

LINKAGE BETWEEN POST-CLOSURE SAFETY CASE REVIEW AND THE AUTHORISATION PROCESS FOR RADIOACTIVE WASTE DISPOSAL FACILITIES

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ABSTRACT

The Environment Agency (the Agency) has responsibilities under the Radioactive Substances Act 1993 (RSA93), for regulating disposal and storage of radioactive wastes in England and Wales, including regulation of the disposal site for UK solid low-level waste (LLW) at Drigg in Cumbria, NW England.

To help inform the next review of the Drigg disposal authorisation, the Agency has required the operator, British Nuclear Fuels plc (BNFL) to submit a Post-Closure Safety Case (PCSC) which will assess the potential long-term impacts from the site. The Agency will review the PCSC, *inter alia*, to determine appropriate authorisation conditions and disposal limits. With the aim of using best practice to determine authorisation conditions, the Agency contracted Galson Sciences Ltd to undertake an international survey of authorisation procedures for comparable facilities in other countries. The overall objective of the review was to determine how PCSC review outputs may be used to support regulatory decisions.

This paper provides an overview of the findings from the international survey, including discussion of: the authorisation process; information considered in the authorisation process; regulatory criteria; post-closure safety cases; and, the regulatory decision-making process. In particular, the paper concentrates on issues that are regarded, from the Environment Agency's perspective, as key points from the international survey pertinent to the future regulation of the BNFL Drigg disposal site. The paper also provides some initial views on how outputs from the PCSC review might be linked to the authorisation.

INTRODUCTION

The Environment Agency (the Agency) is responsible, in England and Wales, for authorisation of radioactive waste disposal under the Radioactive Substances Act 1993, as amended (RSA93).

In accordance with Government policy, the Agency conducts periodic reviews of authorisations for nuclear licensed sites to ensure that appropriate operating practices are employed and that any changes to Best Practicable Means (BPM) are reflected in the Certificate of Authorisation. In 2003, the Agency will commence a review of the Authorisation for the disposal of solid low-level radioactive waste (LLW) at the Drigg site near Sellafield in Cumbria, NW England, which is operated by British Nuclear Fuels plc (BNFL). Drigg has been accepting LLW for disposal since 1959, and is effectively the only site for the disposal of LLW generated by the UK nuclear industry. The site also offers a disposal route for smaller users of radioactive substances, such as hospitals and universities.

In preparation for the next review of the Drigg authorisation, the Agency varied the extant authorisation (1) in January 2000, requiring BNFL to provide information about the environmental safety of the site during the operational lifetime and after its closure. On 30 September 2002, BNFL duly submitted the following documents:

- Operational Environmental Safety Case (OESC)
- Post-Closure Safety Case (PCSC)

The Agency is now reviewing these documents^(a). The outputs from these reviews, *inter alia*, will help to determine appropriate conditions and authorisation limits.

The Agency aims to use best practice when determining authorisation conditions, and commissioned an R&D Project with Galson Sciences Ltd to consider how outputs from PCSC reviews may be used in the Authorisation process. This paper is a summary of the associated R&D Report (2).

The main objectives of the R&D Project were ^(b):

- To examine how regulators of relevant facilities in other countries have linked PCSC review outputs to regulatory requirements and to consider whether these methods are appropriate to the regulatory system in the UK.
- To consider and document general procedures describing how the outputs from the Agency's review of a post-closure safety case may be used to establish authorisation conditions.

INTERNATIONAL SURVEY

An international survey of regulatory practice in the authorisation of solid radioactive waste disposal was undertaken to examine how other regulators have linked PCSC review outputs to regulatory requirements. A questionnaire was sent out to the regulators of thirteen relevant disposal facilities. Responses to the questionnaire were received from nine organisations, including the Agency itself. The range of countries and facilities covered in the survey is shown in Table I.

Table I:- Details of the countries and facilities covered in the international survey

Country	Facility	Status	Depth	Waste
Canada	Intrusion Resistant Underground Structure (IRUS)	Proposed	Shallow	LLW
Czech Republic	Dukovany	Operational (1995)	Surface	LLW
England	Drigg	Operational (1959)	Surface	LLW
France	Centre de L'Aube	Operational (1992)	Surface	LLW/ILW
Norway	Himdalen	Operational (1999)	Surface	LLW/ILW
Spain	El Cabril	Operational (1992)	Surface	LLW
Sweden	Forsmark	Operational (1992)	Shallow	LLW/ILW
Switzerland	Wellenburg	Proposed	Deep	LLW/ILW
USA ^(c)	Waste Isolation Pilot Plant (WIPP)	Operational (1999)	Deep	LLW/ILW

To evaluate how the safety case review process is used in establishing authorisation conditions in other countries, it is necessary to understand the authorisation/review process in those countries and the regulatory criteria against which the safety cases are assessed. Therefore, the questionnaire required information on all these aspects and the responses are discussed briefly below.

