exposures, the regulatory authority is only concerned with the generic justification of radiological procedures, and related controls. Specific justification, at the level of individual patients, is the responsibility of the radiological practitioner and referring physician, and is thus beyond the scope of this document.

Decision B: The source or exposure situation should not be subject to regulatory controls

The characterisation and screening process may indicate that the source or exposure situation being studied is not amenable to regulatory control. This un-amenability may be due to such things as the ubiquitous nature of the source, to the lack of any reasonable regulatory actions that would improve protection, or both. In these circumstances, the regulator will decide that the source or exposure situation under consideration will not be subject to regulatory controls. The ICRP has called this *exclusion* (see Appendix 3). The ICRP has also recommended that sources or exposure situations may also be excluded on the basis of their resulting exposure being trivial, and has further suggested that this can be interpreted based on pre-determined activity concentrations. However, this report suggests a different approach could be that a judgement on the requirement for controls should be made on the basis of a multi-parameter approach in which several characteristics of sources and exposures are examined (see Appendix 2).

While this does not mean that the regulatory authority will completely forget that this source or exposure situation exists, particularly when making future decisions, it does mean that no further regulatory actions will be taken beyond characterisation and screening. This path will be used almost exclusively for natural radiation, for example, some levels of radon exposure, cosmic rays at ground level, or potassium-40 in the human body. Exposures to some artificial radionuclides, such as those exclusively arising from the atmospheric testing of nuclear weapons, may also be considered not amenable to regulatory control.

Decision C: The source or exposure situation is not justified

The regulator may decide, based on characterisation and an *ad hoc* assessment, that a particular source or exposure situation is unjustified, and should thus be prohibited. This decision will generally be based on subjective criteria and social judgement. Radiological input is only part, perhaps a small part, of the information that will contribute to this decision. Examples of uses that have, in some countries, been deemed to be unjustified include:

- The deliberate activation, or addition of radioactive material to such things as food, beverages, cosmetics or other commodities, or products intended for ingestion and inhalation.
- Frivolous use of radiation or radioactive materials, such as the addition of radioactive materials to candy, toys or cosmetics, or the use of x-rays of feet for the measurement of shoe size.

End point 1: Sources and exposure situations that are not authorised because they are unjustified

As described above, some sources or exposure situations may be judged to be unjustified, and will thus not be authorised by regulatory authorities. In the case of planned or proposed operations, these will simply not be allowed. In the case of operations that are already underway, regulatory authorities will require that they cease operation.

Decision D: Further analysis is needed

Characterisation and screening may indicate that the source or exposure situation is justified and controllable, and that it is reasonable for the regulatory authority to consider regulatory controls. Here, the regulatory authority will generally decide that further analysis should be performed before a decision is made with regard to the specific type of regulatory controls that should be mandated. The majority of sources and exposure situations that are reviewed by the regulatory authority will fall into this category. As previously mentioned, the source or exposure situation characterisation will assist in designing a decisional process with an appropriate level of stakeholder involvement.

Evaluation 2: Detailed analysis and optimisation of protection

Many sources and exposure situations addressed by regulatory authorities will require some level of regulatory control. In general, regulatory authorities will want to ensure that radiological protection is optimised in these situations,

and will mandate regulatory controls that are commensurate with the exposures and accident risks remaining after optimisation of protection.

Optimisation of protection plays a central role in assessing radiological protection approaches to public, worker and environmental exposures. Optimisation of protection is applied to all exposure situations, including those exposures that have not yet occurred (justified, planned exposures), exposures following an accident, and exposures in *de facto* situations (e.g. in legacy situations, exposure to naturally occurring radionuclides, or prolonged exposure situations). For those exposures yet to occur (e.g. planned exposures being proposed, or planning for protection in case of post-accident exposures), optimisation of protection is applied during design, planning and implementation of the process or source giving rise to exposures. In situations where the exposures already exist (e.g. legacy situations, discovered situations, long-term natural exposure situations) optimisation of protection is applied in the development, selection and implementation of protective actions. In all these exposure situations, the principle of optimisation of protection is applied in the same fashion.

The focus of optimisation is on the protective actions that can be applied to manage exposures. These actions can be applied to the exposure (e.g. actions applied directly to the individual being exposed, or actions applied along the pathway of exposure), or to the source of the exposure (e.g. shielding at the source, reduction of emission, etc.). The desired result of optimisation of protection is that the exposures do not occur (as with the prevention of accidents or the selection of a process that does not involve radiation or radioactive material) or if this is not possible, that exposures remaining after the optimisation of protective actions are ALARA. In this context, it is also necessary to assess whether the use of BAT is appropriate, or not, for the situation being considered.

In order to assure that, after the optimisation of protection, the absolute value of individual exposures does not exceed levels judged to be acceptable, the concept that the ICRP calls the *dose constraint* is used. For exposures that have not yet occurred, this is achieved by constraining the optimisation process to assure that individual exposures remain below a pre-selected level. That is, protection options that result in individual exposures above the pre-selected dose constraint are rejected as not offering sufficient protection. In controlled situations where *dose limits* also apply, numerical values for dose constraint are selected to be less than or equal to the dose limits that apply (public or worker). In the case of exposures that already exist (e.g. after an accident or other de-facto exposure situations), the limits can not be applied because it is not necessarily, *a priori*, possible to limit exposures below such a pre-defined level. However, dose constraint can be applied in these situations by defining levels

above which exposures should not be allowed. This will result in either the mandatory application of some sort of protective actions at the source or on the exposure situation, or the removal of individuals from the exposure situation. In all these circumstances, protection is optimised below the dose constraint to achieve residual exposures that are ALARA.

The principal role of optimisation is protection of the individual. As such, the previously discussed dose constraints are based on individual exposures. It should be mentioned, however, that the number of individuals exposed, the size and distribution of their doses, and their location in time and space for a particular situation can also be of importance in making decisions regarding regulatory controls. This is, in essence, collective dose. The ICRP is now, however, recommending that the component parts that characterise the collective nature of exposures be expressed separately. The relative importance of these component parts will be judged, and weighted, during the optimisation process to identify the level of residual dose (individual and collective) that is ALARA. It is expected that the ICRP will provide some guidance on how the collective dimension of exposures to large groups of people can best be expressed. Optimisation may also include appropriate protection of the biotic environment, particularly in areas where no people live. The ICRP is expected to give some guidance on this subject.

Practically speaking, optimisation of protection is applied in all circumstances, yet in each circumstance is approached somewhat differently:

- Optimisation of protection for controlled activities, either proposed or ongoing, is performed by the operator, then verified and approved, if appropriate, by the regulatory authority, including broader stakeholder involvement as judged appropriate:
  - For example, in France, prior to getting the authorisation to make a repair on the primary reactor cooling system, there is a regulatory requirement for the utility (EDF) to declare to the regulatory authority the dose estimated for the job, as compared to the relevant dose constraint.
  - In some countries, in order to obtain authorisation to perform an operation, it is necessary to demonstrate that estimated exposure is comparable to or lower than doses that have been received doing the same or similar work at other sites.

- Optimisation of protection in the case of natural exposures is generally performed by the regulatory authority, may involve participation by various stakeholder groups, and could result in regulatory controls or recommendations for remedial actions. Radon is an example of this.

  – For radon in existing dwellings, the regulatory authority sets constraints, in this case, activity concentration levels above which it is recommended that countermeasures should be undertaken. For existing private dwellings, this is generally not a regulatory requirement for the owners, but regulatory authorities work to inform dwelling owners of government recommendations, and to assist with radon level assessments as requested. Constraints on Radon levels are taken into account in the design of new dwellings.

  – For radon in work places, the regulatory authority sets levels above which activity concentrations should not be allowed, and enforces these levels.

- Optimisation of protection in planning for and implementing urgent countermeasures in case of an accident situation is generally performed by the regulatory authority emergency management organisation, and may involve participation by various stakeholder groups.

  – Because accident situations are, by their nature, unpredictable, it is not possible to set a dose limit above which exposures are "not allowed to go" in accident circumstances. However, the regulatory authorities can establish dose constraints above which counter-measures would be required to reduce doses (such as relocation of affected inhabitants, removal of significant portions of the source if possible, change of consumption habits such as home produced milk to children, etc.). The precise numerical value of this dose constraint might be fixed taking deterministic effects, and significant risks of stochastic effects into account. The relative ability of countermeasures and regulatory controls to reduce exposures should also be taken into account. The evaluation of efficiency of countermeasures requires a very significant expert work, and is time and resource consuming. The ETHOS project, conducted in Belarus under a European Commission contract, is a good example of a useful methodology for evaluating the efficiency of countermeasures as well as a direct example of countermeasures to be applied after a nuclear accident.

- For example, in some post-accident situations, it might not be possible to avoid exposure above which there is neither individual nor social benefit (at exposures over 100 milli-sievert) without relocating the affected population such that this would be the only permanent reasonable option. In other circumstances, less severe countermeasures and life-style changes might make it possible to reduce the risk of stochastic effects, with the aspiration that doses would move down, for example toward 1 milli-sievert or below, with time. In both these cases, the concept of optimisation of protection would be used to achieve residual exposures that are ALARA.

- Optimisation of protection in other de-facto situations may also be performed by the regulatory authority, and may again involve participation by various stakeholder groups.

  - The types of *de facto* situations that might arise include the discovery of contamination from a past, unregulated practice (radium factory, thorium processing facility, etc.), or actions taken during the recovery phase of an accident, significantly after the initial contamination event.

  - Where the organisation at the "cause" of the exposure can not be held "responsible" (cannot be identified, was not previously regulated, has gone bankrupt, etc.) the government will generally work with stakeholders to optimise protection.

  - Similarly to accident situations, other *de facto* situations are not amenable to *a priori* fixing of a dose limit above which exposures are "not allowed to go". But again, regulatory authorities can establish dose constraints above which countermeasures would be required to reduce doses (such as relocation of affected inhabitants, removal of significant portions of the source if possible, etc.). Because exposures from these situations will most likely be lower than those potentially arising from accident situations, the precise numerical value of this dose constraint might be fixed considering risks of stochastic effects, and the existing levels of exposure. The relative ability of counter-measures and regulatory controls to reduce exposures should also be taken into account.

