United Arab Emirates

FANR
الهيئة الاتحادية للرقابة النووية
Federal Authority for Nuclear Regulation

Regulatory Guide

Safety Significance Evaluations for Modifications for Nuclear Facilities during Construction (FANR-RG-023)

Version 0

Federal Authority for Nuclear Regulation (FANR)
P.O. Box 112021, Abu Dhabi, United Arab Emirates
regulation@fanr.gov.ae

Table of Contents

Basic Principle of Regulatory Guides

Regulatory Guides are issued to describe methods and/or criteria acceptable to the Authority for meeting and implementing specific requirements in the Authority's regulations. Regulatory Guides are not substitutes for regulations, and compliance with them is not required. Methods of complying with the requirements in regulations different from the guidance set forth by the Regulatory Guide can be acceptable if the alternatives provide assurance that the requirements are met.

Definitions

Article (1)

For the purposes of this Regulatory Guide, the following terms have the meanings set forth below. Other capitalised terms used but not defined herein shall have the meaning ascribed to them in Article 1 of the Federal Law by Decree No. 6 of 2009 Concerning the Peaceful Uses of Nuclear Energy (the Law):

ALARA	As Low As Reasonably Achievable
Defence-in-Depth	A hierarchical deployment of different levels of diverse equipment and procedures to prevent the escalation of Anticipated Operational Occurrences and to maintain the effectiveness of physical barriers placed between a Radiation Source or Radioactive Material and workers, members of the public or the environment, in operational states and, for some barriers, in Accident Conditions.
Design Basis Accident (DBA)	Accident Conditions against which a Nuclear Facility is designed according to established Design criteria, and for which the damage to the Nuclear Fuel and the release of Radioactive Material are kept within authorised limits.
ECCS	Emergency Core Cooling System
Probabilistic Risk Assessment (PRA)	A comprehensive, structured approach to identifying failure scenarios constituting a conceptual and mathematical tool for deriving numerical estimates of risk. Level 1 comprises the assessment of failures leading to the determination of the frequency of core damage. Level 2 constitutes the assessment of containment response and leads to the determination of frequency of containment failure resulting in release to the environment of a given percentage of the reactor core's inventory of radionuclides.
PSAR	Preliminary Safety Analysis Report.
Structures, Systems and Components (SSCs)	A general term encompassing all the elements of a Facility or Activity, which contributes to protection and Safety, except human factors. Structures are the passive elements such as building vessels and shielding. A System comprises several components assembled in such a way as to perform a specific active function and a Component is a discrete element of a system.

Objective

Article (2)

The objective of this Regulatory Guide is to provide guidance for the process and criteria to be used by the Licensees of Nuclear Facilities under Construction in determining, based on a Safety significance evaluation, if a proposed modification requires prior approval by the Authority before its implementation. This Regulatory Guide is aimed at supporting FANR Regulation 01 for Management Systems for Nuclear Facilities (Reference 1); FANR Regulatory Guide 02 on the Application of Management Systems for Nuclear Facilities and Article 2 on "The Management System for Nuclear Installations from the IAEA Safety Guide No. GS-G-3.5" document (References 2 and 3). This Regulatory Guide aims to provide guidance on potential Licence Conditions on modifications, where applicable.

Purpose and Scope

Article (3)

This Regulatory Guide sets forth the Authority's guidance to the Licensees of Nuclear Facilities under Construction in determining if a proposed modification requires prior approval by the Authority before its implementation.

The Regulatory Guide covers the following:

- Applicability and Screening; to determine if Safety significance evaluations is required
- Evaluation; to apply the Safety significance evaluation criteria to determine if approval must be obtained from the Authority
- Documentation and reporting; to document and report to the Authority modifications to be implemented under the Safety significance evaluation process and records

The process flow for the above functions is diagrammed in Appendix 1.

The Regulatory Guide supersedes the FANR Interim Guideline (References 4 and 5) and is applicable only to modifications that impact Nuclear Safety during Construction. It is based, in part on the US Nuclear Regulatory Commission (NRC) Regulatory Guide (RG) 1.187 (Reference 6). An additional guidance may be required for modifications that impact on security (including the Safety/ security interface as required by FANR-REG-08 (Reference 7)) or safeguards; and for the operation of Nuclear Facilities to support FANR-REG-16 (Reference 8) once an Operating Licence is granted.

Terminology

Article (4)

The following section defines and describes the key terms applicable to this guidance.

1. Safety significance evaluation

A Safety significance evaluation is the documented evaluation against the criteria in Article (6) of this Regulatory Guide to determine if a proposed modification requires prior approval by the Authority before implementation.

The definitions of screening and Safety significance evaluations are intended to clearly distinguish between the process and documentation of the Licensee's screenings and the further evaluation that may be required of proposed modifications against the criteria in Article (6). While all Nuclear Facility modifications are subject to Screening, only changes to any Management System or Organisational Arrangement, the Systems, Structures, and Components (SSCs) of the Nuclear Facility, or any of the application documents submitted by the Licensee that have significant Safety implications require evaluation and reporting to the Authority. Article (6) provides guidance for performing Safety significance evaluations.

2. Modification

A change or addition to, or removal from, the Management System of the Nuclear Facility, the Organisational Arrangement, the SSCs, documents or standards referenced or submitted in the Construction Licence application that affects: (1) a Design function, (2) a method of performing or controlling the function, (3) an evaluation that demonstrates how intended functions will be accomplished, or (4) the Quality Assurance programme submitted previously to and accepted by the Authority.

For the purposes of this guidance document, modifications that require evaluation (i.e. screening, Safety significance evaluation) for Authority approval are those that have proceeded to the level of issue for use. It is not intended to apply to preliminary Design documents or all the individual changes that make up a modification. For example, screening is required for a Design package that is complete to the point of release for Construction rather than each analysis, calculation or drawing change that is part of the Design package.

Additions and removals can adversely impact the performance of SSCs and the bases for the acceptability of their Design and Operation. Thus the definition of modification includes changes to an existing provision (e.g. SSC Design requirement, analysis method or parameter or standards), as well as additions or removals (physical removals, abandonment, or non-reliance on a system to meet a requirement) to the SSCs of the Nuclear Facility, Management System, Organisational Arrangements, or Construction Licence application documents.

