The UK Nuclear Industry Good Practice Guide To:

**Monitoring, Interim Review and Continuous Improvement in**

**Periodic Review of Safety**



This Nuclear Industry Good Practice Guide was produced by the Safety Case Forum and published on behalf of the Nuclear Industry Safety Directors’ Forum (SDF)

**Issue 1 – March 2020**

**Revision History**

|  |  |  |
| --- | --- | --- |
| **Issue Number** | **Revision Date** | **Changes** |
| Issue 1 | March 2020 | Initial Publication |
|  |  |  |

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

In the first instance, any such comments should be sent to all of the following:

safetycaseforum@awe.co.uk

Author: Simon Williams (Rolls-Royce)

Contributions have been provided through the Safety Case Forum by
all participating members, particularly:

John Andress (Babcock International)

Sally Forbes (Atomic Weapons Establishment)

Phil Lundberg (BAE SYSTEMS)

Matthew Townsend (EDF UK)

This document was reviewed and approved by the Safety Case Forum
of the Safety Directors’ Forum.

# Foreword

This Guide sets out a good practice approach to identifying how to manage those aspects of plant/facility safety within the scope of the Periodic Review of Safety (PRS) between the ‘stand-alone’ reviews required to be conducted every 5-10 years. During this period, safety can be measured and managed via a series of interim reviews, or via a continuous monitoring process. The latter has the significant benefit that many elements of PRS can be incorporated into normal business, thus reducing duplication and making plant/facility safety an integral part of operations management, however, both approaches can be adapted to enable this.

Consideration is required of plant/facility size and local organisation size, and their integration with associated infrastructure, and the operational regime of the plant/ facility relative to safety – whether risks are continuous, or batch.

The intent is to provide sufficient guidance as to which elements of PRS scope require consideration via interim reviews and/or continuous monitoring, and what constitutes the best vehicle to consider them, given the scale of the plant/facility, organisation in place and operating regime.

## 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,
* To 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 (EHSQS&S) and resolve them, often through working with the UK regulators and Government, both of whom the 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, care and maintenance and waste disposal. The Forum also has members who represent the Ministry of Defence (MoD) 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 new regulatory framework for security. Such sub-groups have developed a number of Good Practice Guides which have been adopted by the industry.

## Sub-Group Description

This Guide has been produced by the Periodic Review Forum, a workstream of the Safety Case Forum, which is in turn a sub-group of the SDF.

The Safety Case Forum was established in June 2012 and brings together a wide range of representatives of nuclear operators, from all the Licensees and Authorisees across the UK, including:

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

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

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.

These guides are 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. They are 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 these guides, 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 ONR and the Defence Nuclear Safety Regulator are consultative members of the Safety Case Forum.

The following companies and organisations are participating members of the Safety Case Forum:

   

  

  

  

   

  

  

Safety Case Forum Guides are available on the Nuclear Institute Website:

<http://www.nuclearinst.com/SDF-safety-cases>

**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.

**Contents**

[Foreword 3](#_Toc30081465)

[Safety Directors’ Forum 4](#_Toc30081466)

[Sub-Group Description 4](#_Toc30081467)

[1 Introduction 8](#_Toc30081468)

[1.1 Background 8](#_Toc30081469)

[1.2 Aims 8](#_Toc30081470)

[1.3 Scope 8](#_Toc30081471)

[1.4 Target Audience 9](#_Toc30081472)

[1.5 Application/Readers Guide 9](#_Toc30081473)

[2 Introduction to the Subject Matter 10](#_Toc30081474)

[2.1 Description 10](#_Toc30081475)

[2.2 Relevant Legislation and Guidance 11](#_Toc30081476)

[3 Guiding Principles/Concepts 12](#_Toc30081477)

[3.1 Principles and Concepts 12](#_Toc30081478)

[4 Guidance 13](#_Toc30081479)

[4.1 Overview of Scope 13](#_Toc30081480)

[4.2 Context for Application 14](#_Toc30081481)

[4.3 Defining Applicability of PRS Elements to Interim Review or Monitoring Activities 14](#_Toc30081482)

[4.4 Spectrum of Approaches 17](#_Toc30081483)

[4.5 Management of Findings 18](#_Toc30081484)

[4.6 Forward Look and Interface with Stand-Alone Review 19](#_Toc30081485)

[4.7 Safety Case Interface 19](#_Toc30081486)

[5 Benefits 20](#_Toc30081487)

[6 Summary of Key Points 20](#_Toc30081488)

[Appendix A: EDF UK – Approach to PRS Interim Reviews 21](#_Toc30081489)

[Appendix B: BAE SYSTEMS use of Safety Case Revalidation 22](#_Toc30081490)

# 1 Introduction

## 1.1 Background

The Safety Case Forum works under the direction of the Safety Directors’ Forum and has a remit to provide guidance to standardise and improve the way in which the safety case is produced and presented. Part of that remit is to review and recommend changes to the way in which the Periodic Review of Safety (PRS) is undertaken.

