Is there a common language and understanding in radiation safety and other safety spheres?

Mr. John Croft, NRPB, United Kingdom Dr. Christian Lefaure, CEPN, France

Introduction and objectives of the Workshop

The aim of this, the 4th European ALARA Network (EAN) Workshop, is to provide an opportunity to put radiological risk management into context with the management of other occupational risks by engaging interested parties (managers, workers, contractors, regulatory bodies, communicators etc) in the exchange of information and experience.

The objectives are, by means of case studies from a range of different work activities (nuclear, chemical, petro-chemical, biological, engineering etc):

- To review the approaches to risk management, both for single and multiple types of risk(s);
- _ To identify the significant factors (technical, legal, economical, social, health impact, ethical...) in the decision making processes;
- _ To examine how the different interested parties perceive the risks and how the parties impact on the risk management process (at the regulatory body, corporate and workstation levels...).

In pursuing these objectives the Workshop needs to be aware that the prevailing safety cultures, eg, at a national level, within a sector and within organisations can be different, and their interaction can affect what is achieved practically. Therefore, to be in a position to improve safety one needs to understand both the developments of these cultures and the terminology that is used. Thus the first part of this introductory paper traces the development of Optimisation as a key principle in radiation protection, provides background information on the work of the EAN and how this Workshop fits within EAN's work programme. The second part briefly reviews the lexicon of terms used in safety matters, proposes working definitions of safety terminology as a starting point and describes various approaches to the decision making process. Subsequent papers will set out views on safety from different standpoints that may, at the end of Workshop, alter our understanding of the terminology and how the various safety philosophies are practically implemented.

Development of ALARA

In 1928 a non-governmental organisation, the International Commission on Radiological Protection (ICRP) was established. This has become the preminent organisation in the radiation protection area and provides internationally accepted recommendations and advice on both the fundamental principles on which appropriate radiation protection can be based and their application. It has important links with other international organisations, such as, the World Health Organisation (WHO), the International Atomic Energy Agency (IAEA), the International Labour Organisation (ILO), the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), the Commission of the European Communities (CEC) and the Nuclear Energy Agency (NEA) of the Organisation for Economic Cooperation and Development (OECD). The latest recommendations from ICRP were published in 1990 in ICRP Publication 60⁽¹⁾ and have been incorporated into what are known as Basic Safety Standards (BSS) documents that have been adopted by the European Communities (EC) and IAEA. These two documents are different in structure in that they have different target audiences and legal status, but are compatible. The European BSS⁽²⁾ is in the form of a Directive that is given legal effect in the national regulations of the countries of the European Community. The international BSS⁽³⁾ is a joint publication of IAEA, Food and Agriculture Organisation of the United Nations (FAO), ILO, OECD/NEA, WHO and the Pan American Health Organisation (PAHO). It does not entail any obligations for Member States to bring their legislation into conformity. Nevertheless it is widely used, particularly by developing countries as a template for legislation.

For several decades ICRP has recommended a system of radiological protection based on three basic principles, Justification of the practice, individual Dose Limits and Optimisation of Protection. Over the years Optimisation has become the cornerstone of radiation protection, and although there have been some changes in how it has been defined by ICRP, the underlying objective of keeping radiation doses "As Low As Reasonably Achievable" (ALARA) has remained constant. Inherent in this approach are judgements on what is "reasonably achievable" – a question which must also be addressed in other safety situations.

Throughout the 1980s and early 1990s, CEPN and NRPB collaborated in a number of CEC research projects with the objective of developing the understanding of ALARA and its practical implementation. At the start of this period, whilst ALARA was recognised as a desirable objective, little practical was done to implement it, with the focus being on keeping doses below dose limits. (Undoubtedly there have been parallels in other safety areas). The initial focus for the development of an understanding of ALARA was on mechanistic approaches using quantitative decision aiding techniques, such as cost-benefit analysis. The joint project quickly identified that if such techniques were to be of use, they had to be set within some kind of structured approaches, or "tools". One such was the 'ALARA Procedure' shown in Figure 1. This provided a strong input to ICRP Publication 55 "Optimisation and Decision Making in Radiological Protection"⁽⁴⁾.