Safety significance evaluations should be applied to a modification being made to an evaluation for demonstrating adequacy of the Nuclear Facility even if no physical change to the Nuclear Facility is involved. Further discussion of the terms in this definition is provided as follows:

Design function is an SSC function that is credited in the Safety analyses or that supports or impacts upon a SSC function credited in Safety analyses. This may include (1) functions performed by Safety-related SSCs or non-Safety-related SSCs, and (2) functions of non-Safety-related SSCs that, if not performed, would initiate a plant transient or Accident.

Design functions include the conditions under which intended functions are required to be performed, such as equipment response times, environmental and process conditions, equipment qualification, single failure criterion, reliability and availability.

Method of performing or controlling a function is how a Design function is accomplished as credited in the Safety analyses, including specific Operator actions, procedural steps or sequences, or whether a specific function is to be initiated by manual versus automatic means. For example, substituting a manual actuation for an automatic one would constitute a change to the method of performing or controlling the function.

Evaluation that demonstrates that intended function(s) will be accomplished is (are) the method(s) used to perform an evaluation (as discussed in Article (4) and (9) of this Regulatory Guide). For example, a thermodynamic calculation that demonstrates the Emergency Core Cooling System (ECCS) has sufficient heat removal capacity for responding to a postulated Accident.

The following changes or activities are not considered Modifications:

- The restoration of a SSC to its “as designed” condition
- Editorial changes

3. Design package

The Design package is the completed Design that contains the information required to procure and construct the modification. A Design package contains, as necessary, the drawings, calculations, analyses, computer programmes, bill of materials, and technical specifications for purchase applicable for all disciplines. Screenings and/ or Safety significant evaluations are applicable to the modification Design package, not to each of the elements that comprise the package. Documents affected by a modification should be identified and documented as part of the Design package for that modification.

4. Departure from a method of evaluation described in the application documents

Departure from a method of evaluation described in the application documents means (i) changing any of the elements of the method described in the application documents unless the results of the analysis are conservative or essentially the same; or (ii) changing from a method described in the application documents to another method unless that method has been approved by Authority for the intended application. Specific guidance for making this determination is provided in Article (6)(8).

5. Facility as described in the Application Documents

Facility as described in the application documents means:

- The structures, systems, and components (SSC) that are described in the application documents,
- The Design and performance requirements for such SSCs described in the application documents, and
- The evaluations or methods of evaluation included in the application documents for such SSCs that demonstrate how their intended function(s) will be accomplished.

6. Procedures

Those procedures are described in the application documents that contain information such as how SSCs are operated and controlled (including assumed Operator actions and response times).

7. Departure from Management Systems and organisational arrangements described in the application documents

The description of a departure from the Management Systems and Organisational Arrangements described in the application documents means a change to the set of interacting elements (Management System) for establishing policies and processes to achieve Nuclear Safety.

8. Programme

A collection of manuals, procedures and processes that are required to comply with a specific Authority regulatory requirement or enables compliance with the Authority regulatory requirement.

9. Methods of Evaluation

Methodology changes that are subject to Safety significance evaluations include changes to elements of existing methods used either in the application documents' Safety analyses or in establishing Design bases described in the application documents and to changes that involve replacement of existing methods of evaluation with alternative methodologies.

10. Screening

Screening is the part of the process that determines whether a Safety significance evaluations is required prior to implementing a proposed modification. Criteria for the screening process are presented in Article (5)(1). Activities that do not meet these criteria are said to "screen out" from further review (i.e. may be implemented without a Safety significance evaluations and do not require Authority approval). Documentation and record keeping requirements for Screening are described in Article (5)(5).

Screening and Safety significance evaluations are not required if:

a) The modification requires a change to the Authority issued Licence and therefore requires a Licence amendment.

b) The modification requires the Authority's approval by some other regulation or Licence condition.

c) The Licensee decides to submit a request to the Authority for approval of a modification.

11. Application Documents

The documents, including the PSAR, referenced in and/ or submitted with the Licensee's application for the Construction Licence of a Nuclear Facility and the additional information submitted by the Licensee.

Applicability and Screening

Article (5)

The Licensee may determine applicability and screen activities to determine if Safety significance evaluations are required based on the guidance provided below.

A Screening is applicable to modifications that involve changes in the SSC Design, any Management System and Organisational Arrangement, or any of the application documents submitted by the Licensee. Changes that require revision to the text of Licences in force require a Licence amendment, which is a separate process from Safety significance evaluations. Once it has been determined that Screening is applicable, the Screening is performed to determine if the modification should be evaluated against the Safety significance evaluations criteria.

Engineering, Design, Quality Assurance and other technical information concerning the modification and affected SSCs should be used to assess whether the modification is a change, addition or removal that affects:

1. A Design function of a SSC
2. A method of performing or controlling the Design function
3. Significantly on radiation Doses to workers, the general public or the environment
4. An evaluation for demonstrating how intended Design functions will be accomplished, or
5. The Quality Assurance Programme submitted previously to and accepted by the Authority.

Article (5)(1)through Article (5)(5) provide guidance and examples for determining whether an activity is a modification to the facility or procedures as described in the application documents that requires a Safety significance evaluation. Activities that are screened out from Safety significance evaluations should be documented as discussed in Article (5)(5). Activities that screen out may nonetheless require application document information to be updated.

1. Screening

In order to determine whether or not a proposed modification affects Quality Assurance, a Design function, a method of performing or controlling a Design function or an evaluation that demonstrates how Design functions will be accomplished, a thorough understanding of the affected SSCs and the proposed change is essential.