It should also be noted that the optimisation of protection in medical application can make use of diagnostic levels as an important and useful tool to indicate whether the level of patient dose from a specific procedure is unusually high.

As a result of the optimisation process, the optimum level of protection will be identified. As previously mentioned, regulatory authorities will generally take a graded approach to regulation, feeling that in some cases the optimum solution is to impose no regulatory controls, while in other cases to impose significant regulatory controls.

As with many other aspects of radiological protection, optimisation of protection is a process of judgement. This is particularly the case when identifying when the optimum level is reached. In general, this is when experts and stakeholders involved in the optimisation process are broadly in agreement that further protection would not reasonably reduce exposures. This will almost certainly entail compromise, at some level, by all parties involved in the decision-framing process (e.g. the regulatory authority, the licensee, other concerned parties or members of the public). Further information on stakeholder involvement processes can be found in several NEA reports (NEA, 1998, 2001a,b and 2004a,b,c), and in Appendix 1 to this document. Under most circumstances, the operator, licensee, institution, organisation or industry responsible for causing the exposure is responsible for optimising protection. This is performed within a legal framework established by the regulatory authorities, and regulatory authorities are also generally responsible for verifying that optimisation of protection has been performed. This is the basis for most regulations in the world. Under some circumstances, regulatory authorities will issue permits or licenses or other permission documents, such as a permit to allow the operation of a clinical x-ray facility or as a license to allow an individual researcher to receive radioactive materials for experiments. In other cases, regulatory authorities will simply inspect, and discuss optimisation of protection more broadly, such as, for example, when inspecting occupational exposures at a nuclear power plant. The type and level of this regulatory authority participation in the optimisation process will vary from case to case. It should also be noted that stakeholders other than the operator and the regulatory authority may be involved in the optimisation process, but again this will vary from case to case and country to country.

Decision E: After detailed analysis, the source or exposure situation is judged to be "not subject to regulatory controls"

Under some circumstances, analysis may indicate that the optimum protection solution, yielding residual doses that are ALARA, is to impose no regulatory controls on the source or exposure situation. Such sources or

exposure situations could then be authorised without regulatory controls. Such decisions will often be developed with input from stakeholder groups. The ICRP has called this *exemption* (see Appendix 3).

There are several types of situations that might fall into this category, each having distinctive attributes, but each conceptually being an authorised release. These include the authorisation to release effluents from a regulated activity, the authorisation of the use of consumer products containing small quantities of radioactive materials, or the authorisation of exposures resulting from natural radioactivity (such as radon) or from an accident situation (such as caesium contamination caused by Chernobyl) where doses or radioactive material concentrations are below some defined regulatory level.

In some circumstances, materials containing radioactivity are created or used by processes that are controlled by regulatory authorities. The optimisation of protection may result in the recommendation that these radioactive materials can be discharged to the environment (in solid, liquid or gaseous form). Such releases from regulatory control are generically called “authorised releases”. In general, in these situations there will most likely be regulatory control imposed up to the point of release of such materials.

The decision to authorise such a release will be based on many considerations, including the exposures that would result from the release, those that would result from *not* releasing, economic considerations, and stakeholder input concerning social and political views. Such issues will be taken into account in the decision-framing and decision-making processes.

There are several types of situations where this may be applicable. For example, nuclear installations, hospitals and research facilities are generally regulated, but are allowed to make gaseous and liquid discharges containing radionuclides. The allowable types and quantities of these authorised releases may vary from country to country. For example, in some countries, discharges from hospitals are only authorised for radionuclides with a half-life shorter than 100 days. Release authorisations may be given on a case by case basis, or in certain circumstances, on a more generic level.

In the case of bulk materials, some countries allow the authorised release from control of quantities of solid or liquid materials containing small amounts of radioactivity. This would be the case, for example, of slightly contaminated concrete or metal from decommissioning operations. The ICRP has called this type of authorised release *clearance* (see Appendix 3).

Consumer products containing small quantities of radioactive material are also authorised to be used without regulatory control. This may be the case for small, sealed “check sources” that are used in the calibration of radiation

detection instruments. Manufactured consumer products, such as watches or instruments having luminous tritium dials, have also been, in some countries, authorised for use without regulatory controls. Again in this case, it is likely that the production of such devices will be subject to regulatory controls. In some countries, for such devices as smoke detectors, there may be a stipulation that they should be returned to the manufacturer for proper disposal, particularly when used in large quantities, such as in large, public buildings (offices, shopping centres, etc.). However, for individual use there is generally no enforced regulatory penalty imposed on the consumer for not following such a requirement.

In the case of existing controllable exposure situations, or accident/ emergency exposure situations, the optimisation of protection can result in the recommendation that, at a certain point, no regulatory controls will be necessary. Here, residual exposures will be agreed to be ALARA, and the affected populations will not be subject to regulatory requirement. This is generally the case for low residential exposure to radon. Regulatory authorities establish a level, based on an optimisation process, below which they do not recommend remediation actions. This can be viewed as an authorisation of these exposures. Similarly, in the rehabilitation stage that would follow, generally long after an accident involving the contamination of lands, regulatory authorities could establish levels below which they would not recommend further remedial actions. This can be viewed as an authorisation of the post-accident residual doses.

It is important to remember, however, that radioactive materials and radiation exposure situations that are not subject to regulatory control are not “forgotten” by the regulatory authority.

For example, extensive dose modelling is done when evaluating gaseous and liquid discharges, and environmental monitoring is generally required. While it is not possible to collect released radionuclides, the exposures that they could potentially cause may be kept in mind by regulatory authorities when addressing future decisions regarding other proposed releases or exposure situations that could affect the same population.

In the case of solid materials that are released from control, again it cannot be reasonably imagined that they will ever be collected or brought back under control. However, extensive dose modelling will have been done when deciding whether release should be allowed, and this may be considered in making future decisions.

Similarly, exposures resulting from existing situations, or in the long-term recovery phase following an accident, may be considered by regulatory authorities when making decisions regarding newly proposed sources or exposure situations that would affect the same population.

In all these cases of releases from regulatory control, the regulatory concern for long-term build-up of released radioactive materials, or for multiple exposures to released radioactive materials, may induce the regulatory authority to consider the doses resulting from previously authorised releases in further decisions. Ongoing releases may also be re-evaluated for these same reasons.

Decision F: Optimised protection requirements are identified and implemented

If the optimised result of regulatory analysis is such that the regulator feels it is important to maintain regulatory control, then the source or exposure situation will require that regulatory conditions be applied to allow its use. Regulatory acts or conditions may include dose registries, environmental measurements, dose modelling, inspection, technical specifications, public information, conduct of further studies, etc. In general, the regulatory authority will wish that "good radiological practice" is followed. Regulatory controls will generally be applied in situations such as:

- The management of exposed workers.
- The management of exposures to the public and non-occupationally exposed workers.
- The management of accident situations.
- The management of exposure to radon and other *de facto* situations under regulatory control (e.g. contaminated site).
- The management of public exposure from the controlled transport and storage of solid and liquid materials.
- The management of the deliberate application of radiation and/or radioactive materials for medical diagnostic and/or therapeutic purposes.

In any situation requiring regulatory control, a graded approach will be taken to most appropriately match the complexity of the case being considered, including, among other aspects, the severity of the risk and stakeholder input.

End point 2: Sources and exposure situations are subject to regulatory conditions

Many sources and exposure situations are subject to regulatory controls. There are many tools and approaches available for the regulatory control of sources and exposure situations, and in general regulatory authorities use a graded approach. For example, low-activity sources and low-dose exposure situations, with little or no risk of an accident that could result in significant exposures, might be regulated by a simple notification from the "operator" to the regulatory authority. For sources or exposure situations with higher radiological risks, regulatory authorities may decide that further controls are necessary. These can include formal review and licensing processes, inspections, requirements for environmental modelling and measurement, requirements for individual dosimetric assessment and/or measurement. The full range of regulatory control choices is available, the most appropriate of which will be selected for each situation being considered. Again, a graded approach will generally be used when identifying required regulatory controls.

Decision G: Review of existing, regulated sources or exposure situations

In some cases, existing situations operating under specified regulatory conditions may require further or new analysis. Such analysis may be deemed to be necessary by the regulatory authority, or the licensee/operator may request such an analysis. The decision to reanalyse a situation may be based on such things as the emergence of new technologies, changing physical conditions, or changing social conditions. This may apply to such things as ongoing regulated activities, or to sites or facilities in decommissioning. Analysis may result in regulatory controls being either tightened or loosened.

Decision H: After detailed analysis, a source or exposure situation is not or is no longer justified

Through social and political analysis processes, the regulatory authority may decide that a source or exposure situation is not justified. Such a decision may be made for a source or exposure situation that passed through the screening process but, after further more intense analysis, does not seem justifiable. This could be the case where broad, stakeholder discussions are needed before a government or regulatory authority decision can be made, and for which detailed technical input, only available through detailed analysis, is needed.

Such a decision may also arise in the case of a regulated source or exposure situation that has been reanalysed and is no longer felt to be justified. This could occur should a new technology be developed that allows an action to

be undertaken without radioactivity or radiation. For example, the development of a new biological testing method, or a new industrial measurement method could provoke government or regulatory authorities to re-examine the justification of approaches using or resulting in radiation. This also may be the case of smoke detectors with the improving technology of optical smoke detectors in lieu of ionising smoke detectors. Clearly, the decision to declare an ongoing, previously-justified action as now unjustified would need very broad, open and transparent discussions before being taken.

In either case, if the result is that the proposed or ongoing activity is not, or is no longer justified, it will not be allowed. Regulatory authorities will then need to ensure that any necessary follow-up activities (cleanup, monitoring, disposal, etc.) are undertaken appropriately.