While all Licensees/Authorisees participating in the work stream undertake significant PRS activities on a 10-yearly review cycle, a range of approaches are taken to any interim review activities, from taking credit for event driven reviews and monitoring on an opportunity basis, to monitoring systems and safety cases on a frequent (e.g. monthly) basis.

The PRS process should encourage nuclear operators to take increased ownership of plant/facility safety, pro-active and forward looking, with a focus on the plant/facility itself, rather than being predominantly a retrospective review of the safety case documentation. To facilitate this, there is an explicit expectation (where it is appropriate to do so) of a shift towards a rolling, “Monitoring, Interim Review and Continual Improvement” process. This should reduce overall effort and maximise benefit by utilising the outputs to update, and keep up-to-date, the facility safety case and to feed current information into other business decision making processes.

Although the overall improvement is aimed at bringing much of the scope of PRS within the scope of normal day-to-day business, this guide must also recognise that there are certain activities that are necessarily conducted over longer timescales, and need a degree of independence from routine business (e.g. trend analysis, confirming the effectiveness of processes and management architectures).

## 1.2 Aims

This document explores how to undertake key elements of PRS that require active oversight and management of plant/facility safety between the longer timescale ‘stand-alone’ reviews carried out every 5-10 years. Different approaches to carrying out these activities are considered, and the context in which each would constitute an optimal approach (in terms of comprehensiveness, timeliness, effectiveness and greatest cost efficiency) is identified.

One of the key objectives of the PRS work stream is to integrate wherever possible the outputs from the PRS into mainstream business activities, to add value, remove duplication and maximise effectiveness and efficiency. Part of the activity of this work package is to: explicitly use outputs of existing business processes, or show how these can be adapted, to demonstrate that PRS safety factors are being assessed and managed in the course of normal business wherever possible, thus reducing the requirement for additional, dedicated PRS processes.

## 1.3 Scope

The work presented in this document considers all elements that comprise PRS of a nuclear plant/facility, throughout the full life-cycle of the plant/facility and encompasses the interfaces with the safety case, PRS management processes and all monitoring and performance measuring activities.

## 1.4 Target Audience

It is hoped that this document will be read by those persons with responsibility for undertaking the PRS, those undertaking associated activities, and those responsible for safety management of the plant/facility, who govern some of the activities used to inform the PRS.

## 1.5 Application/Readers Guide

This guide is complementary to, and should be read in conjunction with, the following Safety Case Forum Guides:

1. “Keeping Safety Cases Live”: this guide recommends good practice to keep plant/facility safety cases updated and current throughout life, such that configuration alignment between the plant/facility, the various tiers of the safety case, and relevant standards is maintained.
2. “Shortfalls Management”: this guide recommends good practice for the systematic identification of findings arising from PRS, the identification of their significance to safety, their processing to identify issues to be addressed, an associated decision-making process, and a framework to manage such issues to resolution.

The first of the above guides effectively addresses a key element of continuous monitoring of plant safety, therefore guidance on how to achieve this aspect is not discussed in detail in this guide. The second of the above guides addresses the management of findings that may lead to shortfalls, so, while this guide identifies activities that may result in findings, it does not discuss how those findings may be processed and managed to resolution, that is addressed in the Shortfalls management Guide.

# 2 Introduction to the Subject Matter

## 2.1 Description

The UK nuclear industry and associated regulators (the Office for Nuclear Regulation and Defence Nuclear Safety Regulator) have recognised the benefit in considering changes in the approach to discharging the PRS requirement given the difficulty the industry has had in closing-out all activities from PRS programmes prior to starting the next round of reviews. PRS activities have generally been carried out as extremely sizable reviews on a 10-year basis, sometimes with additional interim reviews conducted approximately every 3 years, with the output from these activities generally being managed in isolation from normal safety management and improvement activities. This process resulted in the above difficulty in prioritising PRS action closure relative to ‘normal business’ safety activities, and ONR and DNSR also felt that this was distorting overall risk reduction processes due to the emphasis on closing out PRS rather than reducing risk.

The proposed way forward is to move to a ‘continuous monitoring’ model, wherever practicable, with normal safety management processes being used to provide evidence to a PRS review and any findings arising slotted into an overall safety improvement programme, with an emphasis on reducing overall risk. A ‘Stand-Alone’ review, focused on longer-term trend analysis and the appropriateness of processes used, would still be carried out on approximately a ten-yearly basis, to review the performance of the Safety Management Arrangements (SMAs) and their outputs and set the forward programme for the next ten years.