The Authorisation Process

All of the regulators surveyed undertake periodic reviews of the post-closure safety case for the facility and the waste disposal limits. These reviews are conducted at 2 to 10 year intervals. In many countries outside the UK, licencing is a staged process. In addition to periodic review, separate regulatory decisions (licences) are made for key steps in the disposal process:

- Site characterisation.
- Construction.
- Operation.
- Closure / decommissioning.
- Surveillance / monitoring.
- Withdrawal of control / delicensing.

The post-closure safety case is refined at each stage in the decision-making process and the approach, therefore, creates an inherently strong link between post-closure safety and site development, operation and waste management.

Information Considered in the Authorisation Process

There is broad consistency in the types of technical information considered at each authorisation review. The information considered typically includes:

- The qualification or suitability of the operator or disposal organisation.
- The quality assurance and quality control procedures governing waste management and its assessment, and the implementation of these procedures.
- The operational safety case for the facility (i.e., the impact on workers).
- The post-closure safety case for the facility.
- Assessments of waste transport safety.
- The proposed inventory (existing + forecast) and Waste Acceptance Criteria (WAC).
- Information on radionuclide discharges from the facility and their environmental impact.

Typically, the operator of the facility provides this information. Some regulators also consider independent sources of information, for example, issues raised by stakeholders (Norway, UK), independent risk assessments by the regulator (Sweden, UK_(d)) and independent geological interpretation and hydrogeological modelling (Switzerland).

Regulatory Criteria

Quantitative regulatory criteria have been specified in all of the countries surveyed and these criteria are considered at each step in the authorisation process. All of the regulators

surveyed consider quantitative dose criteria, and approximately half also consider risk-based criteria, even though risk criteria may not be specifically defined in national legislation or guidance.

The values of post-closure dose criteria differ amongst the countries surveyed and, in large part, depend on the perceived likelihood of the exposure scenario under consideration. For example in France exposures for “likely” scenarios should lead to doses less than 0.01 mSv/year, whereas when considering less likely human intrusion scenarios, the French system applies higher values of between 5 and 10 mSv/year. A less significant source of variation in the values of dose criteria, results from individual countries adopting slightly more or less conservative values when incorporating international (e.g., ICRP) guidance into national regulations.

There is consistency in the values of post-closure risk criteria; all countries that consider risk have criteria of one in a million (10^{-6}) for the probability that an individual will suffer a serious radiation-induced health effect as a result of the presence of a disposal facility. There appears to be less consistency, however, in the potential receptors considered in regulations. A wide range of potential receptors was identified in the questionnaire responses including: individuals, most exposed individuals, average members of critical groups, representative members of potentially exposed groups and populations of different sizes. The significance of considering different receptors in assessments can be quite important and certainly makes the assessments and criteria difficult to compare. The differences may be due to the way international guidance is transferred into national regulations or policy and the due legislative process that this will entail.

Post-Closure Safety Cases

In the majority of countries regulations do not specify an overall timescale to be addressed in post-closure safety cases and performance assessments. For example, in France, Spain, Sweden, Switzerland and the UK, impacts are evaluated by the applicant/operator until any peak dose or risk has passed, and periods in excess of 50,000 years are typically considered. In the remaining countries timescales are specified; the Canadian system considers a timescale of 50,000 years, although this is currently under review, while the Czech, Norwegian and US systems consider 10,000 years.

In several countries, regulators require that the doses associated with human intrusion scenarios and “degraded repository” or “repository failure” scenarios are evaluated immediately following withdrawal of controls (e.g., 300 years post-closure). It is notable that no credit is given to the potential ability of passive institutional controls to reduce the likelihood of human intrusion and that the consequences of the human intrusion scenarios are estimated on the basis of often conservative assumptions about the ability of the repository barriers and disposal system to contain the waste.