Only proposed modifications based on supporting engineering and technical information that would result in an adverse effect - such as a decrease in capability or a reduction in the level of compliance with standards or requirements - need to be evaluated against Safety significance evaluation criteria. A determination of whether adverse effects exist should consider both direct and indirect effects of the modification. A Safety significance evaluation would be required if:

1. The modification decreases the ability of the SSC to perform its required Safety functions under stated conditions for a specified period of time.
2. The modification reduces existing redundancy, diversity or defence-in-depth, or the integrity of any of the fission product barriers.
3. The modification adds or deletes an automatic or manual Design function of the SSC.
4. The modification converts a feature that was automatic to manual or vice versa.
5. The modification introduces a previously un-reviewed system interaction.
6. The modification adversely affects the ability or response time to perform required actions, e.g. alters equipment access or adds steps necessary for performing tasks.

7. The modification reduces the seismic or environmental qualification of the SSC.
8. The modification introduces previously un-reviewed effects on other units at a multiple unit site.
9. The modification results in a departure from a method of evaluation used in establishing the Design bases or in the Safety analyses.
10. For modifications affecting SSCs and procedures that are not described in the PSAR or other application documents, the modification has a direct or indirect adverse effect on the PSAR or other application documents.
11. The proposed change in Standards, Codes, or regulatory guidance will have a direct or indirect adverse effect on Design, procurement, manufacturing, Construction or Commissioning as described in the PSAR and other application documents.
12. The modification will have a direct or indirect adverse effect on the Licensee Quality Assurance Manual or Management System Manual or PSAR chapters 13, 14 & 17 or Organisational Arrangements previously accepted by the Authority.

In line with the definition of "Modification" stated in Article (4)(2), screening is applicable to additions as well as to changes to and removals from the Facility or procedures. Additions should be screened for their effects on the existing facility Design and procedures as described in the application documents and, if required, a Safety significance evaluation should be carried out. For modifications where an element to be considered as part of the screening criteria has not yet been defined (i.e. defence-in-depth, operator response times, etc.) the modification would screen out against the applicable criteria.

It is acceptable to generically screen a particular type of modification and exempt it from screening for all future modifications of that type. For example, certain issues may be generically screened such as date changes to Construction schedules.

2. Screening changes to the Facility not described in the application documents

Screening to determine that a Safety significance evaluation is required is straightforward when a modification affects an SSC Design function, method of performing or controlling a Design function, or evaluation that demonstrates how intended Design functions will be accomplished as described in the application documents.

However, a Facility also contains many SSCs not described in the application documents. These can be components, sub-components of larger components or even entire systems. Changes affecting SSCs or procedures that are not explicitly described in the application documents can have the potential to affect SSC Design functions that are described and thus may require a Safety significance evaluation. In such cases, the approach for determining whether a modification involves a change to the facility as described in the application documents, is to consider the larger, application document-described SSC of which the SSC being modified is a part. If for the larger SSC, the change affects an application document-described Design function, method of performing or controlling the Design function, or an evaluation demonstrating that intended Design functions will be accomplished, then a Safety significance evaluation is required.

Another important consideration is that a change to non-Safety-related SSCs not described in the application documents can indirectly affect the capability of SSCs to perform their application documents-described Design function(s). For example, increasing the heat load on a non-Safety-related heat exchanger could compromise the cooling system's ability to cool Safety-related equipment.

Seismic qualification, missile protection, flooding protection, fire protection, environmental qualification, high energy line break and masonry block walls are some of the areas where changes to non-Safety-related SSCs, whether or not described in the application documents, can affect the application documents-described Design function of SSCs through indirect or secondary effects.

Equivalent replacement is a type of change to the Facility that does not alter the Design functions of SSCs. Licensee equivalence assessments, e.g. consideration of performance/ operating characteristics and other factors may thus form the basis for screening determinations that no Safety significance evaluation is required.

The following example illustrates the Safety significance evaluation screening process as applied to proposed Facility changes:

- A Licensee proposes to replace a relay in the overspeed trip circuit of an emergency diesel generator with a non-equivalent relay. The relay is not described in the application documents, but the Design functions of the overspeed trip circuit and the emergency diesel generator (EDG) are described in the application documents. Based on engineering/ technical information supporting the change, the licensee determines if replacing the relay would affect the Design function of either the overspeed trip circuit or EDG. If the Licensee concludes that the change would not affect the application document-described Design function of the circuit or EDG, then this determination would form the basis for screening out the change, and no Safety significance evaluation would be required.

3. Screening changes to procedures as described in the application documents

Changes to procedures are "screened in" (i.e. require a Safety significance evaluation) if the change affects how the SSC Design functions are carried out or controlled as described in the application documents (including assumed Operator actions and response times). Changes to a procedure that does not affect how the SSC Design functions described in the application documents are carried out or controlled would screen out. The following example illustrates the Safety significance evaluations screening process as applied to proposed procedure changes:

- The PSAR states that a particular flow path is isolated by a locked closed valve when not in use. A procedure change to remove the lock from this valve such that it becomes a normally closed valve would ‘screen in’ as a change to procedures described in the PSAR. In this case, the Design function is to remain closed and the method of performing the Design function has changed from locked closed to administratively closed. Thus this change would ‘screen in’ and require a Safety significance evaluation to be performed.

4. Screening changes to methods of evaluation used for the application documents

Methods of evaluation included in the application documents to demonstrate how intended SSC Design functions will be accomplished are considered part of the "facility as described in the application documents." Thus use of new or revised methods of evaluation (as defined in Article (4)(9)) is considered to be a change where Safety significance evaluations is applicable and needs to be considered as part of this screening step. Changing elements of a method of evaluation included in the application documents or use of an alternative method must undergo a Safety significance evaluation to determine if prior Authority approval is required.

Changes to methods of evaluation not included in the application documents or to methodologies included in the application documents that are not used in the Safety analyses or to establish Design bases may be screened out.

Methods of evaluation that may be identified in references listed at the end of PSAR sections or chapters are not subject to Safety significance evaluations unless the PSAR states they were used for specific analyses within the scope of Safety significance criteria in Article (6)(8).

Changes to methods of evaluation included in the application documents do not require Safety significance evaluations if the changes are within the constraints and limitations associated with use of the method, e.g. identified in a topical report accepted by the Authority and/ or a Safety Evaluation Report (SER).