On the basis of the above, further formal ‘interim’ reviews between the 10-yearly stand-alone reviews would not be required, and the scope of the stand-alone reviews could be reduced.

The basis of this guidance is therefore to understand where and when it would be appropriate to move to such an approach. SMAs used routinely should be robust enough to deliver continuous monitoring of plant safety. However, before moving to the new process it is recommended that the processes are reviewed to ensure that their coverage is suitable to address the scope of PRS; that evidence will be available at the ten-year point; and to consider how the processes are reviewed to confirm their effectiveness and ensure the evidence is being collated.

Otherwise, this guidance will also recommend, in what contexts the use of interim reviews should be retained, in such a way that their application is adequately efficient.

Areas with benefit in developing a consensus of good practice are:

1. The scope of an ‘interim review’ – identifying an appropriate scope for scrutiny, the depth to which scrutiny should be applied (e.g. looking at the outputs of processes, or the robustness and validity of those processes also).
2. Proportionality of review – how to take account of range of safety significance and consequences of associated faults/hazards, and any other parameters (e.g. facility lifetime) in defining the level of detail and range of safety factors to be addressed in any ‘interim review’.
3. Key stakeholders – specific roles in the technical organisation who should inform or be consulted during interim review activities.
4. The timeframes for ‘interim review’ activities – e.g. annual, three-yearly, a more frequent scrutiny over a limited but varying scope, or an aggregation of many instruments providing a wide-ranging, frequent series of reports?
5. The case for continuous monitoring – can an interim review be effectively replaced via an appropriate range of instruments providing a wide range of frequent reports that feed safety oversight activities? (many of which will already exist in Licensee/Authorisee organisations).
6. Scope and method for managing data for continuous monitoring – what type of parameters should be monitored, and how could these be captured, stored and extracted as necessary?
7. Findings management – how to raise and manage findings in the interim review framework, while not overburdening resources or duplicating activities, and how to interface with extant monitoring processes and longer time-frame PRS activities (e.g. the findings associated with a 10-yearly review).
8. Reporting – what is the appropriate level of detail to report? (there is the potential for a ‘drip feed’ of minor bad news, as positive trends will not be raised as findings), how to interface the output with the safety justification.
9. How to ensure a forward-looking element is incorporated into interim review activities – ensuring that Licence Condition/Authorisation Condition stipulations and IAEA good practice expectations are met for PRS.
10. How to use the ‘interim review’ or continuous monitoring processes to identify and promote the business benefit of PRS, for presentation outside specific Safety forums.

## 2.2 Relevant Legislation and Guidance

This document has been generated with consideration of relevant nuclear safety legislation and guidance. Where appropriate, legislation has been referenced, but the primary legislation that has influenced this document is:

1. Office for Nuclear Regulation Nuclear Site Licence Condition Handbook, February 2017 [Licence Condition 15 relates to Periodic Review of Safety].
2. Joint Services Publication 518, Regulation of the Naval Nuclear Propulsion Programme, Version 4.1, July 2014. [Authorisation Condition 15 relates to Periodic Review of Safety].

The following guidance has also influenced the guidance presented in this document:

1. International Atomic Agency Specific Safety Guide No. SSG-25, Periodic Safety Review for Nuclear Power Plants, 2013.
2. ONR Nuclear Safety Technical Assessment Guide NS-TAST-GD-050 Revision 6, Periodic Safety Reviews, July 2017.

# 3 Guiding Principles/Concepts

## 3.1 Principles and Concepts

This guidance has been prepared considering its application to a range of different nuclear plants and facilities:

1. A large plant/facility, with a range of engineering teams and a relatively large safety management organisation, such that no one individual can hold a detailed understanding of all key aspects of nuclear safety management.
2. A range of plants of common designs that all operate under common processes and controls, such that they can be subject to a single PRS suite of activities, but require relatively large engineering and safety management organisations.
3. A relatively small plant/facility (or a decommissioned large plant/facility, with much reduced potential for safety significant challenge) with small dedicated engineering and safety management organisations, such that single individuals (e.g. plant safety manager) can hold a detailed understanding of all key aspects of nuclear safety management.
4. A facility with a variable scope of nuclear-significant activities taking place over its lifecycle (e.g. a submarine dock) but with generally common features such as safety controls applied and infrastructure in place.

In all cases, it is assumed that the PRS scope, while tailored to the plant/facility activity scope, location and lifecycle stage, will be based on the good practice safety factors identified in IAEA SSG-25, with consideration also given to Leadership and Management for Safety, as scoped and recommended in ONR NS-TAST-GD-050 and the Safety Case Forum’s Guide: “The Periodic Review of Leadership and Management for Safety”.

