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No. 124

Periodic Safety Review for Nuclear Fuel Cycle Facilities

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PERIODIC SAFETY REVIEW FOR NUCLEAR FUEL CYCLE FACILITIES

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SAFETY REPORTS SERIES No. 124

PERIODIC SAFETY REVIEW FOR NUCLEAR FUEL CYCLE FACILITIES

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FOREWORD

The safety of a nuclear fuel cycle facility needs to be reviewed and assessed at appropriate intervals throughout the facility's lifetime, including phases after its shutdown (until decommissioning or release from regulatory control) and, in relation to modifications, ageing management operating experience feedback, technical developments and siting aspects. Such assessments are aimed at ensuring a high level of safety throughout the service life of the facility and need to include all technical, operational, personnel and administrative aspects of operations important to safety.

This publication aims to provide practical information on the conduct of a periodic safety review for a nuclear fuel cycle facility by the operating organization, and on the regulatory review and assessment of such periodic safety reviews. The publication covers the planning and preparation for periodic safety review, use of a graded approach, review of safety factors, global assessment of the safety of the facility and development of an implementation plan to address the findings of the periodic safety review.

The publication elaborates on the requirements for a periodic safety review that are established in IAEA Safety Standards Series No. SSR-4, Safety of Nuclear Fuel Cycle Facilities.

The IAEA wishes to thank all those who contributed to the development of this publication. The IAEA officers responsible for this publication were L.N. Valiveti, J. Rovny and A. Shokr of the Division of Nuclear Installation Safety.

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1. INTRODUCTION

1.1. BACKGROUND

Requirement 5 of IAEA Safety Standards Series No. SSR-4, Safety of Nuclear Fuel Cycle Facilities [1], states:

> "**The operating organization shall conduct systematic safety assessments of the facility, in accordance with regulatory requirements, throughout the lifetime of the facility. On the basis of the results of such periodic safety reviews, the operating organization shall implement any necessary corrective actions and shall consider the need for modifications to enhance safety.**"

A routine safety review of a nuclear fuel cycle facility (NFCF) includes reviewing safety significant events and their resulting corrective actions, any modifications to the facility and updates to safety and operating documentation in order to comply with regulatory requirements and conditions for licensing. Routine safety reviews and assessments are conducted for ensuring safety within the design basis; however, there is a need for accounting the cumulative effects of ageing, change in site characteristics, modifications and technical developments. A review of such aspects can be achieved by conducting dedicated systematic safety reviews, taking all applicable factors into account at defined intervals and assessing them against the current standards.

A periodic safety review (PSR) is a systematic reassessment of the safety of an existing facility carried out at regular intervals to deal with the cumulative effects of ageing, modifications, operating experience, technical developments and siting aspects, and aimed at ensuring a high level of safety throughout the service life of the facility [2]. The PSR complements routine safety reviews but does not replace them.

Regulatory bodies in many Member States require the conduct of periodic assessment of safety of an NFCF. The scope, frequency and context of the reviews may vary among Member States.

IAEA Safety Standards Series No. SSG-25, Periodic Safety Review for Nuclear Power Plants [3], provides recommendations and guidance on the conduct of a PSR for an existing nuclear power plant. Safety Reports Series No. 99, Periodic Safety Review for Research Reactors [4], provides technical information on and practical examples of the conduct of PSR for research reactors.

Nuclear fuel cycle facilities are of various types and sizes and include a wide range of facilities of diverse technologies, hazard level and scale of

operations. This publication aims to fulfil the need for practical guidance on PSR for all types of NFCF. The information provided in this publication is not intended to replace or supersede any of the requirements or recommendations provided in the relevant IAEA safety standards; rather, it is to be used in close conjunction with them.

1.2. OBJECTIVE

The objective of this publication is to provide technical information on and practical examples of (a) conducting a PSR for an NFCF by the operating organizations and (b) review and assessment of the PSR by the regulatory bodies. The publication is targeted at operating organizations, regulatory bodies and technical support organizations dealing with safety of NFCFs. Guidance and recommendations provided here in relation to identified good practices represent expert opinion but are not made on the basis of a consensus of all Member States.

1.3. SCOPE

The NFCFs that are within the scope of this publication are those that are covered in SSR-4 [1], including the facilities for processing, refining, conversion, enrichment and fabrication of nuclear fuel, storage of spent nuclear fuel and reprocessing of spent nuclear fuel, as well as nuclear fuel cycle research and development (R&D) facilities and the supporting ancillary facilities in which radioactive material is handled. Aspects related to nuclear security are outside the scope of this publication.

1.4. STRUCTURE

This publication has five sections, two appendices and nine annexes. Section 2 of this publication presents the general considerations for conducting a PSR for NFCFs. Section 3 presents information on the conduct of a PSR by the operating organization, including the review of safety factors applicable to NFCFs under five topical areas, information on the global assessment of the facility based on the findings from the review of safety factors, and the development of the integrated implementation plan. Section 4 provides information on the review and assessment process of the PSR by the regulatory body, and Section 5 provides details on post-review activities.

The details on documentation of the PSR are provided in Appendix I. Information on the review of the safety factor related to 'utilization' for nuclear fuel cycle R&D facilities is provided in Appendix II.

Annexes I–V provide examples of the regulatory requirements for a PSR for NFCFs in Argentina, Canada, the Czech Republic, France and India, respectively. Annex VI presents an example of a methodology for developing a PSR basis document. Annex VII presents sample contents of a PSR report. Annexes VIII and IX, respectively, provide examples of the use of a graded approach in conducting a PSR and of a methodology for reviewing human factors in PSRs.

2. GENERAL CONSIDERATIONS

A PSR provides an overall assessment of a facility's safety and the quality of its safety documentation [4]. It also determines reasonably practicable actions for safety improvement. The findings of a PSR may also be used for the purpose of communication and consultation with interested parties (including the public) regarding the continued safe operation of the facility.

Based on Member States' experiences with the PSR for NFCFs and similar practices for nuclear power plants and research reactors, an interval of ten years may be considered as reasonable for conducting a PSR. As stated in para. 2.5 of SSG-25 [3], this interval is considered appropriate

"in view of the likelihood, within this period, of the following:

- Changes in national and international safety standards, operating practices, technology, underlying scientific knowledge or analytical techniques;
- The potential for the cumulative effects of facility modifications to adversely affect safety or the accessibility and usability of the safety documentation;
- Identification of significant ageing effects or trends;
- Accumulation of relevant operating experience;
- Changes in how the facility is, or will be, operated;
- Changes in the natural, industrial or demographic environment in the vicinity of the facility;
- Changes in staffing levels or in the experience of staff;
- Changes in the management structures and procedures of the facility's operating organization."

If the first PSR of the facility has not been performed in over ten years of operation, then the PSR needs to be initiated as soon as possible.

Some Member States have alternative arrangements and programmes that, if applied appropriately, can achieve the same results as a PSR. This publication is not intended to discourage alternative arrangements and programmes that achieve similar outcomes to a PSR. However, it is important that any alternative approach followed meets the PSR objectives as well as other relevant requirements for licensing, regulation and operating processes [4].

2.1. OBJECTIVES OF PERIODIC SAFETY REVIEWS

The objective of a PSR, as stated in para. 2.9 of SSG-25 [3], is also applicable for NFCFs:

> "The objective of PSR is to determine by means of a comprehensive assessment:
>
> — The adequacy and effectiveness of the arrangements and the structures, systems and components (equipment) that are in place to ensure plant safety until the next PSR or, where appropriate, until the end of planned operation …
> — The extent to which the plant conforms to current national and/or international safety standards and operating practices;
> — Safety improvements and timescales for their implementation;
> — The extent to which the safety documentation, including the licensing basis, remains valid."

Paragraph 4.26 of SSR-4 [1] states:

> "In accordance with national regulatory requirements, the operating organization shall carry out systematic periodic safety reviews of the nuclear fuel cycle facility throughout its lifetime, with account taken of ageing, modifications, human and organizational factors, operating experience, technical developments, new information on site evaluation and other information relating to safety from other sources."

Paragraph 4.27 of SSR-4 [1] states:

> "The periodic safety review shall confirm that the safety analysis report and other documents (such as the operational limits and conditions and

documentation on maintenance and training) remain valid in view of current regulatory requirements, or shall indicate where improvements may be necessary. In such reviews, changes in the site characteristics, changes in the utilization programme (particularly for research and development facilities), the cumulative effects of ageing and modifications, changes to procedures, feedback from operating experience and technical developments shall be considered. It shall also be verified that items and software important to safety comply with the design requirements."

The review of arrangements that are in place to ensure safety also includes the assessment of culture for safety in the operating organization. The results of a PSR can be used to determine and prioritize the modifications of the facility and identify the improvements necessary in the operating organization of the facility to ensure safe operation of the facility for its intended lifetime.

2.2. ROLES AND RESPONSIBILITIES

2.2.1. Operating organization

Paragraph 2.15A of IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), Governmental, Legal and Regulatory Framework for Safety [5], states (footnote omitted):

> "The person or organization responsible for a facility or an activity, having prime responsibility for safety, shall actively evaluate progress in science and technology as well as relevant information from the feedback of experience, in order to identify and to make those safety improvements that are considered practicable."

The responsibilities of the operating organization in this regard include, but are not limited to, the following:

- Developing a PSR basis document, including the PSR project plan (see Section 2.4.1).
- Managing the systematic conduct of the PSR project, including:
  - Deployment of a PSR project team with the necessary technical knowledge, experience and competence in the conduct of PSRs;
  - Provision of the documentation and information necessary to conduct a PSR;

- Provision of the resources necessary to conduct a PSR and quality management.

— Reporting the results of the PSR and any findings related to any immediate and significant risk (to the health and/or safety of workers, the public or the environment) to the regulatory body.
— Developing and implementing an integrated implementation plan (see Section 3.7) based on the findings of the PSR.
— Establishing a formal communication interface with the regulatory body during all phases of the PSR project (see Section 2.2.3).

When technical support organizations and consultants are engaged for the purpose of conducting a PSR, the operating organization needs to have adequate resources and competence to effectively manage and evaluate their work. IAEA Safety Standards Series No. GS-G-3.5, The Management System for Nuclear Installations [6], provides recommendations on control and supervision of contractors in the implementation of management systems.

2.2.2. Regulatory body

Depending on national regulations, it is often the regulatory body which is responsible for the following matters [4]:

"(a) Establishing the requirements for the PSR;
(b) Reviewing the PSR basis document and agreeing on it with the operating organization;
(c) Reviewing the scope of the project plan, the conduct and findings of the PSR, the resultant corrective actions or safety improvements and their associated implementation plans;
(d) Verifying the prospects for safe operation of the facility for the period until the next PSR;
(e) Taking appropriate licensing actions based on the findings of the PSR;

…….

(g) Informing relevant stakeholders such as the government and the public about the results of the PSR."

Paragraph 3.155 of IAEA Safety Standards Series No. GSG-13, Functions and Processes of the Regulatory Body for Safety [7], states:

> "In undertaking the review and assessment, the regulatory body should not rely solely on safety assessments conducted by the authorized party, nor on those that the regulatory body has commissioned from external consultants or technical support organizations. Instead, the regulatory body should have sufficient full-time staff capable of either performing regulatory reviews and assessments, or evaluating assessments performed for it by consultants."

The regulatory body needs to be aware of possible conflicts of interest that may arise from engaging the same contractors or consultants as the operating organization for conducting the PSR.

2.2.3. Communication

A formal communication protocol is expected to be established to govern communications within and between the following groups [4]:

"(a) Within the organization's PSR project team, to maintain consistency in the review and to avoid duplication of work;
(b) Between the organization's PSR project team and the consultants or contractors who are part of the PSR team;
(c) Between the PSR project management team of the operating organization and the regulatory body during the conduct of the PSR;
(d) Among the review and assessment team members within the regulatory body."

2.3. PHASES OF A PERIODIC SAFETY REVIEW PROJECT

To ensure efficiency and effectiveness, the PSR process needs to be conducted in accordance with the principles of the integrated management system with a strong commitment by management to safety and a strong safety culture. A PSR project typically consists of four phases, as included in this section, which may be overlapped, or subdivided appropriately.

2.3.1. Preparation of the periodic safety review project

The preparation phase includes the establishment of a project team and the development of the PSR basis document by the operating organization. The PSR

basis document brings out the scope, level of detail and timelines of the review, and the governing engineering codes and standards against which the review will be conducted by the operating organization. This document governs how the PSR is to be conducted. An agreement between the regulatory body and the operating organization on the PSR basis document is necessary for smooth conduct of the PSR and to reduce the need for additional iterations based on the regulatory review and assessment of the PSR. Further details on the PSR basis document are provided in Section 2.4.1.

2.3.2. Conduct of the periodic safety review

In this phase, the PSR is conducted by the operating organization in accordance with the agreed PSR basis document. The PSR includes the review of identified safety factors (i.e. the important aspects of safety of an operating NFCF that are addressed in a PSR), conduct of a global assessment considering the findings of all safety factors and their interfaces, and development of an integrated implementation plan for implementation of corrective actions and safety improvements identified in the review process. Sections 2.4 and 3 provide further details regarding the conduct of the PSR by the operating organization.

2.3.3. Regulatory review

In this phase, the regulatory body conducts a review and assessment of the PSR report, which includes the integrated implementation plan submitted by the operating organization. The positive and negative findings are reviewed along with the proposed corrective actions and safety improvements. The regulatory body assesses whether the licensing basis for the NFCF remains valid until the next PSR or the proposed end of the operating lifetime of the facility, whichever is the earliest. On the basis of the review and assessment in this phase, the regulatory body may identify safety issues of concern to be addressed in the integrated implementation plan. Regulatory review of PSR is further addressed in Section 4 of this publication. Annexes I–V provide examples of the regulatory requirements for PSR for NFCFs in Argentina, Canada, the Czech Republic, France and India, respectively.

2.3.4. Finalization of the integrated implementation plan

In this phase, the integrated implementation plan, comprising proposed reasonably practicable safety improvements, is finalized. The finalization of the plan needs to be in accordance with the regulatory review and the schedule for implementation agreed upon with the regulatory body.

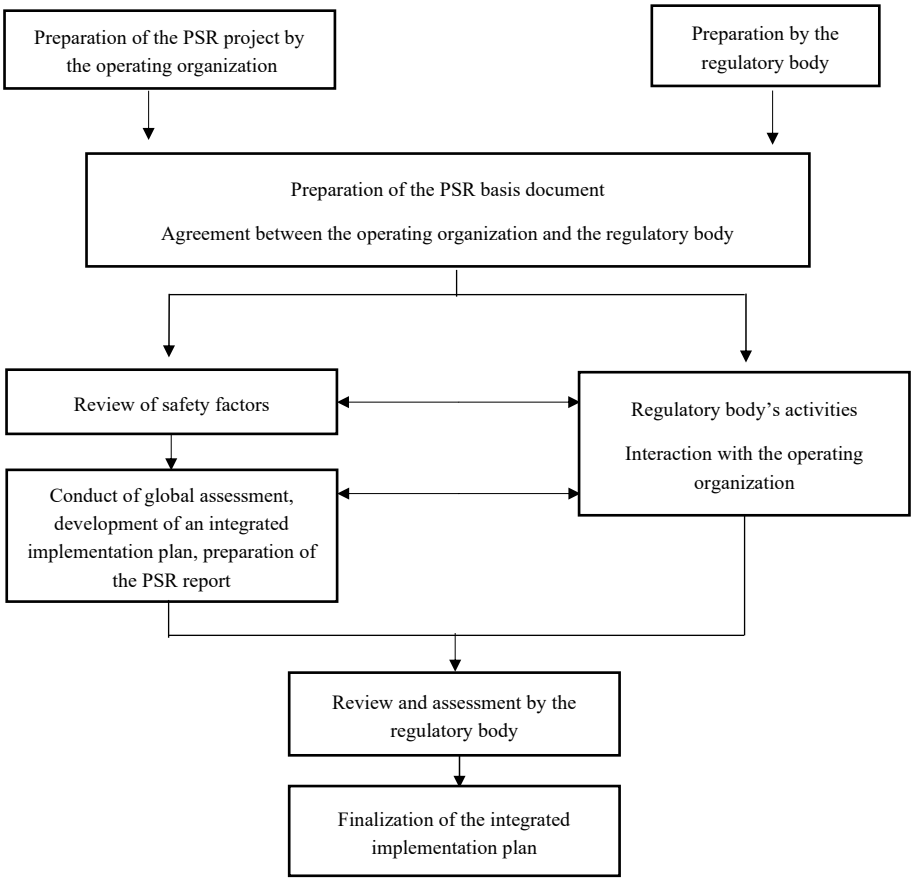

FIG. 1. Overall process for a PSR for a nuclear fuel cycle facility.

Modifications and other safety improvements resulting from the PSR findings need to be implemented after the PSR. The implementation activities are considered to be post-PSR activities and are briefly addressed in Section 5.

2.4. PERIODIC SAFETY REVIEW PROCESS

The overall PSR process for an NFCF is shown in Fig. 1. The process consists of parallel but independent activities of the operating organization and of the regulatory body. The activities of the operating organization in this process are detailed in Sections 2.4.1–2.4.3, and the activities of the regulatory body are detailed in Section 4.

2.4.1. Preparation for the periodic safety review project

The operating organization prepares for the PSR as shown in Fig. 2.

The preparation for a PSR project involves establishing an appropriate project management team and setting up a schedule for the project as the first step. The project management team needs to be led by an experienced senior person with sufficient authority in the operating organization. As the project leader is an overall coordinator responsible to the operating organization for PSR deliverables, it is preferable to select a person with experience in PSRs to lead the team. The team needs to include the facility personnel with relevant experience in operation, maintenance, safety, engineering and, if possible, the PSR process and review of safety factors. This team would be responsible for the completion of PSR within the agreed time frame and allocated resources.

The schedule and the resource allocation for PSR have to account for possible iterations in the review process, interfaces between various safety factors, intensive resource requirements for specific reviews, and the need for review by independent external contractors or consultants in certain review areas.

A PSR is generally conducted by multiple reviewers or review teams working in parallel to review different safety factors and interface areas. Since a PSR is a non-routine activity in facility operation, some of the team members may not have experience conducting one. To ensure the consistency and quality of the reviews conducted, a guidance document for the review teams may be developed at this stage. This document needs to elaborate on the scope of a PSR and applicable current standards and to provide guidance to the reviewers and the review teams regarding the procedure to conduct a systematic, comprehensive and consistent review of the safety factors and proper documentation of the findings.

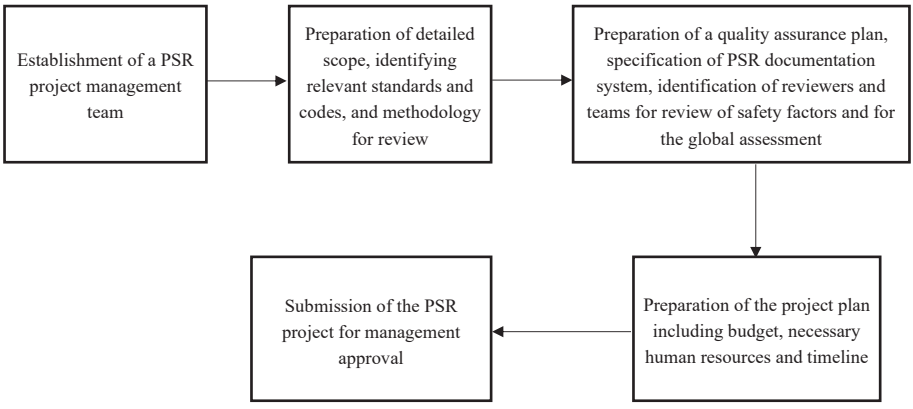

FIG. 2. Process of preparation for the PSR project.

A quality assurance plan for the conduct and documentation of the PSR also needs to be developed for preparation and verification of the PSR documentation. The plan also needs to include the experience, qualification and training requirements for the personnel involved in the PSR process and to address the procedure for coordination among various reviewers and review teams involved in conducting the PSR.

The review of safety factors may be allotted to designated reviewers or review teams. A review team may also be made responsible for multiple safety factors depending on their availability and expertise. The reviewers or review teams for review of safety factors may consist of technical area experts and safety specialists. For review of safety factors relating to management of the facility, the help of external experts may be sought to ensure an independent and objective review.

The review of safety factors may result in positive or negative findings. Positive findings (strengths) reflect the current state of the facility and practices being in line with or exceeding the expectations established in the reference codes and standards. Negative findings (gaps or deviations) are the areas where the state of the facility or practices fall short of the requirements established in the licensing basis or reference codes or standards. Practices that deviate from the facility's own operating and safety documents are also categorized as negative findings in the review.

The global assessment and development of an integrated implementation plan needs to be performed by a team of experts who have the necessary understanding of the interfaces between various safety factors and who can assess the overall impact of the positive and negative findings on the safety of the facility. A separate team for global assessment and development of an integrated implementation plan may be constituted, or these activities may be performed by the project management team itself. The team performing global assessment and development of an integrated implementation plan needs to effectively coordinate with the reviewers or review teams involved in the review of individual safety factors.

The project management team needs to ensure that a project plan is developed to conduct a PSR. This plan includes the estimation of necessary resources including financial and human resources to conduct the PSR and the schedule for the project. The project plan also needs to consider the training requirements for the staff involved in the PSR process.

A PSR basis document based on the above activities needs to be prepared, and this may need to be submitted to the regulatory body for review and assessment. The PSR basis document addresses the following elements:

(a) Scope of the PSR project;
(b) Establishment of a project team and the resources available for the PSR;
(c) Methodology of the PSR and safety factors to be reviewed;
(d) Level of detail to be contained in the review;
(e) Reference codes and standards to be used during the PSR and cut-off dates for considering their revision;
(f) Process(es) for categorizing, prioritizing and resolving the PSR findings;
(g) Project plan, which includes the duration of review and proposed timelines for completion of various activities in the PSR as well as major milestones.