The following example illustrates the screening of changes to methods of evaluation used for the application documents:

- The PSAR identifies the name of the computer code used for performing containment performance analyses with no further discussion of the methods employed within the code for performing those analyses. Changes to the computer code may be screened out provided that the changes are within the constraints and limitations or acceptable criteria identified in the associated topical report (e.g. Validation Report) and SER. A change that goes beyond restrictions on the use of the method should be evaluated against Safety significance criterion Article (6)(8) to determine if prior Authority approval is required.

5. Screening documentation and record-keeping

Record-keeping requirements apply to Screenings for all modifications that are screened out. Documentation of the Screening shall be maintained as Quality Assurance records and subject to a FANR Authority inspection. Documentation of screening for modifications that screen out shall be retained for five years.

The basis for the screening conclusion should be documented to a degree commensurate with the Safety significance of the change. Typically, the screening documentation should be retained as part of the modification package however screening records need not be retained for modifications where a Safety significance evaluation has been performed or for modifications that were never implemented.

Safety significance evaluation process

Article (6)

Once it has been determined that a modification requires a Safety significance evaluation, the written evaluation must address the applicable criteria in Article (6)(1) to Article (6)(9). These criteria are used to evaluate the effects of proposed modifications involving changes in the SSC Design, methods of analysis, methods of Construction testing or other processes or activities associated with the Design and Construction of the Nuclear Facilities.

If any of the below mentioned criteria are met, the Licensee must apply to the Authority for approval prior to implementing the modification. The evaluation against each criterion should be appropriately documented in line with Article (6)(1) through to Article (6)(9) and Article (8) provide the Safety significance evaluations criteria and offer guidance and examples for evaluating proposed modifications.

1. The modification results in an increase in the frequency of occurrence of an accident or transient previously evaluated in the application documents

In addressing this criterion, the first step is to identify the Accidents that have been evaluated in the application documents that are affected by the proposed modification. Then a determination should be made as to whether the frequency of these Accidents occurring would be more than minimally increased.

Accidents and transients have been divided into categories based upon a qualitative assessment of frequency. For example, the American National Standard Institute (ANSI) standards define the following categories for plant conditions for most PWRs:

- Normal Operations – Expected frequently or regularly in the course of power Operation, refueling, Maintenance or maneuvering.
- Incidents of Moderate Frequency – Any one incident expected per plant during a calendar year.
- Infrequent Incidents – Any one incident expected per plant during plant lifetime.
- Limiting Faults – Not expected to occur but could release significant amounts of Radioactive Material thus requiring protection by Design.

A change from one category to a more frequent category (e.g. from Limiting Fault to Infrequent Incident) is clearly an example of a change that results in more than a minimal increase in the frequency of occurrence of an accident or transient.

Changes within a category could also result in more than a minimal increase in the frequency of occurrence of an Accident or transient. Normally, the determination of a frequency increase is based upon a qualitative assessment using engineering evaluations consistent with the application documents' analysis assumptions. However, a plant-specific Accident frequency calculation or Probabilistic Risk Assessment (PRA) may be used to evaluate a proposed modification in a quantitative sense. It should be emphasised that PRAs are just one of the tools for evaluating the effect of proposed modifications, and their use is not required to perform Safety significance evaluations.

Reasonable engineering practices, engineering judgement and PRA techniques, as appropriate, should be used in determining whether the frequency of occurrence of an accident or transient would more than minimally increased as a result of implementing a proposed modification. A large body of knowledge has been developed in the area of Accident frequency and risk significant sequences through plant-specific and generic studies. This knowledge, where applicable, should be used in determining what constitutes more than a minimal increase in the frequency of occurrence of an Accident or transient previously evaluated in the application documents. The effect of a proposed modification on the frequency of an Accident or transient must be discernible and attributable to the proposed modification in order to exceed the more than minimal increase standard.

The following is an example where there is not more than a minimal increase in the frequency of occurrence of an Accident:

- The proposed activity has a negligible effect on the frequency of occurrence of an Accident. A negligible effect on the frequency of occurrence of an Accident exists when the change in frequency is so small or the uncertainties in determining whether a change in frequency has occurred are such that it cannot be reasonably concluded that the frequency has actually changed (i.e. there is no clear trend towards increasing the frequency).

2. The modification results in an increase in the likelihood of occurrence of a malfunction of Safety systems and Safety related items previously evaluated in the application documents

This criterion refers to the failure of SSCs to perform their intended Design functions - including both Safety systems and Safety related items. The definitions and meanings for the terms “Safety systems” and “Safety related items” are based on those used by the Authority. Specifically, “Safety systems” are systems important to Safety, provided to ensure the safe shutdown of the reactor or the residual heat removal from the core, or to limit the consequences of anticipated operational occurrences and DBAs. A “Safety related item” is an item important to Safety, which is not part of a Safety system. The cause and mode of a malfunction should be considered in determining whether there is a change in the likelihood of a malfunction. The effect or result of a malfunction should be considered in determining whether a malfunction with a different result is involved per Article (6)(6).

In determining whether there is more than a minimal increase in the likelihood of occurrence of a malfunction of a SSC to perform its Design function as described in the application documents, the first step is to determine what SSCs are affected by the proposed modification. Next, the effects of the proposed modification on the affected SSCs should be determined. This evaluation should include both direct and indirect effects.

Direct effects are those where the proposed modification affects the SSCs (e.g. a motor change on a pump). Indirect effects are those where the proposed modification affects one SSC and this SSC affects the capability of another SSC to perform its application document described Design function. Indirect effects also include the effects of proposed modifications on the Design functions of SSCs credited in the Safety analysis. The Safety analysis assumes certain Design functions of SSCs in demonstrating the adequacy of the Design. Thus, certain Design functions, while not specifically identified in the Safety analysis, are credited in an indirect sense.

