

The UK Nuclear Industry Guide To:

Peer Review of Safety Cases



This Nuclear Industry Guide was produced by the Peer Review Forum and published on behalf of the Nuclear Industry Safety Directors' Forum (SDF).

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REVISION HISTORY

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1	October 2015	Minor editorial amendments as agreed by Peer Review Forum on 13th October 2015.
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5	March 2022	Approved by SDF.

It is recognised that – through the experience of using these Guides – there may be comments, questions and suggestions regarding its contents.

In the first instance, any such comments should be sent to the Peer Review Forum via email to: insa@sellafieldsites.com and peer.review@dounreay.com

FOREWORD

Safety Directors' Forum

In a sector where safety, security and the protection of the environment is, and must always be, the number one priority, the Safety Directors' Forum (SDF) plays a crucial role in bringing together senior level nuclear executives to:

- Promote learning;
- Agree strategy on key issues facing the industry;
- Provide a network within the industry (including with government and regulators) and external to the industry;
- Provide an industry input to new developments in the industry; and,
- Ensure that the industry stays on its path of continual improvement.

It also looks to identify key strategic challenges facing the industry in the fields of environment, health, safety, quality, safeguards and security and resolve them, often through working with the UK regulators and BEIS, both of whom SDF meets twice yearly. The SDF members represent every part of the fuel cycle from fuel manufacture, through generation to reprocessing and waste treatment, including research, design, new build, decommissioning and care and maintenance. The SDF also has members who represent the Ministry of Defence nuclear operations, as well as "smaller licensees" such as universities and pharmaceutical companies. With over 25 members from every site licence company in the UK, every MoD authorised site and organisations which are planning to become site licensees the SDF represents a vast pool of knowledge and experience, which has made it a key consultee for Government and regulators on new legislation and regulation.

The Forum has a strong focus on improvement across the industry. It has in place a number of subject-specific sub-groups looking in detail at issues such as radiological protection, human performance, learning from experience and the implementation of the regulatory framework for security. Such sub-groups have developed a number of Codes of Practice and Good Practice Guides which have been adopted by the industry.

Sub-Group Description

This document is produced by the Peer Review Forum, which is a sub-group of the Safety Directors' Forum. The Peer Review Forum brings together a wide range of representatives of nuclear operators, from all the Licensees and Authorisees across the United Kingdom, including:

- Civil, commercial and defence activities;
- Design, operation and decommissioning of nuclear facilities;
- Research facilities.

The purpose of the Peer Review Forum is to provide guidance that is useful to, and will benefit the widest possible range of UK nuclear operators.

Independent Peer Review of safety case submissions is performed across the nuclear industry as part of the arrangements for the assessment of safety cases under relevant Nuclear Site Licence Conditions.

This nuclear industry guide provides guidance on good practice on undertaking Peer Reviews with the aim of increasing the likelihood that Peer Reviews will be delivered in a consistent, efficient and effective manner across the UK nuclear industry.

Such guidance is not mandatory, nor does it seek to identify minimum standards. It aims to provide a tool kit of methods and processes that nuclear operators can use if appropriate to their sites and facilities.

This guide is intended to improve the standardisation of approach to the delivery of fit for purpose safety cases, while improving quality and reducing the cost of production. It is designed to cater for all stages of a facility's life cycle and for all processes within that life cycle. This includes any interim, continuous and periodic safety reviews, allowing for the safe and efficient operation of nuclear facilities.

When using the information contained within this guide, the role of the Intelligent Customer shall always remain with the individual nuclear operator, which shall retain responsibility for justifying the arguments in their respective Safety Cases.

The following companies and organisations are participating members of the Peer Review Forum:



Disclaimer

This UK Nuclear Industry Guide has been prepared on behalf of the Safety Directors' Forum by a Technical Working Group. Statements and technical information contained in this Guide are believed to be accurate at the time of writing. However, it may not be accurate, complete, up to date or applicable to the circumstances of any particular case. This Guide is not a standard, specification or regulation, nor a Code of Practice and should not be read as such. We shall not be liable for any direct, indirect, special, punitive or consequential damages or loss whether in statute, contract, negligence or otherwise, arising out of or in connection with the use of information within this UK Nuclear Industry Guide.

This Guide is produced by the Nuclear Industry. It is not prescriptive but offers guidance and in some cases a toolbox of methods and techniques that can be used to demonstrate compliance with regulatory requirements and approaches.

It is emphasised that different licensees have different remits for their Peer Review processes owing to particular aspects of their business and in some cases their unique relationship with MoD regulators and external Design Authorities. Therefore, licensees must use their discretion in applying the guidance in this Good Practice Guide, which is framed for a "typical" licensee.

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1 INTRODUCTION

Independent Peer Review of safety case submissions is carried out across the nuclear industry as part of the arrangements for the assessment of safety cases under relevant Nuclear Site Licence Conditions. The term Independent Peer Review in the UK is broadly equivalent to the IAEA's expectations for Independent Verification as specified in Reference 9. The mechanics for undertaking Peer Review are set out in individual Licensees' management arrangements. The purpose of this paper is to provide a guide to good practice on undertaking Peer Reviews with the aim of ensuring that Peer Reviews will be delivered in a consistent, efficient and effective manner.

This paper is not a rewrite or consolidation of individual Licensees' procedures and guidance. Those procedures recognise that safety professionals undertaking Peer Review are experienced and will use review methods which best suit them for the subject matter being reviewed. This paper disseminates good practices which are considered to be efficient and effective and should therefore be seen to complement the guidance already within Licensees' own arrangements. Whilst this guide is primarily aimed at the review of nuclear safety cases, the principles outlined are considered to be applicable to the review of other types of documentation.

The target audience is Peer Review practitioners, those responsible for managing the delivery of Peer Reviews and those submitting documents for peer review.

Throughout this paper the term Peer Review is used consistently but Licensees may use other terms for the same activity, for example Independent Peer Review (IPR), Acceptance Review, Independent Nuclear Safety Assessment (INSA) and Peer Evaluation.

2 DEFINITIONS

A **peer** is generally defined as somebody who is the equal of somebody else. A **peer**, in the context of peer review, is used in a broader sense to refer to people in the same profession who have the same expertise in terms of their knowledge, experience, status and ability.

A **review** is a formal assessment of something with the intention of instituting change if necessary.

A **safety case** is 'a collection of arguments and evidence in support of the safety of a facility or activity' (Ref 1).

Nuclear safety is 'the achievement of proper operating conditions, prevention of accidents and mitigation of accident consequences resulting in the protection of workers, the public and the environment from undue radiation risks' (Ref 1).

Peer review is 'an examination or review of commercial, professional or academic efficiency, competence, etc. by others in the same occupation' (Ref 1). In the context of nuclear safety case submissions, there are a variety of definitions in the industry, for example 'Peer Review is an independent review of the quality and accuracy of safety related decisions and activities to ensure they have been adequately justified.' Peer review is traditionally undertaken on a completed safety submission.

Intelligent Customer is 'the capability of an organisation to understand where and when work is needed; specify what needs to be done; understand and set suitable standards; supervise and control the work; and review, evaluate and accept the work carried out on its behalf' (Ref 12).

Independent peer review (IPR) is a peer review performed by an individual, or group of individuals, that is independent of the production of the submission under consideration.

Interactive Peer Review provides for a much more flexible approach intended to promote early engagement with a project or safety case team. The interaction may be discussion based, as opposed to document based, with the peer reviewer forming an opinion on the validity of the approach and identifying any potentially contentious areas. This approach is useful to both parties as it flags up challenges early and enables the peer reviewer to identify and optimise the review strategy. The intent of interactive peer review is to avoid significant challenges to a safety submission at the end of its production period. It is essential that the peer reviewer maintains their independence if an interactive approach is taken.

Safety case owner (SCO) is the duty holder, or customer, for whom a safety case submission is being peer reviewed.

3 PURPOSE AND BENEFITS OF INDEPENDENT PEER REVIEW

The purpose of an Independent Peer Review is to review the safety arguments within a safety submission in order to both affirm the positive aspects and to identify weaknesses, errors or omissions, particularly those which could lead to a dangerous condition. Whilst errors and inadequate supporting evidence in a submission should be readily apparent, omissions are particularly difficult for any review process to detect. To identify an omission there must be an expectation which has not been met and this requires the Peer Reviewer to consider hazards which may exist within the scope of the safety submission. Alongside this, a key purpose is to confirm the adequacy of the ALARP case as presented in the safety submission for undertaking the proposed activity.

A Peer Reviewer must maintain a questioning attitude and start from the premise that the activity covered by the safety submission is not safe (see Ref 2). It is the responsibility of the safety submission to demonstrate to the satisfaction of the Peer Reviewer that the proposed design/activity is safe; it is not the purpose of the Peer Review to demonstrate that it is unsafe.

Although Peer Review is carried out independently of the project producing the safety submission, the customer is often the Safety Case Owner. The Peer Reviewer acts as the independent conscience of the organisation, providing advice on the adequacy of the safety submission. However the Peer Reviewer cannot dictate a course of action to the Safety Case Owner. If the review findings are compelling it is highly likely (and borne out by experience) that appropriate action to address the concerns raised would be taken by the Safety Case Owner.