Whilst the practical application of the ALARA Procedure required some guidance, the fundamental steps are readily understandable. Indeed the 'procedure' is generic in nature in that it can be applied to any situation requiring a decision, including those involving safety considerations. Another important feature was the recognition that whilst decision aiding techniques could be used as an input, judgements taking into account qualitative factors would be more prevalent. A number of other systematic approaches or tools were developed such as

- _ 'ALARA Reviews' of radiation protection programmes. These could use check lists or analytical trees as a basis and are similar in nature to 'safety tours' which look at a range of safety issues.
- Predictive ALARA Planning: This was a structured approach for ensuring that ALARA considerations were included in the planning of major projects, such as nuclear power plant outages. The key elements of this approach were the planning of protective actions to achieve ALARA, prediction of the doses involved with each of the tasks in the project, monitoring the evolution of doses and taking corrective actions if needed, and the provision of feedback for future projects.

The theme of schematic representations of various decision making process is returned to later in the paper.

By the late 1980's, it was becoming clear that, whilst the development of structured approaches provided 'tools' to pursue ALARA, this in itself did not achieve anything in practice unless there was a will to positively pursue the ALARA principle – in essence it required commitment from all those involved, often referred to as the stakeholders. Clearly the commitment of management was key, but so also was that of the workforce and the regulators. In many cases it was a challenge for management to convey the commitment to the workforce. It required changing the culture of organisations through training and good management practices. Often this had a beneficial effect on safety in general, and importantly on the operational efficiency. The commitment of regulators has also been important, as it is they who set the regulatory framework and importantly can set the tone in how they enforce the regulations. Many regulators realised that the question "Have you done everything reasonably practicable to restrict exposure?" was a very powerful question – because it is difficult to prove that you have!.

In the second half of the 1980s and the early 1990s there was a number of driving forces that raised the awareness of the need for commitment to ALARA and its benefits. Perhaps the two most important drivers were:-

- _ Messages coming from ICRP that risk factors needed to be revised, which would tighten dose limits and put a downward pressure on dose distributions, and
- _ The emergence of case studies (and a widening dissemination of them) which clearly showed that it was reasonably practical to reduce doses, providing there was commitment to ALARA.

The joint project made contributions to the second of these by fostering case studies and developing EC sponsored training courses on Optimisation as a means of disseminating this knowledge. Another contribution from the joint project to the changing ALARA culture was the publication of a book that brought together all the developments in ALARA, in a format designed to be of use as training material. Its title "ALARA: from theory to practice"⁽⁵⁾ encapsulated the change in culture and effectively signalled the end of the "research and development" phase. It was time to refocus effort.

European ALARA Network (EAN)

By the middle of the 1990s, ALARA was being implemented in most European nuclear power plants (NPPs) as a 'routine practice' as far as external exposure of workers was concerned. However its application in other respects eg, internal exposure and the non-nuclear sector, was far from universal. Even where ALARA was an integral element of a radiation protection programme, there was a need to keep abreast of the latest good practice and learn from the experience of others. These considerations led to the creation of the EAN as a Concerted

Action within the EC 4th Framework programme on Nuclear Safety. CEPN took the role of coordinator, with NRPB providing support.

EAN OBJECTIVES

The objectives today of the EAN remain as when originally established; namely

- _ To further promote the wider use of optimisation in the various sectors of use eg, non nuclear industry, research and the nuclear cycle etc in the European Community and associated countries.
- _ To provide a means for feedback experience and the exchange and dissemination of good radiological protection practices in these areas;
- _ To provide feedback to users and the Commission's work programme on issues requiring attention.

OPERATION AND WORK PROGRAMME

The work of EAN is guided by a Steering Committee which has grown from an initial 8 country representatives to 14 at present (listed in Appendix 1). The main yearly goals of EAN are

- To provide two issues of the ALARA Newsletter, and
- _ To organise an ALARA Workshop on a specific issue in order to identify problems in that area that need further research and development or improvement of the regulations.

The ALARA Newsletter has proved to be successful and popular with over 2,500 recipients on the distribution lists run by the representatives on the Steering Committee. A key philosophy has been to make the material in the Newsletter as accessible as possible. Permission to reproduce Newsletter articles is freely given, providing an acknowledgement is made. Also as the Newsletter is in English, Members of the Steering Committee and their national professional bodies are encouraged to provide translations where appropriate. The EAN has developed a web site http://ean.cepn.asso.fr/ which amongst other material includes all the ALARA Newsletters.