Appendix I provides details on documentation for PSRs, including suggested contents of the PSR basis document. An example methodology for developing a PSR basis document used by an operating organization in France is included in Annex VI.

2.4.2. Review of safety factors

The general process for the review of safety factors is shown in Fig. 3. The safety factors applicable for the PSR for an NFCF are further described in Section 3.

The process of review of the safety factors begins with the collection of relevant information, documents and reports for the review. Additional information for the review may also be obtained from walkdowns (especially for safety factors relating to the facility), interaction with facility staff (especially for safety factors relating to management) and feedback from relevant operating experience. It is also necessary to collect the applicable standards to be referenced during the review.

The sources of facility related information necessary for review of safety factors include, but are not limited to, the following:

(a) The updated safety analysis report;
(b) Design basis information or facility engineering documentation;
(c) Operational data of the facility, including relevant procedures and performance reports;
(d) Reports of the facility's maintenance, periodic testing and inspection programme;
(e) Reports of the ageing management programme;
(f) Periodic reports on safety aspects, including nuclear and radiation safety, radioactive waste management, environmental monitoring, chemical safety and industrial safety;
(g) Event reports, including their investigation and root cause analysis;

(h) Reports related to facility modifications;
(i) A summary of the observations of safety committee and regulatory body;
(j) Reports and implementation plans of previous PSRs.

The documents used for a PSR need to be complete and up to date with the latest status of the facility, accounting for modifications and for changes in operational programmes, procedures and other practices.

The review of each safety factor needs to consider all possible operational states and accident conditions of the facility. The review needs to address the adequacy of provisions to prevent and detect possible failures that challenge the safety of the facility and the adequacy of provisions to contain or mitigate the consequences of such failures. The review also needs to address the capability and effectiveness of the operating organization to take prompt and effective measures to resolve any safety related issues arising in the facility.

The review of the safety factors determines the status of each safety factor at the time of the PSR and also assesses the safety of future NFCF operation (i.e. evidence that safety requirements will continue to be met) until the end of

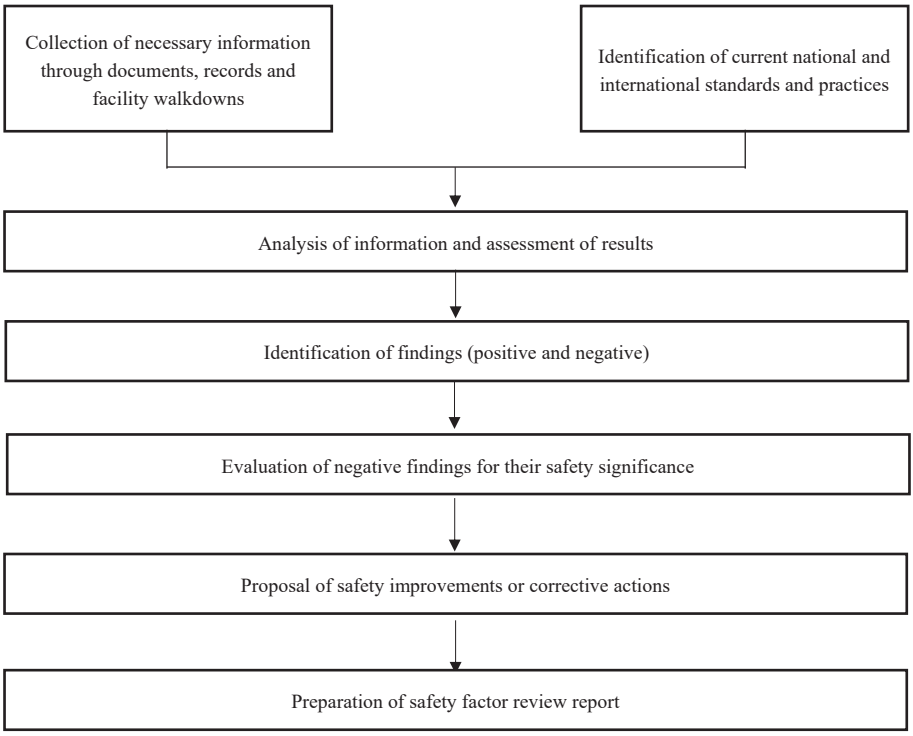

FIG. 3. Process for the safety factor review in the operating organization.

the operating life or until the next PSR. Hence, it is necessary to consider the foreseen and planned evolution of the facility and the operating organization until the next review.

The safety significance of all the findings (both positive and negative) needs to be evaluated on the basis of the review. Subsequently, reasonably practicable corrective actions need to be proposed for the negative findings. The corrective actions proposed can be in the form of modifications to the structures, systems and components (SSCs); enhanced training; changes in procedures and management systems; or other safety improvements. A report on each of the safety factors needs to be prepared on completion of the review, including the scope of the review; details of codes, standards and regulatory requirements that are used as a basis for the review; findings of the review; and proposed corrective actions. The report may also include the proposed categorization and prioritization of findings and corrective actions, respectively, based on their safety significance and the risk reduction achievable. Prompt corrective actions need to be taken in relation to those findings that indicate an immediate and significant danger to the life, safety or health of workers at the facility.

2.4.3. Global assessment and integrated implementation plan

To obtain an overall view of the safety of the facility, an integrated assessment considering the findings and proposed improvements in review of each of the safety factors and interfaces between them is necessary. Such an assessment, termed a 'global assessment' [3, 4], is used to determine the improvements that have an impact across the safety factors. The global assessment needs to address the overlapping areas and any gap areas between the safety factors. It also needs to consider the synergistic effect of:

(a) Negative findings within the same safety factor;
(b) Negative findings across multiple safety factors;
(c) Positive and negative findings that may impact one another.

In cases where the identification of safety improvements for a negative finding is not considered necessary, the review report needs to include a justification regarding the relevant conditions and assumptions. If there is no reasonably practicable improvement that could be identified for a negative finding, the review report needs to describe in detail the compensatory measures taken to address the finding. The risks associated with such situations need to be assessed and an appropriate justification for continued operation needs to be submitted for review and assessment by the regulatory body.

The global assessment is used to summarize all the proposed corrective actions along with their categorization, ranking and prioritization for implementation at a facility level. The global assessment can result in revision of the review of some of the safety factors and improvements proposed. The summary of the global assessment needs to be included in the final PSR report. Section 3.6 gives further details on the conduct of the global assessment by the operating organization of an NFCF.

An integrated implementation plan needs to be prepared addressing the corrective actions identified in the global assessment and their categorization and prioritization. The plan needs to include the schedule, resources and responsibilities for the implementation of the proposed corrective actions. Section 3.7 gives further details on preparation of an integrated implementation plan by the operating organization of an NFCF.

The results of the review including the reports on the review of individual safety factors, the global assessment and the integrated implementation plan are submitted to the regulatory body for review and assessment. Section 3.8 and Appendix I give further details on the documentation related to the PSR of an NFCF.

2.5. USE OF A GRADED APPROACH

Requirement 11 of SSR-4 [1] states:

> "**The use of a graded approach in application of the safety requirements for a nuclear fuel cycle facility shall be commensurate with the potential risk of the facility and shall be based on safety analysis, expert judgement and regulatory requirements.**"

Paragraph 3.2 of IAEA Safety Standards Series No. GSR Part 4 (Rev. 1), Safety Assessment for Facilities and Activities [8], states:

> "A graded approach shall be used in determining the scope and level of detail of the safety assessment carried out at a particular stage for any particular facility or activity, and the resources that need to be directed to it."

Paragraph 3.3 of GSR Part 4 (Rev. 1) [8] states:

> "The main factor to be taken into consideration in the application of a graded approach is that the safety assessment shall be consistent with the magnitude of the possible radiation risks arising from the facility or

activity. The approach also takes into account any releases of radioactive material in normal operation, the potential consequences of anticipated operational occurrences and possible accident conditions, and the possibility of the occurrence of very low probability events with potentially high consequences."

Paragraph 3.4 of GSR Part 4 (Rev. 1) [8] states:

"Other relevant factors, such as the maturity or complexity of the facility or activity, shall also be taken into account in a graded approach to safety assessment. The consideration of maturity relates to: the use of proven practices and procedures and proven designs; data on operational performance of similar facilities or activities; uncertainties in the performance of the facility or activity; and the continuing and future availability of experienced manufacturers and constructors. Complexity relates to:

— The extent and difficulty of the efforts required to construct a facility or to implement an activity;
— The number of related processes for which control is necessary;
— The extent to which radioactive material has to be handled;
— The longevity of the radioactive material;
— The reliability and complexity of systems and components;
— The accessibility of structures, systems and components for maintenance, inspection, testing and repair."

Nuclear fuel cycle facilities include facilities of diverse designs, technologies and processes. They vary in terms of the hazard owing to the quantity, form and hazardous nature of the materials, including radiation and chemical hazards (e.g. flammable, explosive, toxic, reactive, corrosive), and the nature of operations (e.g. manual, mechanized, remote handling).

The use of a graded approach needs to take into account the facility type and the following facility specific attributes (as stated in para. 6.29 of SSR-4 [1]):

"(a) The nature and the physical and chemical forms of the radioactive material that is used, processed and stored at the facility;
(b) The scale of operations undertaken at the facility (i.e. the 'throughput' of the facility) and the inventory of hazardous material, including products and waste in storage;
(c) The processes, technologies and hazardous chemicals that are associated with the radioactive material;

(d) The strategy for radioactive waste management, including available routes for the discharge of effluents and facilities for the storage of radioactive waste;
(e) The proximity and scale of other hazards that could interfere with the safe operation of the facility;
(f) The site, including external hazards associated with the site and proximity of the site to population groups."

In relation to PSRs, a graded approach could be used for the aspects discussed in the following paragraphs.

2.5.1. Safety factors to be reviewed

Some of the safety factors may be combined in the review. For some facilities, the safety factors related to 'equipment qualification', 'actual conditions of SSCs' and 'ageing' may be combined. Combining safety factors related to 'organization, the management system and safety culture' and 'human factors' may also be considered for facilities with smaller operating organizations. Similarly, for facilities with low potential impact on the environment, the safety factors related to 'radiological impact on the environment' may be combined with 'safety analysis'. The safety factors on 'facility operating experience' and 'use of operating experience from other facilities and research findings' may be combined for the facilities that adopt the use of internal and external operating experience in an integrated manner.

2.5.2. Level and detail of review for safety factors

The level and detail of review for each safety factor can vary depending on factors such as facility type, hazard potential and degree of automation used in operations. In some facilities, a high level programmatic review may be performed for some of the safety factors, considering their hazard potential or because these safety factors are being adequately reviewed under other facility programmes, such as an ageing management programme. The justification for adopting such an approach needs to be included in the PSR basis document and agreed to by the regulatory body. In some Member States, the level of detail of review depends on whether the PSR is being carried out first time or is being repeated.

2.5.3. Review teams

The number and composition of review teams performing the PSR, based on the type, size and hazard potential of the facility and the expertise available

in the operating organization, could be another aspect. In smaller operating organizations, where the same group of people have multiple responsibilities, such as for operation and maintenance, each review team may be assigned multiple safety factors. In smaller facilities with a limited number of activities or processes, the review of a safety factor may be assigned to an experienced reviewer instead of a review team. In such cases, the PSR project management team may need to have closer oversight of the quality of the review. The global assessment may also be performed by a separate team or by the PSR project management team itself. There might be no need for external experts for the review of certain safety factors if sufficient in house expertise is available to conduct independent reviews.

2.5.4. Documentation

Another aspect can be the documentation of the PSR results, covering all parts of the PSR, including an introduction, a global assessment of the overall safety status of the facility and an implementation plan for measures resulting from the findings. A graded approach based on the hazard potential of the facility can be applied to the level of detail included in the documentation related to the PSR.

2.5.5. Categorization and prioritization

The need for and the levels of categorization and prioritization of the findings and corresponding corrective actions, proportional to the type of facility and the hazard potential is another aspect for consideration. Categorization and prioritization might not be necessary if the findings are limited and the corrective actions are reasonably practical to implement within the available resources of the operating organization in a reasonable time frame, without safety being adversely affected.

2.5.6. Regulatory review and assessment

This could include the level of detail of the review, the requirements for independent verification (e.g. in safety analysis) and the resources deployed for review of a PSR report by the regulatory body, commensurate with the available safety margins and magnitude of hazard associated with the facility and the activities carried out. The milestones for intermediate reviews, the number of interim submissions necessary and the number of meetings between the regulatory body and the operating organization may also be limited on the basis of the size and hazard level of the facility and the experience of the operating organization in conducting the PSR.

3. CONDUCT OF PERIODIC SAFETY REVIEW FOR NUCLEAR FUEL CYCLE FACILITIES

This section outlines the steps in the conduct of a PSR by an operating organization, including the review of safety factors, performance of the global assessment and development of an integrated implementation plan.

The safety factors that apply to an NFCF are as follows:

— Safety factors relating to the facility:
  - Safety factor 1: Facility design;
  - Safety factor 2: Actual conditions of SSCs important to safety;
  - Safety factor 3: Equipment qualification;
  - Safety factor 4: Ageing.
— Safety factors relating to safety analysis:
  - Safety factor 5: Safety analysis.
— Safety factors relating to performance and feedback of experience:
  - Safety factor 6: Facility operating experience;
  - Safety factor 7: Use of experience from other facilities and research findings.
— Safety factors relating to management:
  - Safety factor 8: Organization, the management system and safety culture;
  - Safety factor 9: Procedures;
  - Safety factor 10: Human factors;
  - Safety factor 11: Emergency preparedness.
— Safety factors relating to environment:
  - Safety factor 12: Radiological impact on the environment.

Sections 3.1–3.5 describe the objectives, scope, tasks and methodology for the review of the safety factors listed above. For nuclear fuel cycle R&D facilities, an additional safety factor on ‘utilization’ of the facility may be considered part of the safety factors relating to the facility. Appendix II provides information on the safety factor on utilization and on how to perform the review of this safety factor. The operating organization needs to consider any other safety factors for review as established by the national regulatory requirements.

Specific safety aspects such as radiation protection, radioactive waste management or fire safety are not considered to be separate safety factors in this publication. As these aspects have a strong technical link to most of the other safety factors, they are reviewed as part of the other safety factors. These

aspects are technically interlinked with, among others, the safety factors on facility design, actual condition of SSCs, safety analysis, operating procedures, radiological impact on the environment and feedback of experience.

The operating organization may also decide to review radiation protection, radioactive waste management or any other specific safety aspects as separate safety factors, as needed. When additional safety factors are being considered, guidance for review of the additional safety factors needs to be developed for reviewers.

A review of the physical security of NFCFs is generally not included in the PSR. Some operating organizations may decide to review physical security as a separate safety factor within the PSR. Guidance on nuclear security measures can be found in IAEA Nuclear Security Series No. 13, Nuclear Security Recommendations on Physical Protection of Nuclear Material and Nuclear Facilities (INFCIRC/225/Revision 5) [9], and other publications in the IAEA Nuclear Security Series.

3.1. SAFETY FACTORS RELATING TO THE FACILITY

3.1.1. Safety factor 1: Facility design

Requirement 8 of SSR-4 [1] states:

"**The design of a nuclear fuel cycle facility shall ensure that radiation doses to workers and other personnel at the facility and to members of the public do not exceed the dose limits, and that doses are kept as low as reasonably achievable in operational states for the entire lifetime of the facility, and that they remain below acceptable limits and as low as reasonably achievable during, and following, accident conditions.**"

Requirement 9 of SSR-4 [1] states:

"**The design of a nuclear fuel cycle facility shall ensure that the facility and items important to safety have the appropriate characteristics to ensure that the safety functions can be performed with the necessary reliability, that the facility can be operated safely within the operational limits and conditions for its entire lifetime and can be safely decommissioned, and that impacts on people and the environment are as low as reasonably achievable.**"

The facility's SSCs important to safety need to be designed and configured with a high degree of confidence in ensuring that they meet the requirements for safe operation of the facility. Adequate design information needs to be available to ensure the safe operation and maintenance of the facility and to facilitate modifications.

3.1.1.1. Objective

The review of this safety factor assesses the adequacy of the facility design as operated and of the supporting documentation of the facility with respect to the current licensing basis and the international standards and practices.

3.1.1.2. Scope and tasks

The review is necessary to verify that the design of the facility and its other characteristics are appropriate to meet the safety and performance requirements of the facility in all operational states and accident conditions. The main aspects that need to be reviewed are:

(a) Completeness and adequacy of the list of SSCs important to safety.
(b) Codes and standards used for the design of the facility in relation to the current standards, to identify the significant changes likely to have an impact on the safety of the facility.
(c) Cumulative effects of all the modifications made to the facility design.
(d) Facility documentation (e.g. safety analysis report, design basis documentation) to verify that it is up to date and reflects changes made during the period.
(e) Process for design modification.
(f) SSCs important to safety with respect to their design features, layout and segregation to ensure that they meet current safety and facility performance requirements, including prevention and mitigation of events that could affect safety. These include:
    (i) Adequacy of the design of SSCs and safety margins for prevention of criticality;
    (ii) Adequacy of design of SSCs for protection against internal and external radiation exposure, including static containment systems (e.g. structures, shielding, enclosures and gloveboxes) and dynamic containment systems (e.g. ventilation);
    (iii) Adequacy of design measures for protection against non-radiological hazards, including the features to prevent fires and explosions with

potential radiological consequences, and protection against toxic chemical exposures associated with radioactive material.

(g) Changes to the characteristics of the site (e.g. population growth, new industrial activity, climate change, characterization of external hazards).

(h) Potential use of the automation and remote handling equipment in facility processes.

3.1.1.3. Methodology

The first step of the review is to determine availability of the necessary information that defines the design basis of the NFCF. The list of SSCs important to safety needs to be checked for completeness or be developed as part of the PSR.

The design of SSCs important to safety needs to be reviewed against the current standards, including design codes identified in the PSR basis document. Deviations from the current standards, if any, need to be identified and their safety significance needs to be determined. Any changes in the requirements and standards that were applicable at the time of the original design need to be evaluated to assess the impact of such changes on safety. This needs to be a systematic, clause-by-clause review of the national and international requirements and standards that are listed in the PSR basis document and any other requirements and standards that are subsequently identified as relevant (i.e. during the review).

Paragraph 5.23 of SSG-25 [3] states:

> "The review should consider the adequacy of defence in depth in the plant design. This should include an examination of:
>
> — The degree of independence of the levels of defence in depth;
> — The adequacy of delivery of preventive and mitigatory safety functions;
> — Redundancy, separation and diversity of SSCs important to safety;
> — Defence in depth in the design of structures …."

The review needs to consider independence of functions, application of single failure criterion and common cause failure risks. It needs to substatiate that the relevant documentation is updated and reflects the modifications made to the facility or process. It also needs to be demonstrated that the cumulative effects of modifications made during the review period have not adversely impacted the safety functions. If the design information is inadequate, or if there is uncertainty about whether an SSC important to safety would be able to perform its safety function, it may be necessary to re-evaluate the design.

Safety requirements for designing NFCFs are established in SSR-4 [1] and those for site evaluation of NFCFs are established in IAEA Safety Standards Series No. SSR-1, Site Evaluation for Nuclear Installations [10]. Further recommendations for specific types of NFCF are provided in Refs [11–16]. Sections 3.2 and 3.4 of Safety Reports Series No. 90, Safety Reassessment for Nuclear Fuel Cycle Facilities in Light of the Accident at the Fukushima Daiichi Nuclear Power Plant [17], include information on performing the review of the design basis of an NFCF and facility specific considerations for this assessment.

3.1.2. Safety factor 2: Actual condition of SSCs important to safety

The actual condition of SSCs important to safety is a significant factor in the review of the facility's safety. The condition of each SSC important to safety has to be thoroughly documented. The review of this safety factor is closely associated with the review of ageing management (safety factor 4). Knowledge of any existing or anticipated obsolescence of facility systems and equipment (e.g. for items that are still in use but for which the spare parts are not available, software which is no longer updated but which is still important) can also be considered in the review of this safety factor.

3.1.2.1. Objective

The objective of the review of this safety factor is to assess the actual condition of SSCs important to safety and to determine if they meet their design requirements. In addition, the review needs to verify that the condition of the SSCs important to safety is well documented. The review also needs to cover the programmes and results of the facility's maintenance, periodic testing and inspections, as applicable.

3.1.2.2. Scope and tasks

The review of this safety factor includes the examination of the following aspects for each SSC:

(a) The results and analyses of walkdowns, inspections and periodic testing reports;
(b) Maintenance and validity of records representing the actual condition;
(c) Operating history and evaluation;
(d) Actual condition against the design basis;
(e) Facility operating programmes, such as in-service inspection, supporting the confidence in the SSC's actual condition;

(f) Current state with regard to obsolescence;
(g) Possible degradation due to service conditions;
(h) Operational limits and conditions;
(i) Existing and anticipated ageing processes.

Paragraph 9.72 of SSR-4 [1] states that "There shall be a programme of monitoring for material degradation for vessels and containers holding mixtures of corrosive chemicals with fissile or highly radioactive materials." The implementation and effectiveness of this programme also need to be reviewed in this safety factor.

3.1.2.3. Methodology

The actual condition of the SSCs important to safety needs to be assessed on the basis of the knowledge of existing or anticipated ageing or obsolescence of SSCs and their operating, modification and maintenance histories. Impacts on the facility from any changes to design standards since the facility was designed or since the last PSR was performed have to be examined during the review.

The review of this safety factor needs inputs from the ageing management programme of the operating organization. Reports of maintenance, periodic testing and inspection of the facility, and walkdowns are effective ways for assessing the condition of the SSC. Additional data may be collected by performing specific tests and inspections as necessary (i.e. on hot cells and gloveboxes).

The validity of the existing records need to be checked to ensure that the actual condition of the SSCs important to safety is correctly represented. The review also takes into account significant findings from ongoing maintenance, periodic testing and inspection programmes.

