TOLERABILITY OF RISK. ITS USE IN NUCLEAR REGULATION IN THE UK

Dr Timothy Walker, Director-General Health and Safety Executive, UK

1. Introduction

In UK law the responsibility for safety is placed on the body which controls the hazard and hence the risk - the operator, in an organisational not personal, sense. The role of the regulator is to ensure that this responsibility is carried out adequately and that risks are being properly controlled. In the UK nuclear regulation is the responsibility of the Health and Safety Executive's Nuclear Installations Inspectorate (HSE/NII). This paper outlines the risk framework of the Tolerability of Risk (TOR) within which regulatory decisions, particularly those related to major hazards, are taken in the UK: it concentrates, as befits this conference, on the application to nuclear installations.

Before moving on it is worth making an important point: all activities entail risk. This is no less true for the production of electricity than for any other aspect of life. Depending on the particular activity, the risks are different in kind, who they effect and their likelihood and different measures can be used to reduce them. It is not the intention of this paper to compare or contrast risks from alternative means of energy production, but it is important to emphasise that absolute safety is not an option.

The Tolerability of Risk approach encompasses this fundamental point.

2. Development of the Risk-based Approach

One feature of nuclear regulation, which is common throughout the world, is that there should be a written record of the safety arguments which underpin the operation of a nuclear installation. This is imposed in different ways in different countries and national approaches lead to differences in the level of prescription and regulatory input. In the UK the requirement to produce a safety case is enshrined in the standard conditions which are attached to all licences, through powers in the Nuclear Installations Act. NII does not prescribe what the content of these nuclear safety cases should be, nor how the arguments should be constructed: indeed, these have changed over the years. As a nuclear site licence is required to operate a nuclear installation in the UK, the operator is usually referred to as a "licensee" and this usage will be adhered to from now on.

In the late 1970's, NII developed Safety Assessment Principles for use by its own inspectors when making judgements on a licensee's safety cases and these were published so all stakeholders were aware of the standards being used.

In common with the majority of UK Health and Safety law the principles were goal-setting not prescriptive. Following the Rasmussen report 1975, which considered the chances of accidents on US PWRs, probabilistic methods to analyse safety, by estimating the risk, were increasingly being used, though this was by no means universal. The approach built on the deterministic approach which had grouped initiating faults or events into classes according to their frequency and required safety measures and set acceptable consequences accordingly.

In the early 1980's, the UK held a public inquiry into the plan to build its first commercial PWR at Sizewell. The Safety Assessment Principles survived close scrutiny during this public inquiry

but it was noted that they were not explicit about the level of risk which was acceptable. The inquiry recommended that HSE should "formulate and publish guidelines on the tolerable levels of individual and social risk to workers and the public from nuclear power stations" and that "the opinion of the public should underlie the evaluation of risk". This use of the word "tolerable" and the attitude to risk, of consulting the public, was new.

In response to these recommendations, the first "Tolerability of Risk from Nuclear Power Stations" document was published in 1988 for public comment.

A revised version was published in 1992, taking account of the comments received.

By 1992, the basic risk framework was increasingly being applied to the regulation of other major industrial hazards. The 1992 version is generally the document referred to as the Tolerability of Risk or TOR. Recently, in 1999, HSE published a further discussion document,

"Reducing Risks, Protecting People" (R2P2) which, among other things, considered how the general concepts of TOR applied to the whole range of health and safety issues which HSE regulates. This document is currently being revised.

3. Meaning of Risk

Before describing the TOR framework it is important to be clear what is meant by "risk".

Risk is used in a variety of ways: depending on context it can be a synonym for frequency (or probability), for consequence, for danger or for a generally adverse outcome. There is extensive literature on risk as perceived and understood but it is clear that the concepts of the chance of occurrence and the resultant effects are fundamental (and can be traced back to the 17th century).

In quantitative usage these may be combined as the frequency (probability) times consequence.

A closely related concept is that of hazard.

"Hazard" is the intrinsic propensity to cause harm, which would include the magnitude and type of harm as well as the potential for it to be realised:

"risk" is the chance of that harm being realised. It is a requirement of UK Health and Safety Law that risks are controlled so far as is reasonably practicable.

In the context of this law a court ruling in 1993 was that "the word `risks' conveys the idea of possibility of danger" rather than "actual danger". This is closer to the concept of hazard and implies that successful risk management must ensure that hazards are addressed. R2P2 expands on this interpretation.

4. The Tolerability of Risk (TOR)

It is important to emphasise again that the risk can never be zero. However suitable control measures can reduce the risk to acceptable or tolerable levels: the TOR framework is based on this fundamental approach to safety and provides guidance on how to determine the degree of control that is needed.

The basic concept of TOR is that of three zones of risk.