Decision I: Reconsider a source or exposure situation that has previously been declared unjustified

As social norms, national circumstances and technology evolve, some decisions regarding sources or exposure situations that have been deemed unjustified may need to be re-evaluated. At that stage, the responsible regulatory authority will need to re-evaluate the technical and social aspect of the situation, and to judge whether under the current circumstances a previously unjustified situation has become justified.

End point 3: Sources and exposure situations not subject to regulatory controls

As described here, the regulatory authority may authorise the use of some sources or the existence of some exposure situations without regulatory conditions. Examples of this include:

- Solid and liquid material that has been released from decommissioning processes.
- The normal use of smoke detectors, or other devices containing small amounts of natural radioactivity, by members of the public.
- Exposure situations judged by the regulatory authority to be authorised based on, among other considerations, exposures being below a pre-defined value (e.g. domestic exposure to radon below an optimised activity concentration).

Once allowed, it will generally not be possible for regulatory controls to directly affect these sources and exposure situations. For example, it will not generally be possible to recollect radioactive material (solid, liquid or gaseous)

that has been released, although it should be noted that the regulated disposal of sealed sources, such as smoke detectors, may be accomplished through their collection at the end of their use.

However, as previously noted, this does not mean that the regulatory authority will forget that these exposures exist. In making future decisions, such as may cause exposure to populations already affected by released materials, the regulatory authority may consider the existence of those sources that have already been released with no regulatory conditions. This could lead to studies, dose assessments, or stakeholder dialogues regarding the decision to be made for such dose-causing future actions.

If concern arises

As a result of the process of regulatory authorisation, some sources and exposure situations will be identified that are not subject to regulatory controls. Particularly with radioactive materials released into the environment (solid, liquid or gaseous), no recovery will be reasonably possible (and may well be virtually physically impossible). In theory, exposures from such materials are allowed, and need not be re-evaluated. This will, in general, be the case.

However, radionuclides that are existing, or have been released in solid, liquid or gaseous form may, in some circumstances, be "rediscovered" and be drawn to the attention of regulatory authorities as a result of some concern arising from an affected stakeholder group. At that point, the material may or may not be traceable to its emission source. This could be the case with radionuclides found in river, lake or ocean sediments, for example. Whether its origin is or is not traceable, these rediscovered situations may re-enter the world of radiation sources and exposure situations and may lead regulatory authorities to characterise and screen such situations, and to follow resulting decisions.

It should also be noted that some areas already affected by authorised releases of radioactive materials may be considered for other human activities which would, or could further, release radioactive materials. In these situations, regulatory authorities may wish to consider all exposures, including those from previous releases, when assessing the authorisation of new human activities.

EXAMPLES OF APPLICATION

In order to more concretely illustrate the process of regulatory authorisation, a few examples will be listed below. These are in part based on work described in *A New Approach to Authorisation in the Field of Radiological Protection: The Road Test Report*, which describes, among other things, the characterisation and screening process in more detail (NEA, 2003h).

There are many ways to divide example cases, however here, to be consistent with the text of this report, with the approach of the ICRP, and with the work documented in "the Road Test Report", examples will be divided into the three following cases:

- Planned, controllable situations, or ongoing situations already under regulatory control.
- Emergency situations.
- *De facto* situations.

As discussed, in all three of these situations regulatory controls may be considered, and the concept of constrained optimisation can be used to determine the type of regulatory controls, if any, that should be applied. Examples of the types of issues and considerations that would be involved in the process of regulatory authorisation in these situations are given here. These are based on the cases that were addressed in the above-mentioned "Road Test Report" (NEA, 2003h).

Planned, controllable situations, or ongoing situations already under regulatory control

- Occupational exposure from ores: This refers to occupational exposures to uranium and thorium in ores exploited for these elements, as well as to phosphate mining where uranium and/or thorium are sometimes found.

- Smoke detectors: This refers to the use of alpha-emitting radionuclides, generally ^{241}Am, in private-use smoke detectors.
- Public exposure to effluents from nuclear facilities: This refers to public exposure that can result from the release of gaseous and liquid effluents from nuclear facilities.
- Public exposure to effluents from a hospital incinerator: This refers to the public exposure that can result from the release of gaseous effluents from a hospital incinerator.
- Occupational and public exposure from a hospital therapy unit: This refers to the occupational and public exposures that can result from the operation of a radiation therapy unit, using a large ^{60}Co source for example.
- Industrial radiography source: This refers to the worker and public exposures that can result from the use and transport of an industrial radiography source, generally ^{192}Ir.
- Occupational exposure from on-site exposure to stored scrap metal at a smelting facility: This refers to the occupational exposure that can occur as a result of the storage of scrap metal contaminated with radioactive scales, as from oil drilling. The possibility that this metal could be melted and result in contaminated metal for re-use is also partially included.
- Waste from a fertiliser plant: This refers to the public exposures that can occur as a result of waste tailings piles from the production of phosphate fertilisers.
- Occupational and public exposure arising from the transport of radioactive material, such as radiopharmaceuticals, or the transport of spent fuel of nuclear power plants.
- Occupational and public exposure is likely to arise from repositories of nuclear waste.
- Occupational and public exposure arising from industrial gauges used for the measurement of liquid or solid levels in a tank, soil density, humidity or paper thickness.
- Occupational or public exposure arising from research activities involving radioactive sources, sealed or unsealed, and electric generators or accelerators.

- Occupational and public exposure arising from real estate activities during measurements of lead in paint using portable X-ray fluorescence devices.
- Occupational or public exposure arising from gamma-ray devices for measurement of snow-level.

Emergency situations

- Post accident recovery: This refers to the public exposures that can occur in the urgent phase of a nuclear or radiological accident. Reference to the transition to the long-term recovery phase (a more controllable existing situation) is also made.
- Radioactive material transport incident.

Existing situations

- Cosmic rays during air flight: This refers to exposure to cosmic rays during commercial air travel (e.g. crew and frequent flyers).
- Cosmic rays at ground level: This refers to public exposure to cosmic rays at the earth's surface.
- Radon in homes: This refers to public exposure to radon in private homes.
- Radon in the workplace: This refers to exposure to radon in the place of work.
- Legacy of past human activities: disused factories of radio-luminescent paintings with radium or thorium.
- Alpha emitters from the discharge of installations of oil and gas industry.

Table 1. Examples of application

Planned, controllable situations, or ongoing situations already under regulatory control	Characterise and screen	Further analysis	Regulatory controls needed	Release from regulatory controls
Occupational exposure from ores	Issue of moderate doses to workers. Can be of importance to stakeholders and regulatory authorities.	Analysis is performed to assess worker exposures, to determine optimum protection, and to assess the appropriate regulatory controls.	Occupational exposure to uranium and thorium ores is regulated. Occupational exposure to thorium-bearing phosphate ores is also, in some cases, radiologically regulated.	
Smoke detectors	Issue of extremely low dose to large population. Of very little stakeholder and regulatory importance.	Analysis is performed to identify an optimum technical construction.	Regulatory controls may be imposed on the technical construction of the smoke detector.	The private use of smoke detectors is generally not subject to regulatory controls.
	Generally very low doses to moderately large populations. This is of high importance to regulators and stakeholders.	Detailed analyses are performed to establish BAT controls on effluent releases, and to assess that public exposures are ALARA.	Regulatory controls (such as measurement and discharge limits) are imposed at the discharge point, and environmental monitoring and modelling are required.	
Public exposure to effluents from hospital incinerator	Generally extremely low doses to relatively small populations. Moderate regulatory importance, very low stakeholder concern.	Public exposures are modelled and assessed.	Regulatory controls (such as measurement and discharge limits) are imposed at the discharge point.	

Source: OECD/NEA.

Table 1. Examples of application (continued)

Planned, controllable situations, or ongoing situations already under regulatory control	Characterise and screen	Further analysis	Regulatory controls needed	Release from regulatory controls
Industrial radiography source	High dose to workers, high concern for regulators, low concern for stakeholders. Normal worker and public exposures are very low. Regulatory need to assure proper source control. Low stakeholder interest.	Worker and public exposures are modelled and assessed.	Regulatory controls (optimised use, worker dosimetry) will be required.	
The need for radiological controls of on-site storage of contaminated scrap metal at scrap-metal smelting facility	Issue of very low worker doses. Some regulatory importance due to possible smelting and re-use. Stakeholder concern due to possible free release of contaminated metals.	Worker dose assessment. Assessment of possible further uses of the recycled scrap metal would also be of interest to the regulatory authority.	The issue of on-site regulatory controls of such slightly contaminated scrap metal (such as piping from an off-shore oil rig) has been addressed differently in different countries. Some countries do not regulate the storage of such materials, while some do require regulatory controls (such as reporting and material tracking).	
Waste from a fertiliser plant	Issue of very low public exposures from process tailing piles. This may be of regulatory importance, but is of low stakeholder interest.	Assessment of public exposures.	This issue has been addressed in different ways in different countries, with some requiring regulatory controls on tailings piles, while others not.	
Occupational and public exposure from the transportation of radioactive materials	Issue of very low public exposure, and fairly low occupational exposure. This is of low stakeholder interest except in case of accidents, but is of regulatory interest.	Assessment of public and occupational exposures, including accident situations.	Transport of radioactive materials is regulated nationally and internationally, according to international standards as well as national approaches.	

Source: OECD/NEA.

Table 1. Examples of application (continued)

Planned, controllable situations, or ongoing situations already under regulatory control	Characterise and screen	Further analysis	Regulatory controls needed	Release from regulatory controls
Occupational and public exposures from radioactive industrial gauges	This issue is of little stakeholder interest, but occupational exposures are of significant regulatory interest.	An analysis for each type of gauge would be performed and submitted by the operator for regulatory review and authorisation.	Regulatory controls would most likely be developed for classes of gauges, with situation-specific controls as needed.	
Occupational and public exposure that could arise from radioactive waste repositories	The siting and operation of waste repositories are generally areas of significant stakeholder interest, and of regulatory interest.	The detailed safety case for the repository would include the assessment of public and worker doses, and exposures over time, and more importantly would discuss the confidence in the safety assessment process.	Waste repositories are regulated in all countries, based on national policies and standards, and on international guidance and guidelines.	
Occupational and public exposure from research activities	This issue is generally of little stakeholder interest, but occupational exposures are of radiological interest.	Research activities are analysed, individually or in groups, perhaps based on source terms, when developing regulatory controls.	Regulatory controls would most likely be developed for classes of research sources, with situation-specific controls as needed.	
Occupational and public exposures arising from the use of radiation-producing instruments: e.g. x-ray fluorescence detectors of lead in paint; gamma-ray detectors for snow level	This issue is generally of little stakeholder interest, but public and occupational exposures are of radiological interest.	An analysis for each type of instrument would be performed and submitted by the operator for regulatory review and authorisation.	Regulatory controls would most likely be developed for classes of instruments, with situation-specific controls as needed.	