Paragraph 5.35 of SSG-25 [3] states:

> "After determining the actual condition of the SSCs important to safety, each SSC should be assessed against the current design basis (or updated design basis: see safety factor 1) to confirm that design basis assumptions have not been significantly challenged and will remain so until the next PSR."

It needs to be ensured that the actual conditions of ventilation systems, fire protection systems and generally inaccessible SSCs are also addressed during the PSR. In those areas that cannot be accessed owing to the operating environment (e.g. high radiation level), remote surveillance or monitoring methods may be used. Consideration also needs to be given to the ageing degradation of neutron absorbers to ensure that their physical integrity remains consistent with the assumptions used in the criticality safety analysis. During the facility walkdowns,

attention needs to be paid to the presence of neutron moderating or reflecting materials that may affect criticality safety.

Instances where it is not possible to determine the actual condition of SSCs — owing to, for example, facility layout or inaccessibility — have to be clearly documented and the safety significance of such uncertainty needs to be determined. Experience from other facilities or knowledge of relevant ageing processes could be used to reduce some uncertainties [4].

3.1.3. Safety factor 3: Equipment qualification

Requirement 30 of SSR-4 [1] states:

> "**A qualification programme shall be implemented to verify that items important to safety are capable of performing their intended functions when necessary, and in the prevailing environmental conditions, throughout their design life, with due account taken of conditions during maintenance and testing.**"

Items important to safety need be qualified to ensure their capability to perform the designated safety function throughout the service life and under all relevant operational states and accident conditions, including those arising from internal and external hazards. A graded approach, based on the safety classification of SSCs, can be used for the review of the qualification of SSCs.

3.1.3.1. Objective

The objective of the review of this safety factor is to determine (a) whether items important to safety are qualified to perform their designated safety function and (b) whether this qualification is being maintained through a programme for maintenance, periodic testing and inspection that provides confidence in the performance of the safety functions until at least the next PSR.

3.1.3.2. Scope and tasks

The review of this safety factor has to include an assessment of the effectiveness of the facility's equipment qualification programme. This programme has to ensure that facility equipment is able to fulfil its safety functions for the period until at least the next PSR. The review also needs to cover the requirements for performing safety functions while subject to the environmental conditions that could arise from the operational states and accident conditions considered in the design. These may include, for example, seismic conditions,

vibration, temperature, pressure, jet impingement, electromagnetic interference, irradiation, corrosive atmosphere, humidity, extreme climatic conditions, fire, and combinations thereof [4].

The review of equipment qualification needs to consider whether the following criteria are met [4]:

— The design identifies a list of SSCs requiring qualification and includes conditions under which they are required to perform a safety function.
— The installed SSCs meet the qualification requirements.
— The records of equipment qualification are adequate.
— The procedures to update and maintain qualification for the service life of the equipment are adequate.
— The modifications or additions to SSCs important to safety compromise their qualification.
— Surveillance programmes exist for ensuring that ageing degradation does not significantly affect equipment qualification.
— The qualified equipment remains protected from adverse environmental conditions, and non-qualified equipment does not impact it adversely.
— The condition monitoring and monitoring of the environmental conditions where the qualified equipment is located are performed regularly to support reassessment of the qualification when necessary.

3.1.3.3. Methodology

The review of this safety factor has to verify that the use of the standards and requirements for equipment qualification at the facility remains valid and includes the following assessments (as stated in SSG-25 [3]):

"— Changes in the equipment classification resulting from design modifications;
— Qualification for all designed environmental conditions;
— The availability of equipment that is required to fulfil safety functions;
— Quality management provisions that ensure that an effective qualification programme is in place."

The review of equipment qualification needs to determine (as stated in SSG-25 [3]):

"— Whether adequate assurance of the required equipment performance was initially provided;

— Whether current equipment qualification specifications and procedures are still valid (for example, initial assumptions regarding the service life of equipment and the environmental conditions);
— Whether equipment performance has been preserved by ongoing application of measures such as scheduled maintenance, condition monitoring, testing and calibration and whether such programmes have been properly documented."

Additionally, the review of equipment qualification needs to determine if:

— The qualified life of equipment is kept updated and is reassessed on the basis of the results of monitoring the environmental conditions and the condition of the equipment;
— The operating experience feedback is applied for identifying unanticipated ageing and degradation mechanisms.

Safety requirements related to qualification of items important to safety in NFCFs are established in SSR-4 [1]. IAEA Safety Standards Series No. SSG-69, Equipment Qualification for Nuclear Installations [18], provides recommendations on implementation of equipment qualification programmes in nuclear installations, including NFCFs.

3.1.4. Safety factor 4: Ageing

Requirement 60 of SSR-4 [1] states:

"**The operating organization shall ensure that an effective ageing management programme is implemented to manage the ageing of items important to safety so that the required safety functions are fulfilled over the entire operating lifetime of the nuclear fuel cycle facility.**"

Safety Reports Series No. 118, Ageing Management for Nuclear Fuel Cycle Facilities [19], provides details on the elements of an ageing management programme and describes the interface between ageing management and PSR for NFCFs. A systematic ageing management programme for an NFCF comprises the following elements [19]:

(a) Identification of SSCs for ageing management;
(b) Identification and understanding of ageing in SSCs;
(c) Minimization of ageing effects;
(d) Detection, monitoring and trending of ageing effects;

(e) Acceptance criteria, corrective actions and mitigation of ageing effects;
(f) Feedback from operating experience and other R&D results on ageing;
(g) Documentation of ageing management.

3.1.4.1. Objective

The objective of the review of this safety factor is to determine whether a systematic and effective ageing management programme is in place and whether ageing in an NFCF is being effectively managed in order to ensure that required safety functions can performed on demand.

3.1.4.2. Scope and tasks

The review of this safety factor generally includes the review of the programme and the technical aspects (see Section 2.5) of the ageing management programme implemented at an NFCF and evaluates the following aspects:

— Coverage of SSCs important to safety in the ageing management programme (including obsolescence);
— Programme and procedures for understanding ageing mechanism of SSCs and timely detection of ageing effects;
— Measures for minimization or mitigation of ageing effects on SSCs;
— Effectiveness of policies and procedures for managing the ageing of replaceable components;
— Potential ageing degradation of SSCs important to safety that might affect their safety function;
— Management of the ageing of SSCs that will be required for safety even after facility shutdown or cessation of operation (e.g. ventilation systems, equipment for material handling, radiation monitoring systems) for long periods;
— Documentation of ageing management.

The review needs to include verification of the adequacy and validity of the following [4]:

- Acceptance criteria for SSCs important to safety in view of the required safety margins;
- Methods for monitoring ageing and for minimizing and mitigating ageing effects;
- Physical condition of the SSCs important to safety and provisions aimed at preventing any aspects that could limit their service life;

- Control of ageing of all materials and SSCs that could impair performance of their safety function;
- Obsolescence management of technologies used in the facility.

3.1.4.3. Methodology

By reviewing ageing management programmes and procedures, management arrangements, facility practices and associated records, the review needs to determine whether [4]:

— A systematic, effective and comprehensive ageing management programme is implemented;
— The ageing management programme covers items important to safety as well as any non-safety related SSCs whose failure might affect the items important to safety or adversely affect a safety function;
— All the relevant degradation mechanisms are identified, and adequate measures are taken to monitor, trend and control the ageing related degradation;
— The ageing management programme ensures continued safe operation until the next PSR.

3.2. SAFETY FACTORS RELATING TO SAFETY ANALYSIS

3.2.1. Safety factor 5: Safety analysis

Safety analysis is a systematic evaluation of the potential hazards associated with the operation of a facility or the conduct of an activity. For NFCFs, there is significant variation of hazards depending on the type of facility and activities, and these may include toxic, cryogenic, corrosive, explosive and flammable hazards along with radiological hazards. The safety analysis methodologies may also vary depending on the potential risk of the facility or activity.

For NFCFs, a facility safety analysis is developed using a variety of methodologies, which may include a hazard and operability study, a failure modes and effects analysis, an event tree analysis and a fault tree analysis. The analyses may include deterministic methods and may be complemented by probabilistic methods where appropriate.

The requirements for performing a safety analysis are established in section 4 of GSR Part 4 (Rev. 1) [8]. References [11–16] provide the facility specific considerations for safety analysis of NFCFs.

3.2.1.1. Objective

The objective of the review of this safety factor is to assess the extent to which the facility's safety analysis is complete and remains valid, with due consideration of:

(a) The adequacy and validity of the list of postulated initiating events (see the appendix to SSR-4 [1]) and associated hazards, with consideration of changes in facility operations and site characteristics;
(b) The changes in characteristics of internal and external hazards (including identification of new hazards and consideration of climate change);
(c) The changes to facility design and modifications to SSCs and operating limits and conditions since the last PSR;
(d) The changes to applicable codes and relevant national and international standards, changes in technology, and changes to analytical methods, including operating experience and additional scientific knowledge;
(e) The findings of reviews of other safety factors (especially the safety factors of facility design, actual conditions of SSCs important to safety, emergency preparedness and radiological impact on the environment);
(f) The adequacy of accepted safety margins considering any associated uncertainties.

3.2.1.2. Scope and tasks

A safety analysis for NFCFs does the following:

(a) Shows that the safety goals, objectives and safety requirements are stated and met under all operating states and accident conditions including considerations for equipment failures and human errors;
(b) Demonstrates adequacy and reliability of items important to safety;
(c) Confirms that the operating limits and conditions are consistent with the design of the facility and safety requirements;
(d) Provides for establishing and validating administrative measures to prevent and mitigate accidents;
(e) Demonstrates defence in depth for all hazards from credible postulated initiating events including radiological and non-radiological (e.g. fire, explosion, toxic release).

A review of a facility safety analysis includes the review of:

(1) Safety goals, safety requirements and acceptance criteria for all operational states and accident conditions;
(2) List of postulated initiating events for completeness, validity and relevance as well as the addition of new postulated initiating events based on changes to facility operations, site characteristics and applicable operating experience feedback from similar facilities;
(3) Facility design basis including facility modifications, operating conditions, changes to site characteristics (e.g. meteorological, seismic, demographic) and the introduction of new internal and external hazards;
(4) Applicable safety analysis methods, national and international codes, standards, technology and related scientific knowledge;
(5) Assumptions, conduct and results of the facility's current safety analysis to ensure its validity and completeness;
(6) Operating limits and conditions for their validity with current conditions and site characteristics of the facility;
(7) The facility's current defence in depth.

3.2.1.3. Methodology

A review of the facility safety analysis is conducted wherein the available list of identified postulated initiating events is reviewed to ensure its validity and relevance. Care needs to be taken to incorporate any new internal and external hazards that arise out of changes in site characteristics (including climate change), facility conditions and operational experience since the last review. The review also includes a review of the safety goals, safety requirements and acceptance criteria for all operating and accident conditions, taking into account other site considerations such as changes in demographics around the facility.

During the review, the knowledge gained from operating experience of similar industrial facilities needs to be incorporated where applicable. Recent experience from adverse environmental events such as flooding, seismic events, tropical cyclones, or a combination thereof has to be reviewed for applicability, and lessons learnt from these events need to be incorporated to improve safety of the existing facility. Safety requirements related to evaluation of external hazards for nuclear installations including NFCFs are established in SSR-1 [10].

The review also needs to account for changes to facility design and operations, and conditions of SSCs important to safety and their ageing management. It has to be demonstrated that the facility in its current state is

capable of ensuring safe operations as defined by the safety goals and national regulatory requirements until the next review.

The review of analytical methods used to derive the results of a safety analysis has to consider changes in technology, and national and international safety standards that are used to arrive at safety requirements. Where necessary, the safety analysis may be repeated, and the results verified. This also needs to include confirmation of the assumptions and the predicted uncertainties associated with analysis to the degree of conservatism required. Finally, any review of safety analysis has to ensure the revalidation of the facility's operating limits and conditions to ensure safe operation till the next scheduled review. Where possible, the review needs to consider improvements in technology and computing capabilities to improve accuracy and reliability of the safety analysis.

Safety Reports Series No. 102, Safety Analysis and Licensing Documentation for Nuclear Fuel Cycle Facilities [20], provides further details regarding review and performance of safety analysis during a PSR.

3.3. SAFETY FACTORS RELATING TO PERFORMANCE AND FEEDBACK OF EXPERIENCE

3.3.1. Safety factor 6: Facility operating experience

The assessment of the facility's operating experience includes a methodical review of the operating experience gained at the NFCF through review of records related to the performance of the facility in various safety areas, the availability of SSCs and other safety systems (their fitness for service), radiation exposure (occupational radiation protection), environmental releases of radioactive and chemical effluents, occupational exposure to chemical hazards (e.g. beryllium, hydrogen fluoride), radioactive waste management, emergency response performance during safety related events and transportation safety. Requirement 73 and paras 9.133–9.137 of SSR-4 [1] establish the requirements related to feedback of operating experience for the safety of NFCFs. IAEA Safety Standards Series No. SSG-50, Operating Experience Feedback for Nuclear Installations [21] provides further guidance on operating experience feedback in nuclear installations, including NFCFs.

3.3.1.1. Objective

The objective of the review of this safety factor is to determine whether the programme for use of feedback of operating experience of the facility is adequate and effective and whether necessary safety improvements have been

carried out based on the key performance indicators related to various safety areas, review of records of operating experience and feedback from review of safety related events.

3.3.1.2. Scope and tasks

The review of this safety factor is a comprehensive review of established safety goals and key performance indicators which are used in a systematic manner to evaluate the progress and performance of a facility in meeting them. Review of the programme for feedback of operating experience includes the review of the following systems and processes:

(a) Reporting, compilation, analysis and communication of operating experience at the facility in a systematic way;
(b) Investigation of important events, their root cause analysis and reporting of such events to regulatory body as necessary;
(c) Examination and anaylysis of trends of events including low level events;
(d) Development and implementation of corrective actions based on review of safety performance and events.

A review of safety performance relies on key performance indicators and the processes for routine recording and self-evaluation of safety related operating experience, including:

(1) Safety related performance data of operating equipment, including malfunctions, near misses and lower level events;
(2) Facility performance associated with maintenance, inspection and testing and replacement of SSCs and identified safety systems;
(3) Availability and performance of safety systems when needed during an event or testing of emergency preparedness;
(4) Facility performance related to radiation doses and dose management for workers (including contractors);
(5) Facility performance related to release of contaminants of concern (both radioactive and chemical compounds) and their impact on the environment;
(6) Facility performance related to occupational exposure of workers from chemical and industrial hazards relevant to the facility;
(7) Facility performance related to the generation, handling, storage and disposal of radioactive waste;
(8) Compliance with regulatory requirements;
(9) Operating experience related to human factors.

The records of radiation doses, release of radioactive effluents and the effectiveness of radiation protection measures are to be reviewed in this safety factor. The review needs to confirm whether these are within prescribed limits and are adequately optimized and managed. The review needs to also take into account the findings of the reviews of other safety factors when performing this task.

3.3.1.3. Methodology

The review of this safety factor includes the review of key performance indicators considering both positive and negative aspects of safety performance. Because processes, activities and equipment in various NFCFs have significantly varied risk, the set of key performance indicators are usually specific to a particular type of facility and have to be established individually. These key performance indicators need to be reviewed for adequacy and representativeness to the overall safety of the facility.

The review also has to examine any other records of operating experience for potential safety concerns. The analysis of trends over the operating lifetime of a facility needs to be reviewed to identify long term trends to ensure overall safety for the next review.

Consideration has to be given to changes in technology, process automation, and the advent of new technologies such as artificial intelligence that may be used to reduce radiological and non-radiological impact on workers, the public and the environment. Where applicable, the PSR needs to consider a review of best available technology, to ensure improvements in safety.

The PSR needs to include a review of the effectiveness of the operating organization's process for the routine evaluation of operating experience to ensure proper feedback. The use of key performance indicators enables comparison and benchmarking with similar types of facilities available locally and internationally. Where the review indicates a weak performance or trend, possible root causes need to be identified and corrective actions initiated.

3.3.2. Safety factor 7: Use of operating experience from other facilities and research findings

For NFCFs, use of operating experience and associated feedback from other facilities and research findings increases prevailing knowledge of the operating characteristics of a facility's design, equipment and safety performance, and could provide data for qualitative or quantitative assessment of safety of the facility.

3.3.2.1. Objective

The objective of the review of this safety factor is to assess the adequacy and effectiveness of the programme for collection, analysis and dissemination of results of the prevailing use of operating experience and associated feedback from other facilities and research findings and use of this operating experience in improving safety of the facility.

3.3.2.2. Scope and tasks

The review of this safety factor has to identify relevant information related to the use of operating experience from similar facilities, that may be important to safety of the NFCF. NFCFs cover a wide range of activities that have similarities with nuclear facilities such as nuclear plants, as well as industrial chemical processing facilities. The review needs to confirm whether the relevance of the external operating experience collected is determined and whether the lessons learnt are used appropriately for safety improvements. The results and recommendations from this review could be used as inputs to facilitate design changes, safety analysis review and to improve safety of current operations.

3.3.2.3. Methodology

An effective operating experience programme relies on timely identification and collection of information and its appropriate dissemination. A process for the collection and storage of such information and a methodical review to derive lessons learnt is also integral to this.

The review of this safety factor includes the verification that the facility has arrangements in place for collecting relevant operating experience feedback from other NFCFs, nuclear power plants and research reactors, industrial and chemical facilities, and also relevant R&D findings. It also includes the review of the effectiveness of the arrangements related to collection, analysis and identification of lessons learnt that are applicable to the facility and the aspect of using findings for timely implementation of safety improvements. Specific focus needs to be provided to major events that provide significant feedback on underlying safety assumptions of an operating facility, such as seismic events, flood events, and major accidents.

The Fuel Incident Notification and Analysis System (FINAS), which is jointly operated by the IAEA and the Nuclear Energy Agency of the Organisation for Economic Co-operation and Development (NEA), is a useful resource for the international exchange of operating experience feedback for NFCFs. The operating organization of an NFCF needs to have a process in place for receiving,

analysing and acting upon such experience. Reference [22] summarizes the operating experience feedback from the events reported to FINAS, including root cause(s), lessons learnt and corrective actions taken to prevent the occurrence of similar events in other NFCFs.

Although many facilities may have arrangements in place to be able to use the operating experiences shared by other facilities, they may not be as well equipped when it comes to the dissemination of research findings. Therefore, the PSR needs to pay special attention to whether the arrangements are adequate for timely feedback of research findings [4]. The key R&D areas related to NFCFs include the development of resistant materials of construction for handling reactive and toxic chemicals, the development of remote handling equipment for fabrication of highly radioactive and advanced fuels, and process control systems.

The review of this safety factor needs to provide a summary of the findings from this process and evaluation of effectiveness of implementation of the learnings from the external operating experience. Further information on the review and process associated with the use of operating experience and associated feedback is provided in SSG-50 [21] and Ref. [22].

The outputs from the review of safety factors 6 and 7 can be used as early inputs to the reviews of other safety factors. Therefore, most of the tasks in the review of these two safety factors need to be addressed at an early stage in the PSR.

3.4. SAFETY FACTORS RELATING TO MANAGEMENT

3.4.1. Safety factor 8: Organization, the management system and safety culture

To help ensure the safe operation of a nuclear facility, lines of authority for safety are established through organizational alignment and effective management structures. These lines allow for effective governance and oversight, and effective discharging of roles, responsibilities and accountabilities.

Management systems need to ensure that the organization's safety responsibilities are met. Such systems need to be clearly defined, integrated across the organization and implemented effectively. They need to give due regard to safety and consider impact on safety explicitly when developing and implementing any changes or new arrangements for managing the organization or its processes.

The combination of organizational factors, effective management systems and other factors, such as strong leadership behaviours, having a capable organization and effective communication, result in a strong safety culture.

A strong safety culture is one where an unsafe behaviour or process is challenged, appropriate corrective action is implemented in a timely manner and learning is proactively sought and shared. Use of external experts for review of this area may be considered to ensure an independent view of this safety factor.

IAEA Safety Standards Series No. GSR Part 2, Leadership and Management for Safety [23] establishes requirements related to the organization, the management system and fostering a culture for safety in nuclear installations including NFCFs.

3.4.1.1. Objective

The objective of the review of this safety factor is to determine whether the organization is a diagnostic one with a strong nuclear safety culture. This can be evidenced by an effective management system and a demonstration of strong leadership behaviours supported by a capable, learning organization that can make good, well informed decisions to ensure safe operation of an NFCF.

3.4.1.2. Scope and tasks

(a) Organization

To understand whether the roles, responsibilities, governance and oversight are defined, communicated and understood, the facility specific review of the organizational elements needs to assess the following, among others:

- The organizational structure and the responsibilities and authorities for each management position to determine whether they support safety;
- Roles, responsibilities, decision making authorities and interfaces associated with key facility processes to determine whether they support safety;
- The organization's vision, values, strategies and standards to determine whether they are clearly defined, effectively implemented and understood by all;
- Interfaces with supporting organizations, including corporate groups, oversight or review boards, support personnel and contractors to determine whether they support safety;
- The operating model to determine whether it has proper governance, oversight and execution of activities that support nuclear facility operation;
- Roles and responsibilities and authorities of corporate, site or facility organizations and managers to determine whether they ensure

accountability at every level and enhance the organizational capacity to resolve problems;
— Interfaces with corporate organizations responsible for functions that affect the nuclear facilities to determine whether they are clearly established and understood;
— The consideration of impact on safety, when making decisions related to major changes, including decisions concerning changes to organizational structures, functions, leadership, policies, procedures, and resources.