The present Workshop is the 4th to be held with the three previous being:

"ALARA and Decommissioning", 1–3 December 1997, Saclav⁽⁶⁾.

- "Good Radiation Practices in Industry and Research", 23–25 November 1998, Chilton⁽⁷⁾.
- "Managing Internal Exposure", 15–18 November, Munich⁽⁸⁾.

Each of these Workshops was structured to facilitate discussion and the identification of recommendations to be made to the EC. In all three Workshops it was noted that decisions involving radiological protection often involve taking into account other safety issues. This was one of the driving forces in the EAN proposing to the Commission, the subject for this the 4th Workshop.

Terminology: is there a common language of safety?

Each industry and each type of hazard tend to develop terminology that whilst having links to general safety terminology, have their own nuances. These differences can cause difficulties in uniform understanding and interpretation of safety decisions. As might be expected translation from one language to another and differences in safety culture can exacerbate the situation. Therefore given the nature of the meeting it was thought appropriate to provide some initial default interpretations of some of the commonly used terminology. The list below is not exhaustive and is not claimed to be definitive. It has been circulated to speakers, with the request that if they use this terminology, but with a different meaning, they explain the difference. At the end of the Workshop, terminology and its use will be reviewed.

HAZARDS AND RISKS

In its Publication 60, ICRP⁽¹⁾noted that the Commission had previously used 'risk' to mean the probability of a defined deleterious outcome, but that the term had also been widely used elsewhere as the product of the probability and severity of an event and, more generally in a purely descriptive manner. It went on to state "The Commission now uses risk only descriptively and in well established expressions such as "risk estimate" and "excess relative risk". It now uses probability when that is what is meant". Underlying this tightening of terminology by ICRP in their area of safety was the common misusage of the terms "risk" and "hazard". These are widely used in safety and therefore we need workable meanings.

Hazard: an intrinsic property or description of anything that can cause harm⁽⁹⁾.

In a general sense a risk is the chance that someone or something that is valued will be adversely affected in a stipulated way. Thus a working definition might be

Risk: the probability that a specified undesirable event will occur in a specified period or as a result of a specified action $^{(9)}$.

Individual risk: the risk to any particular individual, either a worker or a member of the public⁽⁹⁾.

Societal risk: *the risk to society: for example the chance of a large accident causing a defined number of deaths and injuries or economic harm within a defined timeframe*⁽⁹⁾.

The health effects arising from a hazard can sometimes be shown to only occur above a **threshold level of exposure**. Thus safety can be focused on keeping exposure below such levels. Often health effects can be shown to be a function of exposure to a hazard, but the data available cannot identify any threshold. Here, for example as in radiation protection, it is assumed that there is no threshold for an effect. The health effects may either be defined as deterministic or stochastic.

Deterministic effect: an effect where its probability of occurrence will be equal to 1 under certain circumstances, ie, this effect will inevitably occur for the worker when these circumstances are present during his occupation. In radiation protection the severity increases with the level of dose, but in other safety areas this may not be the case.

Stochastic effect: an effect which is not certain to occur, and the probability of occurrence is related to the circumstances of exposure.

Conventional hazards: hazards that can result in immediate deterministic effects such as physical injuries from falls, fire, and electrocution, are often referred to as conventional hazards.

Long term risks: the risks arising from hazards that give rise to stochastic effects such as cancers and leukaemias are often referred to as long term risks.

MANAGING THE RISKS

Prevention: Attitude and actions aiming at avoiding the occurrence of the adverse event: here the occupational health effect. It will, often, be possible to prevent exposure of workers to an occupational risk leading to a deterministic effect, eg, by keeping exposure below a threshold level.

Precautionary Principle: An approach aiming at having a prudent behaviour in front of scientific uncertainties. This is often based on the assumption that there is no threshold for stochastic effects when the existence of such a threshold has not been demonstrated. Applying the Precautionary Principle does not imply that an activity should not be pursued, but it does imply that the potential consequences of an activity and the current uncertainties are taken into account in making a balanced judgement. This is sometimes referred to as adopting a responsible attitude ie, pursuing the activity while reducing the risks, efficiently and equitably – or put another way keeping the risks as low as reasonably achievable.