It is also assumed that the Licensee/Authorisee undertaking PRS will retain the stand-alone review element of PRS, with a focus on the effectiveness of the processes being applied, longer term trend analysis and forward programme. Guidance on executing this aspect of PRS is not incorporated, except to highlight how the interface between this element of PRS and other elements should be managed.

While this guidance generally does not attempt to prescribe how the review and monitoring activities themselves are carried out; it does explicitly recommend one activity as being incorporated into the PRS process; this is the ‘stand-back’ review. This process, initially incorporated into the EDF UK PRS process, involves interviewing key stakeholders in the operational safety of the plant/facility who have current knowledge of the condition of the plant and obtaining their views on what are the most significant issues for nuclear safety of the plant/facility. This information then provides an early indication of potential issues of significance for the PRS.

# 4 Guidance

## 4.1 Overview of Scope

The following safety factors are identified in the IAEA Specific Safety Guide SSG-25 as encompassing the scope of PRS:

1. Plant Design.

2. Actual Condition of SSCs important to Safety.

3. Equipment Qualification.

4. Ageing.

5. Deterministic Safety Analysis.

6. Probabilistic Safety Assessment.

7. Hazard Analysis.

8. Safety Performance.

9. Use of Experience from other Plants and Research Findings.

10. Organisation, the Management Systems and Culture.

11. Procedures.

12. Human Factors.

13. Emergency Planning.

14. Radiological Impact on the Environment.

Additionally, there are two subject areas that are considered sufficiently important to be included although they are not within SSG-25:

15. Radiological Protection (personnel).

16. Decommissioning.

All relevant PRS safety factor content can be bracketed under four groupings of activities:

1. ‘Stand-back’ review: focuses on operational issues – therefore may touch on safety factors 1, 2, 3, 4, 8, 10, 11 and 12.
2. Actual condition of facility: includes alignment with design and ageing management, therefore focused on safety factors 1, 2, 3 and 4.
3. Safety case health and methods: focused on safety factors 5, 6, 7, 8 and 9.
4. Safety management: includes leadership, SQEP and external factors, therefore focused on safety factors 10, 11, 12, 13, 14, 15 and 16.

These groupings are each amenable to particular approaches to review and monitoring, and defining them prevents a requirement to consider each safety factor in-turn, which leads to a great deal of repetition in any guidance. The scope covered under each of these groupings is described in more detail in Section 4.3.

The only specific exclusions from the consideration of continuous monitoring and interim review are:

1. This scope should not focus on the robustness and effectiveness of processes, rather it should work with their outputs. Interrogation of process effectiveness is an activity for longer term, stand-alone reviews. If direct evidence of a ‘broken’ process is obtained, however, this should be flagged for consideration in the relevant safety or technical management forum.
2. Leadership and management for safety, identified as an area for specific review by the ONR, is better suited to consideration in a detailed stand-alone review to test the effectiveness of the processes in-place and analyse long-term trends. If direct evidence of instances of inappropriate safety management are identified, however, these should be flagged for consideration in the relevant forum.

## 4.2 Context for Application

A key aspect to this guidance is the recognition that different means of applying interim reviews or monitoring will be optimal for different facilities, depending on facility size, staffing levels, operating regime and degree of centralisation in their supporting organisations. This has become evident through consideration of practices employed by different organisations. Therefore, this guidance will not recommend a single ‘ideal’ method, but rather identify several different means to achieve the necessary functions, and the contexts in which they would be optimal to apply. This should enable organisations to further improve existing constructs used, and organisations developing a construct to pick one that is appropriate. Key differences in context that need to be addressed explicitly against each of the four groupings of activities are:

1. Facility/organisation size: is PRS carried out for a facility that is sufficiently small that all safety case and engineering condition information is held by a small number of individuals (e.g. a safety case lead and engineering manager) or are there multiple stakeholders across the organisation, or multiple organisations involved in the provision of this information.
2. Operating regime: is the facility operated continuously, or discretely, e.g. in a series of batching operations, such as dockyard refit campaigns, or staged operations such as build or decommissioning.

## 4.3 Defining Applicability of PRS Elements to Interim Review or Monitoring Activities

Consider the four principal areas of review within the PRS process, and how interim review or monitoring activities might address them:

**‘Stand-Back’ Review:** This is an interview/questionnaire-based activity to identify key safety concerns of facility operation and management stakeholders. This is a less-formal means to identify and explore issues of importance to facility operators and management, such that these are not lost in the machinery of the review process.