Source: OECD/NEA.

Table 1. Examples of application (continued)

Emergency situations	Characterise and screen	Further analysis	Regulatory controls needed	Release from regulatory controls
Post-accident recovery	Issue of public exposures near or above dose limits for normal situations. Importance is very high to both the regulator and to the stakeholders.	Analysis of approaches to reduce the exposure of the affected populations.	This situation was addressed, post-Chernobyl, using a regulatory classification of exposure levels (based on contamination levels), and through a series of other, non-regulatory measures. It is likely that urgent countermeasures (evacuation, sheltering, use of stable iodine, etc.) would be imposed, but that longer-term recovery measures would be developed together by stakeholders and governments.	
Radioactive material transport incident	As with any accident situation, this would be of high interest to both stakeholders and regulators.	Analyses would include approaches to prevent accidents, and to mitigate their possible consequences.	National regulations and international standards exist regarding the transport of radioactive materials.	

Source: OECD/NEA.

Table 1. Examples of application (continued)

Existing situations	Characterise and screen	Further analysis	Regulatory controls needed	Release from regulatory controls
Cosmic rays during air flight	Issue of low dose to large population. Low stakeholder interest, but some regulatory interest.	Assessment of exposures; individually for air crews, generically for frequent flyers.	Different approaches have been taken in different countries. Some regulatory authorities have required records using flight-path based dose assessments, some have not imposed regulatory controls.	
Cosmic rays at ground level	Issue of low dose to the entire world population. Generally of extremely low interest to stakeholders. Regulatory control will not reasonably change exposures.			The decision to impose no regulatory controls can be made without further analysis.
Radon in homes	Issue of moderately high public exposures, relatively high regulatory interest, and low stakeholder interest.	Assessment of individual home radon levels, or of the regional potential for high radon levels.	The regulator generally establishes action levels above which members of the public are advised to take actions to reduce radon concentrations.	Individual homes are generally not subject to regulatory requirements.
Discharge of alpha emitters from the oil and gas industry	Main contributor to European population doses from liquid discharges. So far of no regulatory concern, and of no concern to stakeholders.	Detailed analysis Provided by OSPAR.	So far, no regulatory controls imposed.	

Source: OECD/NEA.

Table 1. Examples of application(continued)

Existing situations	Characterise and screen	Further analysis	Regulatory controls needed	Release from regulatory controls
Radon in the workplace	Issue of low to moderately high worker exposures. Of relatively high importance to the regulator, and, depending upon the level, potentially of high importance to stakeholders.	Assessment of individual workplace radon levels, of the potential of a type of workplace for high radon levels, or of the regional potential for high radon levels.	The regulator generally establishes action levels above which actions to reduce radon concentrations will be required.	
Legacy contamination from past human activities	Issue of generally high interest to both regulatory authorities and stakeholders.	Assessment, with stakeholder participation, of public exposures in various scenarios concerning the cleanup and use of the contaminated lands.	The regulatory authority will generally fix clean-up criteria, in consultation with stakeholders. The subsequent use of remediated lands and facilities will be regulated as appropriate for the residual level of contamination.	
Alpha emitters discharged from the oil and natural gas industry	Generally an issue of low stakeholder interest, and of low regulatory interest.	Analysis would concern approaches to assess exposures to workers and the public, and alternatives to discharge.	This issue is addressed differently in different countries. Regulatory authority interest in this area is generally increasing.	Below some level (activity concentration) defined by regulatory authorities, such discharges will most likely be allowed without regulatory control.

Source: OECD/NEA.

CONCLUSIONS

This report has proposed that the process of regulatory authorisation can be viewed as a single, coherent, conceptually simple and transparent process, addressing all types of radiological protection decision making with the same approach. The value and innovation of this approach stems from several aspects:

- All sources and exposure situations are treated in the same fashion, using optimisation of protection below a pre-determined dose constraint. This results in a system that is simple, consistent and coherent. It avoids the need to explain and rationalise, as previously necessary, why some regulatory "levels" were not to be passed (limits), and others required no actions until they were passed (action levels, intervention levels). This single approach can be more easily and transparently applied, and by addressing all situations equally it portrays a positive, proactive image of the government and regulatory authorities.

- This approach has tried to avoid the use of terminology that has been in the past confusing, such as, "exclusion", "exemption and "clearance", "practice" and "intervention". By concentrating only on the process aspects of radiological protection decision making, this approach emphasises the reasoning behind decision pathways rather than specific and narrowly defined terminology. This again simplifies the approach.

- This process explicitly puts stakeholder involvement into the characterisation and screening, and into optimisation of protection. This promotes the appropriate participation of stakeholders in radiological protection optimisation processes, thus enhancing the possibility of accepted, sustainable decisions.

- The somewhat structured approach to characterisation creates a specific tool for regulatory authorities to classify sources and exposure situations very early in the process, thus giving an early orientation towards a final solution.

- The process specifies that no source or exposure situation is forgotten, even if it is not subject to regulatory controls, thus again fostering a positive, pro-active vision of regulatory controls.

- This approach clearly defines three, easily understandable end points and the various considerations that are used when judging where a particular source or exposure situation should end up.

- Based on the endpoint, and on the judged level of costs and benefits of the source or exposure situation, regulatory controls are established at the level appropriate for the situation being considered.

The CRPPH feels that the use of this single, all-encompassing approach will facilitate the development of coherent regulatory decisions in a transparent fashion.

Appendix 1

STAKEHOLDER INVOLVEMENT

In the process of regulatory authorisation described in the report, at several stages the necessity of the stakeholder involvement is mentioned.

Before addressing specifically this problem, it seems to be worthwhile to revisit recent evolution of the approach of public participation in environmental decision making.

Until the 1950s, the managerial model largely dominated relationships between governmental bodies and the public (Beierle, 2002). According to this view, government administrators, and experts belonging to governmental agencies, were committed to identify and pursue the common good. In addition, they were entrusted to deliberate possible choices to ensure the public good, and their policies were relied upon to produce the greatest good for the greatest number of people for the longest time. A sign that this model began to be challenged in middle of the 20th century is the Administrative Procedure Act in the U.S.A. in 1946 and similar legislations adopted with some delay, even many decades, in other countries and now present in almost every legislation of developed countries in the so called Environmental Impact Assessment (EIA). Legislators regulated the process that governmental bodies must follow for their rulemaking. They must provide public notice of the rules they are proposing, information about the basis on which the rules are built, opportunity for public comments and judicial review of the rulemaking process. Still today, this legislation is the cornerstone of public participation in administrative governance.

As the industrialisation process increased, governments were faced with ever-more complex decisions on matters related to environmental policy (resource planning and management, industrial facilities siting, hazardous waste management, remedial actions on contaminated sites), and the managerial model was more and more challenged. Scepticism about the possibility that public managers and experts could adequately identify a public interest

increased, and the result was that the public lost, for several reasons, the hope of finding, in public technical institutions, both expertise and accountability.

In the 1970s, the concept of pluralism began to replace managerialism as the dominant paradigm of administrative decision making (Reich, 1985). According to the pluralist view, governmental administrators and regulators or politicians were not asked to have the impossible role of objective decision-makers in the public interest, but more to be arbiters (judges as third parties) among different possible interests within the society, for instance among operators on one side and the public or workers on the other side. It is recognised that an everlasting public good has not an objective meaning, but rather that a contingent public good has to be debated and arrived at by negotiation among different interested parties, being regulators and politicians, mediators and judges (Williams, 1995). As a reflection of this attitude in the 70s and 80s in many countries, to stress the role as third party of regulator bodies, the structure of public industrial (and nuclear) agencies was revised, with a clear separation of agencies having regulatory responsibilities and agencies aiming at promoting industrial development and applications. The separation of regulator and operator functions has since that time been a necessary element, even if not sufficient, to increase trust in institutions in the decision-making process.

In the 1990s the pluralist model came under pressure from the efforts of regulators to overcome their role of arbiters, from the request of an even more intense participatory perspective with the aim to have mutually acceptable outcomes rather than unsatisfying compromises with "winners" and "losers," and from a desire to have long term stable decisions rather than short-term fixes dictated by the contingent strength of parties involved. This "democratic" or "pragmatistic" model "stresses the importance of the act of participation, not only in influencing decisions but also in strengthening civic capacity and social capital" (Beierle, 2002), "emphasizes interaction among often adversarial interests, but that interaction is viewed less as competitive negotiation than as a way to identify the common good and subsequently act on shared communal goals" (Dryzek, 1997). In the "popular" perspective, the act of participation "makes people more aware of the linkages between public and private interests, helps them develop a sense of justice, and is a critical part of the process of developing a sense of community" (Laird, 1993).

Stakeholder involvement is the effort to look at public participation in environmental decision-framing and decision-aiding processes along the lines of the "popular-pragmatistic" model.