After determining the effect of the proposed modification on the important to Safety SSCs, a determination is made on whether the likelihood of a malfunction of the important to Safety SSCs has increased more than minimally. Qualitative engineering judgement and/ or an industry precedent is typically used to determine if there is more than a minimal increase in the likelihood of occurrence of a malfunction. An appropriate calculation can be used to demonstrate the change in likelihood in a quantitative sense, if available and practical. The effect of a proposed modification on the likelihood of malfunction must be discernible and attributable to the proposed modification in order to exceed the more than minimal increase standard. A proposed modification is considered to have a negligible effect on the likelihood of a malfunction when a change in likelihood is so small or the uncertainties in determining whether a change in likelihood has occurred are such that it cannot be reasonably concluded that the likelihood has actually changed (i.e. there is no clear trend towards increasing the likelihood). A proposed modification that has a negligible effect satisfies the minimal increase standard.

Evaluations of a proposed modification for its effect on the likelihood of a malfunction would be carried out at a level of detail that is described in the application documents. The determination of whether the likelihood of malfunction is more than minimally increased is made at a level consistent with existing application documents-described failure modes and effects analyses. While the evaluation should take into account the level that was previously evaluated in terms of malfunctions and resulting event initiators or mitigation impacts, it also needs to consider the nature of the proposed modification. Thus, for instance, if failures were previously postulated on a train level because the trains were independent, a proposed modification that introduces a cross-tie or credible common mode failure (e.g. as a result of an analogue to digital upgrade) should be evaluated further to see whether the likelihood of malfunction has been increased.

Changes in Design requirements for earthquakes, tornadoes and other natural phenomena should be treated as potentially affecting the likelihood of a malfunction.

Although this criterion allows minimal increases, the Licensee must still meet applicable regulatory requirements and other acceptance criteria to which they are committed. Below is an example where there is less than a minimal increase in the likelihood of occurrence of a malfunction of Safety systems or Safety related items:

- The change involves substitution of one type of component for another of similar function provided all applicable Design and functional requirements (including applicable codes, standards, etc.) continue to be met and any new failure modes are bounded by the existing analysis.

Modifications that would reduce system/ equipment redundancy, diversity, separation or independence would require prior Authority approval because it would result in more than a minimal increase in the likelihood of occurrence of a malfunction of a Safety system or Safety related item.

3. The modification results in an increase in the consequences of an Accident previously evaluated in the application documents

The application documents provide an acceptance criterion and frequency relationship for "conditions for Design". When determining which activities represent "an increase in consequences", it must be recognised that the objective is the protection of public health and

Safety. Therefore, an increase in consequences must involve an increase in radiological doses to the public or to control room operators. Changes in barrier performance or other outcomes of the proposed activity that do not result in increased radiological dose to the public or to control room operators are addressed under the other Safety significance evaluations criteria in Article (6).

Modifications affecting onsite dose consequences that may require prior Authority approval are those that impede required actions inside or outside the control room to mitigate the consequences of reactor accidents.

The consequences covered include dose resulting from any accident evaluated in the application documents. The Accidents include those typically covered in PSAR Chapters 6, 15, and 19 and other events with which the plant is designed to cope and are described in the application documents (e.g. turbine missiles and flooding). The consequences referred to in the Safety significance evaluations criteria do not apply to occupational exposures resulting from routine operations, Maintenance, testing, etc. Occupational doses are expected to be controlled and maintained As Low As Reasonably Achievable (ALARA) through formal Licensee Radiation Protection programmes.

FANR-REG-04 “Regulation Dose Limits and Optimisation of Radiation Protection for Nuclear Facilities” (Reference 9) establishes requirements for protection against Radiation during normal operations and Decommissioning. Safety significance evaluations Accident dose consequence criteria and evaluation guidance are not applicable to proposed activities governed by FANR-REG-04 requirements.

The dose consequences referred to in the Safety significance evaluations criteria are those calculated by the Licensee - not the results of independent, confirmatory dose analyses by the Authority that may be documented in Safety Evaluation Reports.

For a given Accident, calculated or bounding dose values for that Accident would be identified in the application documents. An increase in consequences from a proposed modification is defined to be no more than minimal if the increase (1) is less than or equal to 10 percent of the difference between the current calculated dose value and the regulatory guideline value. The current calculated dose values are those documented in the most up-to-date analyses of record.

The evaluation should determine the dose that would likely result from Accidents associated with the proposed modification. If a proposed modification would result in more than a minimal increase in dose from the existing calculated dose for any Accident, then the modification would require prior Authority approval. Where a change in consequences is so small or the uncertainties in determining whether a change in consequences has occurred are such that it cannot be reasonably concluded that the consequences have actually changed (i.e. there is no clear trend towards increasing the consequences), the change need not be considered an increase in consequences.

In determining if there is more than a minimal increase in consequences, the first step is to determine which accidents evaluated in the application documents may have their radiological consequences affected as a direct result of the proposed modification. Examples of questions that assist in this determination are:

1. Will the proposed modification change, prevent or degrade the effectiveness of actions described or assumed in an Accident discussed in the application documents?

2. Will the proposed modification alter assumptions previously made in evaluating the radiological consequences of an accident described in the application documents?
3. Will the proposed modification play a direct role in mitigating the radiological consequences of an Accident described in the application documents?

The next step is to determine if the proposed modification does increase the radiological consequences of any of the Accidents evaluated in the application documents. If it is determined that the proposed modification does have an effect on the radiological consequences of any Accident analysis described in the application documents, then either:

1. Demonstrate and document that the radiological consequences of the Accident described in the application documents are bounding for the proposed modification (e.g. by showing that the results of the application documents analysis bound those that would be associated with the proposed activity), or
2. Revise and document the analysis taking into account the proposed modification and determine if more than a minimal increase has occurred as described above.

4. The modification results in more than a minimal increase in the consequences of a malfunction of a SSC important to Safety previously evaluated in the application documents

In determining if there is more than a minimal increase in consequences, the first step is to determine which malfunctions evaluated in the application documents have their radiological consequences affected as a result of the proposed modification.

The next step is to determine if the proposed modification does increase the radiological consequences and, if so, are they more than minimally increased. The guidance for determining whether a proposed modification results in more than a minimal increase in the consequences of a malfunction is the same as that for Accidents. Refer to Article (6)(3).