1. Scope and Proportionality: this is dependent on facility size; it could address an entire facility or a system; the key aspect to the scale of the review is that it must be structured such that all stakeholders are given an opportunity to contribute.
2. Contributing Stakeholders: input from operators, maintainers, operational management, designers and safety engineers (these latter two groups to filter findings for safety significance).
3. Accountable Stakeholder: for a specific facility, this should be the License/Authorisation Condition Owner; e.g. safety case manager or engineering manager. Where a site is undertaking a large number of events, accountability may sit better with a central PRS function.
4. Frequency: By its nature, this is not an activity that can be undertaken continuously. Also, if carried out too frequently, it could become routine which would lessen its impact. It is suggested, based on existing experience of its application, that it should be undertaken as part of a 3-yearly interim review, part of an annual review of the validity of basis of facility operation, or partially take the form of senior management walk-throughs. It could also be undertaken as part of the supporting activities underpinning a facility/process readiness review, e.g. where batching is undertaken – for instance, it could be applied before or after routine plant walk-downs to highlight issues for consideration. It is not recommended that it is undertaken on more than an annual frequency, however.
5. Forward Look: this scoping element does not formally address future issues, but by its nature, some future issues will be picked up from the discussions and/or correspondence driving the reviews.

**Actual Condition of Plant/Facility:** This should include alignment with design and ageing management and consider the implications of outputs of inspections, identified defects, ageing effects and modifications. This would be the major focus of an interim review or monitoring process, which should ideally lock into standardised data reporting routes to allow the information to be obtained routinely. This would be used to ascertain status at monitoring intervals and to identify short/medium term trends. If standardised data reporting routes are not in place, then dedicated walk-downs should be introduced.

1. Scope/Proportionality: inputs from the full safety significant plant/facility scope require consideration as necessary. A common standard for reporting and categorisation of findings should be in-place. The intention for continuous monitoring or interim review activities should not be to routinely drill into design substantiation or codes and standards; this would be done where a finding has been identified as sufficiently significant as to be categorised as an issue (and would be done systematically as part of the longer timescale stand-alone review). Consideration of proportionality is also advised, during this element of any review process, to ensure that the bar is set at an appropriate level, e.g. to avoid continually raising ‘chronic’ shortfalls against standards of ageing equipment that will not be addressed during facility lifetime. A review process would be better advised to adopt a proportionate approach, focusing on the severity of potential failure or rate of change of deterioration. A fuller study and audit, as necessary, would be carried out during the longer timescale stand-alone review.
2. Contributing Stakeholders: the key stakeholders are those undertaking walkdowns, checks, inspections, maintenance activities, and reporting events. For a large facility, the reporting processes for all relevant facility condition information may involve a substantial number of stakeholder groups – this is a strong motivation to move towards a continuous monitoring process, to reduce the effort required to integrate all stakeholder inputs. For a smaller facility, the key stakeholders may be sufficiently small in number that compiling inputs for an interim review can be accomplished quickly and easily.
3. Accountable Stakeholder: continuous elements of condition monitoring, with issues escalated to the safety case where necessary, should be under the control of engineering management. Any aspects of review activities being undertaken purely to support PRS should be either controlled by the facility safety case manager or central PRS team.
4. Frequency: where an organisation is of sufficient size to generate and scrutinise this information routinely, it can be readily used as the basis for a continual monitoring process, which may then prove an advantageous means to meet the requirements of interim review, or the continuous monitoring aspects of PRS. It should be noted that the periodicity with which this information is identified and considered by normal business processes will not always be the same; provided coverage is provided on a timescale that allows issues to be identified and addressed in an appropriately timely fashion, this is not an issue for PRS. If not all facility condition information is scrutinised as part of normal business in such a way that this can be claimed to support PRS, then it is recommended that a facility review is carried out for any issues and trends arising, on a frequency that is between annual and 3-yearly, depending on the level of change evident in the facility. For example, a facility in the early stages of life, undergoing few variations in operation, may not require frequent considerations due to a relative lack of modifications to plant and of ageing effects.
5. Forward Look: annual reviews or regular meetings should consider the potential impact of up-coming events that will change the facility configuration or condition (e.g. decommissioning a system), or potential lifetime extensions, as well as having a mechanism to consider trends (e.g. cumulative monitoring).

**Safety Case Health and Methods:** This should consider the effects of changes to the actual condition of the facility, on the safety case, information from operating experience that affects the validity of safety arguments, as well as the implications of changes to methods, e.g. arising from changes to standards, data or regulatory expectations.