(b) The management system

To understand if management systems are defined clearly and implemented effectively to support the vision and goals of the organization, the facility specific review of the management system elements has to include the review of the following:

— Administrative controls such as policies, procedures, checklists and schedules to determine whether they are implemented for activities that affect safety and reliable facility operation;
— Policies and procedures to determine whether they reflect a strong commitment to nuclear, radiological, industrial and environmental safety;
— Management systems, programmes and processes to determine whether they are implemented effectively to identify, assess and mitigate risks to nuclear, radiological, personal and environmental safety as well as to facility reliability and emergency response;
— Management processes to determine whether they are well defined and established for business, policy and organizational changes, and seek to determine whether the scope, pace, resource requirements and effectiveness measures for change initiatives are managed to sustain and improve performance in facility operations;
— Change management processes to determine whether the progress of changes is systematically monitored to verify the intent of each change is met and to identify possible unintended consequences;
— Changes to facility equipment, procedures and processes to determine whether they are planned and implemented systematically to improve safe and reliable facility operation.

(c) Safety culture

To understand if safety culture of the facility or the organization supports the safe design, construction, commissioning, or operation of the NFCF, and that the right working environment and behaviours are established, the facility specific review of safety culture has to review and confirm the following:

— Leaders are doing what is right and behaving appropriately in line with the organization's expectations.
— Motivated, professional, suitably qualified and experienced individuals perform roles to a good standard and are supported in discharging their accountabilities and responsibilities.
— Informed, effective decisions are made at the right organizational level.
— Safety performance is good; the organization continuously learns and changes how things are done to improve.

3.4.1.3. Methodology

The efforts necessary for the review of this safety factor need to be based on the significance of the nuclear hazard(s) associated with the facility as well as the risk context and life cycle stage of the facility.

If multiple facilities at the same site are under the same operating organization, it might be appropriate to review this safety factor at the level of the operating organization, rather than at the level of individual facilities. This approach would be beneficial since the facilities would possibly have common shared management teams, engineering and operations teams and interdependencies between different facilities within the same operating organization.

This review could use a variety of tools and techniques. These could include, but are not limited to:

(a) Review of management system documents;
(b) Review of performance improvement data (including associated investigations and actions by management);
(c) Task observations (including observing, for example, governance meetings, decision making forums and safety meetings);
(d) Interviews or discussions with senior leaders and personnel within the organization to test whether the same views are held throughout the organization;

(e) Review of facility event reports to understand whether the organization, the management system or the safety culture contribute to near misses, accidents or non-compliances;
(f) Safety culture surveys.

Safety Reports Series No. 83, Performing Safety Culture Self-assessments [24], provides practical guidance on self-assessment of the safety culture by an operating organization.

3.4.2. Safety factor 9: Procedures

Procedures in this context include facility operating procedures which enable safe operations, maintenance activities, compliance with operational limits and conditions and other activities related to ensuring the safety of the facility. The management systems procedures are addressed under safety factor 8, 'organization, the management system and safety culture'. Procedures need to be developed collaboratively and incorporate relevant good practices as appropriate. They need to be clear, verified and validated, easily accessible and up to date. Requirement 63 and paras 9.66–9.70 of SSR-4 [1] establish the requirements related to operating procedures for the safety of NFCFs.

3.4.2.1. Objective

The objective of the review of this safety factor is to determine whether the operating organization's process for procedure management is adequate and whether the procedures are fit for the purpose and applied effectively to ensure facility safety.

3.4.2.2. Scope and tasks

The scope of the review of this safety factor includes confirmation of the effectiveness of application of the procedures.

The scope of the review is not to be limited to a paper exercise to check whether the procedures are appropriate for the task, rather it needs to confirm whether the procedures are correctly checked and verified when they are developed, and confirm that they are up to date and relevant.

The procedures that need to be considered during the review include:

(a) Operating procedures for normal operation and accident conditions including design extension conditions;
(b) Maintenance, periodic testing and inspection procedures;

(c) Work permit procedures;
(d) Radiation protection and radioactive waste management procedures;
(e) Specific procedures for high risk operations.

The procedures related to control of modifications and configuration control of the facility may also be reviewed in this safety factor if their adequacy, effectiveness and implementation have not been covered in the review of safety factor 8, 'organization, the management system and safety culture'.

The review needs to confirm that the procedures are used as intended, are followed and compliance is recorded where appropriate. Further, the review also needs to address the identification of non-compliances with procedures and confirm that these non-compliances are adequately recorded, reported and investigated.

3.4.2.3. Methodology

The efforts necessary for the review of this safety factor need to be based on the degree of reliance on the human performance, the complexity of the task, the significance of the hazard and frequency of the task. This review includes seeking evidence of the following [4]:

(a) A process is in place for the documenting and approval of safety related procedures and that the process is effective.
(b) Self-assessments, audits, safety performance and events are suitably recorded to assess whether there is adequate understanding and compliance with these procedures by operating personnel.
(c) Procedures are updated on priority, in response to changes in the assumptions made regarding safety analysis, facility design or operating experience.
(d) The procedures are readily identifiable and easily accessible at the point of use.
(e) The procedures are regularly reviewed and findings of these reviews are acted upon.
(f) The procedures are categorized in accordance with their safety significance.
(g) The people who use the procedures are involved in their development and review.
(h) The procedures adequately address the human–machine interface.
(i) The latest approved version of the procedure is used and that there is adequate control over the distribution process, in particular to ensure that obsolete versions of procedures are removed.

This review could use a variety of tools and techniques to confirm effectiveness of application which has a clear link to safety factor 10, 'human factors'. These could include, but are not limited to:

(1) Facility walkdowns or job observations (with a view to observing specific operations);
(2) Interviews or discussions with team leaders and operators;
(3) Review of facility event reports to understand whether facility procedures contribute to near misses, accidents, or non-compliances.

Further guidance on generic management system process for document control (including procedures) and activities in the document control process is available in paras 5.24–5.28 and appendix II of IAEA Safety Standards Series No. GS-G-3.1, Application of the Management System for Facilities and Activities [25].

3.4.3. Safety factor 10: Human factors

Human factors are integral to ensure the safe design, construction, commissioning and operation of all nuclear facilities. Human factors can often be linked to the root causes associated with many accidents in the industry, some with severe or significant consequences.

3.4.3.1. Objective

The objective of the review of this safety factor is to evaluate the various human factors that may affect the safe operation of the facility and to seek to identify improvements that are reasonably practicable.

3.4.3.2. Scope and tasks

The review of this safety factor needs to consider the effective application of procedures and processes in place. Consideration needs to be given to:

(a) Whether operational claims and controls are appropriate, specifically:
    (i) How reliant is the facility on operational controls?
    (ii) Are the operational claims and controls the right ones?
    (iii) Do the claims and controls take into account user requirements, ergonomics, serenity, etc.?

(iv) Have factors that influence the performance of a task been taken into account (e.g. psychological and physical influences on success or failure of a task)?
(v) Have any interdependencies among operator controls been identified and minimized?
(vi) Have the errors of omission (not doing the action) and commission (doing the action wrong) been considered and tested?
(vii) Are the operator actions that are needed for safe operation assessed to confirm that assumptions made in safety analyses are valid?

(b) Whether operator tasks are achievable and can be reliably completed, specifically:
(i) Are operational controls simple and easy to understand in terms of what the task is, the order and timings of tasks?
(ii) Are the controls understood by the people doing the tasks?
(iii) Are the tasks well defined, implemented and validated?
(iv) Are these tasks overly complex or physically demanding?
(v) Are the systems, task design and support appropriate?
(vi) Are the tasks achievable and reliable to levels claimed in the safety case?
(vii) Does evidential learning indicate that operational controls are not as reliable as they need to be?
(viii) Can end users complete the tasks using the systems or interfaces provided?
(ix) Is due consideration given to human–machine interfaces?
(x) Are staffing levels adequate for the operation of the facility, with due consideration of shift work, absences and restrictions on overtime?

(c) Whether training is appropriate, specifically:
(i) Is the right training in place to support the role and tasks?
(ii) Are the training programmes in place for initial training, refresher training and continuing training adequate, including training for emergency situations?
(iii) Is training sufficient and kept up to date?
(iv) Are there ‘fit for duty’ guidelines (as applicable to the facility or the organization) relating to types and patterns of work, hours, good health and substance abuse?
(v) Are the competence requirements adequate for operating personnel, including maintenance, technical and managerial staff?

3.4.3.3. Methodology

The efforts necessary for the review of this safety factor need to be based on the degree of reliance on the role of the operator and the importance of the operator's role with respect to assuring safety. The review needs to be led by human factors specialists where practicable, but at minimum has to include personnel trained in human performance and reliability.

Typically, the review could include various tools to understand the effective application of procedures which provide confidence that the role of the operator is suitable and appropriately implemented to support safe operation of nuclear facilities. These could include, but are not limited to:

(a) Facility walkdowns (with a view to observing specific operations reliant on humans);
(b) Interviews or discussions with team leaders and operators;
(c) Observation of training programmes;
(d) Review of facility event reports to understand whether human factors are a contributory factor to such events, and to understand whether any themes prevail.

Annex IX provides an example of review by job observation during the review of safety factors in a PSR.

3.4.4. Safety factor 11: Emergency preparedness

Requirement 72 of SSR-4 [1] states that "**The operating organization shall establish arrangements for on-site preparedness for, and response to, a nuclear or radiological emergency.**"

Paragraph 3.1 of IAEA Safety Standards Series No. GSR Part 7, Preparedness and Response for a Nuclear or Radiological Emergency [26] states:

> "The goal of emergency preparedness is to ensure that an adequate capability is in place within the operating organization and at local, regional and national levels and, where appropriate, at the international level, for an effective response in a nuclear or radiological emergency."

SSR-4 [1] and GSR Part 7 [26] establish the requirements related to emergency preparedness and response to a nuclear or radiological emergency at an NFCF. The relevant recommendations and information regarding implementation of these requirements are provided in Refs [27–30].

3.4.4.1. Objective

The objective of the review of this safety factor is to ascertain the adequacy and continued confidence of emergency preparedness arrangements by the operating organization, including plans, staff, facilities, and equipment, and effectiveness of coordination with the authorities responsible for emergency preparedness at local, regional, national and other levels as applicable.

3.4.4.2. Scope and tasks

The scope of the review of this safety factor includes the roles and responsibilities of the operating organization and its capability to enable an effective response in the case of a nuclear or radiological emergency, in coordination with relevant authorities. The capabilities related to the emergency preparedness that are to be reviewed include:

(a) The delegation of clear authorities and responsibilities within the operating organization;
(b) Adequacy of organization and staffing;
(c) Effectiveness of coordination with relevant authorities at various levels (e.g. local, national);
(d) Availability of adequate plans and procedures for handling emergencies;
(e) Maintenance of required tools, equipment and facilities;
(f) Conduct of periodic trainings and exercises for confirmation of capability and continual improvement;
(g) The effectiveness of the arrangements for public information.

In some Member States, the review of emergency preparedness aspects of nuclear installations is done periodically as a separate programme outside the scope of PSR. This approach could be beneficial for multiunit sites, which require coordination at the site and with off-site agencies.

In scenarios where modifications in one of the facilities have an impact on emergency preparedness, the review of adequacy of emergency preparedness need not wait for a PSR.

As some NFCFs handle significant quantities of hazardous chemicals, the review of aspects of preparedness related to the emergencies that may be caused by these hazardous chemicals, their possible effects on operating personnel, and impact on nuclear and radiological safety, are also considered for review during the PSR.

The review of emergency planning needs to consider the adequacy and confidence in:

(1) Emergency response organization (in terms of organization, management, leadership and governance);
(2) Initial identification of the full range of hazards that could result in an emergency scenario (anticipatory activities);
(3) Assessment of the scale and consequences of any emergency and how this information feeds into the development of emergency plans and arrangements (emergency scenarios);
(4) How emergencies are prevented from arising or from escalating to the point where an emergency response is required (prevention and mitigation of emergency scenarios);
(5) How facilities, equipment and personnel are prepared and supported in order to respond in an emergency (emergency preparedness arrangements);
(6) Emergency response and how recovery of the facility is integrated into emergency preparedness and response (emergency response arrangements and generic recovery arrangements) which has to include consideration of the adequacy of the supporting arrangements (e.g. training, dosimetry, documentation, drills and exercises, detection, assessment, notification and monitoring) that support the operational capabilities during both preparedness and response activities.

In addition, consideration needs to be given to:

— Issues that could adversely affect the effectiveness of emergency arrangements;
— Access to site (logistic, transport and other infrastructure) in the case of major events (such as earthquakes) impacting larger geographical areas;
— Verification and revalidation of mutual support agreements.

3.4.4.3. Methodology

The review of this safety factor is carried out by reviewing records and schedules of emergency exercises, training records, emergency procedures and arrangements, etc. The review can also include observing emergency exercises and arrangements in practice and testing the understanding of the operating personnel.

This review includes a review of the documents and records of the management system to confirm whether clear authorities and responsibilities related to emergency preparedness have been delegated at various levels. The

emergency plans and related procedures need to be reviewed to confirm that scenarios considered for emergency preparedness are adequate and in accordance with the safety analysis of the facility. Inputs from the review of the safety factor on 'safety analysis' would be needed for this purpose. The review needs to determine whether the organization and staffing for emergency preparedness and response is adequate to carry out the response activities according to the emergency plan.

The review needs to further confirm the maintenance and availability of the facilities, tools and equipment according to the emergency plan (i.e. storage condition, procedures of use and accessibility). For this purpose, the reviewers would need to conduct walkdowns of the relevant on-site and off-site areas, as necessary.

The records and reports related to training for emergency preparedness and conduct of emergency exercises need to be reviewed to ascertain the effectiveness of training and conduct of exercises. Specific attention needs to be given to the deficiencies observed during the exercises and actions taken to address them. The effectiveness of coordination mechanisms with various authorities can also be assessed by reviewing the records of emergency exercises. During the review, special attention needs to be given to the verification of efficacy of communication facilities including the equipment and procedures for communicating with various authorities and for public information.

3.5. SAFETY FACTORS RELATING TO THE ENVIRONMENT

3.5.1. Safety factor 12: Radiological impact on the environment

Paragraph 2.8 of SSR-4 [1] states:

> "To apply the safety principles, nuclear fuel cycle facilities are required to be designed and operated so as to keep all sources of radiation and all nuclear material under strict technical and administrative control (see Requirement 57). However, these principles do not preclude limited exposures or the release of authorized amounts of radioactive materials to the environment from the facility in operational states. Such exposures and radioactive releases are required to be strictly controlled, to be measured or estimated, to be recorded and to be kept as low as reasonably achievable, in compliance with regulatory and operational limits as well as radiation protection requirements."

Paragraph 9.108 of SSR-4 [1] states:

"The nuclear fuel cycle facility shall establish an adequate environmental monitoring programme to monitor for radionuclides in the environment (from both planned releases and unplanned releases) and to assess the associated environmental impact. The environmental monitoring programme shall include, but shall not be limited to:

(a) Establishing background conditions and data before operation commences;
(b) Establishing action levels and annual limits for effluents for the protection of the public and personnel (e.g. derived annual concentration limits) or annual effluent discharge limits, as well as environmental sampling;
(c) Establishing local and near field environmental monitoring stations to monitor surface water, groundwater, soil and biota;
(d) Record keeping, including records of spills and releases, as well as results of audits and inspections."

The NFCF needs to have an established programme to monitor the radiological impact of the facility on the immediate surroundings and the environment. The data obtained from the established monitoring programme is analysed to ensure the effectiveness of the control measures related to environmental releases.

Some of the nuclear and other radioactive material used in NFCFs also have potential for non-radiological impact on the environment due to their chemical toxicity. Hence, some Member States include the consideration of environmental impact due to chemical toxicity of this material in the PSR of NFCFs. However, the non-radiological aspects are not addressed in this publication.

3.5.1.1. Objective

The objective of the review of this safety factor is to assess the adequacy and effectiveness of the environmental monitoring programme. The review of this safety factor also confirms that all radioactive releases are properly controlled, are within the authorized limits set by the regulatory bodies and are as low as reasonably achievable.

3.5.1.2. Scope and tasks

The scope of this safety factor includes review of the adequacy and comprehensiveness of the radiological monitoring programme established by the operating organization. The tasks generally performed during review of this safety factor include analysis of current radiological monitoring data, comparison with the baseline data, if available, or with the data from previous PSR(s) and trending of historical data, if available. The purpose of these tasks is to verify that the facility continues to operate without significant impact on the environment.

3.5.1.3. Methodology

The review of this safety factor needs to include the following:

(a) Review of compliance with the environmental monitoring programme for radionuclides in the environment that typically includes data on concentration of radionuclides in air, water (including nearby water bodies), soil, flora, fauna, agricultural and marine products, as applicable;
(b) Evaluation of radiological impact of any potential new sources of radiation which may arise from facility modifications or due to degradation of SSCs;
(c) Confirmation of carrying out the sampling and measurements for the radiological monitoring programme are as per the current standards;
(d) Review of the monitoring data along with comparisons with and trends of the available historic data;
(e) Confirmation of radioactive releases through properly controlled and authorized routes within the established limits of the organization or authorized limits set by the regulatory bodies, as applicable;
(f) Actions taken to keep radioactive release as low as reasonably achievable;
(g) Confirmation that selected locations and methods for off-site monitoring for radiation levels and contamination levels are adequate for detecting any abnormal radiation levels or radioactive material release in the environment;
(h) Availability of an action plan for addressing environmental contamination (especially soil and water) in the case of accidental release to environment;
(i) Adequacy of the environmental monitoring programme to take into account any changes in the use of areas in the vicinity of the site.

IAEA Safety Standards Series Nos GSG-9, Regulatory Control of Radioactive Discharges to the Environment [31] and RS-G-1.8, Environmental and Source Monitoring for Purposes of Radiation Protection [32] provide further guidance and information on environmental monitoring.

3.6. GLOBAL ASSESSMENT

Global assessment is performed to arrive at a judgement for continued operation of an NFCF based on a balanced view of the findings from the reviews of the individual safety factors. This judgement needs to take into account negative findings (weaknesses) — along with necessary corrective actions or safety improvements resulting from them — and positive findings (strengths). The global assessment evaluates the impact on safety of findings from all the separate safety factors and therefore needs to be performed after the individual safety factor reviews [4].

The global assessment is performed by an interdisciplinary team having appropriate expertise in the operation, design and safety of the NFCF. The team needs to have an appropriate number of participants from individual safety factor review teams and those who are independent of the safety factor review teams.

The global assessment needs to include the following [4]:

(a) Identification of interface issues and overlapping issues between the various safety factor reviews, to ensure that such issues are appropriately and fully addressed.
(b) Analysis of the identified interfaces and overlapping issues between the various safety factors reviews, which needs to be included in the global assessment.
(c) Prompt communication and regular updates between the review teams, which is necessary and needs to be well organized as the findings from the review of a safety factor could be the input for another safety factor review.
(d) Consideration of all the findings (positive and negative) from the separate safety factor reviews and assessment of whether the corrective actions or safety improvements are reasonably practicable. It is possible that a negative finding following the review of one safety factor is compensated for by a positive finding from the review of another safety factor. Considering any overlaps or omissions between the reviews of the separate safety factors, the global assessment also needs to determine whether additional or grouped safety improvements arising from more than one safety factor review are also reasonably practicable. Identified safety improvements that are judged not to be reasonably practicable might not be pursued any further, in consultation with the regulatory body.
(e) Assessment of risks associated with negative findings, both individually and collectively, and an appropriate justification for continued operation. The justification has to address short term operation prior to the implementation of identified corrective actions or safety improvements. Justification for continued operation also needs to be provided if the global assessment

concludes that it is not reasonably practicable to address some of the negative findings.

(f) Clear distinction between corrective actions and safety improvements that are considered necessary.

(g) Method for the assessment, categorization, ranking and prioritization of corrective actions to address negative findings or safety improvements based on the criteria and methods established in the PSR basis document. The method has to be based on the safety significance and resulting gains of each proposed safety improvement within the global assessment. The approach adopted can be based on deterministic safety analysis, probabilistic safety assessment (if available), engineering judgement, risk analysis, cost–benefit analysis, or a combination thereof.

As a part of global assessment, the following aspects also need to be examined [4]:

(1) Supporting information such as an agreed upon scope and methodology of the PSR, associated regulatory requirements and previously submitted PSR documents, in particular issues raised by and feedback from the regulatory body, peer review missions and any additional reference material;

(2) The time necessary for corrective actions or safety improvements, together with actual benefit to the facility's safety.

The completion of the global assessment results in a prioritized list of findings significant for safety. On the basis of this list, appropriate corrective actions or safety improvements to address the safety issues are to be defined and an adequately resourced programme prepared for their implementation [4]. The proposed actions need to address the root cause of the issue. For example, if there were multiple maintenance issues identified, the improvement needs to address the maintenance programme rather than addressing individual maintenance issues.

3.7. INTEGRATED IMPLEMENTATION PLAN

On completion of the global assessment, the operating organization defines a list of findings along with their categorization and prioritization, and the proposed corrective actions or safety improvements to address those findings. The implementation of these corrective actions or safety improvements needs to be approached in a systematic manner such that the resources are planned and allotted adequately.

Corrective actions or safety improvements may involve modifications to the facility and/or procedures, revisions to the safety analysis or a combination of these actions. To enable the optimization of solutions, corrective actions or safety improvements need to be developed after identifying all potential options for resolving the issue. The implementation plan has to consider:

(a) Priority of actions identified during the global assessment;
(b) Interactions between the individual corrective actions or safety improvements identified during the PSR;
(c) Interaction between the actions identified during the PSR and other actions that have been proposed in the facility during routine reviews outside the PSR.

The plan also has to specify the schedules for implementing corrective actions or safety improvements and the necessary resources, since the implementation of corrective actions or safety improvements would have different execution times. Corrective actions have to be given higher priority and need to be executed in the short term. The plan also has to include confirmation that the facility's safety and operating documents are up to date, together with safety improvements or corrective actions [4].

The integrated implementation plan is reviewed and approved by senior managers of the NFCF, who commit the necessary resources (including human and financial resources) to implement the proposed corrective actions or safety improvements according to the suggested schedule. The integrated implementation plan is then submitted to the regulatory body for review and assessment [4].