There is a high degree of consistency amongst the scenarios and exposure pathways considered in post-closure safety cases in the different countries surveyed. This is particularly so for the “undisturbed”, “natural” and “normal” evolution scenarios considered. That is not to say that the same scenarios and pathways are considered in the safety cases for the different facilities but, rather, that a common understanding of environmental systems results in similar types of scenarios and pathways being considered as appropriate to the particular disposal system.

In general, there is little regulatory stipulation of the scenarios and pathways to be considered in post-closure safety cases. However, regulations in some countries do require consideration of particular scenarios involving human actions. The US regulations relevant to the Waste Isolation Pilot Plant, for example, require consideration of drilling and mining.

There is wide variation in the receptors considered in different post-closure safety assessments, possibly reflecting the different criteria required by different national regulations and government policies. Receptors identified in the questionnaire responses include:

- A rural family at the “worst” location.
- Residents consuming contaminated water and living on site.
- Construction workers, house dwellers and children.
- Hunter-gathers.
- Lake fishermen.
- Present-day farmers.
- Subsistence farmers.
- Non-human biota.

However, while some of the variation in the receptor groups considered in the post-closure safety cases derives from the regulations, further variation is introduced through (i) the geographical locations of the different facilities and the associated differences in present-day and expected future climatic conditions, and (ii) the nature of the human intrusion scenarios considered.

The Canadian regulations and the US regulations for the WIPP stipulate that uncertainty must be assessed through probabilistic assessments of radionuclide release or risk. In the remainder of the countries surveyed, there is no formal requirement for probabilistic risk assessment and uncertainties in post-closure performance are typically evaluated by considering a range of deterministic scenarios and by conducting sensitivity analyses.

Regulatory Decision-Making Process

The post-closure safety case is widely considered to be the primary focus of regulatory review for assessing the safety of the disposal system and establishing limits on its operation (e.g., in terms of waste acceptability and disposal limits). In contrast, the operational safety case is regarded as being of secondary importance because the facility should, by design, be safe during the active control phase.

When reviewing post-closure safety cases and establishing authorisation conditions, regulators in different countries attach different levels of significance to the quantitative regulatory criteria (e.g., dose and risk values) in the regulations. In Canada, the Czech Republic, Norway, Spain and the US, quantitative regulatory criteria are regarded as limits and greater significance is attached to the demonstration of compliance with those criteria. In the remainder of the countries surveyed (France, Sweden, Switzerland and the UK), the regulatory authorities may place equal or greater emphasis on the qualitative aspects of the safety case, including a demonstration of the ALARA (As Low As Reasonable Achievable) principle.

Two main themes are apparent on how the PCSC is linked to authorisation conditions:

- Authorisation conditions are sometimes established directly from assumptions in the PCSC. This approach is particularly applicable to assumptions concerning the waste form, waste conditioning, waste emplacement, repository engineering and repository closure. Establishing authorisation conditions in this way simply requires the operator to fulfil the plans evaluated in the post-closure safety case.
- Disposal limits for each radionuclide and other Waste Acceptance Criteria are commonly derived through an optimisation process comprising several sets of post-closure performance assessment calculations, where different waste inventories, and different options with respect to the nature of the waste form, the waste inventory, and the design of the repository are considered. The aim of these optimisation calculations is to arrive at an appropriate balance between the total amount of waste disposed and the calculated impact (dose or risk). It is common practise to establish waste disposal limits in this way for a wide range of individual radionuclides. This approach is followed in several countries, including the Czech Republic, France, Norway and Spain.

Uncertainty is accounted for in setting disposal limits by assessing the full range of PCSC results. The optimisation process should ensure that calculated doses are lower than accepted safety standards (dose constraints). Arbitrary safety margins are not generally applied to account for such uncertainties.

DEVELOPMENT OF A UK PROCEDURE

Another aim of the project was to develop a general procedure to describe how the review of a PCSC may be used to help establish authorisation conditions, within the constraints of UK legislation and policy.

Regulatory Guidance

The disposal of radioactive waste in England and Wales is currently regulated in accordance with the Radioactive Substances Act 1993, as amended. This Act is not prescriptive in terms of the standards to be applied in granting authorisations to dispose, although it does prescribe the responsibilities and overall procedures for granting such authorisations. Responsibility for granting authorisations rests with the Environment Agency in England and Wales, the Scottish Environment Protection Agency (SEPA) in Scotland, and to the Department of the Environment for Northern Ireland (DOE NI) in Northern Ireland (collectively known as “the Environment Agencies”). In 1997, the Environment Agencies issued Guidance on the Requirements for Authorisation (the “GRA”) (3). The GRA is based on a set of Principles and Requirements, supported by explanatory paragraphs and chapters that describe in more detail the information required in an application. The GRA criteria can be sub-divided into numerical, comparative, and imperative criteria:

Numerical Criteria These criteria are the requirements that specify values of dose or risk, and also the principles that make reference to these requirements and similar quantitative measures.