The primary aim of radiological protection is to provide an appropriate standard of protection for man and environment without unduly limiting the

beneficial practices giving rise to radiation exposure. The optimisation principle is one of the cornerstones of radiological protection: being constrained by restrictions on the doses to individuals or the risk to individuals for potential exposures, any exposure, or the likelihood of incurring exposure, should be *as low as reasonably achievable* (ALARA), economic and social factors being taken into account. This principle was fixed as such in the ICRP Recommendations of 1977 (ICRP, 1997), and iterated in the present (1990 Recommendations) (ICRP, 1991) version that is the base of most of the national legislations in radioprotection. The implementation of the principle was thought to be possible through a semi-quantitative cost-benefit analysis minimising the function "net cost" in comparing different possible options with constraints on individual doses (constrained optimisation). While this approach has been demonstrated to be viable in many situations dealing with strictly operative problems (ICRP, 1983, 1989) it has also shown its limited value in "complex" decisions as the siting of a hazardous facility, the choice of levels for the release or radioactive materials, or the selection of residual contamination levels for unrestricted release (clean-up levels) of a site where previously a hazardous facility was located. A "complex" situation is characterised by multiple legitimate views and ethical principles concerning fairness of the outcome of decisions. The quantitative cost-benefit analysis approach is the "son" of the "managerial-technocratic" model, being the analysis done essentially by the experts of regulatory bodies. The involvement of other parties was considered to be limited to the choice of some numerical values of equation parameters, providing input to the monetary value to reduce or to monitor the emissions, or to identify "objective" health or other components of the detriment.

The current result of the evolution of the radiological protection system, towards increasing public participation in environmental and health related decision-making, can be fully appreciated in the draft of the new ICRP Recommendations RP05 (ICRP, 2004). These are foreseen to be approved, after 5 years of debate – which is also a sign of the times – in their final form during the next year or so. The nature of these draft recommendations has been dictated by the practical experience of about 30 years, gained by finding solutions to many problems in many countries relating to radiological and non-radiological protection issues.

Although the text of the current draft ICRP recommendations will most likely change before it is finally approved, the importance afforded to stakeholder involvement can be seen in the current executive summary where three paragraphs are dedicated to the optimisation of protection, and one of these three is devoted to the participation of stakeholders.

"(S11) The involvement of stakeholders, a term which has been used by the Commission in Publication 82 (ICRP 1999) *to mean those parties who have interests in and concern about a situation, is an important input to optimisation. While the extent of the stakeholder involvement will vary from one situation to another in the decision-making process, it is a proven means to achieve the incorporation of values into decisions, the improvement of the substantive quality of decisions, the resolution of conflicts among competing interests, the building of trust in institutions as well as the education and information the workers and the public. Furthermore, involving all parties affected by the decision reinforces the safety culture and introduces the necessary flexibility in the management of the radiological risk that is needed to achieve more effective and sustainable decisions".* (ICRP, 2004)

Stakeholder involvement is a key concept in modern approaches to risk governance, and has received considerable attention within the OECD (OECD, 2001a, 2001b, 2003, 2004). It is worthwhile to mention also the role played by NEA Committees CRPPH (Committee on Radiological Protection and Public Health) and RWMC (Radioactive Waste Management Committee), which have, over the past 10 years, reflected on stakeholder participation respectively through the three Villigen Workshops (NEA, 1998, 2001b, 2004a), and through the Forum on Stakeholder Confidence (NEA, 2001c, 2003j, 2004d, 2004e).

The list of benefits gained from the involvement of stakeholders, derived from the work done within the CRPPH, can be summarised as follows:

- Responds to shifts in societal attitudes to science, industry and government.
- Offers possibility of resolving tensions between economic and social concerns.
- Helps to prevent disputes and conflicts where it is deployed ex-ante.
- Helps to resolve disputes and conflicts where it is deployed ex-post.
- Increases the substantive quality and sustainability of decisions.
- Builds trust in institutions.
- Educates and informs the public.

The involvement of stakeholders in the process of regulatory authorisation, as described in this report, is appropriate at several stages.

Stakeholder involvement will be important in the characterisation and screening stage. Firstly, stakeholders are important for the identification of those source and exposure characteristics for which decisions can best be arrived at, or can only be arrived at, through involvement of all those parties with valid interests. Stakeholders will be interested in defining the cases for their involvement. Most situations do not need extensive consultation and participation (see Appendix B), in many cases the characteristics of the source and exposure are such that no concern at all arises, or concerns involve only a restricted number of people in the affected workplace. In such cases, the long standing procedures are still valid.

Stakeholder involvement will also be important in the definition of the methodology of screening, specifically in defining a threshold in the score of the characterisation procedure that will trigger a detailed analysis and optimisation and, even more important, at which threshold of the score the procedure should best foresee stakeholder participation.

The optimisation process in complex situations is, however, the main area where stakeholder involvement will be important. While in the previous steps stakeholders are involved at national level (industry organisations, consumer associations, NGOs), the optimisation process must involve the stakeholders affected by the specific situation being considered.

Different stakeholders have different perspectives, perceptions, beliefs, interests and values. Clear aims and objectives will aid in planning a dialogue process and, as well, criteria must be developed for evaluating the process with the people who will be participating. Although it is clear that the decider is responsible for making the final decision, arriving at this stage will require the clear definition of roles between regulators and stakeholders, and these should be well established from the beginning of all the phases of the decision-framing and decision-making processes.

Since trust is hard to gain but easy to lose, building and maintaining trust must be considered of primary importance by regulators and institutions. This requires sustained commitment of substantial resources, being a slow and incremental process. Tools and techniques are available to facilitate this task. These include such things as:

- Involving in the decision-aiding process those who are affected, so that they gain more control.

- Adopting a stepwise decision-making approach, dividing analysis of major decisions into steps, providing feedback after each step, and allowing legal recourse by the affected people if commitments are not kept.

There can be an inherent conflict between the requirements of fair representation, i.e. equal opportunity to participate and influence both processes and outcomes for anyone who feels potentially affected, and competent participation, i.e. construction of the most valid, from both social and technical point of views, understandings and agreements possible. A mutual learning process must be foreseen that is inherent to the trust and consensus building processes.

The optimisation process, taking into account the views of different stakeholders, is considered sometimes a time-consuming process leading to solutions technically not optimised. Practical experience has shown that stakeholder involvement is often the essential key to obtaining societal (and hence, political) acceptance of the results of decisions.

It should be noted, however, that in some cases stakeholders will not wish to accept the source or exposure situation, and that for them the "optimised solution" is for the exposure-causing situation should not be authorised. Under these circumstances, governments will have to decide whether it is best to go forward or not.

Having found the "best solution under the prevailing circumstances" and then having authorised an exposure, the involvement of local stakeholders must be seen has a continuing process with the aim, for the regulatory authority, of demonstrating to all involved parties the compliance of the authorised exposure with the objectives of the process, and to build trust in institutions. In this context, sociologists see public participation in risk and environmental related problems as a valid tool and an opportunity to improve relationships among people and partnerships in the local communities.

Appendix 2

CHARACTERISATION AND SCREENING

The main task in the process of *regulatory authorisation* of a source or an exposure situation is the assessment of the benefits and hazards, and the consequent choice of a graded approach to hazard reduction and control.

Starting the Regulatory Authorisation Process

The process starts with the 'application'. In the context of this Appendix, application means a formal document that asks the Regulatory Authority to express a judgement about a source or exposure situation regarding its compatibility with radiological protection regulations. The applicant can be a user or a legal representative asking for a licensed activity in normal situations or other governmental bodies. The applicant could even be the same regulatory authority whishing to implement and/or regulate protective actions in emergency or *de facto* situations, including activity of emergency or remedial actions operators, or to reconsider situations that in the meantime have provoked concern in stakeholders.

The first step is the determination of the characteristics of the source of radiation or the exposure situation, and of the resulting exposure. Within this procedure, the regulatory authority has to check the compliance of the source and exposure under examination with the principle of justification.

Justification

As established by this principle, no *operation*[1] involving exposures to radiation should be authorised (with the meaning given to authorisation in this report) unless it produces sufficient benefit to the exposed individuals or to society to offset the radiation detriment it might cause. This means that the

1. *operations* in the context of this Appendix means human *activities connected with* the practice, intervention or *de facto* situation for which the application for authorisation is examined.

operation must be justified, taking into account social, economic and other relevant factors (IAEA 1996 (BSS) – par 2.20).

As a general rule, the judgement as to whether an *operation*, involving the use of ionising radiation is justified is established by the regulatory authority in its broad meaning, e.g. legislative authority through laws, sometimes as result of popular consultative referendum, governmental authority, governmental agencies, health or radiological protection authority through regulations. In some countries, governments have established lists of sources and exposure situations for which specific judgements have been made regarding whether or not they are justified or unjustified. In the case that the practices, accident situations or exposures resulting from de facto (pre-existing) environmental conditions that are under consideration can be assimilated to *operations* that have been previously already examined, compliance is adequately demonstrated if these operations are not included on such a list of unjustified sources and exposures.

For instance, according to the Basic Safety Standards (BSS) (IAEA, 1996 – # 2.22), practices, apart from medical applications, that would result in an increase, by deliberate addition of radioactive substances or by activation, of the activity contained in food, beverages, cosmetics or any other commodity or product intended for ingestion, inhalation or percutaneous intake by, or application to, a human being or involving the frivolous use of radiation or radioactive substances in commodities or products such as toys and personal jewellery or adornments are deemed to be not justified.

If the application foresees operations included in the list, than it must be prohibited. Here, the practice or action must not be allowed and all efforts must be made to mitigate or interdict the de facto exposure, according the case considered.

If the application foresees operations not included in the list, the examination will proceed to the following step. If similar types of operations have not yet been the object of a justification assessment, this must be done in the due course of actions when the relevant information about the benefits derived from the operations can be fully evaluated and the judgement if they are sufficient to offset the radiation detriment can be made. For example, new medical or industrial practices must demonstrate results with better or at least equal performances compared with existing technologies, and should have a comparable detriment or lower detriment.

While the regulatory authority responsible for the justification assessment can be at different levels of governmental institutions, depending on the

complexity of the problem, the assessment regarding radiation protection aspects is generally the responsibility of the health or/and radioprotection authority, and must be part of the justification assessment procedure.

The justification of protective actions in case of emergency and defacto exposures can be based, at least partly, on dose constraints established on an international or regional basis. Even if dose constraints are connected with the optimisation process it is clear that they have an impact even on the process of justification. For these situations, and particularly for emergency operations, a dose constraint must be established above which, except cases for saving life or preventing serious injury or preventing catastrophic circumstances that must be treated separately, the exposure is not justified. Below these constraints, regulatory authorities may establish generic "action levels" on an international or regional basis and this strictly belongs to the optimisation process.