A key benefit of Independent Peer Review is that it allows a competent individual (or team), ideally free from project/production pressures, the time to read the safety submission and to think clearly and logically about the hazards and risks inherent in an activity and from this make a judgement on whether the safety submission has demonstrated that these hazards and risks are adequately controlled. Being independent from those responsible for the production of the safety submission allows the Peer Review process to bypass any 'group think' mentality and any pre-judgements on safety that may exist within production teams. Safety Case Owners need to ensure that appropriate time has been factored into their programme schedules to ensure that an appropriate proportionate peer review is conducted.

The overall benefit of Independent Peer Review is that it provides the organisation, often represented by the Safety Case Owner, with confidence that the safety submission is valid, accurate, justified, proportionate and robust.

When planned into a project at strategic points, Independent Peer Reviews can highlight issues that may have been overlooked by those involved in the day-to-day development of the project. This enables any concerns and potential problems to be identified and addressed in a timely manner, thus contributing to the product or

output being right first time, which therefore benefits cost and schedule control for nuclear projects.

Nuclear Site Licensees' arrangements for the assessment of safety cases include for Peer Review. The safety case production processes are set up with the objective of producing fit for purpose, right first time safety submissions. The process incorporates diverse barriers to prevent the production of safety cases which do not deliver this objective (Ref 3) and the Peer Review process provides one of these barriers as indicated in Figure 1 below. These barriers are sequential and one aspect of Peer Review is to confirm that the preceding barriers have been successfully negotiated (i.e. barriers remain effective). Because these are sequential barriers and the Peer Review is providing advice to the organisation, often through the Safety Case Owner, it is desirable that the Peer Review is undertaken before the safety submission reaches the final governance stage. For the barriers to be effective it is essential that at least one is independent of the others.

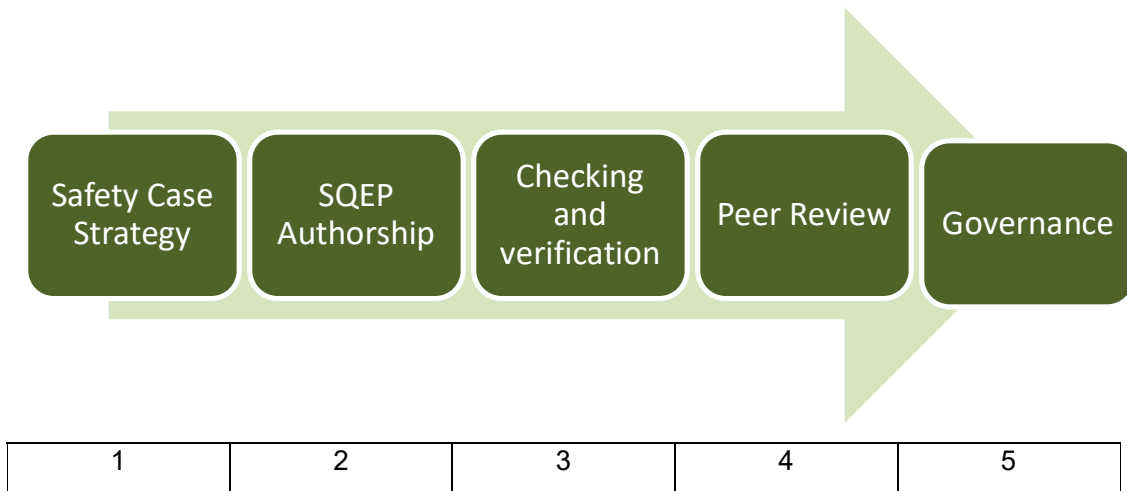


Figure 1: Barriers against the production of ‘not fit for purpose’ safety cases.

Peer Review must not be used as a replacement for internal quality assurance checks. Indeed part of the Peer Review process is to confirm that the submission has already been subject to an adequate level of checking and verification.

The project should engage with the Peer Reviewer at an early stage so that innovative or novel approaches can be discussed and an appropriate Peer Review strategy/plan developed.

4 INDEPENDENCE

4.1 Requirements for Independence

Independent means 'not influenced or controlled by others'. In the context of Peer Review, those undertaking the review must not be directly or indirectly influenced or controlled by the owner, producer and checker of the safety submission being reviewed. This ensures that there is nothing which might affect or call into question their ability to carry out an impartial assessment or to make impartial judgements regarding safety. The requirement for independence covers all personnel involved in the review including sub-contract organisations.

Independent of the **production** of the safety submission means free of involvement, either directly (as the author, or providing supporting information and services to the author) or indirectly (through managerial responsibility for the author or for production of the safety case).

Independent from the **checking and verification** of the safety submission means free of involvement either directly or indirectly in the quality assurance and checking and verification of the safety submission.

It is the Licensee's responsibility to check the degree of independence of each Peer Reviewer for a submission. It is possible that an individual proposed as a Peer Reviewer could have contributed to information being used in an underlying reference for the submission being reviewed and in such cases the Licensee will need to consider the extent to which that information is used and whether this compromises the proposed Reviewer's independence.

For a Peer Reviewer to be considered to be a Suitably Qualified and Experienced Person (SQEP) to undertake the review it is likely that they will have at least similar experience and abilities to the authors of the submission (see definition of peer above). To ensure the Peer Reviewer(s) are not influenced by those who have produced and checked the safety submission, it is good practice for the Peer Reviewers to be at a location physically separate from the authors and checkers as this ensures that discussions between Reviewers and between Reviewers and other parties are not overheard by the authors/checkers. This might give the author/checker the opportunity to regularly intervene in those discussions, unduly influencing the Peer Reviewers. Conversely co-location would encourage effective communication reducing the opportunity for misunderstandings. There is a need to consider this balance but in most instances physical separation is preferable.

Independence from the **ownership** of the safety submission may not be so straightforward because the Peer Review is being carried out on behalf of the organisation, usually through the Safety Case Owner who is also (usually) funding both the safety case and its Peer Review. To ensure the Reviewer will not gain any immediate benefit from the approval or implementation of the safety submission and is not in a position where line management or contractual pressure could influence a

favourable review outcome, there should be no direct line management dependency between the Safety Case Owner and the Peer Reviewer. Licensees should have a Peer Review process owner / group to oversee peer review activities and to act as their intelligent customer for contracted peer review services. Further guidance on this aspect is included in Appendix B.

A Peer Review process owner / group can provide a buffer between the Peer Reviewer and the Safety Case Owner, and this arrangement also decouples the funding provided by the Safety Case Owner from that received by the Reviewer.

In all cases, the level of independence should be appropriate to the safety category of the submission. Licensees each have their own requirements for the level of independence required for each category of safety submission and how this may be recorded.

- 1) For longer term Peer Reviews it is good practice to regularly re-affirm the independence of the review team.

The safety submission production and checking/verification personnel and possibly the review team personnel will change and any potential for a conflict in the level of independence needs to be identified and addressed before it compromises the review. If during the course of a Peer Review it is identified that a Reviewer's independence is compromised this should be immediately brought to the attention of the Peer Review process owner / group and a way forward agreed. This may require aspects of the safety submission to be subject to additional Peer Review by another Reviewer. Each case must be considered on its own merits.

4.2 Challenges to Independence

It is particularly important to be aware of the dangers of Peer Reviewers losing their independence and becoming part of the project team's decision making process. Peer Reviewers should not advise projects on what decisions to make or what safety argument would be acceptable and must not provide verbatim text to be written into a safety submission. It is acceptable for a peer reviewer to ask whether the project have considered a particular solution as highlighting alternative options is good for testing any optioneering performed. If a Peer Reviewer is aware that a better solution or something important has been missed, then they should point this out in clear and unambiguous terms whilst being careful not to compromise their independence when giving such advice to a Project.

Examples of advice which could compromise independence include which design option should be taken, what technology to use, how to protect against/mitigate a hazard.

Interactive Peer Review or longer term projects have potential for degrading the independence of the Reviewer. The Reviewer will frequently be asked to agree to or accept an aspect of the safety case which is still in development.

2) Good practice is to 'not object' rather than to 'accept/agree' for proposals still in development.

Whilst this may seem to be semantics, it is the difference between remaining independent and implicitly becoming part of the project's decision making process.

Peer Reviewers will at times need to discuss issues of concern with others and it is important that in doing this their independence is not compromised. As set out above, it is expected for Licensees to have a Peer Review process owner and some have specific Peer Review managers who can be used as a 'sounding board' for discussing issues of concern.

All the above has concentrated on remaining independent of the upstream barriers, but there are threats to the independence of Peer Reviewers from the downstream barriers. This comes from the following types of statements which projects can make:

- "the safety committee have provisionally accepted this proposal".
- "a similar proposal was peer reviewed previously and accepted".
- "the facility will have to stop all operations if this is not approved".
- "we've discussed this with the ONR and they have no concerns".

Being influenced by any of these types of statements immediately degrades the independence of the Peer Reviewer. Peer reviewers should ignore and discourage statements of confidence from projects which may compromise their independence. It should also be noted that such statements may not be completely accurate.

5 COMPETENCE

The Peer Reviewer must have at least a comparable degree of technical competence and experience to the author of the safety submission. Peer Reviewers should therefore have appropriate academic, professional or vocational qualifications in the relevant subject matter.