Zero-risk objective: This terminology is similar to "prevention" above. However there are perception or interpretation problems with using this terminology. Any activity undertaken by man has some hazard associated with it. Even where there is a threshold for the effect, there is a probability (albeit small) that the safety measures will not be sufficient in every set of circumstances. In practice society through its regulations tries to ensure that this risk is reduced to an insignificant level – this is what we commonly refer to as "safe". However many people forget about the residual insignificant risk and equate "safe" with zero risk. This perception can also translate across to stochastic risks where there are no thresholds and hence zero risk is unattainable. Thus using the term "zero risk objective" might create an expectation that cannot be fulfilled.

Occupational Exposure Standard (OES): This is set at a level at which, based on current scientific knowledge, it is judged that there is a minimal risk to the health of the workforce if exposed via inhalation to the substance day after day. If exposure to a substance that has an OES is reduced at least to that level, then adequate control has been achieved⁽⁹⁾.

Maximum Exposure Level (MEL): This is normally set for substances which may cause health effects, such as cancer or occupational asthma where it is not possible to identify reliably a threshold of exposure on which to base an OES. MELs are also set for substances for which "safe" thresholds may be identifiable, but control

to these levels is not reasonably $practicable^{(7)}$. In effect MELs are at the boundary between the unacceptable and tolerable levels of risk (see below). In radiation protection we refer to these as Dose Limits.

ALARA: As low as reasonably achievable. This derives from ICRP's definition of Optimisation⁽¹⁾.

"In relation to any particular source within a practice, the magnitude of individual doses, the number of people exposed, and the likelihood of incurring exposures where these are not certain to be received should all be kept as low as reasonably achievable, economic and social factors being taken into account. This procedure should be constrained by restrictions on the doses to individuals (dose constraints), or the risks to individuals in the case of potential exposures (risks constraints), so as to limit the inequity likely to result from the inherent economic and social judgements. (The optimisation of protection)".

ALARP: As low as reasonably practicable. This is the UK equivalent to ALARA and uses "reasonably practicable" because there is significant precedent in its use in safety legislation in the UK. In practical terms ALARA and ALARP are the same.

BAT: The "best available technology" concept has been used in the environmental context, particularly protecting the public against industrial hazards. The BAT approach implies that cost is not a relevant factor.

BATNEEC: "Best available techniques not entailing excessive cost". This is now often used in preference to the BAT principle. It appears to be quite similar to ALARA as it implies selection of the most cost effective available means in preventing, minimising or rendering harmless the polluting releases. In all cases BAT can then be properly modified by economic considerations⁽¹⁰⁾.

Tolerability of Risk (TOR)

Tolerability of Risk (TOR) is a framework approach to safety developed by the Health and Safety Executive (HSE) in the UK. This stemmed from considerations in the nuclear industry, particularly at the Sizewell B Public Inquiry where the chairman of the Inquiry recommended that HSE should "formulate and publish guidelines on the tolerable levels of individual and societal risks to workers and public from nuclear power stations". In response HSE developed a Tolerability document⁽¹²⁾, which was an input to ICRP's recommendations in their Publication 60. A revised version of HSE's document "The Tolerability of Risk from Nuclear Power Stations"⁽¹³⁾ was published in 1992. This in turn has fed into a wider review of approaches to safety "Reducing Risks, Protecting People"⁽⁹⁾. This is developed in more detail in the paper from W. Holmes (HSE) "The UK Approach to the Management of Risks". However for completeness the key terms used in the Tolerability of Risk approach are given below and shown schematically in Figure 2.

Unacceptable (level of risk): Here an activity giving rise to such a level of risk is regarded as unacceptable whatever the benefits. Thus such an activity would be ruled out unless it can be modified to reduce the degree of risk to below the unacceptable level. A special implication of that definition, when applied to the exposure to ionising radiation, is the setting up of individual dose limits above which the risk is considered as unacceptable.