Comparative Criteria These are the principles and requirements that require the design to be optimised and the use of best practicable means (BPM). Although quantitative measures may be used, the essence of the comparative criteria is to show that the doses and risks from the proposed design are less than those of alternatives (taking account of other factors accordingly).

Imperative Criteria These are the requirements and supplementary information paragraphs that require particular types of information to be presented.

The GRA criteria are not prescriptive. It is the applicant or operator's responsibility to justify the information it provides as being appropriate and adequate. When a PCSC is assessed against such criteria, it is necessary to evaluate whether the criteria is 'passed' or 'failed'. However, in reality, it is rarely a 'pass/fail' assessment, and the outcome is more likely to be pass with conditions attached (e.g. further information required). Furthermore, there is a need to make an assessment of the significance of each issue. That is to say, how important any failure to fully satisfy the criterion is, with respect to radiological impact or other safety measure, disposal system understanding and control over site management. Figure 1 illustrates how the Agency intends to address significance when reviewing the Drigg PCSC. (4)

Regulatory Actions Available

When a PCSC review has been completed, there are a number of regulatory instruments that may be used under RSA93. The instrument used may depend on whether the PCSC is for an existing or new facility. In order of decreasing severity, the actions available are as follows:-

Instrument	RSA93	Comment
Prohibition	s22(1)	If the Agency is of the opinion that continued disposal involves an imminent risk of pollution of the environment or of harm to human health, it may serve a notice under this section. [Because of the imminent risk phrase and the considerable uncertainty in a PCSC, it is unlikely that a Prohibition Notice would be issued as a result of a PCSC review.]
Enforcement	s21(1)	If the Agency is of the opinion that the operator of a facility is failing, or is likely to fail, to comply with any limitation or condition in the authorisation it may serve a notice under this section.
Authorisation	s16(8)(b)	An authorisation may be granted " <i>subject to such limitations or conditions as the...Agency thinks fit.</i> "

To ensure consistency when authorising waste disposal, the Agency has developed a template authorisation. The template consists of a number of schedules; schedule 1 contains general conditions that are applicable to all authorised waste types, followed by a number of media / disposal route-specific schedules (e.g. disposal to air, to water, to another site, etc.) There is also a schedule which specifies information to be supplied and improvements to be carried out.