Peer Reviewers must also have an understanding of the principles and concepts in safety and safety management and of the safety regulatory framework, standards, guidelines and codes of practice pertaining to the subject of the submission. For efficient delivery of the review, the Peer Reviewers must also have a good understanding of the methods and acceptability criteria used by the Licensee responsible for the safety case, as this ensures that comments relating to the Licensee's methodologies and procedures are avoided. It is beneficial for the Peer Reviewer to have knowledge of the methodologies and procedures used by other Licensees such that suggestions for improvements to the submission based on good practice from elsewhere can be made.

Peer Review may be undertaken on a single safety submission or a whole series of documents making up the complete safety case. For submissions where specialist aspects are involved (such as human factors or criticality), the Peer Review is likely to be undertaken by several individuals reporting to a Lead Peer Reviewer. The Lead Reviewer should have a broad range of experience, across all of the different aspects covered in the submission, to perform the role effectively.

For multi-document safety submissions the Lead Reviewer must have a reasonable understanding of the issues across all the subject areas covered by the submission such that they can see the totality of the submission and are therefore capable of spotting weaknesses, omissions and inconsistencies across the case and can understand, and if necessary challenge, issues raised by the specialist Reviewers. The Lead Reviewer must also be able to see where compromises may be necessary. It is vital that errors and inconsistencies in the Peer Review are avoided.

The Lead Reviewer, in collaboration with the Licensee's Peer Review process owner/manager, will also be responsible for selecting the Reviewers for individual reports/papers within a multi-document submission. Work flows within the Peer Review world can be variable, with peaks and troughs of demand, as well as safety submissions which are not available for Peer Review on the timescale expected. Many organisations choose to supplement staff Peer Reviewers with contractor support. However, where Peer Reviewers are employed, the Lead Reviewer should select Peer Reviewers for a particular review from a SQEP group who are independent.

- 3) Good practice is to retain, or have access to, the services of a number of individuals competent to undertake Peer Reviews in their field of expertise and who can be called upon to undertake reviews as required.

Introducing individuals to the role of Peer Reviewer requires them to be closely supervised, and their output scrutinised by an experienced Peer Reviewer. To support learning when introducing new peer reviewers, the Lead Reviewer should perform a high level review of the same submission and discuss the differences between the two reviews before providing feedback to the safety case owner.

The IET Competency Framework for Independent Safety Assessors (Ref 4) which supports the Code of Practice (CoP) for Independent Safety Assessors (Ref 5) provides additional information on the technical, behavioural and knowledge competencies required of Peer Reviewers and on the methods of justifying those competencies. Figure 2 below summarises the typical attributes of a competent and professional nuclear industry peer reviewer. Actual knowledge requirements will vary depending on the specific peer review activity.

Knowledge	Professional skills	Behaviours and character
<ul style="list-style-type: none"> • Safety cases • Periodic Safety Reviews • ALARP/BAT/BPM principles • Hazard identification techniques • Management of nuclear safety/nuclear regulation • Management of health and safety at work • Nuclear safety principles, targets and criteria (e.g. ONR SAPs) • Licensee's internal criteria and procedures relevant to submission • Facility/project purpose and history • Awareness of Nuclear Delta® • Intelligent customer <i>(when responsible for Peer Review work contracted out)</i> 	<ul style="list-style-type: none"> • Ability to communicate complex concepts • Influencing and negotiation • Analysis and problem solving • Time management and planning • Ability to draw conclusions and make judgements • Report writing • Record keeping • Team forming and leadership <i>(particularly relevant for Lead Reviewer role)</i> • Maintains Continuous Professional Development (CPD) 	<ul style="list-style-type: none"> • Is objective, consistent, targeted, transparent, pragmatic, proportionate, respectful, resilient, persistent • Has attention to detail but remembers the bigger picture • Speaks up and encourages others to speak up • Has integrity and trustworthiness • Self reflects and knows own limits • Advises without taking responsibility

Figure 2: Typical attributes of a competent and professional peer reviewer

6 SCOPING A PEER REVIEW

6.1 Introduction

The fundamental requirement that the assessment of work is planned and managed such that it delivers the required outputs is identified in the Safety Directors' Forum Good Practice Guide for Independent Oversight (Ref 6). This approach is reiterated in the IET CoP for Independent Safety Assessors (Ref 5).

For Peer Review of safety submissions it is not practical to have a 'one size fits all' approach; the depth and detail of the review plan must be tailored to suit the particular submission. **For simple or single submissions, rather than producing a self-standing plan it might be most appropriate and proportionate to simply record that the Peer Review will be carried out in accordance with an existing procedure for undertaking Peer Review.**

For larger or more complex submissions, particularly those involving peer reviewers from different disciplines, a written peer review plan should be developed and agreed as part of the early engagement phase of the review (Section 6.3). If following commencement of the Peer Review the Reviewers consider that the scope of the review needs to be changed, then this will need to be agreed with the customer and a revised review plan prepared.

In cases where Peer Review plans are required, they should as a minimum identify:

- What is to be reviewed.
- Who is to undertake the review.
- The acceptability criteria to be adopted.
- How the outputs of the review are to be captured.
- What the final outputs or staged outputs are to be.

The most important element of the plan for any Peer Review is proportionality. As a fundamental principle the scope and extent of the plan and of the Peer Review must be proportionate to the safety significance of the proposals being considered.

4) For large or complex submissions requiring peer review, it is good practice to set up an opening meeting with the project to discuss the scope for the Peer Review.

An opening meeting can help the Peer Reviewer to gain an overall appreciation of the content of the submission, the programme, authors etc. and to discuss possible Peer Review approaches and expectations.

6.2 Early and on-going engagement

The early appointment and engagement of (particularly) the Lead Peer Reviewer is highly advantageous in that it helps the Peer Review Team understand the key decision making processes, problematic areas and major commitments required in

support of the proposal, often before the safety submission is produced, and allows Peer Reviewers to provide initial feedback. It also enables the Reviewers to advise the project of subject areas and issues which are likely to be of most interest and areas of immediate concern which may be potential show stoppers. In addition, early engagement also allows the Peer Reviewers to see the proposals in the wider context, allowing interfaces to be identified and understanding the imperatives for the project to be undertaken.

5) For Peer Review relating to existing facilities, it is good practice to include a site visit as part of early engagement with the project.

Site visits are another way for enabling the Reviewers to place the proposals in the wider context.

For major projects there are benefits in retaining the Peer Review team for the entire duration of the project as this retains an understanding within the Peer Review team of why the safety case is as it is. Whilst this obviously improves efficiency as the same repeat challenges are not made at each stage on the project safety submissions and the Lead Reviewer or the project does not need to re-educate Reviewers, caution is required as the Reviewers need to remain independent of the project. For major projects there will be gaps in Peer Review involvement as the safety submission moves from one to another of its various stages (Preliminary Safety Report (PSR), Pre-Construction Safety Report (PCSR) etc.). It is important that the Peer Review team do not become distant from the project during these gaps and should maintain routine contact with the project.

Such continuing engagement enables the Reviewers to keep abreast of any developing issues which may affect the next safety submission.

For all peer review tasks, it is important that there are appropriate knowledge management arrangements in place such that a peer review task can be continued by a different set of peer reviewers if required. See section 8.4 for more detail.

6.3 Preparing a peer review plan

Safety submissions submitted for Peer Review come in a variety of shapes and sizes, from single reports for a plant or safety case modification to multi-document complete cases for new facilities. As discussed in section 6.1, a peer review plan may not be required for a simple of single submission.

6) It is good practice, in cases where a peer review plan is needed, to set a Peer Review plan down in writing and consult with the customer during its preparation so that there are 'no surprises' later on.

The review plan for a single safety document could be a complete review of a single document by a single Reviewer using the Licensee's criteria and general Peer

Review procedures to judge acceptability and with outputs as written comments and a final Peer Review report of form.

At the other end of the spectrum there are two types of 'large safety case submission' where the approaches to the review plan are completely different.

For new facilities or major modifications where the safety submissions are likely to be staged in the traditional manner, a separate Peer Review plan may need to be prepared at the appropriate time for each stage, or the original plan updated, as it may not be possible to prepare the plan for say the Pre-Inactive Commissioning Safety Report (PICSR) at the Preliminary Safety Report (PSR) stage. For all staged submissions the scope of the Peer Review must be proportionate to the safety significance of the proposals.

7) At an early stage (e.g. Preliminary Safety Report) it is good practice to plan for a review of the entirety of the safety submission to confirm that there are no potentially safety significant omissions in the case.

For later submissions (e.g. Pre-Construction Safety Report (PCSR), PICSR) in line with the principle of proportionality, the plan should restrict the review to only those safety significant aspects of the case, perhaps with a high level review of the aspects claimed to not be safety significant in order to confirm this is indeed the case. It is normally the case for these types of staged safety cases and Peer Reviews that some concerns cannot be closed at the time and resolution of them will be deferred to the next staged submission (for example if additional trials/experiments are required). In this case the Review Plan needs to capture previous on-going concerns in order to ensure they are addressed at the next submission.

All review plans should identify the personnel who will participate in the review and which aspects/documents they are to review. Where documents will have Government Protective Markings and any additional markings imposed by the customer, the plan should also confirm that the Reviewers have an appropriate security clearance level.