1. Scope and Proportionality: this would consider open change requests, modifications and their justifications and the cumulative effects of changes to facility design/management on the safety case, ideally on a fairly frequent basis before issues have the opportunity to aggregate, and either hazards propagate or configuration issues arise. Consideration should also be given to changes to accepted safety methods, customer expectations, operating experience, regulator expectations and good practice standards: the impact of these on the safety case should be considered, but no mandate for immediate update put in force, this may be carried out over longer PRS timescales. Consideration of upcoming events and any impact on the safety case arising allows a forward look.
2. Contributing Stakeholders: given information on actual condition of the facility is available via the engineering organisation, the principal stakeholders are those most familiar with the facility safety case, and any central safety case function that can provide a wider perspective on industry practice. The ideal conduit for this would be a regular safety management meeting or an annual review of facility safety, chaired by plant/facility manager or an equivalent accountable stakeholder, which could inform ongoing authorisation to operate.
3. Accountable Stakeholder: recognition of the health and currency of the safety case, and management of any issues identified, falls within the remit of the facility safety case manager.
4. Frequency: it is suggested that safety case health should be considered on at least an annual basis, but that only highly significant changes to safety case methods (e.g. arising in response to a major event, such as a nuclear accident) should be considered on a more frequent timescale.
5. Forward Look: Annual reviews, or more regular safety management meetings, should consider up-coming events that could impact facility safety arguments.

**Safety Management:** This grouping of safety factors should address operating experience, organisation changes, facility manning, training, SQEP, and safety culture.

1. Scope and Proportionality: some of the scope under this grouping of factors is well suited to continuous monitoring or review on interim timescales – emergent issues such as consideration of events and safety implicated changes to the organisation, frequently reported metrics associated with safety culture, and aspects that are assessed on a generally annual basis, e.g. demographics. This information is obtained and processed in most organisations of sufficient size, but may not be directly considered for its impact on facility safety, e.g. safety culture metrics. The key objective should be to confirm that these aspects are receiving appropriately systematic attention involving the correct stakeholders. For a smaller facility on a scale that does not require these processes, information may be obtained via expert elicitation from key staff and management, possibly with interfacing input from other facilities, e.g. where part of the same organisation. Other scope elements under this grouping, such as consideration of management of issues and leadership, are more appropriate to be assessed over longer timescales, such as the 10-year period.
2. Contributing Stakeholders: it should be ensured that the stakeholders with oversight of safety management include the facility safety case management, and that all aspects that would benefit from senior oversight are elevated appropriately within the organisation. If this is not taking place through the existing processes, consideration should be given to including this information in an annual review of safety.
3. Accountable Stakeholder: while some aspects, such as learning from events, may sit with the facility safety and engineering management, other aspects, such as leadership and organisation change require oversight from senior management.
4. Frequency: while it is preferable for this information to be undergoing a degree of consideration through normal business (and some aspects, such as organisation changes, are required to do so via LC compliance), it is recommended that impacts on facility safety are specifically considered at least once annually in a review.
5. Forward look: the nature of many of the inputs identified above is that they address future issues, e.g. demographics, read across of operational experience.

## 4.4 Spectrum of Approaches

The area-specific considerations in the previous section should be developed to identify a range of approaches that would embody good practice by allowing the scope identified to be addressed in a way that would either address all elements of the PRS process, or complement a longer timescale review such that all elements of PRS could be addressed. Where an approach has particular challenges that would make achieving PRS expectations difficult, this should be noted. Specific approaches to be presented should include:

1. Facility-driven continuous monitoring – facility or system-based reports, owned and produced at least once a year by experts, with collations on a yearly/multi-year basis to identify trends. Most useful where considering small scale facilities for which a small number of staff can access and process the information needed. Includes actual condition issues, safety case health, changes to relevant standards etc. The challenge is how to ensure appropriate scrutiny of outputs, consistency of process application and how to address site wide issues and organisational aspects to an appropriate degree.
2. Process-driven continuous monitoring – use of a range of established processes (e.g. maintenance, in-service inspections findings, condition monitoring) and where appropriate working parties/review boards/management meetings to scrutinise information and findings across the range of safety factors, and raise and track actions. Most useful where multiple, similar facilities are under the control of a single organisation and/or where a unified suite of corporate processes are applied, rather than local processes. Includes actual condition issues, safety case health, changes to relevant standards, cross organisational learning from events, etc. The challenges are how to ensure that routine detail is appropriately interrogated, rather than all focus being on events (e.g. making use of event-driven comprehensive reviews, such as those for life extension), and that ‘stand-back’ and lower frequency review elements are utilised to prevent trends being lost in the detail.
3. Formal interim reviews – use of a specific PRS-driven interim review at a 1 to 5-year periodicity, to address the PRS factors, generate specific documentation and utilise a specific findings categorisation and tracking scheme. This may be most useful for facilities undergoing little change, with minimal facility monitoring activities. The challenge is how to set the frequency and process to prevent the PRS from becoming entirely reactive.
4. Event driven reviews within a 10-yearly PRS cycle – no specific interim reviews, but make use of findings from event driven reviews and activities within the 10-yearly PRS cycle, and monitoring of PRS actions to provide information on any issues affecting nuclear safety. The challenge is to show how the longer timescale PRS can pick up and manage all issues in a manner that is timely – this approach is likely to have to fall back on process or facility-driven continuous monitoring that is taking place outside the PRS process.