The safety improvements and the integrated implementation plan, including the categorization and prioritization of the proposed corrective actions or safety improvements, may need to be updated after the review and assessment of the PSR report by the regulatory body.

3.8. DOCUMENTATION

During a PSR of the NFCF, the operating organization needs to make available all the required documents to the PSR project team. The PSR project team will prepare the results of the PSR for the NFCF. The PSR results cover aspects such as the basis for the PSR, individual safety factors reports, the global assessment report and the integrated implementation plan. The PSR report could be a single document or divided in parts, covering different aspects of the PSR.

The operating organization has to be ready to provide internal documents to the regulatory body, if the internal documents are referred to in the PSR. For this purpose, it is necessary to establish a channel of correspondence for communication related to the PSR between the regulatory body and operating organization.

The details on the content of the various documents and reports relating to PSRs are given in Appendix I. Annex VI provides sample contents of a PSR basis document. Annex VII provides an example for the content of a PSR report, based on the practice of an NFCF in France.

4. REVIEW PROCESS OF THE REGULATORY BODY

The requirements for a PSR are established by the national legislative framework or the regulatory body. The regulatory review and assessment of PSRs covers the following steps:

(1) Designate a competent manager and teams for the review of the PSR basis document, safety factor reports and the PSR report including the integrated implementation plan, as necessary.
(2) Review and assess the PSR basis document.
(3) Monitor the conduct of the PSR, if necessary, to confirm that it is being conducted in line with the PSR basis document.
(4) Review and assess the PSR report and identify any issues of concern.
(5) Review and assess the integrated implementation plan.
(6) Regulatory decisions (e.g. licence renewal) if any, based on the PSR are communicated to the operating organization.

Depending on the size and type of the facility, the regulatory body may need to identify or appoint a responsible person as a project manager for the assessment of the PSR. The project manager would coordinate all PSR related activities within the regulatory body, with the operating organization and among any external agencies and stakeholders as necessary. Further, the regulatory body would also need to identify the necessary assessors or review team for the review and assessment of the PSR report. The regulatory body may choose to select external experts for the review and assessment of the areas in which it does not have necessary expertise. The regulatory body may consult the operating organization in this case, regarding the framework to ensure confidentiality of certain information to be submitted by the operating organization.

The PSR basis document submitted by the operating organization is reviewed by the regulatory body. The review and assessment of the PSR basis document includes the agreement on the governing codes and standards, PSR project timelines, and intermediate review steps as necessary. The format and contents of the PSR reports are also agreed upon at this stage.

Subsequently, a detailed review and assessment plan needs to be prepared for the review of the PSR reports. The plan needs to include the assessment criteria, resources (human and financial resources, including the need for external support), lead time for completion of reviews, and submissions required to be made by the operating organization at the intermediate milestones. The need for independent safety analysis, verification or validation of the data submitted has to be considered during the preparation of the review and assessment plan by the regulatory body.

In some Member States, the operating organization submits the review reports of individual safety factors for review by the regulatory body prior to submission of the complete PSR report. However, necessity and acceptability of such submissions are to be agreed upon during the review and assessment of the PSR basis document so that the assessment plan prepared by the regulatory body can suitably account for such submissions.

The regulatory body needs to ensure consistency in the review performed by the various assessors involved in the review and assessment of the PSR report. For this purpose, the regulatory body needs to develop assessment criteria and may need to conduct necessary training and briefings for the assessors involved in the review and assessment process for the PSR reports. The regulatory body also needs to ensure that reviews are effective and efficient.

During the PSR process, the regulatory body may interact with the operating organization. The purpose of this interaction is to confirm whether the PSR is being conducted in line with the agreed basis document. During such interactions, the regulatory body needs to adopt a pragmatic approach to ensure that the intervention is within the bounds of the agreement between the regulatory body regarding the PSR.

When the PSR reports are submitted, the regulatory body needs to review and assess the PSR findings, proposals for improvements and corrective actions. The assessors also need to consider the impact of positive findings in the review and assessments.

During the review and assessment, the regulatory body or the assessors may communicate with the operating organization as necessary to obtain necessary information or clarifications required for the assessment or regarding any additional issues identified by the assessors. The results of these interactions need to be documented for future reference. If the assessors feel the need for additional submissions (which were not anticipated during the review and assessment plan),

analysis, verification or validation to complete the review, the same may be brought to the notice of the project manager for consideration in the plan.

The assessment teams or assessors for the safety factors need to prepare reports summarizing the review and assessment conducted, and clearly highlight all the significant safety issues that need to be resolved. The assessment reports also need to outline the acceptability of the safety improvements and corrective actions proposed by the operating organization.

Paragraph 8.34 of SSG-25 [3] states:

> "In the event that the PSR identifies a finding that poses an immediate and significant risk to the health and/or safety of workers or the public or to the environment, the regulatory body should verify that the operating organization takes prompt action and does not wait until the end of the PSR before taking corrective action or implementing safety improvements."

An integrated PSR assessment report needs to be prepared considering the individual assessment reports of the safety factors, global assessment and the integrated implementation plan. The integrated assessment report needs to address the adequacy of the PSR report, acceptability of the global assessment and proposed corrective actions, and remarks on the proposed integrated implementation plan. During the integrated assessment, the combined effect of various negative findings needs to be considered. Reviewers need to look for the aspects that may not have been addressed by the individual safety factors.

The regulatory body needs to critically review the acceptance of justifications provided by the operating organization, especially in cases where the operating organization states that the identification of safety improvements for a negative finding are not considered necessary or that there is no reasonably practicable improvement that could be identified for the negative findings.

The integrated PSR assessment report prepared by the regulatory body is discussed with the operating organization to reach an agreement on the integrated implementation plan. The finalization of the integrated implementation plan is done on the basis of the convergence achieved in the meetings between the operating organization and the regulatory body. If the PSR is used as basis for operating licence renewal or other regulatory actions, then the regulatory body needs to take an appropriate decision and communicate the same to the operating organization.

5. POST-REVIEW ACTIVITIES

A PSR may be considered complete after the review and assessment of the integrated implementation plan by the regulatory body and communication of regulatory decisions, if any, regarding the PSR to the licensee. A formal communication regarding the completion of the PSR activities may be sent by the regulatory body to the operating organization even if there are no regulatory decisions that need to be communicated.

The post-review activities by the operating organization include implementation of the identified safety improvements according to the schedule in the integrated implementation plan. The regulatory body may periodically monitor the implementation of the corrective actions and the other commitments given by the operating organization during the review of the PSR report. For this purpose, the regulatory body and the operating organization need to plan for communication and follow up on the implementation of the corrective actions. Significant delays in implementing corrective actions need to be brought to the notice of regulatory body, along with the justification for the same, for necessary review and assessment by the regulatory body.

When the results of the PSR are proposed for justifying the operation of the NFCF beyond the established time frame (i.e. licence term, the original facility design, relevant standards or national regulations), the adequacy and effectiveness of the SSCs and other arrangements that are in place to ensure facility safety need to be determined, considering the time period until the revised end date of the facility's operation.

After the PSR is completed, a change in the facility documentation may be necessary due to the implementation of safety improvements and modifications resulting from the PSR. Such documentation may include, for example, design basis reports, safety analysis reports, operating limits and conditions, procedures for operation and maintenance, emergency preparedness procedures, and training manuals. A good configuration management process would ensure that the necessary facility documentation is updated in a timely manner during the implementation.

Appendix I

DOCUMENTATION OF THE PERIODIC SAFETY REVIEW

This appendix is an adaptation of appendix II of SSG-25 [3] and provides details on the content of the various documents and reports relating to a PSR.

The following documents are produced during a PSR by the operating organization:

(a) The basis document for the PSR;
(b) Safety factor report(s);
(c) The global assessment report;
(d) The final PSR report, including the integrated implementation plan.

The suggested contents of these documents are given in the following subsections.

I.1. SUGGESTED CONTENTS OF THE PERIODIC SAFETY REVIEW BASIS DOCUMENT

A PSR basis document includes three main parts:

(1) General

This includes:

- Scope and objectives of the PSR and the future operating period that will be considered by the review.
- Cut-off dates to be used, that is, the dates beyond which updates to standards and codes and new information (e.g. more recent facility operating experience) will not be considered during this PSR.
- The facility licensing basis at the time of initiating the PSR.
- Relevant regulatory requirements.
- List of safety factors to be reviewed within the PSR and the interfaces between them.
- Description of the systematic review approach to be used to ensure a complete and comprehensive review.
- Processes for identifying, categorizing, prioritizing and resolving negative findings.

— Process for ensuring that any immediate and significant risks to the health and/or safety of workers or the public or to the environment identified during the PSR will be addressed without delay.
— Methodology to be used for the global assessment and the planned document structure of the global assessment report.
— Guidance for preparation of the integrated implementation plan of safety improvements.
— Systematic method to be used for recording outputs from the PSR, including the proposed formats of:
    - The safety factor reports;
    - The global assessment report;
    - The final PSR report, including the integrated implementation plan of safety improvements.

(2) Safety factors

The following information needs to be provided for each safety factor:

— Objectives and scope of the review;
— Applicable regulatory requirements; national, international and industry safety standards; codes and methods; and operational practices selected as the basis for the safety factor review and, where relevant, their hierarchy;
— Input documents and processes to be reviewed;
— Specific methodologies to be used for the review and a justification for the approach to be followed;
— Expected outputs.

(3) Project plan for the PSR

This includes:

— Organization of the project, including roles and responsibilities;
— Time schedule, including any major milestones and cut-off dates;
— Project and quality management processes;
— Processes for ensuring consistency between separate safety factor reviews;
— Training;
— Internal communications;
— The plan for communicating with, interfacing with and gaining relevant approvals and agreements from the regulatory body.

I.2. SUGGESTED CONTENTS OF THE SAFETY FACTOR REPORT

The safety factor report includes the results from the review of each safety factor following the approach detailed in the PSR basis document. The findings specific to each safety factor are documented and ranked according to their safety significance. The following is an example of the structure of a typical safety factor report:

(1) Title (name of the safety factor);
(2) Introduction;
(3) Scope of the review, including a list of the documents and aspects of safety reviewed;
(4) Review criteria (e.g. reference standards, operating practices, safety assessment criteria);
(5) Review methodologies applied;
(6) Review of performance since the previous PSR;
(7) Comparison with review criteria and discussion of the results;
(8) Evaluation of the safety significance of negative findings, together with proposed safety improvements and their prioritization;
(9) Review of future safety for the period addressed in the PSR;
(10) Conclusions;
(11) References;
(12) Appendices.

I.3. SUGGESTED CONTENTS OF THE GLOBAL ASSESSMENT REPORT

The PSR results for all safety factors are evaluated through a global assessment, and the following items are documented:

— Significant PSR outcomes, including positive and negative findings (strengths and deviations);
— Analysis of interfaces, overlaps and omissions between safety factors and between individual negative findings;
— An overall analysis of the combined effects of the positive and negative findings;
— The category, ranking and priority of safety improvements proposed to address negative findings;
— An assessment of defence in depth;

— An assessment of the overall risk;
— Justification for proposed continued operation or long term operation, as applicable.

I.4. SUGGESTED CONTENTS OF THE FINAL PERIODIC SAFETY REVIEW REPORT

The final PSR report provides an overview of the PSR and includes the following topics:

— Summary of the outcomes of the safety factor reports.
— Summary of the outcomes of the global assessment report, including.
  - Identification of negative findings arising from deviations between the present state of the facility and current safety standards and operational practices;
  - Evaluation of the safety significance of these negative findings;
  - Overall judgement on the acceptability of continued facility operation.
— Integrated implementation plan, including proposals for resolving negative findings by safety improvements or corrective actions, and their safety significance and priority.
— Assessment of the safety of future NFCF operation.

Appendix II

SAFETY FACTOR ON UTILIZATION

This appendix, adapted from Ref. [4], provides information on the review of the safety factor related to 'utilization', especially in nuclear fuel cycle R&D facilities, and how to perform this review.

In nuclear fuel cycle R&D facilities, the design and safety provisions have to include the categorization of the R&D activities or experiments according to their safety significance, robust procedures for their safety analysis, their commensurate approval according to safety significance, and installation and formal commissioning programmes for activities or experiments with major safety significance.

II.1. OBJECTIVE

The objective of the review of this safety factor is to determine whether the existing arrangements are adequate to ensure the safety of experiments and utilization of the facility, as well as whether changes in the utilization are adequately addressed.

II.2. SCOPE AND TASKS

The evaluation includes review of the following:

(a) Ongoing experiments and utilization, and any foreseeable changes;
(b) Adequacy of configuration management and arrangements for use and control of experiments and utilization of the facility;
(c) Review and approval process for use and control of utilization of the facility;
(d) Changes in the facility documentation with respect to utilization;
(e) Assessment of special operational limits and conditions that may be required for an experiment;
(f) Qualification of the personnel associated with experiments and utilization;
(g) Review of the hazard identification and consequence analysis mechanism for new experiments and utilization.

II.3. METHODOLOGY

The review of this safety factor has to determine whether:

— Adequate assurance of the safety of experiments was initially provided;
— Equipment qualification, specifications and procedures are valid (e.g. regarding service life) with reference to current standards, for ongoing experiments and any foreseeable changes in experiments or utilization.

The review has to evaluate the adequacy of the arrangements with regard to the following:

— Review and approval of new experiments or utilization;
— Changes in the existing utilization;
— Training and qualification of the personnel associated with experiments and activities;
— Quality of the procedures;
— Records of radiation doses and radioactive releases due to experiments;
— Categorization criteria and the associated routes of approval according to the safety significance of the experiments and activities;
— Storage conditions and disposal of experimental devices.

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Annex I

REGULATORY REQUIREMENTS FOR PERIODIC SAFETY REVIEWS: ARGENTINA

I–1. INTRODUCTION

Nuclear fuel cycle activities in Argentina include uranium conversion and purification, fuel fabrication, radioactive waste management and spent fuel storage. In addition, the country has several research and development (R&D) facilities, as well as uranium enrichment activities such as the reactivation of a gaseous diffusion mock-up and advancements in enrichment by laser technologies. Although there are no activities related to direct reprocessing of uranium fuel, the country operates a radiochemical laboratory that processes irradiated uranium from the filters of the molybdenum by fission production plant. Finally, uranium mining production sites, although not currently in operation, are under regulatory control and considered within the fuel cycle for the Argentine regulatory framework, with ongoing remediation and licensing plans. The licensing process classifies the facilities as Class I, II or III, according to a graded approach. The required periodic safety assessments of these facilities vary accordingly.

I–2. LEGAL AND REGULATORY FRAMEWORK

By Law No. 24.804, the National Nuclear Activity Law [I–1], which was passed on 25 April 1997, the Nuclear Regulatory Authority of Argentina (known as ARN) is empowered to regulate and control nuclear activity within the territory of Argentina. The Act designates ARN as responsible for adopting regulatory standards related to radiological and nuclear safety, safeguards, physical protection and transport of nuclear material. Currently, there are 64 regulatory standards and 10 regulatory guides in force.

Requirement 2 of the Basic Radiation Safety Standard [I–2] establishes that to operate a facility or carry out a practice, the responsible organization has to hold a licence or registration, as applicable, issued by the regulatory authority. For nuclear fuel cycle facilities (NFCFs), the duration of the licence is 5 years, which is specified in the licence.

Operating organizations are required by the national safety standards and by the licence to periodically review the safety conditions and the documentation

of the facility, and notify the regulatory body of any deviations. Moreover, any significant modification has to be previously approved by the regulatory body.

This legal framework includes the performance of a comprehensive safety assessment when renewing the operating licence of an NFCF for an additional period, corresponding to a periodic safety review (PSR). The licence establishes that at least six months prior to the licence expiration, the operating organization has to send to the regulatory body updated versions of the mandatory documentation (see Section I–3), along with a report that summarizes the operational safety performance of the facility during the last five years, including the description of any significant change. It is also expected to include the operating organization's prospects for the next five years (considering ageing). The report has to demonstrate that adequate conditions of safety, security and safeguards are maintained.

The regulatory authority, through an independent regulatory evaluation of the safety assessment, verifies that the facility continues to comply with current regulatory requirements, and that all corrective actions requested during the validity of the operating licence have been completed or properly addressed.

I–3. PERIODIC SAFETY REVIEW METHODOLOGY

The mandatory documentation to renew the licence includes, at least, the following:

(a) Safety report (including the safety assessment);
(b) Management system manual;
(c) Operation manual;
(d) Maintenance manual;
(e) Code of practices (including the monitoring plan and waste management plan);
(f) Emergency plan;
(g) Preliminary decommissioning plan;
(h) Design information questionnaire for safeguards purposes;
(i) Design report of physical protection.

A review committee established by the regulatory body, with additional assistance of technical support groups if required, conducts an independent analysis of the submitted documentation, taking into account regulatory experience including: the inspection and operational reports from the last five years, incidents or accidents in the facility and the corresponding corrective actions taken by the organization, safety culture, human factors and recent

regulatory requirements, among other things. A report is made summarizing all the analysis and concluding the assessment with a final recommendation regarding the licence renewal.

Licence renewal for Class II and Class III fuel cycle facilities is carried out in a simplified process of at least one step, applying a graded approach. Consequently, the operating organization has to submit a unique radiological safety assessment that integrates all relevant aspects of radiological safety in the facility. In addition, the corresponding requirements of safeguards and physical protection have to be fulfilled.

I–3.1. Safety factors considered in the periodic safety review

The main areas to be reviewed by the operating organization and the regulatory body in the PSR are:

I–3.1.1. Facility design

This safety factor includes a comprehensive review of cumulative changes or modifications made to the facility regarding structures, systems and components (SSCs) important to safety. In addition, the planned replacement of critical components for the next period has to be specified.

I–3.1.2. Safety analysis

This includes a review of the updated safety analysis case, including facility specific risks and hazards and considering normal operation and accident conditions. If necessary, this may include a re-evaluation of criticality.

I–3.1.3. Safety performance

This is an overall assessment of the operating experience, including lessons learnt from events, human factors, staff retraining programmes, records, performance of the safety systems and the compliance with current state of regulatory standards. In the case of recent regulatory requirements, a graded approach is to be used with enough flexibility to allow a transition period.

I–3.1.4. Radiological protection

This reviews radiation dose exposure records, changes in monitoring plan and other procedures, radioactive waste management activities and the reassessment of public doses if needed.

I–3.1.5. Management system

Using the framework of the national standard ‘Management system for safety in installations and practices’, this safety factor includes responsibilities, organization and administration, resources, promotion of safety culture, involvement of stakeholders and integration of different systems.

I–3.1.6. Maintenance plan

This is a comprehensive review considering the ageing of components is required as part of the renewal of the operating licence. It also includes the review of maintenance records and the results of periodic testing.

I–3.1.7. Emergency and decommissioning plans

This safety factor reviews emergency and decommissioning plans to verify that the lessons learnt and experience gained from the operating performance and the emergency drills have been included.

I–4. REVIEW PROCESS OF THE REGULATORY BODY

The PSR assessment and the conclusion of the technical report made by the regulatory body determine whether a renewal of licence is recommended. If the reports conclude that significant changes, improvements or additional evaluations need to be done, licence renewal cannot be recommended. This leads to an iterative process between the regulatory body and the operating organization until safe conditions are guaranteed. During this process, the responsibilities established in the licence are maintained.

If the conclusion is positive with no comments, or the findings and opportunities for improvement have no substantial impact on safety, licence renewal is recommended from a technical standpoint. In this case, the organization is expected continue working on the observations and regulatory requirements, if any, under the concept of continuous safety improvement.

An official file is created with the intervention of the legal and financial departments of the regulatory body, and the new licence text is drafted and circulated among different departments. The final version of the licence text is approved by the regulatory body’s highest authorities and through a legal resolution. The licence document is sent to the operating organization and the result is published in the official bulletin of the country.

I–5. POST-REVIEW ACTIVITIES

The findings of the assessment are communicated to the operating organization through an official note. The regulatory body may issue "regulatory requirements of mandatory compliance" in a time bound manner, which are reviewed during regulatory inspections. Failure to comply with regulatory requirements may result in a sanction that, in the most serious cases, could result in suspension of the operating licence.

Additionally, the conditions described in the PSR are verified through routine regulatory inspections to ensure safe operation for the entire period until the next licence renewal. The main regulatory activities during inspections include verifying compliance with mandatory documentation, verifying safety systems and equipment operation, performing radiation field measurements, taking samples for radiological analysis in the laboratory and reviewing installation records. This inspection plan is developed, taking into account the type of facility and using a graded approach.

REFERENCES TO ANNEX I

[I–1] National Nuclear Activity Law, Law No. 24.804, https://servicios.infoleg.gob.ar/infolegInternet/anexos/40000-44999/42924/norma.htm

[I–2] Basic Radiation Safety Standard, AR 10.1.1 Rev. 4.

Annex II

REGULATORY REQUIREMENTS FOR PERIODIC SAFETY REVIEWS: CANADA

II–1. INTRODUCTION

Canada has a developed nuclear fuel cycle programme supporting its current nuclear power plants that consist of Canada deuterium uranium (CANDU) reactors. Canada is also a major producer of uranium, with several mines and mills primarily located in the province of Saskatchewan.

Front end uranium processing facilities are located in the province of Ontario, with a uranium refinery in Blind River and a conversion facility in Port Hope that produce enriched UF_6 and natural UO_2. Canada also has three operating fuel fabrication facilities in Ontario (Port Hope, Toronto and Peterborough) that support production of fuel bundles for its CANDU fleet. Also, Canada has active fuel research facilities in Ontario at Port Hope and Chalk River.

At the back end of the fuel cycle, Canada currently has storage facilities for the storage of spent fuel primarily on the sites of its nuclear power plants. In 2022, the Canadian Nuclear Safety Commission sought to ensure its readiness to regulate small modular reactors as proponents are considering various fuel processing methods that include reprocessing, TRI–structural ISOtropic fuel assembly and high assay low enriched uranium processing.