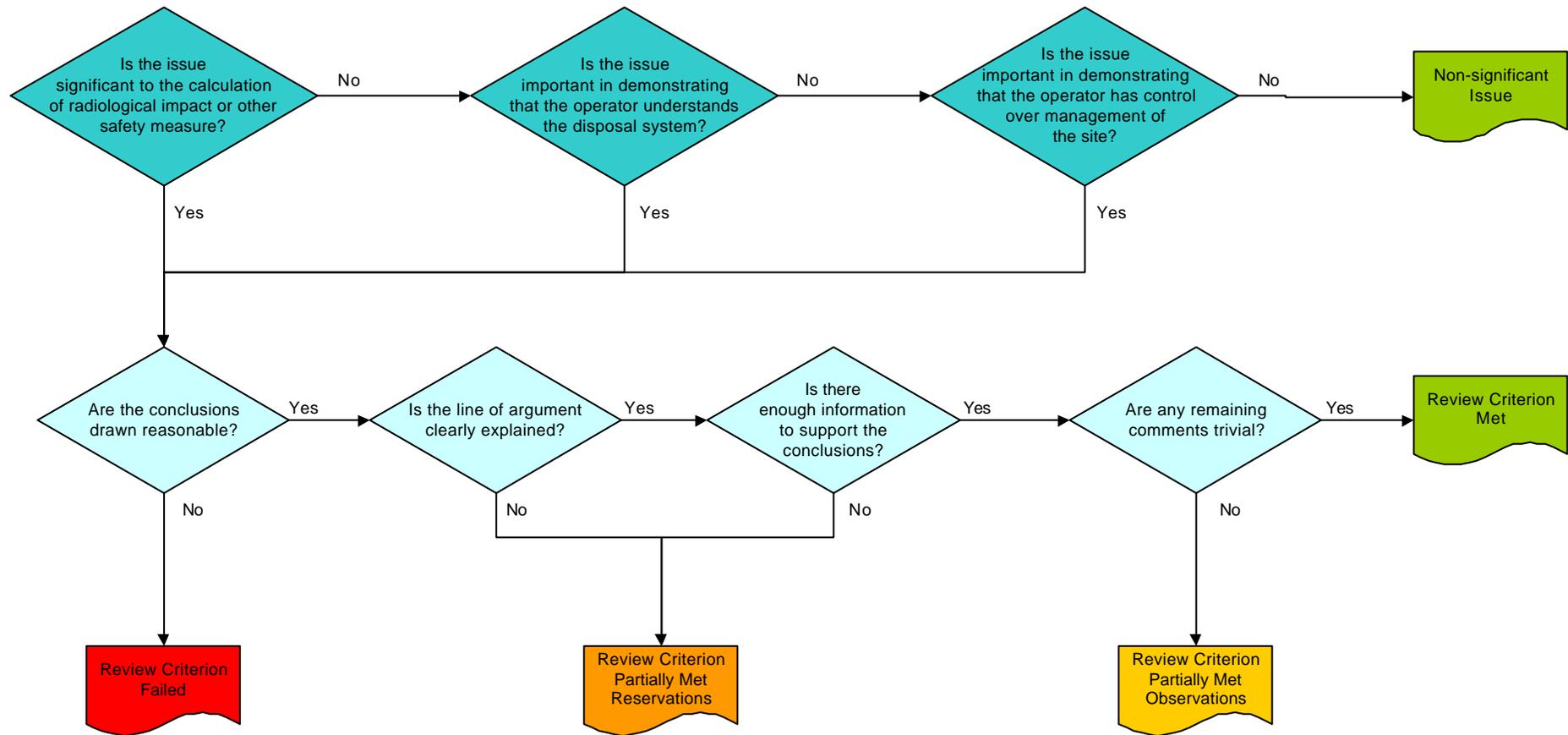


Figure 1: Assessing the significance of review criteria and comments.

If an issue or requirement is deemed sufficiently important, it may be explicitly included in the Authorisation. Issues of lesser importance may be included in a document called an "Environment Agency Requirement" (EAR), associated with Schedule 1. For example standard conditions 5 and 9 from Schedule 1 of the template authorisation state:-

- "5. If required by the Agency, the Operator shall only dispose of radioactive waste at such times, in such a form and in such a manner *as the Agency specifies.*"
- "9. If required by the Agency, the Operator shall take such samples and conduct such measurements, tests, surveys, analyses and calculations, including environmental measurements and assessments, at such times and using such methods and equipment *as the Agency specifies.*"

Numerical Limits

The past few years have seen a debate in the UK over the potential for the use of quantitative methods for establishing operational discharge limits (5, 6, 7, 8, 9, 10, 11). During this debate, the nuclear industry has argued in favour of establishing limits based solely on quantitative estimates of environmental impact (12). Regulatory authorities, including the Agency, have on the other hand identified the need to consider a wider range of policy and other constraints when establishing discharge limits (6).

This debate has centred on routine liquid and gaseous discharges, but a comparable situation exists with respect to the disposal of solid radioactive waste, in terms of a relationship between environmental impacts and quantitative disposal limits. For example, BNFL has indicated its intent to calculate the radiological capacity of the Drigg site as part of its 2002 post-closure radiological safety assessment for the site (13). BNFL has proposed that for some radionuclides, it is reasonable to assume that there is a direct linear correlation between the disposed inventory and post-closure risk (13). The implication is that estimates of post-closure risk can be used as the starting point for a simple back-calculation of how much of each radionuclide the disposal facility could accept, at some chosen level of "acceptable" quantified risk.

Several approaches could be taken to the derivation of quantitative disposal limits, but the two key approaches are traditional optimisation and back-calculation of radiological capacity from dose or risk estimates as proposed by BNFL (13).

As noted above, the traditional optimisation approach is followed in several countries and entails making iterative risk assessment calculations whilst adjusting the waste inventory, the nature of the waste form, and the inclusion and design of repository engineered barriers, to arrive at an acceptable combination of calculated impact, waste form, inventory and repository design.