One important aspect to be agreed and included in the Plan is whether the scope of the Peer Review is to include implementation of recommendations to address shortfalls/deficiencies. Such decisions and their rationale are an integral part of the ALARP justification for the facility. It needs to be recognised that such decisions may not be taken for a number of years after the safety submission is prepared and any review of them may need to be treated as a separate element of the overall Peer Review.

A safety submission will use the Licensee's own acceptability criteria in shaping the safety argument and confirming that the case it has made is adequate and ALARP. There is no need to repeat the Licensee's criteria in the review plan. However there are other criteria against which the adequacy of the case should be tested and these should be identified in the review plan. These include:

- Clear safety argument summary
- Understandable and useable
- Clear claims, arguments and evidence
- Visibility of acceptability criteria adopted
- Safe Operating Envelope and Limits and Conditions defined.
- Suitable management arrangements

Reference 7 contains additional criteria against which the adequacy of a safety case should be tested. As ever, proportionality is essential.

The Reviewers need to ensure that they retain their independence during the preparation of the plan and be cautious of the project/authors attempting to steer the scope of the review away from certain topics/issues which may attract significant Peer Review concerns.

6.4 Relationship between customer, author, and reviewer

Another benefit of early engagement is that it allows the development of the professional relationship between the customer, those producing the safety submission and the Peer Reviewers.

To maximise the benefit to the project of the Peer Review, it is essential that the interaction between the project/safety case authors and the Reviewers is professional and open.

A sign of a good relationship between the Reviewers and the project/safety case authors is when the project/safety case authors advise the Reviewers of impending issues. Similarly it is a sign of a good relationship when the Reviewers flag potential concerns and seek clarification from the authors/project before preparing and issuing written comments. This is particularly important where the peer review output won't be reported for some time into the future.

7 UNDERTAKING THE PEER REVIEW

7.1 Introduction

Peer Review is undertaken primarily using the Reviewer's experience of having prepared and undertaken reviews of similar safety submissions combined with an understanding of the Licensee's guidelines and procedures and the various industry guides on preparing safety cases, on the content of safety cases and on undertaking Peer Review.

When reviewing a safety case document it is expected that the review will normally be undertaken in the following sequence:

- Understand the scope of the assessment and the hazards considered.
- Prepare a list of expectations of, in broad terms, the hazards/causes which should be covered and the safety case outputs.
- Read the document to gain an overall appreciation of the safety arguments and to determine areas for detailed scrutiny.
- Read the document again with particular attention to the important areas/aspects identified on first read.
- Discuss points of clarification with the project/author.
- Prepare the Peer Review comments/issues.

The Peer Reviewer is not an infallible examiner; the Reviewer must make an objective, pragmatic assessment of the safety arguments presented. Highlighting relatively trivial issues can make the customer and the project question the competence of the Reviewer and thus undermine the whole review process. For each issue raised, the Peer Reviewers must themselves question whether a change to the safety argument to address that issue would add value.

8) It is good practice, at commencement of the review of a safety submission, for the Peer Reviewer to gain confidence that the 'checking and verification' barrier against the production of a 'not fit for purpose' safety case has been completed effectively.

If checking and verification has not been completed, the Reviewer should confirm the status of the submission within that process and decide whether it is appropriate to commence the review. It should be noted that peer reviewing a submission prior to it completing a 'checking and verification' process could lead to the peer review taking longer or the peer reviewer may get distracted with issues that should be addressed by 'checking and verification' hence potentially leading to them missing out on potential errors or omissions in the case.

7.2 General considerations

Appendix A provides a checklist of general issues to be considered as part of a Peer Review, however it is stressed that not all of the general issues are relevant to every safety submission and proportionality is essential.

Concerns may be identified during Peer Review that are outside the project's/document's scope, for example:

- Where the document is an interim issue and the concern applies only to the final issue.
- Where the concern is related to how the project/document interfaces with other projects/documents within the overall safety case and the concern is more appropriate to another project/document.
- Where the concern is a generic issue with regards to the production of the overall safety case but is beyond the scope or responsibility of the specific document to address.

In each case, it is important that the concern is captured and addressed appropriately. In the first two cases, it may be appropriate to record the concern against the Peer Review of the next issue or other project/document so that when the other document is submitted for Peer Review the concern is already in place. In the third case, each project area needs to have a process for capturing and addressing such issues wherever they have been identified, for example through the use of a Forward Action Plan (FAP). Such concerns will not be resolved through the Peer Review, and it is important that an appropriate route to resolve the concern is in place, for example through a corrective action process, escalation to management, oversight and audit. The Peer Reviewer and the project should take appropriate responsibility for raising the concern through the most appropriate alternative route, depending on the concern and the route taken.

7.3 Good practice in specific areas of a peer review

7.3.1 Hazard Identification

Hazard identification studies may have been carried out, but they may not have successfully identified all significant hazards. It is also the case that the faults which lead to accidents are often those which have not been identified at HAZOP or where a particular combination of seemingly unrelated events has not been considered or has been dismissed as not credible. There is little a Peer Review can do to identify such failings of a hazard identification exercise and there is no added value in the Peer Reviewer going over the exercise again. Instead, the Peer Reviewer should determine their confidence in the completeness of the study.

To do this, the Reviewer should confirm that the hazard identification study was properly constituted, based on approved inputs (such as drawings) and procedures and that the appropriate personnel were present throughout the study.

If necessary, a sample check of the transfer of hazards from the hazard identification through to the fault schedule and into the hazard analyses may need to be performed to provide confidence in the transcription of faults and to ensure that all identified hazards have been subject to appropriate assessment.

Hazard identification study records should also be sampled to confirm that where faults/hazards have been dismissed on the basis that safeguards are present, those safeguards have been transferred out of the hazard identification study records into the fault schedule and/or engineering schedule.

It should also be confirmed that all hazard identification study actions have been satisfactorily completed, reviewed and closed.

7.3.2 Process Substantiation

Where possible, the review of a main safety submission should commence with the process description and substantiation as this provides the plant and process technical detail which should underpin the hazard assessments. Reviewing these documents first, in addition to facility visits when appropriate, also provides useful background information for the Peer Review team.

The key feature of process substantiation is that it demonstrates an understanding of the underlying science and should therefore identify process hazards and provide realistic predictions of the behaviour of the process under fault conditions. Peer Review should confirm that the process substantiation demonstrates that there are adequate safety margins between normal process parameters and those at which a hazard might be realised and in so doing provide information on appropriate alarm and trip set points and numerical values for inclusion in Operating Rules.

For new facilities or major changes to existing facilities, the Peer Review should confirm that process optioneering is reported and the selected process and proposed process parameters are shown to inherently reduce risks to ALARP whilst still achieving the overall business objectives of the facility.

7.3.3 The Useable Safety Case

Some safety cases have been criticised as being impenetrable tomes which do not satisfy the needs of any of their audiences. There is a need for detailed technical analyses within safety cases but for most of its end users, such detail is not important. The safety case should therefore be structured so that each of its (several) audiences can obtain the information they need from it. The safety case should be able to act as an entry point for accessing all relevant supporting information on which it is built. It is a Peer Review function to confirm that the safety case under review meets this fundamental principle.

In response to recommendations made in the Nimrod Review (Ref 2) the SDF Safety Case Forum produced a guide on how to write a useable safety case (Ref 3) which adopts six principles plus the fundamental requirement for good preparation. This is known as **PSHAPED** (Preparation, Succinct, Home grown, Accessible,

Proportionate, Easy to understand, Document-lite). It may be helpful for the Peer Reviewer to confirm that the safety case broadly delivers on each of the six principles. At the very least the case should contain a short summary which delivers a succinct safety argument and which can be used for basic training of operators.

It is worth noting that the criticisms levelled at the independent review of the safety case for the Nimrod MR2 aircraft in Reference 2 provide very clear guidance on what must be included within the scope of a Peer Review of safety submissions.

7.3.4 ALARP

There is plenty of guidance available for assessors on determining whether risks are ALARP and which Peer Reviewers should be aware of, however it is seldom as simple as the guidance portrays to be satisfied that risks have been reduced to ALARP.

The Peer Review must judge the adequacy of the safety submission within the overall context of the facility and the site and indeed, on occasion, within the context of the UK nuclear industry. To enable this, the Peer Review should not be bounded by the absolute scope of the activity covered by the safety submission.

There is a big difference between what might be an acceptable overall ALARP argument in the safety case for a degraded legacy facility in a remote location which must undergo POCO (Post Operational Clean Out) as soon as possible and that in the safety case for a new facility being built solely for commercial reasons close to densely populated areas. A new facility required to treat the POCO wastes from the degraded facility will also have a different ALARP position to that for a new commercial facility as it is tied into the risks posed by the degraded facility.

The Peer Reviewer therefore needs to assimilate the ALARP arguments in the detailed assessments with the overall ALARP position taking account of the bigger, strategic picture. The difficulty the Peer Reviewer has is that ALARP arguments are usually subjective and few Licensees have the metrics necessary to make objective decisions.