II–2. LEGAL BASIS AND REGULATORY GUIDANCE

All nuclear activities consistent with the international obligations of Canada are under the purview of the Nuclear Safety and Control Act (NSCA) [II–1] and its associated regulations. The Class I Nuclear Facilities Regulations [II–2] (known as CINFR) under the NSCA mandate a PSR only for nuclear power plants at an interval specified by the licence. For NFCFs, a safety assessment of the facility and operating organization's performance, with a focus on all the safety factors, is conducted as part of licence renewal. Also, the regulatory framework in Canada, through its licence, licence conditions handbook and regulatory documents, requires a nuclear facility to periodically review key documentation such as safety analysis, environmental risk assessments, decommissioning plans and programme documents to ensure safe operations in compliance with all the regulatory requirements and modern standards.

For NFCFs, the prevailing requirements for a licence renewal application are documented in the regulations under the NSCA. These include the General Nuclear Safety and Control Regulations [II–3] and CINFR among others.

II–3. PERIODIC SAFETY REVIEW METHODOLOGY

The operating organizations of the NFCFs are required to update safety documentation, such as safety analysis, environmental risk assessments, decommissioning plans and programme documents linked to key safety factors, whenever there is a significant change to the facility operations or periodically, as per the period specified in the facility licence which is currently five years. The safety factors considered for review are grouped under 'safety and control areas' and 'specific areas' that cover all safety factors listed in this document along with other matters of regulatory interest. The safety and control areas and specific areas typical for the NFCFs in Canada are listed in Table II–1 [II–4].

II–4. REVIEW PROCESS OF THE REGULATORY BODY AND POST-REVIEW ACTIVITIES

All safety factors associated with a PSR are reviewed for each NFCF as part of a licence renewal process which is conducted periodically. This licence renewal process incorporates a safety assessment that includes technical assessments covering all key safety factors, assessment of safety performance of the operator over the past licence period, assessments that confirm siting of the facility and its overall safety case, and public feedback through a public hearing process. An independent commission then decides on licence renewal, taking all aspects of the facility operations into consideration as well determining the next licence period.

TABLE II–1. SAFETY AND CONTROL AREAS USED BY THE CANADIAN NUCLEAR SAFETY COMMISSION

Safety and control area	Definition	Specific areas
Management system	Covers the framework that establishes the processes and programmes needed to ensure an organization achieves its safety objectives, continuously monitors its performance against these objectives and fosters a healthy safety culture.	— Management system; — Organization; — Performance assessment, improvement and management review; — Operating experience, problem identification and resolution; — Change management; — Safety culture; — Configuration management; — Records management; — Supply and contractor management; — Business continuity.
Human performance management	Covers activities that enable effective human performance through the development and implementation of processes that ensure a sufficient number of licensee personnel are in all relevant job areas and have the necessary knowledge, skills, procedures and tools in place to safely carry out their duties.	— Human performance programme; — Personnel training; — Personnel certification; — Work organization and job design; — Fitness for duty.
Operating performance	Includes an overall review of the conduct of the licensed activities and the activities that enable effective performance.	— Conduct of licensed activity; — Procedures; — Reporting and trending; — Outage management performance; — Safe operating envelope; — Severe accident management and recovery; — Accident management and recovery.

TABLE II–1. SAFETY AND CONTROL AREAS USED BY THE CANADIAN NUCLEAR SAFETY COMMISSION (cont.)

Safety and control area	Definition	Specific areas
Safety analysis	Covers maintenance of the safety analysis that supports the overall safety case for the facility. Safety analysis is a systematic evaluation of the potential hazards associated with the conduct of a proposed activity or facility and considers the effectiveness of preventative measures and strategies in reducing the effects of such hazards.	— Deterministic safety analysis; — Hazard analysis; — Probabilistic safety analysis; — Criticality safety; — Severe accident analysis; — Management of safety issues (including research and development programmes).
Physical design	Relates to activities that impact the ability of SSCs to meet and maintain their design basis given new information arising over time and taking changes in the external environment into account.	— Design governance; — Site characterization; — Facility design; — Structure design; — System design; — Component design.
Fitness for service	Covers activities that impact the physical condition of structures, systems and components to ensure that they remain effective over time. This area includes programmes that ensure all equipment is available to perform its intended design function when called upon to do so.	— Equipment fitness for service / equipment performance; — Maintenance; — Structural integrity; — Ageing management; — Chemistry control; — Periodic inspection and testing.
Radiation protection	Covers the implementation of a radiation protection programme in accordance with the radiation protection regulations. The programme has to ensure that contamination levels and radiation doses received by individuals are monitored, controlled and maintained as low as reasonably achievable (ALARA).	— Application of ALARA; — Worker dose control; — Radiation protection programme performance; — Radiological hazard control.

TABLE II–1. SAFETY AND CONTROL AREAS USED BY THE CANADIAN NUCLEAR SAFETY COMMISSION (cont.)

Safety and control area	Definition	Specific areas
Conventional health and safety	The implementation of a programme to manage workplace safety hazards and to protect workers.	— Performance; — Practices; — Awareness.
Environmental protection	Covers programmes that identify, control and monitor all releases of radioactive and hazardous substances and effects on the environment from facilities or as the result of licensed activities.	— Effluent and emissions control (releases); — Environmental management system; — Protection of people; — Assessment and monitoring; — Environmental risk assessment.
Emergency management and fire protection	Covers emergency plans and emergency preparedness programmes that exist for emergencies and for non-routine conditions. This area also includes any results of participation in exercises.	— Conventional emergency preparedness and response; — Nuclear emergency preparedness and response; — Fire emergency preparedness and response.
Waste management	Covers internal waste-related programmes that form part of the facility's operations up to the point where the waste is removed from the facility to a separate waste management facility. This area also covers the planning for decommissioning.	— Waste characterization; — Waste minimization; — Waste management practices; — Decommissioning plans.
Security	Covers the programmes needed to implement and support the security requirements stipulated in the regulations, the licence, orders or expectations for the facility or activity.	— Facilities and equipment; — Response arrangements; — Security practices; — Drills and exercises; — Cyber security.

TABLE II–1. SAFETY AND CONTROL AREAS USED BY THE CANADIAN NUCLEAR SAFETY COMMISSION (cont.)

Safety and control area	Definition	Specific areas
Safeguards and non-proliferation	Covers the programmes and activities needed for the successful implementation of the obligations arising from the Canada–IAEA safeguards agreements, as well as all other measures arising from the Treaty on the Non-Proliferation of Nuclear Weapons.	— Nuclear material accountancy and control; — Access and assistance to the IAEA; — Operational and design information; — Safeguards equipment, containment and surveillance; — Import and export.
Packaging and transport	Programmes that cover the safe packaging and transport of nuclear substances to and from the licensed facility.	— Package design and maintenance; — Packaging and transport; — Registration for use.

REFERENCES TO ANNEX II

[II–1] Nuclear Safety and Control Act (S.C. 1997, c. 9).

[II–2] Class I Nuclear Facilities Regulations (SOR/2000-204).

[II–3] General Nuclear Safety and Control Regulations (SOR/2000-202).

[II–4] CANADIAN NUCLEAR SAFETY COMMISSION, Safety and Control Areas, https://nuclearsafety.gc.ca/eng/resources/publications/reports/powerindustry/safety-and-control-areas.cfm

Annex III

REGULATORY REQUIREMENTS FOR PERIODIC SAFETY REVIEWS: CZECH REPUBLIC

III–1. INTRODUCTION

The main goal of the PSR of nuclear facilities, as applicable to the Czech Republic, is to confirm the current state of compliance with Czech legal requirements of nuclear safety and security, technical safety, radiation protection and monitoring, and emergency preparedness as well as with all the applicable safety requirements (i.e. applicable safety standards and internationally recognized good practices taking into consideration operating experience, relevant results of R&D and the current state of technology). NFCFs in the Czech Republic are located on both the Czech nuclear power plant sites and include fresh fuel storage facility at the Temelin nuclear power plant and spent fuel storage facility at the Temelin and the Dukovany nuclear power plants.

III–2. LEGAL BASIS AND REGULATORY GUIDANCE

In the Czech Republic, PSR is part of the compulsory safety assessments required by law (Act No. 263/2016 Coll., Atomic Act [III–1]). The responsibility for performing the PSR rests with the licensee (operating organization) of the nuclear facility, which is ČEZ, a. s. For a successful PSR, the licensee follows detailed regulatory guidance on PSRs, as provided by the Czech regulatory body (the State Office for Nuclear Safety, SÚJB). Decree No. 162/2017 Coll. [III–2] summarizes the requirements of a PSR (general requirements, period of conduct, scope, contents of review of the individual safety factors and documentation of the PSR). The regulatory safety guide BN-JB-2.9 (Rev. 1.0) [III–3], issued in 2019 by the SÚJB, further elaborates the requirements for PSRs and provides detailed guidelines for PSR preparation and conduct as well as evaluation of the results and findings. PSR for a particular nuclear facility has to be performed within ten years of the completion of the previous PSR (except for the first PSR which has to be performed within the first six years of the start of facility operations). The results of the PSR are one of the important inputs for the SÚJB for making a decision on granting the licence for the continued operation of the nuclear facility.

III–3. PERIODIC SAFETY REVIEW METHODOLOGY

In general, the PSR strategy adopted in the Czech Republic is applicable to all the nuclear facilities operated by the licensee, and the PSR methodology is equal for both the nuclear power plants and the NFCFs — that is, for both fresh and spent nuclear fuel storage facilities. During a PSR, the review of the 14 safety factors identified (compliant with IAEA Safety Standards Series No. SSG-25 [III–4]) is performed by the licensee according to the PSR basis document as agreed with the SÚJB. The PSR basis document contains detailed methodology (Methods and criteria for PSR) for the review of each safety factor. The review involves evaluating clearly defined criteria which are derived from the applicable requirements. The criteria are defined so that they are relevant for all the nuclear facilities operated by the licensee, but the methodology provides clear identification of specific nuclear facilities to which a given criterion applies.

Considering the vast scope of PSRs and variations in the hazard potential of the different types of nuclear facilities and activities performed, it is generally advisable to apply a graded approach to PSRs. In the context of a PSR in the Czech Republic, the graded approach is understood as an appropriate use of resources that makes reasonable effort in proportion to the complexity of processes and activities affecting nuclear safety and security, technical safety, radiation protection, radiation monitoring and emergency preparedness, and takes into consideration the seriousness of possible consequences of any deviations or discrepancies in such processes and activities.

The following text provides three examples of the use of a graded approach in PSRs as applied in the Czech Republic.

III–3.1. Areas of interest

The first example of graded approach, as applied in the Czech PSRs, is the concept of so called areas of interest, which are derived from the previous experience of ČEZ, a. s., on the potentially problematic areas of operation of the reviewed nuclear facilities. The possible sources of information used for the definition of the areas of interest include, but are not limited to:

- Internal and external operating experiences;
- Requirements of the regulatory body resulting from inspection findings;
- Outcomes and findings from international missions;
- Internal and external controls, audits and inspections;
- Results from relevant projects involving activities to meet the regulatory requirements (e.g. action plans for long term operation).

The areas of interest are defined in the phase of the PSR project preparation for each of the safety factors and the review is subsequently focused primarily on these areas of interest.

III–3.2. Selection of review samples

A graded approach is also used in selecting review samples, for example, for the purpose of reviewing safety factor 2, 'actual condition of SSCs important to safety'. As it is not feasible to review all the SSCs in the nuclear facility, only a limited sample of SSCs is used for the review based on their safety classification and, thus, taking into consideration their importance to nuclear safety. The review sample of SSCs comprises all systems of the highest safety classes (1 and 2) and is complemented by several systems of safety class 3 and safety related systems that are selected using a graded approach according to their influence on nuclear safety, based on the results of probabilistic safety assessment and accident management.

The same approach is followed to review safety factor 9, 'procedures': the review sample contains all the procedures that are of the highest importance to nuclear safety. Other procedures are selected for review based on the graded approach. Similarly, the samples for review of the other safety factors are selected using the graded approach and the selection considers the defined areas of interest.

III–3.3. Evaluation of criteria

The review of each safety factor consists of evaluating a set of criteria divided into thematic groups. Each criterion is evaluated by examining an evidence sample to prove that the requirements are met. Within the evaluation, a graded approach is applied with respect to the importance levels of the criteria. The importance levels indicate the classification of the criteria according to the origin of the corresponding requirement used for their formulation. In brief, level 1 criteria are based on the requirements of national legislation, level 2 criteria are derived from IAEA or WENRA (Western European Nuclear Regulators' Association) requirements which have no equivalent in national legislation, and level 3 is assigned to criteria based on recommendations from national and international safety guides or other descriptive documents. The graded approach is applied with respect to these levels of importance by keeping the sample size of selected evidence varied and changing, to show that the requirements are met.

III–4. REVIEW PROCESS OF THE REGULATORY BODY

Within the preparatory phase of the PSR project, the PSR basis document (including the detailed methodology of safety factors review) is sent to the SÚJB for any comments. After the PSR, results and findings are summarized in the integrated PSR assessment report which has to be sent to the SÚJB no later than three months before the deadline for completing the PSR. The SÚJB then reviews the final PSR documentation, including the proposed integrated implementation plan (action plan).

III–5. POST-REVIEW ACTIVITIES

After completing the PSR, the licensee establishes the so-called executive committee of the action plan which approves and monitors the implementation of the action plan as agreed with the SÚJB. This includes planning and supervision of remediation of deviations and safety improvements implemented in compliance with the approved schedule. For remediation of deviations, a graded approach is applied so that the deviations are remedied within the time determined according to their safety significance (high, middle, low, very low and with no influence on safety). The progress in the action plan implementation is periodically reported to the SÚJB.

REFERENCES TO ANNEX III

[III–1] STATE OFFICE FOR NUCLEAR SAFETY, Atomic Act, Act No. 263/2016 of Coll., 14 July 2016, https://sujb.gov.cz/fileadmin/sujb/docs/legislativa/zakony/Act_263_2016_web.pdf

[III–2] STATE OFFICE FOR NUCLEAR SAFETY, Implementing Decree No. 162, 25 May 2017, on The Requirements for Safety Assessment According to the Atomic Act, Decree No. 162/2017 Coll., https://sujb.gov.cz/fileadmin/sujb/docs/legislativa/vyhlasky/Decree_162_2017_20220309.pdf

[III–3] STATE OFFICE FOR NUCLEAR SAFETY, "Periodic Safety Review" Safety Guide, BN-JB-2.9 (Rev. 1.0), SÚJB, Prague (2019).

[III–4] INTERNATIONAL ATOMIC ENERGY AGENCY, Periodic Safety Review for Nuclear Power Plants, IAEA Safety Standards Series No. SSG-25, IAEA, Vienna (2013).

Annex IV

REGULATORY REQUIREMENTS FOR PERIODIC SAFETY REVIEWS: FRANCE

IV–1. INTRODUCTION

In France, PSRs consist of in-depth examination of a nuclear facility's compliance with applicable standards, including an in-depth examination of the effects of ageing, remediation of deviations detected and improvements in the level of safety as per the best international practices. The NFCFs in operation in France include nuclear fuel fabrication facilities, fuel reprocessing facilities, conversion and enrichment facilities, tails management facilities, radioactive waste management facilities and associated laboratories.

IV–2. LEGAL BASIS AND REGULATORY GUIDANCE

In France, the operating licence of nuclear installations is not limited in time. However, the regulation (Article L593-18, Environmental Code [IV–1]) requires that the licensee of a nuclear facility periodically review its facility, considering international best practices. In accordance with the regulation, these reviews have to take place at least every ten years and they need to assess the situation of the facility in terms of the applicable rules to update the facility's risk assessment towards the public and the environment, taking into account the state of the facility, the operating experience feedback, the development of knowledge and the rules applicable to similar facilities.

Before the PSR begins, a PSR basis document that outlines the framework of the PSR is submitted to the nuclear safety authority. The PSR basis document is subject to regulatory review, and the response from the nuclear safety authority needs to be considered by the licensee during the PSR process.

IV–3. PERIODIC SAFETY REVIEW METHODOLOGY

A PSR is an opportunity to thoroughly examine the condition of the facilities to verify that they comply with the applicable safety documentation. It also aims to improve the level of safety of the facilities. PSRs generally contain the following parts:

— Scope of the PSR: Defines the reference period, which is at least the previous ten years of facility's life, whether it is in operation or in decommissioning, and the perimeter of the PSR (a part or the whole facility);
— Applicable safety documentation: Includes lists and versions of the safety documents and regulations applicable to the facility;
— Regulatory changes and evolutions since the last PSR: Includes a compliance check of the facility with main new technical regulations;
— Facility modifications since the last PSR (or within the past ten years): Includes a description of any substantial changes that occurred within the previous ten years that may have had an impact on the facility's safety;
— Analysis of the operating experience feedback: Includes ten years of process and surveillance monitoring data and operation balances;
— Lessons from events that occurred during the assessed period: Includes analysis of root causes to find potential recurrences and to identify whether preventive and corrective measures implemented since the previous assessment were effective;
— Process updates: Describes the evolutions of the state of the art since the last PSR;
— Forecast: Lists the foreseen changes and evolutions of the facility for the next ten years;
— Compliance review and ageing management: Aims at ensuring that changes at the facility and its operating conditions still comply with the applicable regulations and its technical safety documentation;
— Human factors analysis: Defines the scope in the PSR basis document and is focused on organizational aspects or on workers specific tasks;
— Safety reassessment: Aims at analysing the safety level of the facility, considering its evolutions since the last PSR, its foreseen evolutions towards the next PSR, and its improvements with regards to best available national and international techniques and practices — in particular, guides, standards, recommendations or requirements adopted for installations of the same nature, at the time of the reassessment — including a reassessment of emergency preparedness;
— Environmental reassessment: Aims to analyse the impact of normal facility operation to its environment and it is focused on monitoring soil and groundwater contamination and liquid and gaseous effluents, while undertaking an assessment of best available technologies regarding waste management, energy savings, etc., given that the main objective of the PSR is to verify that the facility complies with the French regulation and to identify technologies that can be implemented to reduce the facility's impact on the environment;

— Action plan: Includes, based on the conclusions of the different studies and analysis, corrective actions to be carried out (with an associated target completion time) and safety improvements that could be implemented to reach the requirements of the latest safety standards, considering a graded approach;
— Conclusions report: Contains summary of the studies and analyses carried out for the PSR;
— Decommissioning plan: Includes an updated plan, in light of the PSR conclusions, with changes that may have an impact on the dismantling of the facility.

IV–4. REVIEW PROCESS OF THE REGULATORY BODY

The regulatory body conducts a review and assessment of the PSR report submitted by the operating organization. It seeks the support of technical support organizations for the review and assessment, as necessary. The regulatory body then sends a report with its comments to the operating organization. In addition to the actions defined in the action plan, the licensee can give undertakings in response to the recommendations and observations of the review and assessment by the regulatory body.

This review and assessment is concluded when the regulatory body sends a report to the minister in charge of nuclear safety and, if necessary, sends a decision to set new requirements to the licensee. The report and the decision are published on the web site of the French Nuclear Safety Authority (L'Autorité de sûreté nucléaire, or ASN, www.asn.fr).

IV–5. POST-REVIEW ACTIVITIES

After the conclusion of the PSR, the regulatory body monitors the implementation of the licensee's undertakings and action plan, on an appropriate frequency.

REFERENCE TO ANNEX IV

[IV–1] Article L593-18, Environmental Code, https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000047717722

Annex V

REGULATORY REQUIREMENTS FOR PERIODIC SAFETY REVIEWS: INDIA

V–1. INTRODUCTION

In India, NFCFs comprise all facilities related to the nuclear fuel cycle, including mining, milling and nuclear fuel fabrication. In the context of the Indian nuclear programme, a few other industrial activities such as heavy water production, though not part of the nuclear fuel cycle, are under the regulatory control of the nuclear regulatory body.

V–2. LEGAL BASIS AND REGULATORY GUIDANCE

NFCFs are required to have a valid licence for operation as per the legal requirement. This licence has validity period of five years. For a renewal of the licence, the NFCF is required to submit a PSR report to the regulatory body. The regulatory guidance for conducting a PSR for renewing the licence for operation of an NFCF is available in the Atomic Energy Regulatory Board (AERB) safety guidelines, Renewal of Licence for Operation of Nuclear Fuel Cycle Facilities other than Nuclear Power Plants and Research Reactors (AERB/FE&BE-FCF/SG-1) [V–1].

V–3. PERIODIC SAFETY REVIEW METHODOLOGY

The operating organization carries out the PSR and submits the PSR report to the regulatory body at least six months before the expiry of the existing licence for operation. The PSR report is then reviewed by the regulatory body. The regulatory body may conduct special regulatory inspection of the facility for verification of specific safety aspects brought out during the PSR. The safety factors reviewed in the PSR include the following aspects.

V–3.1. Plant performance

The review of this safety factor includes the review of capacity utilization, records of in-service inspections, maintenance and testing of equipment, major modifications and automation carried out in the plant.

V–3.2. Safety performance

This review addresses safety relating to the organization and management systems, as well as significant events and incidents, including those related to nuclear safety, radiation safety, industrial safety and fire safety. The review considers the data on the occupational radiation exposures to verify that they are within the constraints and prescribed limits. This review also considers the information related to the violation of technical specifications (operational limits and conditions), if any. Further, the compliance status of licensing conditions, regulatory inspection observations, and observations arising from periodic emergency exercises are also reviewed. It also considers positive observations such as safety awards won by the plant and initiatives taken by the facility in promoting safety.

V–3.3. Procedures

Information on the availability of updated procedures related to operations, maintenance, inspection, radiation protection, industrial safety and work permit procedures is included. Further, the status of updating the licensing documentation and other facility documentation is also reviewed.

V–3.4. Waste management and radioactive waste disposal

The records of release of gaseous and liquid effluents from the NFCF are reviewed. Records of generated solid waste and its disposal are also reviewed.