It was postulated that, above a certain level, risks were not acceptable and could not be tolerated except in exceptional circumstances. At lower levels the risk might be tolerable if it were considered the benefits were great enough, provided that there was proper control of the hazards and the risks have been reduced so far as is reasonably practicable. An even lower level of risk could be regarded as generally acceptable and insignificant. These levels are shown in the figure: which is known in the UK as the TOR triangle.

TOR considered a range of risks from a variety of activities and from these derived proposed numerical values for the boundaries between these zones for both Individual Risks (IR) of death, for workers and the public, and the tolerable level of Societal Risk (SR), in terms of an accident involving multiple fatalities.

Other societal effects, which are wider than injury to particular people or groups of people were also considered. It should be noted that IR is not the risk to an specific person, but the risk to a hypothetical individual who has a particular relationship to the plant in terms of location, pattern of life etc.

Although the general concept of TOR did not rely on numerical estimation of risk, to compare the risk posed by any given installation with the TOR criteria formally a quantitative estimate of the risk must be made.

TOR therefore devotes some pages to the discussion of the use of Probabilistic Safety Analysis (PSA) as a systematic approach to doing this.

The nuclear industry in many parts of the world contributed to the development of PSA, which is based on the analysis used by Rasmussen: it is referred to as QRA - Quantitative Risk Analysis - in some other industrial sectors.

The limitations of PSA, which mean the estimates cannot be precise, were also considered in TOR and the importance of good engineering and sound management in ensuring safety emphasised. PSA can give estimates "of the order of the risk to compare with criteria: in addition the importance of particular systems can be seen and weaknesses in the design identified.

5. TOR as a Risk Framework

It should be emphasised that TOR is not a legal requirement: rather the tolerability concept is used by regulators as the framework within which they apply Health and Safety law.

One of the main advantages of a goal-setting form of regulation, compared with a prescriptive approach, is that the licensee (who knows the plant best) has to consider what control measures can be put in place in the context of the particular activity being undertaken, and is not constrained by predetermined requirements.

This enhances the ownership of safety by the licensee and promotes better safety.

Within the tolerable region the operator must demonstrate that risks have been reduced as low as reasonably practicable - ALARP.

This concept is fundamental in UK Health and Safety law and is over fifty years old.

It requires a comparison of the risk and the sacrifice (money, time, trouble) involved in taking measures to avert the risk.

If the sacrifice is grossly disproportionate (ie much larger) than the benefit from reducing the risk, then the requirement has been met and implementation of additional measures is not required. The ALARP concept is equivalent to the ICRP approach, used in radiation protection, of ALARA (as low as reasonably achievable).

ALARA does not, however, have the legal precedent in the UK which has been established for ALARP. The requirement to demonstrate risks are ALARP must be met whether the considerations are made qualitatively against a background of good practice guidelines or through a numerical analysis, or, as is often the case, by a combination of these approaches. Quantitative risk analysis is a valuable technique for informing the judgement but is not sufficient alone to make the decision.

6. Application to Nuclear Regulation

So far this paper has discussed general features of the application of the tolerability of risk concept and how it is applied to the whole gamut of health and safety aspects of work activities in the UK. We now consider some of the specifics in relation to nuclear regulation, where the concept originated. It is of course fundamental that the licensee is responsible for safety and Nil's regulatory activities are to ensure that the licensee is discharging its duties under the law correctly.

Following the introduction of the TOR concept, HSE revised its Safety Assessment Principles, which at that time were in the form of two documents, one for nuclear power plant and the other for nuclear chemical plant, into a single document for all nuclear installations The resulting Safety Assessment Principles for Nuclear Installations (SAPs) were published in 1992 alongside the second version of TOR.

SAPs lay down good practice for new nuclear installations in terms of engineering, operations, management of safety and also set out the requirements for safety analysis to demonstrate robust tolerance to faults. SAPs also set out risk criteria and to complement the fault analysis a licensee should carry out a PSA to estimate the risks and compare the results with these criteria. It was made clear that the PSA was only part of the information which needed to be considered in justifying the safety of an installation.

The SAPs risk criteria are set out in a similar form to the TOR triangle with Basic Safety Limits (BSL) at the unacceptable/tolerable boundary and Basic Safety Objectives (BSO) at the tolerable/broadly acceptable boundary. BSL/BSO are given as annual frequencies for accident conditions and doses for normal operation exposures. The accident criteria are mainly in the form of surrogates, ie dose to public, worker death, large releases, loss of control and criticality, rather than fatalities and take account of both Individual Risk (public and workers) and Societal Risk. For example, the so-called dose staircase for lower offsite releases is based on a reducing frequency of events giving higher doses to the hypothetical individual considered. If compounded these would mean the BSL and BSO would be roughly the same as the TOR limits for IR, but they also take account of the other potential effects such as the need for countermeasures resulting from such releases. The Large Release criterion is specifically aimed at societal risk in which significant numbers of people could be affected.