Consideration should be given to not only one approach being most appropriate for particular circumstances/constructs, but also the potential to flex between the models identified. The previous sub-section identified that, for different groupings of safety factors, it may be optimal to flex between the spectrum of approaches, such that monitoring and review elements take place at different frequencies. For example, for a large facility:

1. Carry out a ‘stand-back’ review of the full facility scope (e.g. possibly in a rolling regime of multiple reviews) on a three-yearly periodicity.
2. Carry out monitoring of actual condition of equipment continuously via identification of non-conformances arising from maintenance and inspection returns and operational events, to be considered using routine processes, with anything of nuclear safety significance being raised to regular (e.g. monthly, quarterly) safety management meetings.
3. Consider safety case health issues relating to emergent events via regular (e.g. monthly/quarterly) safety management meetings.
4. Consider safety methods changes and short/medium term safety management trends via an annual review of safety that informs authorisation to operate.

There is likely to be considerable variation between exact approaches, as a particular approach would be matched to the relevant engineering organisation construct.

## 4.5 Management of Findings

For all of the activities identified in the previous sections, there are two principal means by which findings of significance to safety would be managed:

1. Where an existing process is in place, e.g. to manage non-conformances, it is recommended that findings are dealt with using the process, and records maintained in accordance with the process, rather than duplication being introduced by a parallel management process being applied for PRS purposes. However, for such processes, it should be ensured that there are sufficient records to allow trends to be mapped, and for ‘deep dives’ to confirm process effectiveness to be carried out, e.g. as part of a stand-alone review.
2. Where an activity is carried out to address the scope of the PRS safety factors, and does not have a dedicated operational management system, e.g. a discrepancy between facility configuration and safety case, it is recommended that this is managed as a PRS finding. Such a process would be most efficiently operated as a single system for all PRS findings, that sentences the findings on the basis of safety significance, and those that are not screened out would be assigned to a Safety Improvement Programme with an appropriate priority. Detailed guidance on management of PRS shortfalls will be provided in a dedicated Safety Case Forum Guide, as noted in Section 1.5.

## 4.6 Forward Look and Interface with Stand-Alone Review

As noted previously, elements of the continuous monitoring process incorporate a consideration of future plant/facility safety. These can be formalised via hold point control plans for discrete processes or annual facility reviews, etc.

However, developing a more complete picture of ongoing plant/facility safety for future operation should be an output of the stand-alone review. This should make use of trend analyses and aggregated information from the continuous monitoring and/or interim review process to inform the review, in addition to the dedicated interrogation of process effectiveness and organisation capability, etc. The PRS findings that are not addressed via established processes (from which trends and aggregated data should be obtained) should be managed via the same Safety Improvement Programme for both the continuous/interim, and stand-alone, review elements of PRS.

## 4.7 Safety Case Interface

It would be expected that any changes to claims, arguments or evidence arising from findings captured via established processes should be integrated with the relevant elements of the safety case via the practices recommended in the Safety Case Forum Guide “Keeping Safety Cases ‘Live’”. This may involve updating specific safety case documentation or schedules of key controls. Where the processes are established, a graded approach should be in-place recognising the significance of the change to safety, to ensure significant issues are addressed in as timely a fashion as possible.

PRS findings captured within the Safety Improvement Programme should be considered to identify an appropriate integration point reflecting safety significance and timeliness dependent on the safety significance of the issue.

# 5 Benefits

The approach described in this guidance provides a means to identify the most efficient and effective means of undertaking those PRS duties associated with interim review or continuous monitoring for a particular facility or organisation, drawing from industry experience to date.

# 6 Summary of Key Points

This guidance considers the recognised approach to carrying out PRS across the UK nuclear industry, which addresses coverage of the safety factors that address the scope of PRS, which utilises a detailed review on approximately a 10-yearly periodicity, supported by interim reviews on a more frequent basis. Such an approach can be optimised by, wherever practicable, instating/exploiting existing processes for the identification and management of safety related issues, to address elements of the PRS safety factors. This information can be used to inform trend analyses, and findings not addressed through the originating processes themselves should be incorporated into a Safety Improvement Programme across the totality of PRS.