V–3.5. Management of ageing

The review of this safety factor is to determine whether a systematic and effective ageing management programme is in place and whether there are adequate arrangements to maintain required safety margins in SSCs important to safety during future plant operations.

V–3.6. Emergency preparedness

The review of this safety factor considers the status of emergency plans and emergency operating procedures for both on-site and off-site emergencies. The records of emergency exercises are reviewed to verify the effectiveness of emergency planning.

V–3.7. Environmental impact assessment

This is a review of the records of effluents released and their comparison with the permissible limits, records of off-site monitoring of contamination and radiation levels, documentation on environmental data and change in land use. The review is carried out to determine whether there is adequate surveillance and assessment of environmental impact by the NFCFs.

V–3.8. Organization and administration

This review considers roles and responsibilities of licensed persons and training facilities and programmes of the operating organization. The organization and administration aspects are reviewed to determine whether the organization and administration are adequate for a safe operation of the plant.

V–4. REVIEW PROCESS OF THE REGULATORY BODY

For NFCFs in India, the PSR is coupled with licensing. The period for licence renewal of the NFCF is five years. A graded approach is used in reviewing the PSR report, based on the hazard associated with the facility. On completion of the review and assessment, the regulatory body issues a renewed licence to the facility. The important observations arising out of the review and assessment by the regulatory body are included as licensing conditions for a time bound implementation.

V–5. POST-REVIEW ACTIVITIES

On renewal of the facility's licence, the PSR review of the NFCF is completed. The action items arising out of the review are implemented by the plant in a time bound manner. The status of compliance of the action items forms a part of the periodic submissions from the facility. During regulatory inspection, the regulatory body verifies the compliance of the licensing conditions.

REFERENCE TO ANNEX V

[V–1] ATOMIC ENERGY REGULATORY BOARD, Renewal of Licence for Operation of Nuclear Fuel Cycle Facilities Other than Nuclear Power Plants and Research Reactors, AERB Safety Guidelines, Guidelines No. AERB/FE&BE-FCF/SG-1, Mumbai (2010).

Annex VI

EXAMPLE METHODOLOGY FOR DEVELOPING A PERIODIC SAFETY REVIEW BASIS DOCUMENT

This annex presents an example of a methodology for developing a PSR basis document based on the practice of an operating organization in France.

VI–1. DEVELOPMENT OF THE PERIODIC SAFETY REVIEW BASIS DOCUMENT

The PSR basis document aims to define the PSR framework with a graded approach. This is based on a five step analysis:

(1) Collect input data.
(2) Analyse the collected data.
(3) Define an exhaustive list of potential topics.
(4) Prioritize identified topics based on different criteria and with a graded approach.
(5) Finalize the PSR programme of work.

VI–1.1. Step 1: Data collection

Before undertaking a PSR, various types of data need to be collected. Table VI–1 provides a non-exhaustive list of data that is collected at this stage.

VI–1.2. Step 2: Analysis of collected data

The aim of this step is to analyse the collected data to identify possible topics to be addressed during the PSR. The collected data is concisely analysed to identify, for each area, whether there has been an evolution that has an impact on the safety assessment. The following aspects need to be considered during the analysis:

— Evolution of technical requirements: Some of the updated requirements may have an impact on the safety of the facility; at this stage of the process, those which apply to a part of the facility or the whole facility are considered.

— Event feedback: It is considered only if a similar event(s) can occur in the facility or if the lesson learnt from an event can enhance the safety of the facility.
— Developments in the state of the art: These are only considered if the evolution applies to the facility or if they can enhance the safety of the facility.

TABLE VI–1. EXAMPLES OF DATA COLLECTED BEFORE A PSR

Area	Examples of collected data
Safety case, authorizations and inspections	— Different authorizations related to the facility, depending on the regulatory framework: discharge of radioactive or chemical effluents, commissioning, facility creation, important modifications; — Facility's safety documentation: safety cases, safety rules, dismantling plan, transport, waste management, environmental assessment; — Site wide safety case, if existing; — Specific authorizations by the regulatory body (e.g. related to specific operations); — Specific requirements or recommendations from the regulatory body.
Outputs of previous PSR (if available)	— Review of compliance work (i.e. progress report) and response to undertakings.
Evolution of regulation since the last PSR	— Changes in regulation that may have an impact on safety case (e.g. fire regulation, radiation protection).
Operating experience feedback and facility modification since the last PSR	— Operating experience feedback: accumulation of fissile material in equipment, drifts of process parameters, flowsheet balances, etc.; — Significant changes in the facility (e.g. change of process, implementation of new safety measures, dismantling and decommissioning operations).
Ageing assessment and compliance review	— Results of existing periodic inspections and tests, existing compliance controls actions, existing obsolescence assessments, existing maintenance report.

TABLE VI–1. EXAMPLES OF DATA COLLECTED BEFORE A PSR (cont.)

Area	Examples of collected data
Monitoring	— Radiation protection: operational dosimetry of workers, passive dosimetry, extremity dosimetry, dosimetry by type of operation; — Environment monitoring (i.e. radioactive material and chemical): piezometric measurements, liquid and gaseous effluents monitoring; — Legacy waste monitoring.
Events feedback	— Identification of relevant events that occurred since the last PSR, using the operator's database and national or international databases (e.g. FINAS[a]).
Evolution of external hazards	— Identification of changes in the vicinity of the facility that can threaten it (e.g. new chemical facility, new roads with chemical transportation) or necessitate the revision of consequences assessment to the public (e.g. new housing area); — Evolution of site meteorological conditions, seismic knowledge, etc.
Developments of state of the art	— Publication of new standard to address or assess specific hazards, change in design standards that impact safety, evolution of calculation and modelling codes.

[a] FINAS: Fuel Incident Notification and Analysis System.

VI–1.3. Steps 3 and 4: Topics to be addressed and their prioritization

These steps consist of a systematic analysis to identify the topics to be considered in the PSR and prioritize them using a graded approach. The two main topics of PSR that are analysed are described below:

VI–1.3.1. Compliance review and ageing management programme

The purpose of the compliance review and ageing management programme is to ensure that changes in the facility and its operation due to modifications or ageing, as well as changes in its environment, do not jeopardize the compliance

of SSCs with safety requirements. The methodology for guiding the compliance of SSCs consists of the following sequential steps:

— Identification of SSCs and their requirements and grouping them, if necessary, into families.
— Summary inventory of the compliance of the facility, focusing on the following items:
    • Knowledge from the initial equipment qualification report;
    • Feedback from corrective or curative maintenance actions, periodic inspections and tests, and identification of ageing phenomena;
    • Evolution of operating conditions for SSCs important to safety and their environment;
    • Feedback resulting from the analysis of compliance actions, particularly if a continuous compliance verification process exists at the facility.
— Definition of a programme for verifying the compliance review and ageing management of SSCs. If the compliance review and ageing management programme is based on representative SSCs, the selection of the latter needs to be justified and explained in the PSR basis document.
— Prioritization of the compliance review and ageing management programme based on:
    • A graded approach;
    • Considering phenomena of ageing and obsolescence;
    • The evolution of the facility in the ten years after this PSR (including the considerations of dismantling and decommissioning).

VI–1.3.2. Safety reassessment

Similarly to a compliance review and ageing management programme, the safety assessment programme is set using the following approach, which includes consideration of organizational and human factors as well as environmental topics:

— Hazard identification, which aims to identify hazards already assessed in the existing safety case and potential new hazards to be assessed (e.g. evolution of facility vicinity, regulatory requirements).

— Screening of PSR input data (see step 1 ‘data collection’), which aims to determine whether a potential risk reassessment needs to be undertaken in the PSR, mainly based on these seven criteria:
    - Regulatory requirements (e.g. evolution of regulations, new requirements);
    - Specific requirement from the regulatory body;
    - Undertakings by the licensee which can be considered in the PSR;
    - Facility, site characteristics and environment evolutions, and operating experience feedback that impact the existing safety case (new hazards identified are considered);
    - Evolution of methods, knowledge and state of the art that impact the existing safety case;
    - Learning from events identified in step 1 that could enhance the safety of the facility;
    - State of the facility and its evolution until the next PSR. This is particularly important for a facility in decommissioning or in the dismantling stage as radioactive material and chemicals are progressively removed and the inherent risk to the facility is constantly evolving.
— Definition of an exhaustive list of possible and required safety reassessments to be undertaken in the PSR, including identification of methods and tools to be implemented (based on the data collected in step 1).
— Prioritization of possible and required safety reassessments to finalize the PSR reassessment scope. At this stage, if some safety assessments identified in the previous step are not integrated in the PSR scope, their exclusion has to be justified.

VI–1.4. Step 5: Finalization of the PSR programme of work

As the topics are prioritized in step 4, the topics covering safety assessment, compliance review and ageing management are reviewed together to:

— Define the key topics to be addressed in the PSR programme (i.e. topics which are more likely to lead to enhanced safety of the facility).
— Justify the selection of these key topics.
— Ensure the consistency among the safety assessment, compliance review and ageing management programmes.

The output of this step is also used to estimate the costs and plan all the tasks for the PSR project.

VI–2. TYPICAL SUMMARY FOR A PSR BASIS DOCUMENT

A PSR basis document typically has the following components:

(1) Introduction
   — Context;
   — PSR objective.
(2) Facility and its environment description
   — Facility description;
   — Vicinity description.
(3) Safety case description
(4) PSR scope
   — Facility boundaries;
   — Period covered by the PSR.
(5) PSR inputs
   — Regulation evolution;
   — Safety case evolution;
   — Facility modifications;
   — State of the art, knowledge and methods evolution;
   — Future of the facility in the 10 years following this PSR;
   — Pre-analysis of operating experience feedback;
   — Pre-analysis of occurred events.
(6) PSR framework definition
   — Compliance review and ageing management scope and methodologies;
   — Risk reassessment scope and methodologies;
   — Environmental reassessment scope and methodologies.
(7) Human factor scope
(8) PSR content description
(9) PSR project organization
(10) PSR programme

Annex VII

EXAMPLE OF THE CONTENTS OF A PERIODIC SAFETY REVIEW REPORT

This annex presents an example of the contents of a PSR report, based on the practice of an operating organization in France.

This PSR report comprises 13 sections as follows:

— Section 0: Introduction
— Section 1: Facility description and site characteristics
— Section 2: Current safety documentation
— Section 3: Regulation changes since the previous PSR
— Section 4: Facility modifications, monitoring and operating balance report
— Section 5: Incident/accident analysis
— Section 6: Evolution of state of the art, knowledge and methods
— Section 7: Future of the facility for the ten years after this PSR
— Section 8: Compliance review and ageing management
— Section 9: Human factor analysis
— Section 10: Safety reassessment
— Section 11: Environmental reassessment
— Section 12: Conclusions and integrated implementation plan

Sections 0–7 describe inputs on which the reassessment work, compliance review and ageing management studies are based. Sections 8–11 address the result of the reassessment work and present the PSR findings, and Section 12 concludes and justifies the integrated implementation plan through a graded approach.

VII–1. SECTION 0: INTRODUCTION

This section of the PSR report is an introduction with a brief reminder of the scope of the PSR, as agreed upon with the regulatory body. It includes:

— The general objectives of the PSR (e.g. relicensing, partial relicensing, compliance with regulatory framework);
— The physical scope of the PSR (some parts of the facility may have been excluded from the scope of the PSR basis document) and the period considered (i.e. generally a period of ten years before the submission of the PSR);

— The technical scope of the PSR with a brief enumeration of the list of tasks agreed upon with the regulatory body after acceptance of the PSR basis document and may include, if needed, the tasks requested by the regulatory body;
— A brief description of the structure of the report.

VII–2. SECTION 1: FACILITY DESCRIPTION AND SITE CHARACTERISTICS

This section of the PSR report aims to describes the facility and its vicinity, and the site characteristics:

— Buildings, workshops and processes are briefly described;
— Site characteristics and their evolutions are described when needed, such as external hazards (e.g. meteorological conditions, flooding);
— Description of vicinity includes the evolution of the surroundings of the facility since the last PSR — especially those related to population changes (e.g. new residential areas) and to new potential hazards linked to new industrial facilities.

VII–3. SECTION 2: CURRENT SAFETY DOCUMENTATION

This section of the PSR report is mainly informative; it includes a reminder of the evolution of the safety documentation of the facility (and the site wide safety documentation, if existing), especially since the last PSR. Depending on the facility, the documentation may include:

— Authorizations related to the facility as per the regulatory framework, such as discharge of radioactive or chemical effluents, commissioning, facility creation and important modifications;
— Safety documentation, such as safety cases, safety rules, dismantling plan, transport, waste management and environmental assessment;
— Site wide safety case, if existing;
— Specific authorizations by the regulatory body (e.g. related to specific operations);
— Specific requirements from the regulatory body;
— Undertakings by the licensee during the review and assessment by the regulatory body of other PSR reports that may be applicable to the facility.

This section of the report also consists of a progress report on the previous implementation plan, especially regarding the undertakings given by the licensee during the last review of the PSR report by the regulatory body.

VII–4. SECTION 3: REGULATION CHANGES SINCE THE PREVIOUS PSR

This section of the PSR report presents a description of the changes to the main regulation and the technical requirements which affect the safety case since the last PSR. It presents the steps taken by the facility and the continuous process to comply with those requirements.

Actions are defined for any non-conformities identified in this section. Those actions are therefore added to the integrated implementation plan (i.e. section 12 of the PSR report).

VII–5. SECTION 4: FACILITY MODIFICATIONS, MONITORING AND OPERATING BALANCE REPORT

This section of the PSR report presents the analysis of operating and monitoring reports and facility modifications since the previous PSR. This analysis aims to:

— Review the operation of the facility: the performance of the processes, the operations carried out and the facility's impact on the environment.
— Demonstrate the operating organization's capability to operate, maintain and sustain the facility as well as to carry out cleanup and dismantling operations, if applicable.
— Collect required data to carry out the PSR.

Typical analyses are performed on the following data:

— Inputs and outputs of the process (flowsheet balances);
— Operational radioprotection monitoring;
— Radioactive and conventional wastes (including buffer state);
— Gaseous and liquid effluents;
— Internal and external transports;
— Chemical and radiological monitoring of environment (e.g. underground water, surface water, aquatic environments, dosimetric monitoring).

Depending on the facility and its state, other subjects can also be considered in this section such as:

— Modifications to the facility which have an impact on nuclear safety;
— Feedback on dismantling and decommissioning operations, if applicable;
— Changes in organizational and management aspects (e.g. severe accidents management, facility modification management, personnel training and maintenance management).

If unexplained anomalies or drifts are identified in this section, an action plan is considered and integrated in section 12 of the PSR report.

VII–6. SECTION 5: INCIDENT/ACCIDENT ANALYSIS

This section of the PSR report includes an analysis of incidents and accidents that occurred since the last PSR. This analysis principally aims to demonstrate the operating organization's ability to:

— Consider experience feedback from events through its events management system.
— Potentially identify recurrent events not identified through its events management system.
— Ensure that measures implemented are relevant and efficient to avoid similar events.

The national and international events that occur in nuclear and non-nuclear facilities with similar risks are also considered in this section.

If recurrent events are found or if it appears that the measures implemented to avoid potential events are insufficient, an action plan is considered and integrated into section 12 of the PSR report.

VII–7. SECTION 6: EVOLUTION OF STATE OF THE ART, KNOWLEDGE AND METHODS

This section of the PSR report identifies the evolution of knowledge, methodologies, and state of the art since the last PSR. This section includes

changes relating to the following aspects that can impact the safety demonstration of the facility:

— Methodologies chosen by the licensee since the last PSR;
— New or modified regulatory body guidelines;
— International standards (e.g. International Organization for Standardization, IAEA);
— National standards;
— Modelling and calculations codes.

If needed, this section also includes updated reference data (e.g. radionuclides and chemical properties, meteorological data) that is used to reassess risks of the facility.

VII–8. SECTION 7: FUTURE OF THE FACILITY FOR THE TEN YEARS AFTER THIS PSR

The purpose of this section is to identify the foreseen evolution of the facility and its management for the next ten years (the duration until the next PSR). It aims to anticipate future changes that may have an impact on chemical and nuclear safety, such as:

— Waste management or treatment of effluents;
— Process modifications that require a new licence (or licence change);
— Increasing uranium enrichment;
— Future evolution of the close vicinity of the facility (e.g. building of a new facility to retrieve legacy wastes);
— Future evolution in licensee's organization (human factors);
— Decommissioning and dismantling operations and their milestones (e.g. radiological and chemical materials reduction, removal of SSCs important to safety).

VII–9. SECTION 8: COMPLIANCE REVIEW AND AGEING MANAGEMENT

The aim of this section is to present the result of compliance review and ageing management assessment undertaken during the PSR in accordance with the PSR basis document.

The compliance review and ageing management assessment is mainly focused on SSCs important to safety and/or important to the environment. Therefore, the overall approach is generally based on the following steps:

— Collection of SSC data: list of SSCs, safety and environmental requirements, SSC documentation (e.g. design specifications, qualification reports);
— Analysis of SSC documentation such as exhaustiveness of qualification reports, design justification and substantiation;
— Compliance review and ageing management assessment which includes in situ inspections (e.g. thickness measurements, state of the SSCs, identification of changes in SSCs' vicinity that could affect their performance);
— Analysis of compliance review and ageing management assessment which addresses findings and associated action plan.

The compliance review and ageing management assessment could be challenging for a facility that has numerous SSCs to check. Therefore, the use of representative equipment may be considered. If the overall approach is based on sampling, then the analysis checks whether identified irregularities found on representative SSCs are specific to those SSCs or if all the SSCs of their family are also affected. If necessary, new representative SSC surveillance programmes are defined for each family and existing SSC surveillance programmes are updated.

Actions identified in section 8 of the PSR report are therefore considered in section 12 related to the integrated implementation plan.

VII–10. SECTION 9: HUMAN FACTOR ANALYSIS

This section of the PSR report is a summary, outlining the human factor assessment carried out by a human factor expert, based on the programme defined in the PSR basis document. The objective of the review is to provide confidence that the role of the licensee is suitable and is appropriately implemented to support the safe operation of nuclear facilities. It consists of:

— Verifying that the operational practices implemented comply with the safety requirements defined in the facility's safety case (compliance review of practices);
— Ensuring that general organizational arrangements will enable the installation to meet the challenges of the next ten years.

The content of this section depends on the human factor programme defined in the PSR basis document. However, it generally includes:

— Justification of the PSR human factor programme defined in the PSR basis document.
— Analysis of events relating to human factor aspects that occurred in the facility.
— Analysis of operational practices and of the general organizational arrangements.
— Recommendations made by the human factor specialist to enhance operational practices or the general organizational arrangements. Those recommendations are therefore considered in section 12 related to the definition of the integrated implementation plan.

VII–11. SECTION 10: SAFETY REASSESSMENT

This section of the PSR report provides a summary of all the safety analyses which have been agreed upon with the regulatory body in the PSR basis document. It aims to determine that the adequacy and effectiveness of the arrangements and SSCs that are in place ensure the safety of the facility until the next PSR (or, where appropriate, until the end of planned operation) while considering the national and international best practices.

The structure and content of this section depend on the safety assessment scope defined in the PSR basis document. This section includes:

— Reminder of the scope of each subject or theme (e.g. hazard description, reassessment perimeter, reassessment objectives).
— Brief description of the methodologies used to reassess the subject or theme.
— References of safety analysis undertaken during the PSR.
— Reassessment conclusions, which include, if needed, recommendations to enhance safety arrangements in accordance with the graded approach. Those recommendations are therefore considered in section 12 related to the integrated implementation plan.

VII–12. SECTION 11: ENVIRONMENTAL REASSESSMENT

This section of the PSR report provides a summary of all the analyses related to the environmental impact which have been agreed upon with the regulatory body in the PSR basis document. It aims to determine the adequacy

and effectiveness of the arrangements and SSCs that are in place to minimize the facility's impact on the environment during normal operation. This section includes:

— Reassessment of the arrangements in place to reduce environmental impact of the facility and a comparison of them with the best available techniques;
— Chemical and radiological impact (e.g. on soil, groundwater);
— Results of noise emission measurements;
— Analysis of the relevance of the existing environmental impact assessment;
— Reassessment of waste management documentation.

Based on the findings of these analyses, recommendations to reduce the impact from normal operation can be formulated and are considered in section 12 of the PSR report related to the integrated implementation plan.

VII–13. SECTION 12: CONCLUSIONS AND INTEGRATED IMPLEMENTATION PLAN

The objective of this section in the PSR report is to provide the conclusions of the PSR. An action plan (integrated implementation plan) is developed, based on the findings of the review. In accordance with a graded approach, this integrated action plan comprises improvements that can reasonably be implemented to enhance plant safety or limit environmental impact of the facility until the next PSR. Recommendations from previous sections are transformed into actions and are prioritized based on several criteria, such as:

— Compliance with regulations;
— Compliance with facility safety cases;
— Ageing management of SSCs;
— Adequacy and effectiveness of the arrangements to ensure the safety of the facility;
— Future of the facility (or part of the facility);
— Timescales of action implementations;
— Economical and technical feasibility.

A justification is required for recommendations which are not retained as actions in the integrated action plan.

The final integrated implementation plan is synthetized as a table which includes an action number, origin of the action (section and paragraph), description of the action, priority and timescale for implementation. It also includes actions implemented before the submission of the PSR report to the regulatory body.

Annex VIII

EXAMPLE OF A GRADED APPROACH TO PERIODIC SAFETY REVIEW FOR A NUCLEAR FUEL CYCLE FACILITY

This annex presents the process of using a graded approach during PSR of NFCFs adopted by an operating organization in the United Kingdom.

VIII–1. USE OF A GRADED APPROACH IN PERIODIC SAFETY REVIEWS

A graded approach to PSR is a flexible selection process based on the facility context, specifically:

— Life cycle stage;
— Scale and complexity of current or future operations;
— Hazards and associated risks;
— Level of confidence in the effective application of company arrangements for managing safety.