If at any moment of the regulatory authorisation procedure, a new or an old practice or a protective action for emergency and existing situations is declared justified or unjustified, an administrative document must be produced, and the lists of justified or unjustified sources and exposure situations must be changed accordingly. The justification assessment (both positive and negative), being dependent on the available technology and on the detriment evaluation, should be periodically revisited.

Characterisation

Given the ubiquitous nature of ionising radiation, a system of radiological protection as proposed in this report, in which all the sources that raise concern are considered, should include an approach to quickly and simply screen and characterise situations. Such a tool is essential to ease regulatory burdens.

Following the report of the CRPPH Expert Group on the Evolution of the System of the Radiological Protection (EGRP) (NEA, 2002), in which the idea of a broad and large concept of authorisation process was for the first time elaborated, NEA contracted two consultants – Richard Osborne and Frank Turvey – to critically test key ideas of the EGRP report. In the framework of this analysis, they developed (NEA, 2003h) an example of such a tool. This uses sets of characteristics for sources and for exposures, and provides suggested criteria for screening. These can be used by regulatory authorities to broadly characterise the complexity of a given situation. This will assist regulatory authorities when deciding on whether a particular source or exposure situation can be authorised, with or without radiological controls, and when deciding on the level of stakeholder involvement that would be useful in the decision-making process.

As mentioned in the introduction, this report has been inspired by the seminal work of Osborne and Turvey on the application of the process of regulatory authorisation. In this Appendix, their work on the characterisation is revisited in the light of the work done by the EGRA and their text reported and quoted to illustrate, as necessary, concepts, applications and the value of the method. In this way it is hoped that this report can be read essentially as a stand-alone document and the reader can have a clear idea of the full regulatory authorisation process, as seen by EGRA, without referring to other bibliographic sources not always easy to find.

A clarification on categorisation and characterisation could be useful. Category is called a set in which each element has a common quality that identifies the category, whereas the character is the sum of characteristics that identifies an entity among its similar elements. Each characteristic can then be classified in several categories. Characterisation of an entity (in our case a source and an exposure) is then the act of determining all, or at least as many as possible, of the characteristics that attribute a well distinct character to the entity, and assigning for each characteristics a definite category. Osborne and Turvey note that there is "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." In the process of characterisation, what Osborne and Turvey and with them the EGRA have tried to seek is a way of identifying the important characteristics of a source or exposure situation, and to describe them collectively in categories. This aims at quantifying a graded value for each category using numbers in a constrained scale within each characteristic. Certainly, a well tuned method of characterisation would require much more work and expertise, but the method proposed could be a starting point for an international reflection on that matter. A common, agreed upon approach would be certainly very useful.

The essential characteristics of sources and exposures, namely those that are likely to give rise to public concern and that are important to safety, selected by Osborne and Turvey, are listed in Tables 1 and 2. These lists are not intended to be definitive and exhaustive but, containing what is viewed to be most of the key characteristics, these lists have been used to test the concepts of EGRP-EGRA.

In Table 1, the identification of a source character is made through characteristics that describe: radiotoxicity, security, size/activity, origin, application, containment, dose rate, waste (meaning the method foreseen for the managing any waste – disposal, storage, other – generated by the process under consideration), and physical state.

Table 1. Source characteristics for use in characterisation process

200

Characteristics	Categories			
Radiotoxicity*	Low = 1	High = 4		
Security	Fissile = 4	Other = 1		
Size*	< 1 kBq = 0	>1PBq = 4	Other = 1	
Origin	Natural = 0	Artificial = 4	Other = 1	
Application	Medical = 0	Industrial = 3	Research = 1	Other = 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	
Max. score: 31	**Source character score (% max.)=**		**Total score:**	
Max. score: 38	**Source character score (% max.)=**		**Total score:**	

* Relevant for stakeholders, to be double counted in case of "grey" combined character score (35-65%).

Source: OECD/NEA.

In these tables, nine and eight characteristics respectively are identified for source and exposure. Other choices could have been made, but Osborne and Turvey suggest that "the inclusion of further characteristics tend to lessen the effect of the existing characteristics on the final outcome and also reduce the overall simplicity of the process".

The categories are graded in importance within each characteristic on a scale of 0 to 5 with the total being 5. Within a characteristic there are at least two categories and at most four.

Table 2. Exposure characteristics for use in characterisation process

200

Characteristics	Categories			
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	
Max. score: 31	**Source character score (% max.)=**		**Total score:**	
Max. score: 46	**Source character score (% max.)=**		**Total score:**	

* Relevant for stakeholders, to be double counted in case of "grey" combined character score (35-65%).

Source: OECD/NEA.

The system caters to the possibility that some characteristics in the tables may not be relevant. If this is so, they may be ignored, but the maximum possible score would be reduced. Under such circumstances, the method would still be applicable, however, because what matters to establish the character of a source or exposure is the score expressed as a percentage of the maximum possible score.

Having allocated values to each source and exposure characteristic, and determined the total score (the sum of the values of each chosen category for each characteristic) for the source or the exposure situation, the score may now be expressed as a percentage of the maximum possible score. In such way the source and exposure character scores are derived. These may then be averaged to get a combined value for the examined source and exposure. This numerical description of the character of a source and exposure can be a regulatory tool, based on a multi-parameter approach. These scores can contribute to the screening of the application for authorisation, and for the decision on whether the situation under consideration should clearly not be subject to regulatory

controls, or whether a detailed analysis and optimisation (see Figure 1 in the main text) is needed, according to the scheme proposed in Table 3.

Table 3. Screening of sources and exposure situations according to the total score

Combined score	Screening decision
< 35%	Source and exposure not subject to regulatory controls
35-65%	Detailed analysis and optimisation – grey score
> 65%	Detailed analysis and optimisation + stakeholder involvement

Source: OECD/NEA.

Screening

For screening, the suggestion given by Osborne and Turvey is that if the combined source and exposure character exceeds 65%, the application should go into the detailed analysis and optimisation procedure. This would mean that it is submitted to the full authorising process by the regulatory authority and will probably end up in the class of sources and exposures situations that will be subject to regulatory controls. Moreover, the combined source and exposure character high score reveals a 'complex' situation for which the involvement of stakeholders must be foreseen.

On the contrary, Osborne and Turvey suggest that if the combined source and exposure character is below 35%, the application regards a situation that can be authorised without any further consideration about possible protective actions, and assigned directly to the class that is not subject to regulatory controls. Although again here, some consultation with stakeholders may be warranted.

A combined character score between 35% and 65% ("grey" score) requires a further detailed analysis and optimisation before the regulatory authority could judge whether the application can be assigned to the class that is subject to regulatory controls or to the other that is not subject to regulatory controls. The result of characterisation in these cases is somewhat ambiguous. Regulatory authorities should develop internal decision-making policy and processes for these situations, in order to decide whether to further proceed with detailed analysis, and to assess the degree of stakeholder involvement appropriate for the situation under consideration.

For situations that are near the 35% and 65% borders, the NEA suggests (NEA, 2003h) that the regulatory authority could gain further insight into which path to follow if more weight is given to some source and exposure characteristics that are of greater concern to stakeholders. This is done assigning a double counting to those characteristics that are indicated by asterisk in each of the tables. Situations near the borders can be re-valuated in this way. The double counting will most likely push the score further from, or nearer to, the borders and will help the regulatory authority in screening. From the experience of studied cases, authors (NEA, 2003h) report that the amount of movement is usually slight and gives merely a hint to the regulator of the direction of the stakeholder thinking.

The characterisation gives a rather simple and automatic tool to the regulatory authority to assist in choosing which path to follow in the authorisation process. Being based on multi-attributes, this has the advantage of motivating the selection on a variety of considerations, instead of focalising on a single parameter, such as activity or activity concentration of the source. The more explicit acknowledgement of this multi-attribute approach, which is already implicitly or explicitly used by regulatory authorities, would significantly assist in building acceptance of regulatory decisions regarding sources or exposure situations.

Amenable to control

In addition to having a low total character score in the proposed multi-parameter characterisation, a source or exposure can be classified as "authorised", or better, "accepted as it is", and excused from regulatory controls according to "controllability" criteria.

An important consideration that is specified in this process of characterisation, but that is of a rather more fundamental nature than the other considerations, is the decision as to whether a source or exposure situation is "amenable to control". If this is not the case, justified sources or exposure situations will generally be directly authorised without radiological controls. However, this decision still involves a specific amount of judgement, in that, physically, one could always imagine a way to implement dose-reducing controls in almost any situation. For example, it would be "physically possible" to have people live beneath lead shields in order to reduce exposures from cosmic rays at the earth's surface, but this would clearly be ridiculous. On the other hand, judging whether to have "frequent flyers" at least informed that they may be subject to above-average exposures is a more complicated decision.

In the BSS (IAEA, 1996 – par 1.4), as examples of exposures that are unamenable to control, the cases of ^{40}K in the body, cosmic radiation at the surface of the earth and unmodified natural radioactivity concentration in most raw materials are reported.

In their report, Osborne and Turvey do not consider controllability as a characteristic of a source or exposure, even if they discuss the case and consider that this aspect is covered by the characteristic's "origin" for source and "type" for exposure. It seems better to have a separate judgement for the controllability as is the case, for example, for the justification.

The "controllability" criteria, incorporating the value judgement of the regulatory authority, is then added in parallel to the characterisation procedure as a screening tool in the regulatory authorisation process.

Test cases

In their report, Osborne and Turvey tested characterisation and screening criteria in a certain number of test cases, belonging to situations which, in the current jargon of radioprotection, could be related to exclusion, exemption, regulatory control, clearance mechanisms, and to practices or interventions. The test cases considered are listed in Table 4 in order of the score for the combined source and exposure character. The higher the score the stronger is the signal to the regulator that stakeholder input should be considered. The lower the score, the lower should be the need for regulatory actions and control.