5. The modification creates a possibility for “an Accident of a different type” than any previously evaluated in the application documents

This criterion deals with creating the possibility for Accidents of similar frequency and significance to those already included in the licensing basis for the Facility. Thus, Accidents that would require multiple independent failures or other circumstances in order to "be created" would not meet this criterion.

Certain Accidents are not discussed in the application documents because their effects are bounded by other related events that are analysed. For example, a postulated pipe break in a small line may not be specifically evaluated in the application documents because it has been determined to be less limiting than a pipe break in a larger line in the same area. Therefore, if a proposed Design change would introduce a small high energy line break into this area; postulated breaks in the smaller line need not be considered “an Accident of a different type”.

The possible Accidents of a different type are limited to those that are as likely to happen as those previously evaluated in the application documents. The Accident must be credible in the sense of having been created within the range of assumptions previously considered in the licensing basis (e.g. random single failure, loss of offsite power, etc.). A new initiator of an Accident previously evaluated in the application documents is not a different type of Accident. Such a change or activity,

however, which increases the frequency of an Accident previously thought to be incredible to the point where it becomes as likely as the Accidents in the application documents, could create the possibility of “an Accident of a different type”. For example, there are a number of scenarios such as multiple steam generator tube ruptures that have been analysed extensively. These scenarios are of such low probability that they may not have been considered to be part of the Design basis. However, if a change or activity is proposed such that a scenario such as a multiple steam generator tube rupture becomes credible, the change or activity could create the possibility of “an Accident of a different type”. In some instances these example Accidents could already be discussed in the application documents.

In evaluating whether the proposed modification creates the possibility of “an Accident of a different type”, the first step is to determine the types of Accidents that have been evaluated in the application documents. The types of credible Accidents that the proposed modification could create that are not bounded by application documents-evaluated Accidents are Accidents of a different type.

6. The modification creates a possibility for a malfunction of a SSC Important to Safety with a different result than any previously evaluated in the application documents

Malfunctions of SSCs are generally postulated as potential single failures to evaluate plant performance with the focus being on the result of the malfunction rather than the cause or type of malfunction. A malfunction that involves an initiator or failure whose effects are not bounded by those explicitly described in the application documents is a malfunction with a different result. A new failure mechanism is not a malfunction with a different result if the result or effect is the same as, or is bounded by, that previously evaluated in the application documents. The following example illustrates this point:

- If a pump is replaced with a new Design, there may be a new failure mechanism introduced that would cause a failure of the pump to run. But if this effect (failure of the pump to run) was previously evaluated and bounded then a malfunction with a different result has not been created.

Certain malfunctions are not explicitly described in the application documents because their effects are bounded by other malfunctions that are described. For example, failure of a lube oil pump to supply oil to a component may not be explicitly described because a failure of the supplied component to operate was described.

The possible malfunctions with a different result are limited to those that are as likely to happen as those described in the application documents. For example, a seismic induced failure of a component that has been designed to the appropriate seismic criteria will not cause a malfunction with a different result.

However, a proposed modification that increases the likelihood of a malfunction previously thought to be incredible to the point where it becomes as likely as the malfunctions assumed in the application documents, could create a possible malfunction with a different result.

In evaluating a proposed modification against this criterion, the types and results of failure modes of SSCs that have previously been evaluated in the application documents and that are affected by the proposed modification should be identified. This evaluation should be performed consistent

with any failure modes and effects analysis (FMEA) described in the application documents, recognizing that certain proposed activities may require a new FMEA to be performed. Attention must be given to whether the malfunction was evaluated in the accident analyses at the component level or the overall system level. While the evaluation should take into account the level that was previously evaluated in terms of malfunctions and resulting event initiators or mitigation impacts, it also needs to consider the nature of the proposed activity. Thus, for instance, if failures were previously postulated on a train level because the trains were independent, a proposed activity that introduces a cross-tie or credible common mode failure (e.g. as a result of an analogue to digital upgrade) should be evaluated further to see whether new outcomes have been introduced.

Once the malfunctions previously evaluated in the application documents and the results of these malfunctions have been determined, then the types and results of failure modes that the proposed modification could create are identified.

Comparing the two lists can provide the answer to the criterion question. An example that might create a malfunction with a different result could be the addition of a normally open vent line in the discharge of an emergency core cooling system pump. The different result of a malfunction could be potential voiding in the system causing it not to operate properly.

7. The modification results in a Design basis limit for a fission product barrier as described in the application documents being exceeded or altered

Safety significance evaluations under this criterion focuses on the fission product barriers - fuel cladding, reactor coolant system (RCS) boundary, and containment - and on the critical Design information that supports their continued integrity. Guidance for applying this criterion is structured around a two-step approach:

- Identification of affected Design basis limits for a fission product barrier
- Determination of when those limits are exceeded or altered.

<u>Identification of affected Design basis limits for a fission product barrier</u>

The first step is to identify the fission product barrier Design basis limits, if any, that are affected by a proposed modification. Design basis limits for a fission product barrier are the controlling numerical values established during the licensing review as presented in the application documents for any parameter(s) used to determine the integrity of the fission product barrier. These limits have three key attributes:

- The parameter is fundamental to the barrier's integrity. Design basis limits for fission product barriers establish the reference bounds for Design of the barriers. They are the limiting values for parameters that directly determine the performance of a fission product barrier. That is, Design bases limits are fundamental to barrier integrity and may be thought of as the point at which confidence in the barrier begins to decrease.

For purposes of this evaluation, Design bases parameters that are used to directly determine fission product barrier integrity should be distinguished from subordinate parameters that can indirectly affect fission product barrier performance. Indirect effects of changes to subordinate parameters are evaluated in terms of their effect on the more fundamental Design bases parameters/ limits that ensure fission product barrier integrity. For example, auxiliary feedwater

(AFW) Design flow is a subordinate parameter for purposes of this evaluation, not a Design bases parameter/ limit. The acceptability of a reduction in AFW Design flow would be determined based on its effect on Design bases limits for the RCS (e.g. RCS pressure).