Broadly acceptable: The levels of residual risk are regarded as insignificant and further effort to reduce risk is not likely to be required as resources to reduce risks are likely to be grossly disproportionate to the risk reduction achieved.

Tolerable: This refers to a willingness to live with a risk so as to secure certain benefits in the confidence that it is being properly controlled. This implies that

- _ The nature and level of the risks are properly assessed and the results made available.
- _ The risks are not unduly high and kept as low as reasonably practical (ALARP), and
- _ The risks are periodically reviewed to ensure that they still meet the ALARP criteria.

It is emphasised that the above terms relate to the approach in the UK, and there are subtle differences with how similar terms were used by ICRP in its publication $60^{(1)}$. This stated "Exposures that are not unacceptable are then subdivided into those that are "tolerable", meaning that they are not welcome but can be reasonably tolerated, and "acceptable", meaning that they can be accepted without further improvement ie, when the protection has been optimised".

If the last phrase "ie, when the protection has been optimised" had been omitted, then there would be equivalence between "broadly acceptable" and "acceptable". In the current UK approach "broadly acceptable" is linked to a level of individual risk which is regarded as insignificant. However ICRP's statement can be interpreted as meaning that providing the doses have been optimised, ie, ALARA has been achieved, the

situation is "acceptable" irrespective of the doses and levels of risk, provided they are not in the unacceptable region. This is the interpretation of the ICRP statement in France.

It must be recognised that the safety cultures in different countries will have developed other formulations and definitions. Undoubtedly these and the other terms above will be the subject of discussion during the Workshop; not least in respect of who makes these judgements and how.

Decision Making Process

The decision making process can often be complex, involving different groups of people and a range of factors. To aide understanding the process is often presented in a schematic form, however these can vary considerably, dependant on the viewpoint of the target audience and the aspect of the process that one wants to emphasise. Some examples are given below. The intention is not to explain these in detail, (in many cases this will be done in other presentations) but to seed ideas for future discussion.

Earlier in the paper the ALARA Procedure was introduced (Figure 1). This is intended to represent the stages in the decision making process on ALARA, but if you remove any reference to ALARA it can be seen that the process is equally applicable to any situation. Figure 3 is an example from the USA⁽¹⁴⁾ depicting how a regulatory body might develop a strategy to manage a hazardous agent. It depicts a high level decision process with the emphasis on the inputs to the decision: it does not tell you how to evaluate the inputs in order to make a decision. Figure 4 is a development from Figure 3 and is used in the later presentation from A. Oudiz on decision making related to the risks from asbestos⁽¹⁵⁾.

Figure 5 is an example from the UK⁽¹⁶⁾, which in the context of managing Health and Safety, outlines a conceptual framework for identifying key areas for which performance standards are necessary to establish control and measure performance. The overlapping circles represent interactions between domains. It is in fact an aggregation of a number of smaller diagrams which are used to visualise specific interactions. Figure 5 does not represent a linear decision making process but seeks to indicate that the characteristics of the organisation, the premises, the plant etc all influence the management of the situation.

The fundamental point coming from above is that whilst schematic representations of the decision making process are useful, there is no universal recipe for making decisions on health and safety. It comes down to the totality of the approach to safety, including Regulatory infrastructure, good management, appropriate resources, well trained staff etc. An important attribute is the ability to seek out and utilise feed back experience, not just from ones own area of work, but from other sectors – which in essence is the purpose of this Workshop

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Figure 1 – ALARA Procedure [5]



Risk cannot be justified save in extraordinary circumstances

Control measures must be introduced for risk in this region to drive residual risk towards the broadly acceptable region

If residual risk remains in this region, and society desires the benefit of the activity, the residual risk is tolerable only if further risk reduction is impracticable or requires action that is grossly disproportionate in time, trouble and effort to the reduction in risk achieved

Level of residual risk regarded as insignificant and further effort to reduce risk not likely to be required as resources to reduce risks likely to be grossly disproportionate to the risk reduction achieved

Negligible risk

Figure 2 – Tolerability of Risk [9]



Figure 3 – Example of the US National Research Council [14] on the development of a regulatory strategy



Figure 4 – Example of a schematic view of radiological risk management in major nuclear installations (from paper of A Oudiz [15])



Figure 5 – Example of a framework for setting performance standards [16]