Where to use continuous processes, annual or other frequent reviews, hold point-based reviews or longer-term interim reviews, should be informed by the process architecture in place, the scale of the plant/facility under review and its operating regime (i.e. continuous operation or batched).

Examples of applications of this philosophy are presented in Appendices A and B of this guidance.

# Appendix A: EDF UK – Approach to PRS Interim Reviews

A1 Problem Statement.

The conventional approach to PSR has included a review of the design safety justification for the plant (the ‘safety case’) every 10 years. This creates some challenge – typically a peak of workload at PSR time (for both the review work and the upgrades needed) and hence the potential for delay before incorporating upgraded standards into the safety case.

A2 Example of Use of Interim reviews to improve safety.

A solution to this conventional approach is to introduce management arrangements to keep the safety case live, dealing with changes needed as they occur. For one operator this has been done by the establishing a routine annual review of the entire safety case, section by section, against a set of ‘warning flags’ such as time limits, cumulative effects of plant or safety case changes, time pressures to historic safety case work, validity of ALARP judgements, age of the case, etc.

Where warning flags are raised, a more detailed review of the relevant section of the safety case is scheduled. Where this more detailed review finds that the safety case requires upgrade work, then this is commissioned and planned accordingly. As well as the direct benefit of maintaining the safety case in a more ‘live’ condition, it also promotes knowledge development and retention by safety case teams.

A3 So what does the PSR do?

Given that the safety case is now routinely reviewed and maintained by normal business processes, the volume of work under the PSR is significantly reduced. It does, however, still need to challenge the effectiveness of the safety case health review work, from an independent perspective. For example, the PSR needs to:

* Examine the process - for robustness.
* Observe meetings – to ensure that the process is applied diligently and with appropriate challenge.
* Check that internal standards being used, are benchmarked and updated routinely, against external modern standards.
* Test, by sampling, that the changes to external standards are correctly picked-up by the process and are enacted in the safety case and plant changes as required.

# Appendix B: BAE SYSTEMS use of Safety Case Revalidation

B1 Safety Case Revalidation Process.

For a process which involves a sequence of activities which is then repeated, the safety case may be developed such that a different section of the case covers each activity. Thus, in a sequence, only one part of the safety case is actively controlling the process. When the sequence is repeated at a later date, the safety case for a particular activity will need to be re-invoked. Given that there may be a significant period of time between each sequence (more than a year depending on the sequence drumbeat), it may be appropriate to undertake a revalidation process to capture any changes required since the last time the activities were undertaken.

The revalidation process should typically look at the following to determine whether the safety case remains fit for purpose or alternatively needs updating:

* Incidents/reportable events which have occurred on-site or similar sites.
* Learning from Experience (LfE) outputs from any reviews undertaken since the last time the activity was performed.
* Changes to organisation or responsibilities.
* Changes to planned operations.
* Appropriateness of ALARP statements.
* Status and/or progress against outstanding Forward Action Plans (these could be driven by previous interim or periodic reviews, changes in regulatory expectations, continuous improvement against good practice, etc.).
* Changes to reference documents (see below where these are design substantiation reports).

Supporting design substantiation reports should also be revalidated and the process should look at the following to determine whether they remain valid or alternatively need updating:

* Changes to design.
* Changes to safety functional or other requirements (driven by changes to the safety case or planned operations).
* Operating and maintenance history feedback.
* Feedback from plant walk-downs or condition surveys.

The output of the revalidation process should either confirm that the safety case remains fit for purpose for the duration of the activity or identify what changes are required to make it fit for purpose.

Depending on the nature of the safety case, such a revalidation process may only review a subset of the safety factors considered in a periodic review.

B2 Operational Readiness Reviews.

Operational readiness reviews are typically held where activities are being controlled by a hold point control process. As such they take a broader view of safety than might be encompassed directly by the safety case. Hold point control processes are typically employed during build and commissioning as well as decommissioning activities where a staged process to operations is being employed. It is important that there is a clear statement of the activities which are being released by the hold point.

Typically, the review will consider the following:

* Material state of the plant/facilities is sufficiently mature for the activities to proceed including maintenance being in date.
* The safety case for the activities is in place and authorised.
* Pre-requisites for the activity phase have been, or will be, completed including confirmation that the structures, systems and components claimed as safety measures are available.
* The relevant procedures to undertake the activities have been produced and authorised.
* All relevant personnel have been appropriately trained, and are SQEP.
* Suitable arrangements are in-place to control the progression of activities.

The review panel, typically, review all the evidence presented covering each of the above points to determine whether it is safe to proceed and whether it is wise to proceed.

Depending on the scope of a readiness review, this potentially captures quite a wide range of the safety factors considered in a periodic review.