To demonstrate the issue, let us take a theoretical example of the new facility (A) which will treat POCO wastes from a degraded facility (B). The degradation of B cannot be reversed or stabilised and therefore the risks from it are increasing year on year. The safety case for facility A argues that it is not ALARP to provide defence in depth against a number of significant hazards (i.e. it is not intended to meet modern standards in all cases) because this would increase the build time and the lifetime costs and reduce throughput (i.e. design, hardware, testing and maintenance of the additional defences). It is argued that the additional summed risk from facility B due to the delay in its POCO as a result of the delay to the start of facility A operations is significantly greater than the integrated additional risk from facility A operating over its planned life without modern standards defence in depth.

In respect of these types of argument, the Peer Reviewer should confirm:

- Facility A risk with and without defence in depth has been assessed and that the additional risk is summed across all faults where this argument is made and integrated over the life of the facility.
- There is evidence that in each case the provision of defence in depth would actually extend the facility build time and by how much.
- That the estimated risk from facility B is a best estimate value.

It is possible that these types of ALARP arguments could be extended to all aspects of design and construction which shorten the programme to active operations on facility B, e.g. not meeting external hazards criteria, not applying current design codes and guides in all cases. Peer Reviewers should at least be aware of this possibility and robustly challenge such arguments.

Safety cases for existing facilities will usually identify shortfalls/deficiencies and make generalised recommendations to address those shortfalls. The optioneering of the design solutions to those shortfalls and the ALARP review of them will normally come somewhat later. The decisions on which recommendations are accepted or rejected are the remit of the facility management team. Such decisions may also be subject to independent challenge. As noted in the previous section, the Peer Review Plan should specifically identify whether the facility management's decisions on implementing recommendations are within the scope of the Peer Review.

7.3.5 Integration of Hazards Analyses and Substantiation

Claims relating to the integrity or performance of safety control must be supported in the associated substantiation documents.

Production schedules for safety cases usually have the hazard analyses undertaken before the engineering substantiation, for obvious reasons. The feedback loop from the substantiation to the hazard analyses to capture substantiation deficiencies or failures is often compromised by programme pressures. Peer Reviewers should be aware of this and on completion of the Peer Review of the engineering substantiation, the impact on the fault analyses of identified substantiation deficiencies or failures should be reviewed and if necessary the Reviewer should request that the analyses be revised accordingly or supplements to the safety case produced.

7.3.6 Claims, Arguments and Evidence

In fault/hazard analyses and substantiation there must be a clear trail from claims through the arguments to the evidence that supports the argument. The arguments developed in the safety case must be supported with verifiable and relevant evidence (i.e. documented, measurable, etc.); not by opinion or assertions. In some cases professional judgement will be used as evidence, but in such cases the Peer Reviewer needs to confirm that the person making the judgement is SQEP to do that and the basis for that judgement is fully explained.

Some Licensees prepare safety justifications using a rigid structure based on claims, argument and evidence which obviously makes the trail through them much clearer than if the various strands are distributed across the safety case. Whichever, it is the task of the Peer Reviewer to confirm that the claims are clear, the associated arguments support the claim and that the evidence supporting the arguments is valid.

All too often the 'devil is in the detail' so the Peer Reviewer needs to take a 'deep slice' approach through a sample of the claims, arguments and evidence trails to gain confidence that the arguments are not built entirely on judgements and assumptions.

The Peer Reviewer needs to be able to differentiate between high level claims (e.g. the processing of this material will not result in increases to effluent discharges) which are effectively re-stated principles and lower level claims (failure of item X will not result in a release of activity) and should consider whether an assumption is actually a hidden claim. In all cases the Peer Reviewer needs to determine the significance of the claim to the overall safety case and the test of the underlying evidence needs to be proportionate to the significance of the claim.

In the particular case of key assumptions, the safety submission should test the sensitivity of the safety case and its outputs to changes in key assumptions, particularly where the evidence supporting the assumption is not robust. The safety submission should not attempt to gloss over weaknesses in arguments and evidence but should identify any weaknesses, explain why there are weaknesses and assess their significance to the overall safety argument. This is particularly important when evidence items being used to support the safety case are old or contain judgements/opinions that are difficult to revisit or not produced to current modern standards. The Peer Reviewer should confirm that such a balanced approach is clearly presented. Similarly the Peer Reviewer should confirm that the submission clearly identifies assumptions and judgements as such and ensures that they are not masquerading as facts.

Where an important claim is based on an understanding of the behaviour of novel systems or processes the evidence should be established from appropriate research and development. Analytical methods used as evidence, including any computer code analyses, should be confirmed to be fit for purpose with adequate verification and validation. If a limit on the validity of an approach exists this should be clearly stated and the approach shown to be within the valid region. The use of inferred or extrapolated information needs to be carefully substantiated. Where evidence is essentially based on previous experience, this must be shown to be relevant to the new safety case.

The Peer Reviewer needs to distinguish fact and evidence from opinion and judgement and ensure that the safety case does not offer opinion as fact.

7.3.7 Visibility and Application of Appropriate Standards

For safety assessments, hazard analyses and engineering substantiation it is obviously essential that the criteria against which safety is being judged are clearly stated, correct and complete. 'Criteria' here is used in a general sense to mean safety principles, deterministic and probabilistic criteria, national, international and corporate design standards, codes and practice, guidance, specifications, quality assurance standards, etc.

As it is the purpose of Peer Review to identify errors or omissions in a safety submission, it is part of the Peer Review function to confirm that the appropriate criteria are selected and applied in the safety argument. Thus the Peer Reviewer must confirm that the criteria being used to judge acceptability are clearly stated in the submission and through sampling, build confidence that they are appropriately applied. This does not mean re-doing calculations but rather the Peer Reviewer using their experience to judge that the substantiation is adequate.

Within engineering justification/substantiation reports the Peer Reviewer should also confirm that design operating and fault condition parameters are clearly stated and used in the detailed engineering analyses.

7.3.8 Excessive Pessimism / Invalid Modelling

Peer Review considers errors and omissions which render the safety submission optimistic or erroneous in its conclusions. To ensure that the safety argument is valid and accurate, the review should also consider whether the modelling used is appropriate. Appropriateness of modelling includes applicability of the model to the situation, level of accuracy, and extent of conservatism. Appropriate conservatism varies with the situation, and does not always mean beyond credibility.

The use of 'not credible' models undermines the value of the safety case in the eyes of its audience and can lead to high risk estimates and recommendations for engineering improvements which are expensive and, if the models are invalid, possibly unnecessary. It can also detract attention and resource from other issues which may, in reality, be far more important.

The safety submission should provide sufficient description of the model parameters for the Peer Reviewer to be able to make a quick judgement on its credibility.

It is reasonable for the Peer Reviewer to expect that the Licensee's own procedures and methods will have been fully applied and referenced. Where methods are applied that deviate from Licensee's own arrangements or are not covered by the Licensee's arrangements then the Peer Reviewer should be presented with suitably referenced information that supports the use of those methods or models. In cases where shortfalls in the Licensee's arrangements are identified, as a result of peer reviewing a submission, then this should be highlighted to the Peer Review Process Owner in addition to the submission of comments to the author/project.

7.3.9 Poor quality and how to deal with it

If upstream barriers are effective then the production of a poor quality safety submission should not be encountered at the Peer Review stage. If however the Peer Reviewer finds that they are encountering a number of significant errors or omissions which suggest that the overall document quality is poor and checking/verification has not been carried out with sufficient rigour (i.e. Barriers 2 and 3 in Figure 1 have failed), it is important to first make the Safety Case Owner and the author aware of these findings. With the agreement of the Safety Case Owner, the review may then switch to a high level mode in order to identify any other major deficiencies with the submission which would warrant Reservation status (see Section 8). The submission should then be returned to the author for amendment and re-submission. There is no value added by rejecting out-of-hand a submission which is of poor quality and to then (later) reject the amended (improved quality) version because of major technical deficiencies which were apparent in the initial version. However the time and cost of the high level review will be a factor in the decision to continue the Peer Review.

On the other hand, if the number of significant concerns identified by Peer Review is such that the submission is unlikely to be acceptable with the document in its present form or if the Peer Reviewer considers the entire approach taken in the case to be incorrect, then the review should be terminated and the Safety Case Owner informed. An example of the latter situation would be if a probabilistic assessment had been used when the Peer Reviewer considers the case should have been made based on a fully deterministic engineering analysis demonstrating that the hazard cannot in fact be realised.

8 REPORTING THE REVIEW

8.1 Peer Review Comments

Licensees are expected to have procedures for capturing the output of a Peer Review.

For reviews of documents the norm is to have Peer Review comments written in a tabulated form which allows for written responses to each comment, thus providing a complete record of the review and its outcome. However this may not be appropriate for all reviews, particularly interactive Peer Review. When planning the review it is normal to agree with the customer and the project how the review is to be reported.

This may well be in minutes of meetings or records of discussions. The Reviewer should be aware that the records of the review form part of the Lifetime Records for the facility under consideration.

Licensees are expected to have their own system for categorising the importance of Peer Review comments. An example categorisation system is:

Reservation / Category 1 / Major	Issue of nuclear safety such that the safety case is inadequate
Observation / Category 2 / Intermediate	Issue of nuclear safety but does not prejudice the overall adequacy of the safety case
Minor / Category 3	No nuclear safety implications and does not prejudice the overall adequacy of the safety case. Concern is relevant to the production of the document.