A licensee must present its safety case to NII in support for an application for permission to carry out specific activities. This requirement applies to all stages of the lifecycle of the installation.

Some of the more significant for new installations are:

- design concept stage which avoids the licensee wasting money on an unacceptable concept (Preliminary Safety Report);
- pre-construction which reduces the risk of major modifications being required during construction (Pre-construction Safety Report);
- pre-commissioning which ensures that all necessary actions have been undertaken which cannot be achieved once radioactive material is present (Pre-Commissioning Safety Report);
- pre-operation - before the installation begins routine operation (Pre-Operation Safety Report).

It should be noted that significant modifications of operating installations may well follow the same series of stages.

Though SAPs were written primarily for new installations they are also used when assessing older installations. For a new installation, it would be expected that most of the SAPs would be met fully and that the risks estimates would be below the relevant BSOs.

For existing installations this may not be the case and the ALARP concept has to be applied, bearing in mind that the design standards may have been different when the installation was built from current ones and that the installation's future life expectancy may be limited.

Nevertheless, significant improvements to older plants have resulted from the application of TOR approach during the periodic safety reviews both for power plants and other installations

The programme of Magnox Reactor Long Term Safety Reviews [LTSR] (the current international and UK terminology is now Periodic Safety Reviews [PSR]) began in the 1980's and led to such improvements as tertiary boiler feed systems, secondary shutdown systems and improved monitoring systems for pressure vessels.

In summary, an adequate safety case must demonstrate that:

1. engineering, operational, managerial good practices are met and the installation is robustly fault tolerant

AND

2. risk estimates are below BSOs

OR

that an argument can be made that it would be grossly disproportionate to take further measures.

In the foregoing, the concentration has been on how TOR considerations play a part in the demonstration of safety through safety cases. The same concept also applies in the inspection and enforcement activities which Nil undertake.

As with assessment, inspection is a sampling activity: by using risk considerations sampling can be targeted to those areas where the risks are greatest.

When incidents occur the regulator's response can be moderated by an understanding of the risks and effort targeted to those areas of most concern and enforcement, if needed, can be applied proportionately.

7. Application to the Regulation of Other Major Hazards

Although today we are addressing the regulation of the nuclear industry it is interesting to reflect on the similarity with the approach to major hazards that can occur in other industry sectors. Lessons can be learned about regulation that can be shared across industry sectors.

For example, the release of large quantities of toxic chemicals can have similar consequences to a nuclear incident and demand similarly rigorous regulatory control arrangements. The chemicals sector in the UK is regulated by HSE's Hazardous Installations Directorate through a system of "permissioning", in which the operator is required to present the HSE with a report setting out their demonstration of the safe operation of the establishment and HSE has to examine and comment on it.

The HSE assessment, of whether the major accident protection and mitigation measures are adequate, is a consideration of whether risks have been reduced so far as is reasonably practicable. Most of the safety reports during the introduction of new regulations (Control of Major Accident Hazards Regulations 1999. [COMAH] which implement in the UK the "Seveso II" Directive) have been describing existing establishments but over time this will be replaced by demonstrations of new plant and processes prior to construction and operation. There is a real opportunity here to provide regulatory control at the design stage or when plant is replaced or upgraded, as is the case in nuclear regulation.

The TOR framework is also applied in determining consultation distances around chemicals establishments, which are used as the basis for preparing major incident response plans. It also serves as a land use planning constraint

to prevent the building of new residential and other sensitive developments close to the chemicals establishment.

HSE aims to carry out formal enforcement activity in a consistent and proportionate way, not only within an industry sector but also across industries.

Essentially, the most important factor to take into account is the degree of risk that the duty holder's failings create compared with the risks that may remain after all the necessary controls have been applied.

We call this a "risk gap " analysis. In addition where there are residual risks, despite all the practicable controls being in place, and the consequences of an accident are serious, then even small digressions from the required standard of control can lead to formal enforcement. This process is described in what HSE call the " Enforcement Management Model (EMM)", which relates to the TOR framework.

The diagram illustrates the scale of the tolerability of risk as it moves from being broadly acceptable to unacceptable (R2P2) and is superimposed with an indication of the corresponding "risk gap" descriptions used in the EMM . Although the development of this approach is still continuing it illustrates how HSE aims to link its enforcement to the TOR framework.

8. Conclusion

The concept of tolerability of risk was developed to explain the measures and standards applied in the regulation of risks from nuclear power.

TOR also sets out a clear framework for nuclear regulatory decision-making and has been the basis of nuclear regulation for many years. This framework has stood the test of time and has assisted in raising standards of safety in the nuclear industry in the UK. Increasingly in the UK the TOR concept has been applied more widely to more types of work-related risk.