Back-calculation approaches have recently been discussed in IAEA (14). Briefly, the approach involves comparing dose and risk results from safety assessment calculations, conducted in accordance with standard principles and approaches, with appropriate radiological protection criteria. Peak doses (or risks) from a wide range of scenarios are compared with the appropriate dose limit (or risk criterion), and disposal limits are derived in terms of the total activity (measured in Becquerels, Bq) of each radionuclide that can safely be disposed, and the specific activity (measured in Bq/kg).

Other considerations

In addition to limiting the overall capacity of a disposal site, consideration may also be given to the rate of disposal. To avoid unnecessary accumulation of waste on the generating sites, the rate of disposal would ideally match the rate of waste arisings (e). However, there may be other reasons why a regulator would want to control the rate of disposal, such as providing flexibility for future waste disposals by preserving disposal capacity.

Disposal limits could, in theory, be established for all of the individual radionuclides in the various wastestreams. As it would be impractical and costly to apply and demonstrate compliance with limits for every individual radionuclide, however, it is suggested that individual radionuclide limits should only be applied to those key radionuclides that contribute significantly to post-closure risk. In addition to limits on individual radionuclides derived from consideration of post-closure impacts, it is recognised that it may be necessary to establish further limits on specific radionuclides or groupings of radionuclides to account for other drivers, such as operational safety or high mobility in the environment (e.g. tritium).

IAEA (14) also discussed a method for calculating the specific activity limits, which might allow disposal of short-lived Intermediate Level Waste (ILW) to a LLW repository. However, due consideration must be made of the spatial scale at which disposal limits are applied, so that the apparent 'dilution' of small volume, high activity waste (i.e. sources) in large volume waste streams does not lead to unacceptable disposals.

Waste Acceptance Criteria (WAC) should be consistent with the post-closure safety case. In the UK, WAC are normally specified by the Operator. It may, however, be appropriate for the regulator to impose WAC in the authorisation (even if they are identified by the Operator), for specific issues that are identified in the PCSC as significantly contributing to post-closure risk.

Whilst not discussed in detail here, policy and stakeholder issues will always form an important consideration in the Authorisation process. For example, a regulator agreed decommissioning programme is reliant on having a disposal facility that will accept the waste arisings from that programme.

Framework Procedure

From the above discussion, it can be seen that establishing appropriate conditions when authorising radioactive waste disposal is a complex issue. Figure 2 illustrates a framework against which all the various drivers and issues may be considered.