It is vitally important to the success and standing of the Peer Review not to over-categorise comments. This point cannot be over-emphasised. Spelling mistakes, grammatical preferences, the erroneous omission/inclusion of the word 'not', mis-referencing, poor substantiation of low safety category items and many other such topics are not issues of nuclear safety and should not be categorised as Reservation / Category 1 / Major comment. If there are an excessive number of such errors, the judgement could be made that the preparation and checking of the submission had not been to an adequate standard (Barriers 2 and 3 in Figure 1) and this may be the subject of a Reservation / Category 1 / Major comment.

Conversely, it is also important that Peer Review comments are not under-categorised.

All written comments categorised as Reservation and Observation should, so far as is practicable, be self-standing, clear and unambiguous and provide specific references to the relevant section of the document where the concern lies.

Whenever possible Peer Review comments should not be phrased as questions seeking clarification as these types of issues should have been addressed by talking

to the project/author before going into print however it is recognised that sometimes the peer reviewer may need to record a clarifying question in writing to ensure that it is addressed. Written comments should clearly state the Reviewer's concern/objection and what the Reviewer expects to be done to address the concern; remembering however that the Reviewer is not assisting in the production of the assessment.

9) It is good practice to discuss significant concerns (especially Reservations) with the submission's author before formally issuing the set of written comments.

This ensures that the Reviewer has fully understood the case being made and is confident in the comment category, and the author has an opportunity to provide any additional clarification and has early warning of the concerns.

The extent of Peer Review concerns on a submission should be proportionate to the safety significance of the content of the submission. For example, if the safety case covers only relatively low consequence/risk hazards, it would not be proportionate to report Reservations nor a large number of Observations. If this was the case then Barriers 2 and 3 in Figure 1 have not delivered their objectives and this aspect should become the focus of the Peer Review, rather than the content of the submission.

Peer Review concerns should be consolidated into the smallest set possible. Repeating the same comment because the topic of concern arises in several places in a submission is not good practice.

10) After drafting comments, it is good practice for the Reviewers to go through the comments again to satisfy themselves that they are consolidated and proportionate, and also to question against each concern what further action would be taken if the response from the project/author is negative.

For any comments where the Reviewer would take no further action if the response is negative, the Reviewer should reconsider whether the comment is an issue of nuclear safety and adds value. If not, the comment should be re-categorised or possibly removed.

Over-zealous Peer Reviewers can undermine the entire review process. It is not the purpose of Peer Review to ensure every 'i' is dotted and 't' crossed. The Reviewer needs to be pragmatic, focus on issues of nuclear safety and view the submission holistically, taking a broad judgement on its adequacy.

Reviewers must not take a confrontational stance, refusing to accept a submission unless every concern, no matter how trivial, is addressed through amendments to the submission. This does not add value to the submission, nor to the wider perception of the Peer Review process.

Resolution of Peer Review concerns should ideally (in the eyes of a Peer Reviewer) be through the author/project accepting all the concerns and amending the safety case/submission accordingly. This ideal situation rarely occurs; in most cases discussion between the parties is necessary to increase the likelihood of achieving a mutually acceptable outcome.

Certainly all-party agreement to the resolution of Reservations is essential. In the early stages of the safety case for a new facility or major modifications to an existing facility, the resolution of Reservations can be passed onto the next stage of the safety case development as the argument/evidence required to fully address a Reservation may not be available at the time. However, the peer reviewer should be confident that the Reservation is likely to be addressed in the subsequent stage(s) and that it is unreasonable for it to be addressed at this stage. Inclusion of outstanding issues in a documented forward plan association with the submission helps ensure that Reservations are not forgotten about at subsequent stages. Significant issues should not be deferred to later stages if they are likely to have an impact on the approach taken for delivery of the overall safe operating envelope.

The number of iterations of written review comments should be kept to a minimum. Normally, no more than two iterations of written review comments is recommended; more than this suggests a lack of communication between the Reviewer and the project/author in resolving the initial concerns. The second iteration should be viewed as being required to capture any misunderstandings from the discussions following the initial set of comments and to focus on the changes to the submission in response to the initial comments. The second iteration should not be used as an opportunity to pick up issues previously overlooked, unless of course they come to light as a result of the discussions and responses to the initial concerns.

It can be beneficial to prepare a brief summary of the content of the document/topic and an overview of the Peer Review findings. These summary statements will assist the Peer Reviewer in the preparation of the final Peer Review report, which might be several months if not a few years after the review of some of the document submissions was actually carried out.

There is often a perception that Peer Review can be a negative process as the focus is often on the aspects that require improvement (e.g. highlighting errors and omissions) however the peer review process can also be positive. If in the opinion of the Reviewer the submission is exemplary or has other good attributes then this should also be communicated.

11) It is good practice to provide positive feedback/comments on the presentation and adequacy of the case being made.

12) It is good practice to provide feedback on poor aspects of a safety case where this is relevant.

8.2 Peer Review Conclusions

The culmination of the Peer Review process is the provision of evidence that a Peer Review has been conducted and the outcome of that review recorded. Licensees normally have a template setting out their requirements for concluding a peer review activity. This conclusion can be presented in various formats such as a Peer Review Letter or Peer Review Report or a Peer Review Certificate.

A Peer Review Report summarises the scope and overall findings of the review, with sufficient detail to enable these to be understood. The report should explain the methods used to select the areas of the safety submission which were subject to detailed Peer Review and the criteria used for making those decisions. The Peer Reviewers used for the project should be identified, the scope of their reviews stated, and their SQEPness to undertake those reviews demonstrated.

The report should clearly state the final Peer Review position on the overall safety submission and confirm whether:

- The declared subject or purpose of the safety case is adequately addressed.
- The claims and arguments are adequately supported by evidence.
- The safety arguments are balanced and objective.
- The conclusion that risks are ALARP and relevant good practice has been adopted in the design/operations.
- The documentation has been prepared in accordance with the organisation's management arrangements.
- Unresolved Peer Review issues of nuclear safety are identified and explained and the action plan to address these is recorded and acceptable.

Licensee organisations normally have a procedure in place for the escalation of unresolved Reservations.

It is expected that the Peer Review will be complete before the safety submission passes to the final governance stage. If the submission is revised following the final governance stage, the Peer Reviewer should check the revisions to provide assurance that the changes have not affected the conclusions of the Peer Review.

In the event of submissions changing after a peer review it is expected that Peer Review Records (where applicable) are amended or reissued to clearly capture the final issue of the submission.

8.3 Position Statements and Interim Reports

For long term projects, it is beneficial to prepare position statements (also known as interim reports) as the review progresses.

Such position statements should summarise the topics and/or documents which have been subject to review and the output of the review of them, in a similar way to a final Peer Review report. Position statements provide the project with confidence

as the design progresses that there are no outstanding major issues. There may be major issues but it would be expected as part of an interactive review that an action plan to address them had already been put in place.

The timing and number of position statements expected to be produced should be agreed with the customer and the project as part of the Peer Review plan.

8.4 Peer Review Records

Peer Review is an integral part of the approvals process for safety submissions and the records of it form part of the Lifetime Records for the facility/activity. The responsibility for retaining the auditable trail from a Peer Review resides with the Safety Case Owner, however it is essential that Peer Reviewers maintain a work file for each Peer Review in which all the relevant documentation associated with the Review is collated. This file forms the auditable record of the work done in undertaking the Peer Review, demonstrates the quality of the work undertaken and provides sufficient information for another Peer Reviewer to continue the task if the original Peer Reviewer is no longer available.

The Peer Review file may typically contain the following items:

- All versions of the documents being reviewed.
- Peer Review comments and authors responses.
- Peer Review Letters, Reports and/or Certificates.
- Records of communications with the Safety Case Owner, Peer Review process owner/manager, document authors or plant operators, relevant to the Review.
- Minutes and other records of meetings relevant to the Peer Review.

It is not intended that a peer review file should form a duplicate copy of the Safety Case Owner's records. The fundamental principle is that documents should be maintained within a document management system that enables traceability and version control to be achieved. Where peer reviews of documents have taken place it is essential that there is a clear record of which version was reviewed, that that version is retrievable and that the peer review comments associated with each specific version is captured/managed through the workflow process.

Additional information on maintaining and managing records is provided in References 8 and 10.

8.5 Post Peer Review Continual Improvement

Upon completion of a peer review activity, in order to learn from experience it can be beneficial to identify and record aspects that could be improved for future.

This allows the identification of any lessons to be learnt and if acted upon facilitate or improve future peer review activities for the licensee.

8.6 Safety Case Implementation

Upon completion of a peer review task, the submission follows the appropriate governance route for the organisation and is subsequently implemented. If the governance process results in the submission requiring amendment then it is normally expected that the peer reviewer will be given the opportunity to review the updated submission to determine whether their original peer review conclusions have been impacted as a result of the amendments before the submission is implemented.

Nuclear industry peer reviewers are not normally involved in the independent oversight of the implementation of safety cases however they are requested to be involved in this stage then the guidance given in reference 6 should be adhered to.

9 CONCLUSIONS

A well-structured Peer Review adds value to a safety case, whilst also maintaining the requirement for independent examination for consistency and integrity.