This allows the PSR team to customize the review, focus the team's efforts during the review, and inform the level of detail required for the global assessment. A graded approach is not intended to justify the exclusion of consideration of specific safety factors; rather it is used to justify the scope and scale to which the individual safety factors are to be reviewed.

A bespoke review allowing focus on key areas enables a value adding outcome both in terms of safety (primary consideration) and cost (secondary consideration), which supports continuous demonstration of safety and management of risk in that facility.

A graded approach to PSR covers the entire breadth of scope and depth of scale of possible reviews and allows for anything from a detailed deep dive review to a light touch review. Therefore, use of a graded approach is an inherent consideration when developing the strategy for the PSR (PSR basis document) and the approach taken needs to be justified in the PSR basis document.

VIII–2. METHODOLOGY ADOPTED

This annex is not intended to prescribe any specific methodology for using a graded approach for PSRs, but to provide an example of the use of methodology adopted at an operating organization in the United Kingdom.

Evidence needs to be provided for all safety factors as part of the PSR. A graded approach is about determining what safety factors the review needs to focus on (the scope) and then in how much detail (the scale). Both the breadth of the scope and depth of the scale are entirely at the discretion of the facility to decide. It may be that there is already a wealth of strong evidence to support a particular safety factor and, in this case, it will not be a focus of the review but will still be reported on in terms of the claim made in support of the safety factor and the evidence to underpin that claim.

The application of a graded approach is subjective. All four factors in the previous section need to be considered when determining the use of graded approach. One view may be that only a relatively light touch review is needed of a relatively new, modern facility with simple operations which has well understood and managed hazards, and a detailed deep dive review of an ageing facility with complex operations and high hazards. However, it may be that the ageing facility has demonstrable evidence of managing risks and a good level of confidence in the effective application of arrangements, especially on ageing management. In this instance, a strong justification can be made for not doing a detailed deep dive review, but perhaps not a completely light touch either.

A graded approach to PSR is decided when developing its PSR strategy. The following text is a step by step walkthrough of the method for developing the strategy, supported by a fictional example.

VIII–2.1. Step one: Demonstrate understanding of the facility context

By collaboratively discussing and documenting the facility context (an activity led by the PSR team and supported by the relevant key stakeholders), this step sets the scene for the development of the PSR strategy and is a point of reference to return to at each stage in the following discussions to test the elements of the proposed strategy.

For example: The facility is reaching the end of its life cycle, having operated for over 50 years. It has operated beyond its original design basis life and once operations cease in the next ten years or so, it will be subject to a lengthy post-operational clean out, a prolonged period of surveillance and maintenance, and then be finally fully decommissioned by 2040.

The current operations are somewhat complex but well established and have not changed significantly from the original operating design, apart from

a handful of modifications as new technologies became available. There are no planned changes to the operations, however a potential new workstream may be introduced for the latter years of operation. A final decision has yet to be made, and this decision sits with the site strategy team.

The facility's hazards are well understood: internal exposure (inhalation, ingestion, contaminated wound), direct radiation and criticality. The hazards are considered to be well managed (evidence included to support this) but they will be examined in the context of the totality of the safety factors when developing the PSR strategy.

The risk of the facility is considered broadly acceptable. Despite managing relatively high hazards, the strong safety record, combined with demonstrable operating experience, minimal safety events and adequate protection in place, is judged to support the qualitative view of broadly acceptable risk. However, the facility is ageing and the risk profile is changing. The rate of change of the risk profile is not expected to increase significantly over the remaining lifetime of the facility such that it would warrant a change to the hazard management strategy.

VIII–2.2. Step two: Discuss and agree on the level of confidence in the effective application of company arrangements for managing safety

The safety factors are considered generally in groups (see Sections 3.1–3.5 of this publication). They are used as the basis for a collaborative discussion for developing the PSR strategy. The safety factors are supported by a series of prompts and the prompts are intended to ignite and support a healthy discussion. It is not mandatory to answer all of the questions, and this is not intended to be a prescriptive format or template. An exercise is carried out against each safety factor group, whereby the group of facility experts from the safety case, engineering, operations, maintenance, behavioural safety and other disciplines as required (e.g. technical support) list evidence to support the overall claim (or otherwise) of that particular safety factor group.

The following questions may help during that discussion:

— Does the safety case reflect the way safety is provided?
— Is there clarity of what is important to safety? (Is the hazard management strategy and safe operating envelope complete? Are there gaps in key measures in keeping the plant safe or is the focus more on mitigation?)
— Does the existing evidence support this claim? Does it contradict this? Is the evidence accurate, valid, reliable, etc.?
— Is additional evidence needed to support the claim? If yes, specifically what is needed? (This answer may determine tasks for the PSR and therefore needs to be addressed well.)

— Can a combination of existing evidence be used rather than generating new evidence?
— Does it matter if there is a gap in evidence if there is high confidence from a collection of other sources?
— What are the confidence gaps? How big are the gaps? What is the uncertainty due to these confidence gaps?
— What elements need to be considered as part of the PSR strategy?

If there is a high degree of confidence in any of the safety factors, it should be considered whether or not that confidence needs to be tested and challenged to determine whether it is well placed or whether the PSR report simply pulled together existing arguments and evidence to support the claim.

If there is a low level of confidence (mainly from multiple sources of contradictory evidence or lack of strong evidence), this naturally becomes an area of interest for the PSR.

This exercise itself is an interactive and visual one, with evidence arranged into four coloured categories against each safety factor as follows:

— Strong evidence (green)
— Weak evidence (amber)
— Contradictory evidence (red)
— To follow up or unknown (grey)

For example, for safety factors relating to the facility, there could be the following analysis.

(a) Claim
    — There is sufficient confidence that the engineering safety systems deliver their safety functions.
(b) Subclaims
    — The facility is used for what it is designed to do and configuration control is effective.
    — Plant modifications are implemented according to safety case intent.
    — The plant conforms to modern codes, standards and good practices or the position relative to them is understood and justified.
    — SSCs' conditions are understood and monitored.
    — SSCs are appropriately tested and maintained.
    — The ageing management programme is effective.

Strong Evidence

- There is a dedicated, fully staffed, fully trained condition monitoring team. All SSCs have been categorized as per the condition; the condition is understood and continuous monitoring is in place. See resource and training records, independent assurance and condition reports of the SSCs.
- Reliability modelling is applied and technical function supports understanding of all degradation mechanisms. Technical information of degradation mechanisms is shared between and/or gathered from facilities across the site and at a national forum. See reliability and technical databases, learning from operating experience feedback, forum outputs, etc.
- Every item important to safety has been considered by the dedicated plant health committee and funding has been allocated and prioritized for those important SSCs that need to be replaced in the next five years. See minutes from plant health committee meetings and finance sanctioning reports, contracts for replacement activities, etc.
- Current condition of SSCs across the plant is known, understood, maintained and monitored, and there is evidence that this information supports better decisions. See plant health reports, minutes from decision making forums and independent audits.
- Evidence that degraded conditions are escalated to management and corrected. See event reporting.
- There is understanding of the safety importance of the equipment as evidenced in the plant engineering documentation and through qualification interviews with the operating staff.
- There is a good maintenance history with no maintenance backlog and clearly planned maintenance outages for the facility. This was specifically subject to a recent peer review which reinforces this.
- Ageing management is specifically covered in the plant health reports and these are discussed quarterly with the site ageing management team. There is also good evidence of learning being shared both ways throughout the facility, other facilities on the site, and the site central ageing management capability team.

Weak Evidence

- For those SSCs that will be obsolete in the near future, alternatives are being considered. See records.

Contradictory Evidence

- Obsolescence of one piece of equipment occasionally interrupts operations — not a safety issue but an operational issue. See event reports raised.
- The facility does not conform to all modern standards, given its age of construction and the difficulty of access in some areas of the facility. However, a full justification as to why this is acceptable has been considered by suitable qualified and experienced engineers and approved at the management safety committee. This is reviewed annually. See management safety committee minutes and decision making.

To follow up or unknown

- Potential for additional workstream in the future at the facility — not confirmed as to what facility will be used and, if this facility, then what the impact on the equipment could be. To follow up with site strategy team.

FIG. VIII–1. Arguments/evidence presented visually through colour coding.

(c) Arguments/evidence
— See Fig. VIII–1.
(d) Analysis of the evidence.

In conclusion, there is good, solid documentary evidence to support the claim for this group of safety factors. Although obsolescence is identified as an issue for one piece of equipment, there is work underway to investigate and identify a solution, and this is an ongoing task separate from the PSR and under normal business arrangements. A potential future workstream has not been confirmed and so it is considered outside the scope of the PSR. No further tasks have therefore been identified to be completed as part of the PSR but the PSR could sample some of the listed evidence to test it.

In this case, the PSR report would simply pull together the arguments and documented evidence based on the above analysis. This could be supported by a walkdown of the facility, further discussions with engineering representatives or interrogation of evidence to test the arguments and evidence.

VIII–2.3. Step three: Customize and finalize a periodic safety review strategy

The resultant, collective information from all the safety factor groups is used to identify any areas of particular interest that the PSR strategy needs to explore within the scope and the scale of its review. The strategy can then be developed in terms of key steps, deliverables, interfaces, resources and timescales. The possible options for the scope and scale of review may be, for example:

(a) The scope of the review could consider every safety factor in detail, based on the outcomes of steps one and two.
(b) The focus of the review may simply be a few targeted activities to complement improvements or activities and continuous review processes already in place in the facility (this may be more applicable to specific areas such as plant engineering where the maturity of the condition monitoring programme for SSCs contributes to a continuous review).
(c) More emphasis could be placed on just some aspects of the review (e.g. a lighter review but with a deeper focus on, for example, the organizational safety factors of the PSR because it would add more value).
(d) A combination of a detailed consideration of some safety factors and a few targeted activities for other safety factors.

If option (a) is chosen as the intended strategy, there is a further question to answer: If the scope and scale of the review leads the PSR down a path of a

wholescale fundamental review of safety due to lack of confidence in all safety factors, why is this? Does the facility not have confidence in safety today and if not, why? Is there a more fundamental issue with either the site processes for managing safety or the effective application of them?

In particular, if it is concluded that a wholescale rewrite of the safety case (and supporting safety assessments) is warranted due to a review of safety factors relating to safety analysis, the PSR needs to be asking why are these not maintained as live? The PSR is not expected to be focused on rewriting the safety analysis every ten years; it needs to aim at demonstrating that the organization is proactive and that safety analyses are regularly maintained in line with company processes and arrangements.

VIII–2.4. Step four: Revisit the facility context to assess whether the approach for the periodic safety review is the right one

This is an important step because it forces the facility to take a step back from the proposed strategy to review whether the approach feels right within the facility context. Does it seem like the review is over the top or complex in terms of what would be reasonable given the context of the facility? Would the proposed strategy be a distraction to the facility in terms of hazard and risk reduction? Does the proposed strategy add value to the facility, primarily in terms of safety benefit? If not, why not? And does the strategy need to be adapted to do more or to do less?

VIII–3. SUMMARY

In summary, the safety factors provide a grounding for a consistent approach to developing the PSR strategy. A graded approach to PSR provides the flexibility for the facility to determine what supporting activities (if any) are required to support demonstration of the claim against each safety factor, or whether the existing evidence is current, valid and extensive enough to provide confidence in that claim. Each PSR is bespoke but the basis and principles on which they are developed is the same.

Annex IX

EXAMPLE OF REVIEW BY JOB OBSERVATION IN A PERIODIC SAFETY REVIEW

IX–1. INTRODUCTION

The review of some of the safety factors relating to safety culture, procedures or human factors in a PSR may require using methods to understand the effective application of procedures to ascertain that the roles of operating personnel are suitable and appropriately implemented to support safe operation. This can be done by job observation through plant walkdowns and interviews or discussions with operators and team leaders.

The following text is a sample report on review of human factors in a specific maintenance task (functional test of glovebox isolation valves) by job observation. The example is based on the practices in an NFCF operating organization in the United Kingdom. The example is given for illustrative purpose and not based on any particular facility.

IX–2. HUMAN FACTORS ANALYSIS

IX–2.1. Task: Functional test of glovebox isolation valves

A review of human factors was conducted to ascertain that that the role of the operator is suitable and is appropriately implemented to support safe operation of the facility, specifically:

— Whether the operational claims and controls are appropriate;
— Whether the operator tasks are achievable and can be reliably completed;
— Whether the training for the operator is appropriate.

IX–2.2. Observations

IX–2.2.1. Person

The maintenance personnel clearly and comprehensively describe how the test was conducted. Several queries were raised by the human factor and radiological safety assessors which the maintainers were able to address using their knowledge and experience of the task.

The facility has a dedicated team of electronics and instrumentation maintainers and mechanical maintainers. Two suitably qualified and experienced maintainers and a health physics monitor are required to complete the task.

It is reported that the maintenance team comprises a small team with a supportive team leader. Within the team, there are different levels of experience. The two maintainers that supported the walkthrough have two years of experience and have been recruited due to staff shortages. The junior maintainers were able to talk confidently through the general processes and specific task steps which helped the assessors to understand how the task is completed.

It is also reported that the maintainers undertake on-the-job training and are supervised by the team leader while carrying out maintenance tasks in order to become fully competent.

The maintainers did not receive any formal safety case training on what faults and consequences against which the equipment they are testing protects, although they do understand the hazards associated with the task. However, it is reported that when the team leader supervises the on-the-job training, they explain the importance of the equipment, its safety function and why it is needed for nuclear safety.

IX–2.2.2. Task

The task is logically organized and there is a continuous use maintenance instruction that describes step by step how to functionally test the glovebox pressure switch and the solenoid cut-off valves.

Two suitably qualified and experienced maintainers are required to complete the task due to the location of the equipment in the room. When the maintainers are tasked to undertake the test, they are not required to undertake any other tasks simultaneously.

Throughout the task, the maintainers are required to check the glovebox rotameter when gas is being fed and when it is shut off because this provides feedback on the gas flow rate. When the gas is shut off, there is a note with the instruction that the expected reading on the rotameter is below zero. However, when the gas flow is returned, there is no equivalent guidance for an expected rotameter reading. In addition, there is no step for the maintainers to check and record the rotameter level before starting the task, which would provide a good point of reference for the expected rotameter reading when gas is flowing. This is an issue because it is important that maintainers confirm the gas flow status by observing the rotameter, yet there is no guidance or comparison to give confidence that the gas flow has been fully returned to its correct state after maintenance.

During the review, concerns were raised regarding the method that is used to confirm when the pressure switch trips and meets its safety function. Since

the maintainer is working at height and balancing both the multimeter and portable multifunction calibrator, it was reported that a 'click' sound is used as indicator because it was difficult to observe the readings on both instruments simultaneously while adjusting the dials. The maintainers found this method more reliable due to the awkward location of the pressure switches and the need to use two pieces of equipment while working at height. The requirement to listen for and confirm the click is not included in the maintenance instructions. The location and accessibility of the pressure switches, which are safety mechanisms, are an issue because they impact the way the test is completed, which has resulted in maintainers having to develop an alternative way to confirm that the equipment meets its safety function that is not captured in the maintenance instruction.

Once the test has been completed, it is crucial that the maintainers close the test valve and reopen the main gas isolation valve at the glovebox. It is noted that this step is not prominent in the maintenance instruction and the importance of ensuring that this is completed is not emphasized. In addition, the review of the underpinning safety assessments have identified that there is a valve locking device designated as a safety feature to prevent inadvertently closing a gas isolation valve. During the walkthrough, it was discovered that the gas isolation valves on two gloveboxes were not locked. Although changing the configuration of the gas isolation valve would require removing the cover to access the valve (which provides some protection against inadvertent activation), the current arrangement is not considered adequate to meet the requirements of the safety feature.

A review of operational experience highlighted that there are positive instances where faults during maintenance of the gas isolation valves have been identified by the maintainers.

IX–2.2.3. Equipment

Two gloveboxes in Room A have pressure switches and solenoid cut-off valves which were tested. The gloveboxes and pressure switches are clearly labelled and have a corresponding tag.

The portable multifunction calibrator provides pressure, temperature, electricity and frequency measurements, simulation and calibration. It has a large graphical display and clearly shows the unit measurement that corresponds to the reading. The maintainers reported that this is very simple to use and is an essential, standard piece of equipment required to carry out a variety of maintenance tasks.

The multimeter used to complete the task is a handheld electronic measuring instrument that measures voltage. It has a digital display that clearly shows the numerical voltage reading.

A key task requirement, as referenced in the maintenance instruction, is for the second maintainer to observe the rotameter reading. During the walkthrough, the rotameters were found tucked underneath the gloveboxes and the maintainers had to take a few moments to find the correct one. The location of the different rotameters that correspond to the different gloveboxes and pressure switches is not included in the maintenance instruction. In addition, during the walkthrough, the maintainers referred to the equipment as a flowmeter rather than a rotameter. This suggests that the use of the term rotameter in the maintenance instruction is not the most meaningful to the maintainer. A shortfall has previously been raised in this review concerning the rotameter coverage in the maintenance instruction.

IX–2.2.4. Environment

For access to the pressure switches, an aircraft type staircase is used that has a series of steps with a small platform on the top to allow the maintainer to maintain a stable balance while working at height. The staircase has wheels to allow convenient transport between rooms, locks in place to prevent the steps from moving once they are parked and provides a solid platform to stand on and work from.

The access to undertake work on these safety mechanisms in Room A was found to be ergonomically poor and disregarded the physical capabilities of the maintainer. In addition, three other pressure switches that maintainers were required to complete work on were located high on the back right hand side wall of the room and access for aircraft stairs was restricted by the presence of gloveboxes. It is acknowledged that while it may not be practicable to recommend that these items be relocated, it is important that the maintainers are given an adequate provision to store their equipment while working at height in order to adequately complete the task.

At the time of the walkthrough, the lighting, temperature and noise levels in the room were considered adequate and comfortable. However, part of the task involves observing a rotameter that is located underneath a glovebox. The dial on the rotameter was not clearly visible by the ambient lighting in the room, and additional lighting is necessary for visual accuracy.

IX–2.3. Analysis

The observations were analysed by two human factor specialists. The maintenance errors that are of most concern in terms of safety are latent errors. This means that failures may not be revealed as an equipment or system failure until sometime after the maintenance error occurred, because the issue was undetected by the maintainer during the test procedure. During the walkthrough,

the maintainers reported that they were unaware of any instances where following the test procedure in accordance with the instructions had resulted in an unrevealed equipment failure. In addition, there was positive evidence from operating experience that maintainers had identified faults during testing and work was stopped and investigated. The error analysis considered the following types:

— Omission error (component or part not installed or replaced);
— Incorrect action (wrong component or part installed or replaced; wrong check carried out);
— Not restored to operational state error (system not reactivated or deactivated);
— Procedural error (failure to carry out inspection).

Table IX–1 lists the potential errors discovered during the analysis.

IX–2.4. Conclusion

Overall, the findings of the walkthrough of this particular task were that the task is logically organized and well understood by the maintainers present. A good level of confidence was gained that the test is being carried out reliably. The maintainers were knowledgeable about the procedures undertaken and demonstrated professionalism throughout the process. However, issues were raised with the access and location of the gas isolation valves in the room and additional task support is required within the maintenance instruction. These are being taken forward as improvement activities to be risk prioritized in line with all other facility improvements. Given the minor nature of the improvement, it is not considered to be a PSR specific improvement, rather this is raised through the normal condition reporting routes.

TABLE IX–1. POTENTIAL ERRORS DISCOVERED DURING THE ERROR ANALYSIS

Potential errors	Safeguards and error recovery	Confidence discussion
Maintainer does not confirm that the drop in pressure trips the glovebox feed at the correct point.	— There is a step by step written instruction document that details how to carry out the test for glovebox pressure switch and solenoid cut-off valves. — The instruction document has a 'tick box' column next to each step to allow maintainers to confirm when they have completed a step. This provides a place keeping mechanism in the event of a distraction. — Two maintainers are required to complete the task and they do not attend to any other task simultaneously. — One maintainer is located at the relevant glovebox and part of their role is to observe the rotameter to confirm the readings. — The instruction includes a requirement to check the glovebox rotameter to confirm that the trip has actuated at the expected level. — The maintainers explained the importance of ensuring that the pressure to the glovebox trips at the correct point.	There is good confidence that there are sufficient protections and opportunities for error recovery that make this error manageable. It is worth noting that the check of the rotameter could be enhanced if additional task support was provided to ensure that maintainers know where the rotameter is located in the room.
Maintainer forgets to reopen the isolating valve at the glovebox following the test.	— The test is undertaken by two suitably qualified and experienced maintainers. — The maintainers test the gas isolation valves one at time and are not required to undertake another task simultaneously.	There is good confidence that there are sufficient protections and opportunities for error recovery that make this error manageable.

TABLE IX–1. POTENTIAL ERRORS DISCOVERED DURING THE ERROR ANALYSIS (cont.)

Potential errors	Safeguards and error recovery	Confidence discussion
	— There is a step by step written instruction that details how to carry out the test for glovebox pressure switch and solenoid cut-off valves. — The instruction document has a 'tick box' column next to each step to allow maintainers to confirm when they have completed a step. This provides a place keeping mechanism in the event of a distraction. — The instruction includes a step for maintainers to open the gas isolation valve after the test has been completed in order to ensure that the safety mechanism is correctly returned to service. There are two forms of feedback to show that the valve has been reopened: 1. The glovebox depression gauge would indicate that the glovebox is under depression; 2. There would be a gas supply into the glovebox indicated by the rotameter. — Discussion with engineering support confirmed that the isolating valve at the glovebox is a fail-safe, which means that if the valve remained closed and the glovebox was not under depression, the gas supply to the glovebox would trip and be isolated. There is a step in the instruction to ensure that the gas flow is returned to the glovebox by observing the rotameter. However, this error would place a demand on the safety mechanism. Therefore, this would benefit from an improvement being implemented.	However, an improvement has been raised because the step to open the gas isolation valve following the test is not prominent, therefore its importance is not emphasized.

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