Table 4. Summary of the test cases considered

200

Test case	Combined character score	Stakeholder adjustment
1. Radioactive releases from nuclear facilities	82	↑
2. Radioactive releases from a hospital incinerator	65	↑
3. Public exposure on a contaminated site	55	-
4. International trade in a commodity, artificial activity	52	↑
5. Industrial radiography source	48	-
6. Radon in home, high concentration	46	↓
7. Exposure to natural radioactivity in ores in the workplace	45	-
8. Waste from a phosphate fertiliser plant	45	↑
9. Application of depleted uranium as medical shielding	44	↑
10. Radioisotope therapy unit in a hospital	42	↑
11. Radon in home, low concentration	41	↓
12. Radon in workplace, high concentration	40	↓
13. Storage of contaminated scrap metal, workplace exposure	40	↑
14. International trade in a commodity, natural activity	39	↑
15. Return to contaminated site	37	↓
16. Radon in workplace, low concentration	34	↓
17. Cosmic ray exposures of pilots when flying	33	↑
18. Retailing of ionising chamber smoke detectors	31	↑
19. Cosmic ray exposure of public at ground level	29	↓

Source: OECD/NEA.

The two criterion levels, at 65% and 35%, are shown by the shaded rows. The right-hand column shows the effect of double counting the characteristics that are judged to be of most concern to stakeholders, with the arrow direction indicating an increase or decrease of the score.

To help the reader in better understanding the methodology proposed by Osborne and Turvey, in Table 5 the summary of the score assignments for each source and exposure characteristics considered is reported for the different test cases studied. Trying to follow the characterisation procedure for a particular case is the best way to become familiar with, and to practice the method and to discover its advantages and disadvantages. A much more detailed discussion can be found in the original report (NEA, 2003h).

It is clear that the characteristics chosen, the categories, the numerical values assigned, and the selection of numerical thresholds for screening are subjective. The system must be tuned and debated at the national and international level. The characterisation, however, seems to be a valid tool to help regulators in deciding a graded approach to control the risk derived by the use of ionising radiation and in selecting “complex” situations in which the involvement of stakeholders can be beneficial to frame decision-aiding and decision-making processes.

Table 5. Summary of scores for characteristics of the sources and exposures considered

(adapted from NEA, 2003h)

Source characteristics	Category	1 Release from nuclear reactor		2 Release from hospital incinerator		3 Public exposure in contaminated site		4 International trade in commodity (artificial activity)		5 Industrial radiography source		6 Radon in home (high concentration)		7 Natural radioactivity in ores; occupational		8 Fertiliser plant waste storate		9 Depleted uranium hospital shield	
		M.	S.	M.	S.	M.	S.	M.	S.	M.	S.	M.	S.	M.	S.	M.	S.	M.	S.
Source																			
***Radiotoxicity**	Low **1**; High **4**	4	4	4	4	4	1	4	4	4	4	4	4	4	4	4	4	4	1
***Security**	Fissile **4**; Other **1**	4	4	4	1	4	1	-	-	4	1	4	1	4	1	4	1	4	1
***Size**	< 1 kBq **0**; > 1 PBq **4**; Other **1**	4	4	4	1	4	1	4	1	4	1	4	1	4	1	4	1	4	1
***Origin**	Natural **0**; Artificial **4**; Other **1**	4	4	4	4	4	4	4	4	4	4	4	0	4	0	4	0	4	0
***Application**	Medical **0**; Industrial **3**; Research **1**	3	3	3	0	-	-	3	1	3	3	-	-	3	3	3	3	3	0
***Containment**	Sealed **1**; Unsealed **3**; Machine **1**	3	1	3	3	3	3	3	3	3	1	3	3	3	3	3	3	3	1
***Dose rate at 10 cm**	< 1 μSv/h **0**; > 1 mSv/h **4**; Other **1**	2	2	2	2	-	-	2	2	2	0	4	1	4	1	4	1	4	0
***Waste**	Dispersed **2**; Stored **1**; Disposed **2**; Other **0**	3	3	3	3	3	0	3	0	3	0	-	-	2	2	2	2	2	2
***Physical state**	Gaseous **3**; Liquid **2**; Solid **0**	31	29	31	19	26	11	27	15	31	18	3	3	3	0	3	0	3	0
Source character; Score			94		61		42		56		58	26	13	31	15	31	15	31	6
Source character (% of maximum)		10	10	10	7	8	2	10	7	10	5		50		48		48		19
Stakeholder source characteristics only items; Score			100		70		25		70		50	8	5	10	7	10	7	10	4
Stakeholder source characteristics only (% of maximum)			95		63		38		59		56		63		70		70		40
Source character with stakeholder charactereistics double counted %			94		61		42		56		58		53		54		54		24
Exposition																			
***Choice**	Voluntary **0**; Imposed **4**; Other **1**	4	4	4	4	4	4	4	4	4	1	4	0	4	1	4	1	4	4
***Origin**	External **1**; Internal **4**	4	4	4	4	4	4	4	4	4	1	4	4	4	4	4	1	4	4
***Type**	Normal **1**; Potential **4**	4	4	4	4	4	1	4	1	4	4	4	1	4	1	4	4	4	1
***Benefit/Detriment**	Poor **4**; Reasonable **1**; Good **0**	4	1	4	1	4	4	4	1	4	0	4	0	4	1	4	0	4	4
***Duration**	Chronic **4**; Other **1**	4	1	4	4	4	4	4	1	4	1	4	4	4	4	4	4	4	4
***Risk**	Low **0**; Medium **1**; High **4**	4	1	4	0	4	0	4	0	4	4	4	1	4	0	4	1	4	0
***Receptor**	Worker **1**; Patient **1**; Public **3**; Other **0**	3	3	3	3	3	3	3	3	3	1	3	3	3	1	3	1	3	3
***Number Exposed**	> 10^6 **4**; < 10 **0**; Other **1**	4	4	4	1	4	1	4	1	4	0	4	0	3	1	3	1	4	1
Exposure character; Score		31	22	31	21	31	21	31	15	31	12	31	13	31	13	31	13	31	21
Exposure character (% of maximum)			71		68		68		48		39		42		42		42		68
Stakeholder exposure characteristics only items; Score		15	12	15	12	15	12	15	9	15	6	15	4	15	4	15	6	15	12
Stakeholder exposure characteristics only (% of maximum)			80		80		80		60		40		27		27		40		80
Exposure character with stakeholder characteristics double counted %			74		72		72		52		39		37		37		41		72
Total																			
Combined character score: average (source + exposure) %			**82**		**65**		**55.0**		**52**		**48**		**46**		**45**		**45**		**44**
Average stakeholder only characteristics %			**90**		**75**		**52.5**		**65**		**45**		**45**		**48**		**55**		**60**
Combined character score with stakeholder characteristics double counted %			**85**		**68**		**55.0**		**56**		**48**		**45**		**45**		**47**		**48**

* *Indicates double counted to account for stakeholder influence* - *Indicates non applicable* *M indicates maximum score possible. S indicates score assigned.*

Table 5. Summary of scores for characteristics of the sources and exposures considered *(continued)*

(adapted from NEA, 2003h)

Source characteristics	Category	10 Radioisotope therapy unit in hospital		11 Radon in home (low concentration)		12 Radon in workplace (high concentration)		13 Storage scrap metal		14 International trade in commodity (national activity)		15 Return to contaminated site		16 Radon in workplace (low concentration)		17 Cosmic rays; pilots flying		18 Ionising chamber smoke detector retail		19 Cosmic rays; public ground level	
		M.	S.	M.	S.	M.	S.	M.	S.	M.	S.	M.	S.	M.	S.	M.	S.	M.	S.	M.	S.
Source																					
***Radiotoxicity**	Low **1**; High **4**	4	4	4	4	4	4	4	4	4	1	4	1	4	4	-	-	4	1	-	-
***Security**	Fissile **4**; Other **1**	4	1	4	1	4	1	4	1	-	-	4	1	4	1	4	1	4	1	4	1
***Size**	< 1 kBq **0** ; > 1 PBq **4** ; Other **1**	4	1	4	0	4	1	4	1	4	1	4	1	4	0	-	-	4	1	-	-
***Origin**	Natural **0** Artificial **4**; Other **1**	4	4	4	0	4	0	4	0	4	0	4	4	4	0	4	0	4	4	4	0
***Application**	Medical **0**; Industrial **3**; Research **1**	3	0	-	-	-	-	3	3	3	1	-	-	-	-	3	3	3	1	3	1
***Containment**	Sealed **1**; Unsealed **3**; Machine **1**	3	1	3	3	3	3	3	3	3	3	3	3	3	3	-	-	3	1	-	-
***Dose rate at 10 cm**	< 1 μSv/h **0**; > 1 mSvh **4**; Other **1**	4	4	4	0	4	1	4	1	4	0	4	1	4	0	4	1	4	0	4	0
***Waste**	Dispersed **2**; Stored **1**; Disposed **2**; Other **0**	2	2	-	-	-	-	2	1	2	2	-	-	-	-	-	-	2	2	-	-
***Physical state**	Gaseous **3**; Liquid **2**; Solid **0**	3	0	3	3	3	3	3	0	3	0	3	0	3	3	-	-	3	0	-	-
Source character; Score		31	17	26	11	26	13	31	14	27	8	26	11	26	11	15	5	31	11	15	2
Source character (% of maximum)			55		42		50		45		30		42		42		33		35		13
Stakeholder source characteristics only items; Score		10	7	8	4	8	5	10	6	10	4	8	2	8	4	-	-	10	4	-	-
Stakeholder source characteristics only (% of maximum)			70		50		63		60		40		25		50		-		40		-
Source character with stakeholder characterestics double counted %			59		44		53		49		32		38		44		33		37		13
Exposition																					
***Choice**	Voluntary **0**; Imposed **4**; Other **1**	4	0	4	0	4	0	4	1	4	4	4	0	4	0	4	1	4	1	4	1
***Origin**	External **1**; Internal **4**	4	1	4	4	4	4	4	4	4	4	4	1	4	4	4	1	4	1	4	1
***Type**	Normal **1**; Potential **4**	4	4	4	1	4	1	4	4	4	1	4	1	4	1	4	4	4	1	4	1
***Benefit/Detriment**	Poor **4**; Reasonable **1**; Good **0**	4	0	4	0	4	0	4	0	4	1	4	0	4	0	4	0	4	0	4	0
***Duration**	Chronic **4**; Other **1**	4	1	4	4	4	1	4	1	4	1	4	4	4	1	4	1	4	1	4	4
***Risk**	Low **0**; Medium **1**; High **4**	4	1	4	0	4	1	4	0	4	0	4	0	4	0	4	1	4	0	4	0
***Receptor**	Worker **1**; Patient **1**; Public **3**; Other **0**	3	1	3	3	3	1	3	1	3	3	3	3	3	1	3	1	3	3	3	3
***Number Exposed**	> 10^6 **4**; < 10 **0**; Other **1**	4	1	4	0	4	1	4	0	4	1	4	1	4	1	4	1	4	1	4	4
Exposure character; Score		31	9	31	12	31	9	31	11	31	15	31	10	31	8	31	10	31	8	31	14
Exposure character (% of maximum)			29		39		29		35		48		32		26		32		26		45
Stakeholder exposure characteristics only items; Score		15	5	15	4	15	2	15	6	15	9	15	4	15	2	15	6	15	5	15	5
Stakeholder exposure characteristics only (% of maximum)			33		27		13		40		60		27		13		40		33		33
Exposure character with stakeholder characteristics double counted %			30		35		24		37		52		30		22		35		28		41
Total																					
Combined character score: average (source + exposure) %			**42**		**41**		**40**		**40**		**39**		**37**		**34**		**33**		**31**		**29**
Average stakeholder only characteristics %			**52**		**38**		**38**		**50**		**50**		**26**		**32**		**20**		**37**		**17**
Combined character score with stakeholder characteristics double counted %			**44**		**39**		**38**		**43**		**42**		**34**		**33**		**34**		**32**		**27**