- The limit is expressed numerically. Design basis limits are numerical values used in the overall Design process, not descriptions of functional requirements. Design basis limits are typically the numerical acceptance criteria used in the Accident analysis methodology. The Facility's Design and operation associated with these parameters as described in the application documents will be at or below (more conservative than) the Design basis limit.
- The limit is identified in the application documents. They may be located in a vendor topical report that is incorporated by reference in the application documents.

Effects (either direct or indirect) on Design basis parameters covered by another regulation or Technical Specification need not be considered as part of evaluations under this criterion.

Examples of typical fission product barrier Design basis limits are identified below:

Barrier	Design Bases Parameter	Typical Design Basis Limit
Fuel Cladding	Departure from Nucleate Boiling Ratio (DNBR)	Value corresponding to the 95/95 DNB criterion for a given DNB correlation
	Linear heat rate	Peak linear heat rate established to ensure clad integrity
Reactor Coolant System Boundary	Pressure	Designated limit in Safety analysis for specific accident
Containment	Pressure	Containment Design pressure

The list above may vary slightly for a given Facility and/ or fuel vendor and may include other parameters for specific Accidents. For example,

- PWR licensees may use a 100% pressuriser level as a limiting parameter to ensure RCS integrity for some accident sequences
- A peak containment temperature may be established in the application documents as an independent limit for ensuring the integrity of the containment.

If a given facility has these or other parameters incorporated into the application documents as a Design basis limit for a fission product barrier, then changes affecting it should be evaluated under this criterion.

Two of the ways that the Licensee can evaluate proposed modifications against this criterion are as follows. The Licensee may identify all Design bases parameters for fission product barriers and include them explicitly in the procedure for performing Safety significance evaluations. Alternatively, the effects of a proposed modification could be evaluated first to determine if the

change affects Design bases parameters for fission product barriers. The results of these two approaches are equivalent provided the guidance for "exceeded or altered" described below is followed. In all cases, the direct and indirect effects of proposed modifications must be included in the evaluation.

Exceeded or altered

A specific proposed modification requires prior Authority approval if the Design basis limit for a fission product barrier is "exceeded or altered." The term "exceeded" means that as a result of the proposed modification, the Facility's predicted response would be less conservative than the numerical Design basis limit identified above. The term "altered" means the Design basis limit itself is changed.

The effect of the proposed modification includes both direct and indirect effects. Extending the maximum fuel burn-up limits until the fuel rod internal gas pressure exceeds the Design basis limit is a direct effect that would require the Authority approval. Indirect effects provide for another parameter or effect to cascade from the proposed modification to the Design basis limit. For example, reducing the Design flow of auxiliary feedwater pumps following a loss of main feedwater could reduce the heat transferred from the RCS to the steam generators. That effect could increase the RCS temperature, which would raise RCS pressure and pressuriser level. The Safety significance evaluations of this change would focus on whether the Design basis limit associated with RCS pressure for that Accident sequence would be exceeded.

Altering a Design basis limit for a fission product barrier is not a routine activity, but it can occur. An example of this would be changing the DNBR value from the value corresponding to the 95/95 criterion for a given DNB correlation perhaps as a result of a new fuel Design being implemented (a new correlation or a new value for the "95/95 DNB criterion" with the same fuel type would be evaluated under Article (6)(8) below). Another example is re-Designing portions of the RCS boundary to no longer comply with the code of Construction. These are infrequent activities affecting key elements of the defence-in-depth philosophy. As such, no distinction has been made between a conservative and non-conservative change in these limits. In contrast with these examples, altering the AFW Design flow or other subordinate parameter/ limit, is not subject to the "may not be altered" criterion because AFW Design flow is not a Design bases limit for fission product barrier integrity.

Evaluations performed under this criterion may incorporate a number of refinements to simplify the review. For example, if an engineering evaluation demonstrates that no parameters are affected that have Design basis limits for fission product barriers associated with them, no Safety significance evaluations against this criterion is required. Similarly, most parameters that require evaluation under this criterion have calculations or analyses supporting the Facility's Design. If an engineering evaluation demonstrates that the analysis presented in the application documents remains bounding, then no evaluation against this criterion is required. When using these techniques, both indirect and direct effects must be considered to ensure that important interactions are not overlooked.

8. The modification results in a departure from a method of evaluation described in the application documents used in establishing the Design bases or in the Safety analyses

The application documents contain the licensing basis information for a Nuclear Facility, including a description on how regulatory requirements for Design are met and how the Facility responds to various Design basis Accidents and events. Analytical methods are a fundamental part of demonstrating how the Design meets regulatory requirements and why the Facility's response to Accidents and events is acceptable. As such, in cases where the analytical methodology was considered to be an important part of the conclusion that the Facility met the required Design bases, these analytical methods were described in the application documents and received varying levels of the Authority review and approval during licensing.

As Safety significance evaluations provide a process for determining if prior Authority approval is required before making changes to the Facility as described in the application documents, changes to the methodologies described in the application documents also fall under the provisions of the Safety significance evaluations process, specifically this criterion. In general, the Licensee can make changes to elements of a methodology without first obtaining the Authority's approval if the results are essentially the same as, or more conservative than, previous results.

If the proposed modification does not involve a change to a method of evaluation, then the Safety significance evaluations should reflect that this criterion is not applicable. If the modification involves only a change to a method of evaluation, then the Safety significance evaluations should reflect that criteria in Article (6)(1) to Article (6)(7) are not applicable.

The first step in applying this criterion is to identify the methods of evaluation that are affected by the change. This is accomplished during the application of the screening criteria in Article (5) (5).

Next, the Licensee must determine whether the change constitutes a departure from a method of evaluation that would require prior Authority approval. As discussed further below, for purposes of evaluations under this criterion, the following changes are considered a departure from a method of evaluation described in the application documents:

- Changes to any element of analysis methodology that yield results that are non-conservative or not essentially the same as the results from the analyses of record.
- Use of new or different methods of evaluation that are not approved by the Authority for the intended application.