The points of good practice identified in this guide are summarised below:

- 1 For longer term Peer Reviews it is good practice to regularly re-affirm the independence of the review team.
- 2 Good practice is to 'not object' rather than to 'accept/agree' to proposals still in development.
- 3 Good practice is to retain, or have access to, the services of a number of individuals competent to undertake Peer Reviews in their field of expertise and who can be called upon to undertake reviews as required.
- 4 For large or complex submissions requiring peer review, it is good practice to set up an opening meeting with the project to discuss the scope for the Peer Review.
- 5 For Peer Review relating to existing facilities, it is good practice to include a site visit as part of early engagement with the project.
- 6 It is good practice, in cases where a peer review plan is needed, to set a Peer Review plan down in writing and consult with the customer during its preparation so that there are 'no surprises' later on.
- 7 At an early stage (e.g. Preliminary Safety Report) it is good practice to plan for a review of the entirety of the safety submission to confirm that there are no potentially safety significant omissions in the case.
- 8 It is good practice, at commencement of the review of a safety submission, for the Peer Reviewer to gain confidence that the 'checking and verification' barrier against the production of a 'not fit for purpose' safety case has been completed effectively.
- 9 It is good practice to discuss significant concerns (especially Reservations) with the submission's author before formally issuing the set of written comments.
- 10 After drafting comments, it is good practice for the Reviewers to go through the comments again to satisfy themselves that they are consolidated and proportionate, and also to question against each concern what further action would be taken if the response from the project/author is negative.
- 11 It is good practice to provide positive feedback/comments on the presentation and adequacy of the case being made.
- 12 It is good practice to provide feedback on poor aspects of a safety case where this is relevant.

The various principles discussed in this document for performing peer reviews of nuclear safety cases can also be applied to the peer review of other types of documentation (e.g. Management of Change submissions, Nuclear Baseline submissions, Environmental documents, Environmental Safety Cases, REPPiR Hazard Evaluation and Consequence Assessments, Nuclear Safeguards Accountancy and Control Plans, Nuclear Security Cases, etc. A summary of the key principles that can be applied to any type of submission requiring a peer review is shown in Appendix C.

10 REFERENCES

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- 11 Safety Directors' Forum, Good Practice Note on Intelligent Customer, 2018.
- 12 Safety Assessment Principles for Nuclear Facilities, Office for Nuclear Regulation, 2014 Edition, Revision 1 (January 2020).

11 GLOSSARY

ALARP	As Low As Reasonably Practicable
ASW	Agency Supplied Worker
BEIS	Department for Business, Energy & Industrial Strategy
CoP	Code of Practice
CSW	Contractor Supplied Worker
DBA	Design Basis Accident
FAP	Forward Action Plan
FMEA	Failure Modes and Effects Analysis
HAZOP	HAZard and OPerability study
IAEA	International Atomic Energy Agency
IC	Intelligent Customer
IET	(The) Institute of Engineering and Technology
INSA	Independent Nuclear Safety Assessment
IPR	Independent Peer Review
ITA	Independent Technical Assessment
MoD	Ministry of Defence
NORMS	National Objectives, Requirements and Model Standards
ONR	Office for Nuclear Regulation
PCSR	Pre-Construction Safety Report
PICSR	Pre-Inactive Commissioning Safety Report
POCO	Post Operational Clean Out
PSA	Probabilistic Safety Assessment
PSHAPED	Preparation, Succinct, Home Grown, Accessible, Proportionate, Easy to Understand, Document-lite
PSR	Preliminary Safety Report
QA	Quality Assurance
REPPIR	Radiation (Emergency Preparedness and Public Information) Regulations
SDF	Safety Directors' Forum
SFR	Safety Functional Requirement
SQEP	Suitably Qualified and Experienced Person
SSC	Structures, Systems and Components

APPENDIX A

Checklist of issues to be considered in the Peer Review of a safety submission

Note: Not all issues are relevant to every submission.

- Robust systems of verification have been completed prior to release of documentation for Peer Review.
- The scope is correct and matches the boundaries of responsibility of the licensee.
- The relationship between the safety case under review and other related project deliverables, safety cases (or projects) is clearly defined and justified.
- The level of assessment and substantiation is proportionate to the hazard and safety case categorisation.
- Suitable modern standards and acceptability criteria are selected and identified.
- Any known issues or outstanding Peer Review concerns on related documents/safety cases have been considered.
- Adequate arrangements are in place for an ALARP review process with an appropriate level of involvement of all stakeholders.
- Confirm that the safety case accurately represents the current status (or design intent) of the facility in all physical, operational and managerial aspects (i.e. the case is factually correct).
- Confirm that the period of validity of the safety case is clearly stated.
- Where there is an extant safety case, confirm that a suitable and thorough review of the safety case against modern standards (e.g. hazard identification, risk assessment) has been undertaken by the safety case team and an integrated improvement plan suitably identified for revision of the safety case documentation.
- Confirm inventories and flowsheets are understood and justified as appropriate.
- Confirm that the safety principles used are acceptable and adequately met. These include normal operation, fault and accident conditions for both the public and the workforce.
- Confirm that the hazard assessment methods and information used are acceptable and appropriately applied and that assumptions used are reasonable and supported by an appropriate level of evidence. If novel

techniques are used, confirm they are acceptable, valid and justified (specialist advice and support may have to be sought on these issues).

- Confirm the assessment is based on a credible representation of reality yet incorporates appropriate conservatism.
- Confirm deterministic and probabilistic risk acceptability criteria are defined and met, so far as is reasonably practicable.
- Confirm that all Safety Systems, Structures and Components (SSCs) and Safety Functional Requirements (SFRs) have been identified and derived from the risk assessment and that assigned safety functions and requirements are accurate and complete. These requirements should be captured in an unambiguous form such that the requirements on the engineering substantiation are clear and there is no need for additional interpretation.
- Confirm that all safety measures that form the safe operating envelope are proportionate and are captured clearly (e.g. outputs from human factors substantiation, criticality assessments, etc).
- Confirm that all waste streams are identified and that disposal routes are identified and available. For new facilities this may require comparison against the sites lifetime plans to confirm replacement/refurbishment of existing waste treatment/disposal facilities are included in that lifetime plan.
- Confirm that substantiation reports are complete and approved for use and that there is evidence of adequate and accurate information being fed into assessments and documentation. All assumptions, data, drawings, plant configuration and models should be validated. Acceptability criteria should be stated and justified.
- Appropriate detailed technical assessments (e.g. Finite Element models, Seismic Assessments) feed into the engineering substantiation and risk assessment and are complete and verified and sensitivities are examined.
- Confirm that the correct engineering standards, codes and guides are identified and used as the basis for the assessment against modern standards.
- Confirm that where appropriate, all substantiation reports have been subject to an appropriate level of Independent Technical Assessment (ITA).
- Confirm that there is adequate integration of the findings of the engineering substantiation with the Design Basis Accident (DBA) analysis and Probabilistic Safety Assessment (PSA) to provide consistency between all assessment strands.
- Hazards from and dependencies on other facilities are identified and related claims or assumptions are substantiated.

- Dependencies on external services and utilities are identified and the ability of the facility to remain in a safe state and to be monitored as such in the absence of those external services/utilities is demonstrated.
- Confirm the management arrangements for the facility/project/modification are described and justified as suitable.
- All references and supporting information should be identified and be easily accessible.
- Confirm that categorisation of engineering or safety shortfalls/deficiencies are appropriate.
- For new facilities/processes, confirm that there are no engineering or safety shortfalls/deficiencies.
- Confirm that the methodology for assessing improvement actions to address shortfalls/deficiencies meets the standard set by the Licensees company standards.
- Confirm that a baseline (in terms of the current safety assessment) has been established for judging the significance of shortfalls, and that these shortfalls are being set in a suitable context so their significance is clear.
- Scrutinise closely the suitability of improvement actions to address shortfalls/deficiencies asking the following questions:
 - Are they focussed on trends and themes from a collective set of shortfalls/deficiencies?
 - Are they set in the wider context of ALARP priorities for the site?
 - Is there evidence that the proposed action is feasible and does not introduce other unacceptable risks or hazards?
 - Do the improvement actions collectively reduce risk and is this manifest from the PSA?
- Confirm that the claims and conclusions of the summary report for the safety submission (whether representing an intermediate stage or final completion of the process) are rigorously substantiated by the supporting referenced assessments and that any limitations or caveats are transparent in the summary report. The summary report should be clear, readable and transparent about the assessment work undertaken and its outputs.

APPENDIX B

Use of supply chain in peer review

A Licensee may wish to contract out a Peer Review, either in part or in its entirety, in order to manage resource levels and workloads ('peak lopping'), to seek specific technical expertise that they may otherwise lack, or simply as the chosen business model for the company. Normal practice across the industry ranges from a full in-house programme of peer reviewers employed by the Licensee to a fully contracted out arrangement, with various combinations in between.

This appendix identifies relevant good practice targeted specifically for use of the Supply Chain within the Peer Review Process. This supplements the guidance within the rest of the document, which remains applicable, irrespective of who completes the peer review. In addition, there is relevant good practice available for the use of Contractors within the Nuclear Industry and application of the Intelligent Customer (IC) role [Ref. 11].