* *Indicates double counted to account for stakeholder influence* - *Indicates non applicable* *M indicates maximum score possible. S indicates score assigned.*

Appendix 3

DISCUSSION OF EXCLUSION, EXEMPTION AND CLEARANCE

As stated earlier in this report, the terms exclusion, exemption and clearance, are not used here. These terms have been the source of much discussion and, in the view of many, a source of confusion in the radiological protection community, and also among the broader audience of regulatory authorities and the public.

However, while these terms are not used in this report, the concepts that they embody are integral to the process of regulatory authorisation. Figures 1, 2 and 3 describe the broad aspects of the process, and show where the concepts of exclusion, exemption and clearance are included.

Exclusion

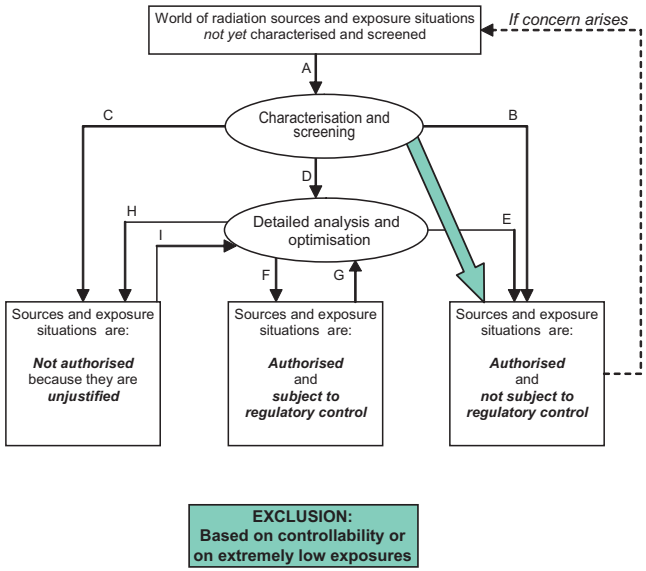
This concept has been described in various recommendations, standards and directives by the ICRP, the IAEA and the European Commission. It essentially has been used to describe sources and exposure situations that are not considered to be within the scope of recommendations, standards or directives. Principally, two rationales have been put forward as to why sources and exposure situations can legitimately be excluded. The first suggests that sources and exposure situations can be excluded based on their unamenability to control. That is, if no form of regulatory control could reasonably reduce exposures, then there is no point in considering such sources or exposure situations. The second argues that sources or exposure situations can be excluded if they cause extremely little exposure such that regulatory control would afford little reduction in risk.

Whatever the rationale, one of the key objectives of exclusion is to avoid the unreasonable expenditure of regulatory resources that would yield little exposure reduction. To this end, the choice to exclude is made early in the process of regulatory authorisation. This concept has generally been applied to sources and exposure situations dealing with naturally occurring radioactive materials, for which no reasonable regulatory controls would reduce exposures.

The concept of exclusion has been embodied in decision B as described in this report, and is shown explicitly here as a decision based on characterisation and screening. In the context of this report, the source or exposure situation is authorised with no need of regulatory controls.

The logic of this report suggests that regulatory authorities might, at the screening stage, decide that regulatory control could not reasonably enhance protection for sources or exposure situations that are not amenable to control.

Figure 1. Exclusion

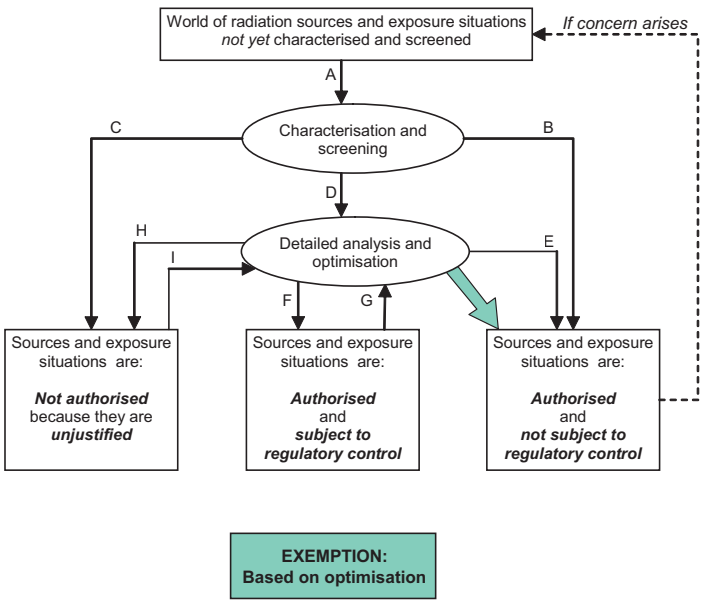


Exemption

This concept has also been described in various recommendations, standards and directives by the ICRP, the IAEA and the European Commission. It essentially has been used to describe sources and exposure situations that are excused from regulatory consideration. The rationale that has generally been used for excusing sources and exposure situations is that the exposure that they cause is "trivial", or "negligible".

As with exclusion, one of the key objectives of exemption is to avoid the unreasonable expenditure of regulatory and private resources. The choice to exempt is generally made based on a detailed optimisation analysis. This concept has generally been applied when considering, for the first time, whether or not a source or exposure situation should be subject to regulatory controls. The rationale that has been used to make the choice to exempt is usually based on the exposures from the source or exposure situation being extremely small, and the benefit from the object or process causing the exposure being considerable. The concept of exemption has been embodied in decision E as described in this report, and is shown explicitly here as a decision based on detailed analysis and optimisation. In the context of this report, the source or exposure situation is authorised with no need of regulatory controls.

Figure 2. Exemption

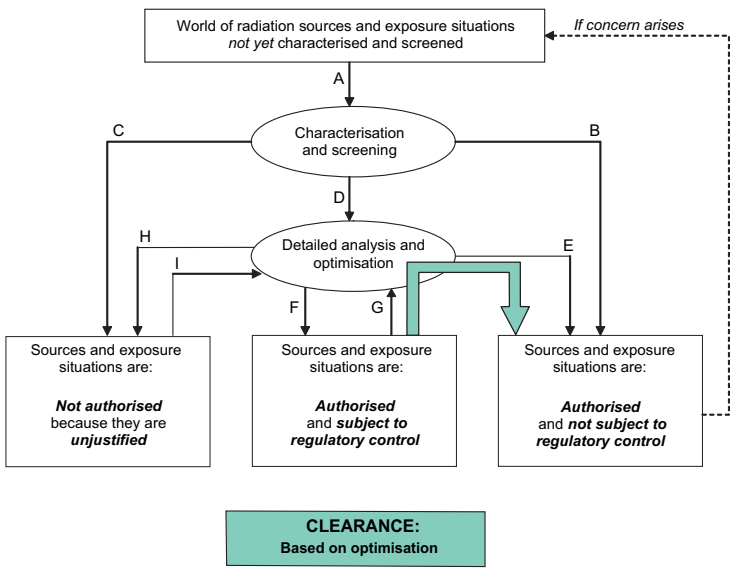


Clearance

This concept has been described in various standards and directives by the IAEA and the European Commission. It essentially has been used to describe solid radioactive materials that arise from within authorised, regulated processes and that are excused from further regulatory controls, in other words, released for unrestricted use. The rationale that has generally been used for excusing these sources is that the exposure that they cause is "trivial", or "negligible".

Here again, one of the key objectives of clearance is to avoid the unreasonable expenditure of regulatory and private resources. The choice to clear material is generally made based on a detailed optimisation analysis. This concept has generally been applied when considering what should be done with slightly radioactive, solid materials that have been generated, contaminated or activated during an authorised operation. The rationale that has been used to make the choice to clear material is usually based on the exposures from the source or exposure situation being extremely small, and the costs associated with regulatory control being considerable for little exposure reduction. The concept of clearance has been embodied in decisions G and E as described in this report, and is shown explicitly here as a decision based on detailed analysis and optimisation. In the context of this report, the release of materials for unrestricted use is authorised with no need of regulatory controls.

Figure 3. Clearance



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