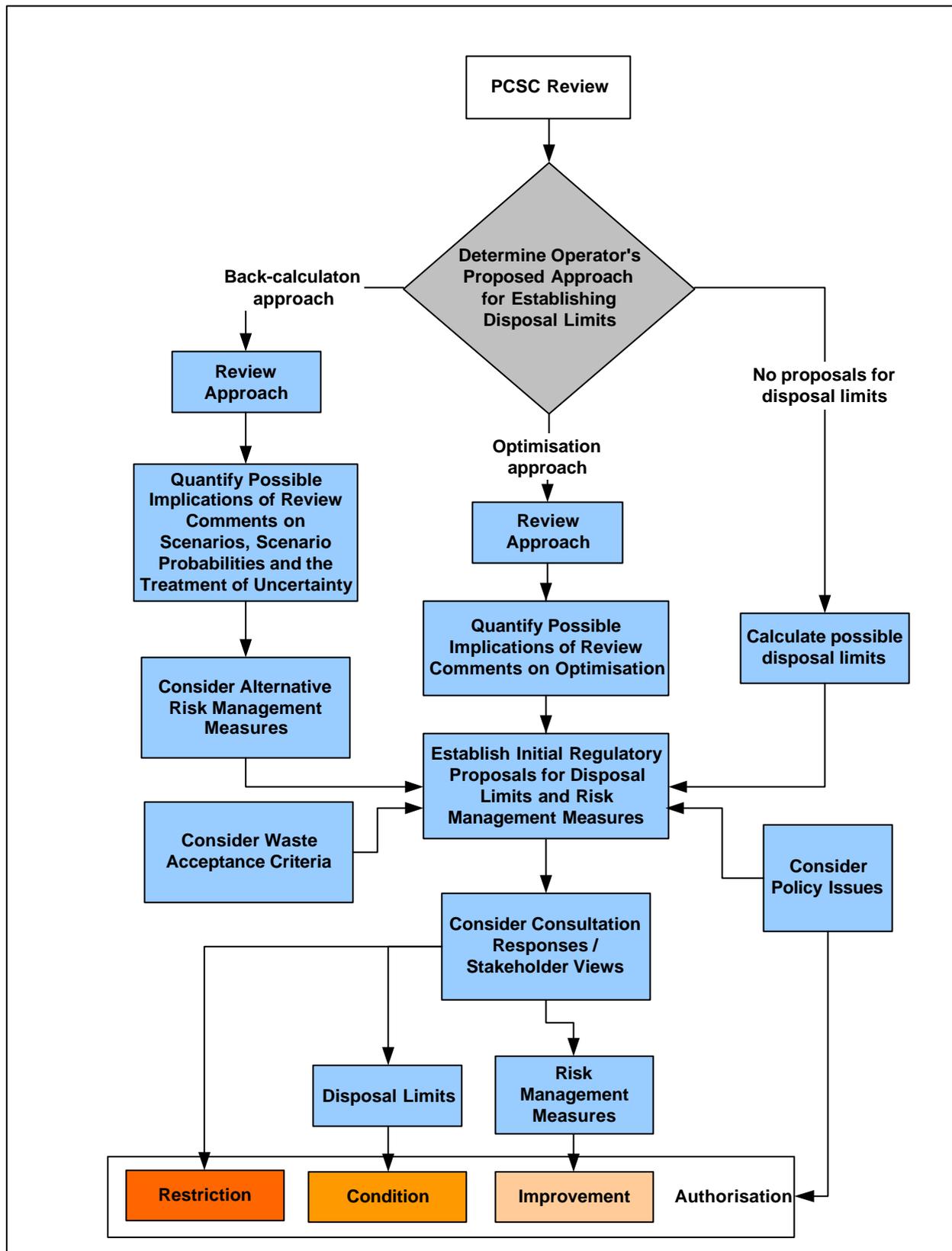


Figure 2: Suggested procedure for reviewing and establishing quantitative disposal limits.

CONCLUSIONS

The Environment Agency has surveyed regulatory practice in a range of countries for the authorisation of solid radioactive waste disposal. Key findings from the international survey are that:

1. Authorisation processes in other countries are often staged. In addition to periodic authorisation reviews, separate regulatory decisions are made for key steps in the disposal process including:
 - Site characterisation.
 - Construction.
 - Operation.
 - Closure / decommissioning.
 - Surveillance / monitoring.
 - Withdrawal of control / delicensing.

Such staged authorisation procedures ensure strong links between post-closure safety and site development, operation and waste management.

2. Review of the PCSC is of primary importance in the authorisation process. The operational and other safety cases are of lesser importance because present-day operations associated with the disposal facility should be safe by design.
3. Authorisation conditions may be derived directly from assumptions made in the PCSC. For example, assumptions regarding disposal facility engineering or the waste inventory may be reflected in the authorisation.
4. Quantitative waste disposal limits may be derived by optimising the inventory, waste form and/or facility design to achieve acceptable estimates of post-closure impact. However, it is also important to take a range of other considerations into account, including *inter alia* policy and stakeholder issues, WAC, and the possible need to establish limits on the rate of disposals and the scale at which disposal limits should be applied.

The Environment Agency has examined possible approaches to the review of post-closure safety cases, and has developed a detailed plan for the review of the 2002 PCSC for the LLW disposal site at Drigg in NW England. This plan centres on assessing the safety case against relevant regulatory review criteria and includes a procedure for assessing the significance of review comments.

The relationships of the possible review conclusions with the authorisation process have been examined, and a general procedure developed linking the various outputs from safety case reviews to different types of authorisation conditions and other regulatory action.

Potential methods for estimating quantitative disposal limits have been assessed, and a more specific framework has been proposed for establishing quantitative disposal limits as part of the authorisation review process.

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Footnotes

- a For a summary of the Agency's review methodology, see (15).
- b Another aim of the project was to determine how estimates of dose and risk might best be used in presenting and supporting the Agency's decisions related to the long-term safety of radioactive waste disposal facilities. However, this aspect is not covered in this paper.
- c The US regulatory authorities were unable to respond to the questionnaire. However, publicly available information was used in the survey.
- d In the UK, the Food Standards Agency (FSA) is a statutory consultee to the authorisation process and conducts independent assessments of the impacts of the facility on the food chain.
- e UK Government policy (Cm2919, para. 52) directs operators to make best use of available disposal rates.