Maintenance of an External Peer Review Capability

If the Licensee routinely uses the supply chain for Peer Reviews or considers it likely that they will do, then they should prepare for this eventuality.

The expected Peer Review requirements should be planned and consideration given to what external support will be needed, including the technical disciplines and the volume of work. Planning in advance is particularly important for specialist areas with very limited available expertise. There can be a draw on this experience across numerous projects and more than one Licensee. Experience within the industry has shown that failure to properly plan and budget for Peer Review is a regular cause for schedule delays to the programme.

Depending on the reasons for using externally sourced peer reviews there will be a different approach taken to maintaining the capability. Some Licensees prefer to work with a small number of known individuals and appreciate the benefits of a close working relationship that comes from this approach. This approach works especially well when the subcontractors join the in-house peer reviewers as regular part-time team members. There are advantages in terms of consistency, understanding of processes and plant, minimal need for repeat training etc however this exposes the Licensee to risks associated with the availability of specific individuals and potential challenges to independence.

Other Licensee's may establish framework agreements with larger consultancy firms. This can provide the benefits of a breadth of expertise available, increased likelihood of peer reviewer independence and redundancy to cover any unavailability. It may however lead to a need to provide more IC oversight on each task, training for multiple individuals and generally a lack of consistent experience in a particular area or of a specific plant/facility.

Whatever arrangements are put in place, the Licensee should ensure appropriate IC engagement and approval at this stage to ensure they meet the expected Peer Review requirements of the organisation.

Good practice is early identification and planning for external support requirements and ensuring appropriate IC involvement at this stage.

Licensees have standard arrangements in place for placing and agreeing contracts and for management of financial budgets. It should be ensured these arrangements do not prejudice any aspects of peer review good practice (e.g. setting Key Performance Indicators (KPIs) on a contract that could incentivise Peer Reviewers not to raise comments or artificially curtail the amount of time spent on a task).

Industry experience has shown that peer review work is rarely sub-contracted by the lead reviewer, however, if this was required then the IC should approve these arrangements and the SQEP status of the full review team.

Specification and appointment for the task

The IC can specify the Peer Review be performed either through use of standard processes and templates or by providing a detailed specification on a task by task basis dependent on the situation. A good time to do this is after the scope of the task has been confirmed and agreed the need to contract out the peer review.

It is important to ensure that the Peer Review supplier is given a formal process to use for the peer review activity.

It is good practice to provide a process (e.g. a one-page flowchart) showing each stage in an independent peer review, together with who is responsible for each stage.

When appointing an external peer reviewer to a task, the Licensee's IC should ensure the individual is SQEP for the task and should specify the scope and requirements of the review. Confirming SQEPness is usually undertaken via review of Curriculum Vitae (CV) and adequacy of experience and qualifications, supported by interview as required¹. There is guidance within the main body of this GPG (see Sections 5) regarding the typical attributes of a competent and professional nuclear industry peer reviewer. Any proposed changes to the appointed peer reviewer or their scope of work should be identified to the IC and the changes approved in a similar manner.

It is expected that the individual conducting the peer review will work to the same company technical standards and processes as normally applied by an internal

¹ Appointments & information presented on CVs should be managed in a GDPR compliant manner.

reviewer. Access to the organisation's management system should be made readily available. In addition, depending on the work location of the reviewer and their experience and plant knowledge it may be necessary to require the reviewer to conduct a site visit, to provide them with Licensee specific training or provide appropriate presentation briefings and additional background material.

Good practice is for the IC to formally confirm the external reviewer is SQEP for the task, be integrated in the setting to work process and perform oversight of the contracted peer review tasks.

Conduct and Oversight of the Peer Review

Licensees tend to grade or categorise their safety cases on safety significance and then apply appropriate controls to ensure adequate safety case quality. It is expected that these arrangements will remain the same for externally led reviews and that there will be no reduction in standards.

It is common for the Licensee to use standardised templates for the delivery and recording of each stage of a peer review.

Licensees do not tend to track performance of individual peer reviews via Key Performance Indicators (KPIs) due to the potential to adversely impact the quality or independence of the review. For externally led reviews, some general monitoring of performance to cost and schedule is preferred, with IC oversight of the quality of the work.

The IC should provide oversight of the review and the approach for this will depend on the working arrangements in place. This could consist of some, or all, of:

- Formal acceptance of comments / completion prior to passing to the safety case owner;
- Close working relationship with the peer reviewer, usually when the Licensee regularly uses a small pool of known individuals;
- Formal routine communications requirements specified at the start of the review (such as key stages for IC interaction during the peer review or following the identification of significant issues);
- Compliance with Licensee's peer review process and other applicable management system arrangements;
- Sampling approach, either via sampling aspects of each review or by sampling a proportion of the reviews completed by the reviewer. Particularly at the start of a new contract / working relationship; and/or
- Specific requirements set out on a task by task basis.

The IC must satisfy themselves that they are providing sufficient oversight of the Peer Review process on behalf of their Licensee.

Throughout the Peer Review process the reviewer will be expected to resolve any issues identified with the owners / producers of the safety case. There may be instances where these issues are not readily agreed at the working level to everyone's satisfaction. There should be established arrangements for elevating and resolving such issues. It would also be good practice to ensure the peer reviewer has access to any safety reporting arrangements the Licensee has in place, should the issue not be resolved and the reviewer feel further action is warranted.

Good practice is to ensure there are clear arrangements for resolution of issues identified by the peer reviewer with escalation routes as necessary to ensure that their independence can be maintained.

Ensuring Independence

The use of externally supplied peer reviewers may present additional challenges to ensuring independence, both at a technical level and at a commercial level. For example, in specific technical areas, with limited available expertise there may be a pull on the same individuals from both the design and production side and the peer review function. This must be managed to ensure the reviewer has not been involved in earlier stages of the safety case process, prior to their involvement in the peer review. Similarly, there could be commercial challenges to independence, with peer reviewers being requested to review documents produced elsewhere within their own organisation. Careful consideration should be given to how to maintain independence at an organisational level via use of different companies, as well as with the individual(s) being expected to perform the peer review task(s).

In some scenarios, there may be no option but to use an individual from a company that is already involved with the work. In this instance consideration should be given to what additional actions can be taken and governance established to manage this challenge to independence. For example, consider physical location of the reviewer, management reporting lines, increased IC involvement etc.

For long-term projects there is the potential for further challenges to occur (e.g. via people moving between organisations or organisational re-structuring etc). The IC must monitor the position as part of their oversight activities and take any action necessary should the independence of the peer reviewer be challenged.

Good practice is to maintain independence of the reviewer both at an individual level and at a supplier level and take steps to protect the peer review barrier against any challenges to independence.

Maintaining Core Capability

When using the supply chain for Peer Review there is the potential to challenge the long term ability of the Licensee to discharge their intelligent customer requirements. The risks from this will depend on why the supply chain is being used and the level, or proportion, of work that is discharged in this way.

The Licensee's Peer Review process owner should manage the challenges in this area via appropriate vulnerability analysis and succession planning, etc when appropriate. Reference 11 should be referred to for relevant good practice in this area.

Good practice is to ensure core Peer Review capability is maintained to adequately direct and accept contracted peer reviews in line with the principles of acting as an Intelligent Customer.

APPENDIX C

Key principles for performing any peer review activities

Why	<ul style="list-style-type: none">• Identify why a peer review (or a series of peer reviews) is required
What	<ul style="list-style-type: none">• Identify what requires to be peer reviewed• Identify what supporting information needs to be made available• Identify what procedure(s) are applicable• Define what scope should apply for the peer review task• Identify what specialisms are required by the peer reviewer(s)• Identify what acceptability criteria are to be applied by the peer reviewer(s)• Identify what benefits are gained by having a peer review performed
When	<ul style="list-style-type: none">• Identify when the peer review activity needs to start• Identify when the submission/information will be available• Identify when the peer review needs to be completed by• Identify when author(s) will respond to peer review comments
Where	<ul style="list-style-type: none">• Identify where the peer review can be conducted (physically, organisationally and virtually)• Identify whether the peer reviewer needs to make a site visit
Who	<ul style="list-style-type: none">• Identify who is the customer for the peer review activity• Identify who is going to pay for the peer review activities• Identify who is available, independent and SQEP to perform the peer review• Identify who the main contact for the peer reviewer should be• Identify key information providers that the peer reviewer can approach• Identify who will have intelligent customer oversight of contracted peer review activities
How	<ul style="list-style-type: none">• Identify how submissions are going to be appropriately technically and quality checked before peer review commences• Identify how the peer review activity is to be conducted (e.g. peer review procedures)• Identify how are peer review interactions and comments to be captured (e.g. a tabulated form to allow responses to be captured)• Written peer review comments produced should be self-standing, clear and unambiguous, such that specific linkage is provided to where any concern lies. They should also be relevant, constructive, proportionate, impersonal, polite, timely and categorised.• Comments should be consolidated into the smallest set possible.• Peer review comments need to be pragmatic and focus on the key issues having viewed the submission holistically and taking a broad judgement on the adequacy of the content being reviewed.• Peer reviewer(s) must remain independent throughout the task.• Identify how any interim or final outputs are to be delivered