By way of contrast, the following changes are not considered departures from a method of evaluation described in the application documents:

- Departures from methods of evaluation that are not described, outlined or summarised in the application documents (such changes may have been screened out as discussed in Article (5) (4));
- Use of a new Authority-approved methodology (e.g. new or upgraded computer code) to reduce uncertainty, provide more precise results, or other reason, provided such use is (a) based on sound engineering practice, (b) appropriate for the intended application, and (c) within the limitations of the applicable Safety Evaluation Report

(SER). The basis for this determination should be documented in the Licensee evaluation against this criterion.

- Use of a methodology revision that is documented as providing results that are essentially the same as, or more conservative than, either the previous revision of the same methodology or another methodology previously accepted by the Authority through the issuance of a SER.

Article (6) (8) (a) provides guidance for making changes to one or more elements of an existing method of evaluation used to establish the Design bases or in the Safety analyses. Article (6) (8) (b) provides guidance for adopting an entirely new method of evaluation to replace an existing one. Examples illustrating the implementation of this criterion are provided in Article (6) (8) (c).

a. Guidance for changing one or more elements of a method of evaluation

The Licensee is provided with the flexibility to make changes to methods of evaluation whose results are "conservative" or are not important with respect to the demonstrations of performance that the analyses provide. Changes to elements of analysis methods that yield conservative results, or results that are essentially the same would not be departures from approved methods.

Conservative vs. non-conservative results

Gaining margin by changing one or more elements of a method of evaluation is considered to be a non-conservative change and thus a departure from a method of evaluation for purposes of a Safety significance evaluation. Such departures require prior Authority approval of the revised method. Analytical results obtained by changing any element of a method are "conservative" relative to the previous results, if they are closer to Design bases limits or Safety analyses limits (e.g. applicable acceptance guidelines). For example, a change from 310 kPa to 331 kPa in the result of a containment peak pressure analysis (with Design basis limit of 345 kPa) using a revised method of evaluation would be considered a conservative change when applying this criterion. In other words, the revised method is more conservative if it predicts more severe conditions given the same set of inputs. This is because results closer to limiting values are considered conservative in the sense that the new analysis result provides less margin to applicable limits for making potential physical or procedure changes without the Authority approval.

In contrast, if the use of a modified method of evaluation resulted in a change in calculated containment peak pressure from 310 kPa to 275 kPa, this would be a non-conservative change. That is because the change would result in more margin being available (to the Design basis limit of 345 kPa) for the Licensee to make more significant changes to the physical Facility or procedures.

"Essentially the same"

The Licensee may change one or more elements of a method of evaluation such that results move in the non-conservative direction without prior Authority approval, provided the revised result is "essentially the same" as the previous result. Results are "essentially the same" if they are within the tolerance for the type of analysis

being performed. Variation in results due to routine analysis sensitivities or calculational differences (e.g. rounding errors and use of different computational platforms) would typically be within the analysis tolerance and thus considered "essentially the same." For example, when a method is applied using a different computational platform (mainframe vs. workstation), results of cases run on the two platforms differed by less than 1%, which is the tolerance for this type of calculation. Thus the results are essentially the same, and do not constitute a departure from a method that requires prior Authority approval.

The determination of whether a new analysis result would be considered "essentially the same" as the previous result can be made through benchmarking the revised method to the existing one, or may be apparent from the nature of the differences between the methods. When benchmarking a revised method to determine how it compares to the previous one, the analyses that are done must be for the same set of plant conditions to ensure that the results are comparable. Comparison of analysis methods should consider both the peak values and time behaviour of results, and engineering judgement should be applied in determining whether two methods yield results that are essentially the same.

b. Guidance for changing from one method of evaluation to another

The Licensee is provided with the flexibility to make changes from one method of evaluation to another provided that the new method is approved by the Authority for the intended application. A new method is approved by the Authority for intended application if it is approved for the type of analysis being conducted, and applicable terms, conditions and limitations for its use are satisfied.

It is incumbent upon the user of a new methodology - even one generically approved by the Authority - to ensure that all conditions and limitations under which the method received the Authority approval are identified. The applicable terms and conditions for the use of a methodology are not limited to a specific analysis; the qualification of the organisation applying the methodology is also a consideration. The Licensee can apply methods that have been reviewed and approved by the Authority without requiring further Authority approval. Methods that have been otherwise accepted as part of another plant's licensing basis (Shin Kori 3&4) are still subject to the Authority approval. The Licensee may continue to seek plant-specific approval to use new methods of evaluation.

When considering the application of a methodology, it is necessary to adopt the methodology and apply it consistent with applicable terms, conditions and limitations. Mixing attributes of new and existing methodologies is considered a revision to a methodology and must be evaluated as such per the guidance in Article (6)(8)(a).

Considerations for determining if new methods are technically appropriate for the intended application

The following questions highlight important considerations for determining that a particular application of a different method is technically appropriate for the intended application, within the bounds of what has been found acceptable by the Authority, and does not require prior Authority approval.

- Is the application of the methodology consistent with the Licensee's licensing basis? Will the methodology supersede a methodology addressed by other regulations or the plant Technical Specifications (Core Operating Limits Report or Pressure/Temperature Limits Report)? Is the methodology consistent with relevant industry standards?

If application of the new methodology requires exemptions from regulations, exceptions to relevant industry standards and guidelines, or is otherwise inconsistent with a Facility's licensing basis, then prior Authority approval will be required. The applicable change process must be followed to make the plant's licensing basis consistent with the requirements of the new methodology.

- If a computer code is involved, has the code been installed in accordance with applicable software Quality Assurance requirements? Has the plant specific model been adequately qualified through benchmark comparisons against experimental test data, plant data, or approved engineering analyses? Is the application consistent with the capabilities and limitations of the computer code? Has industry experience with the computer code been appropriately considered?

The computer code installation and plant-specific model qualification is not directly transferable from one organisation to another. The installation and qualification should be in accordance with the Licensee's Quality Assurance programme/ software quality assurance programme and plant requirements.

- Is the plant configuration the same as described in the methodology? If the plant configuration is similar, but not the same, the following types of considerations should be addressed to assess the applicability of the methodology:
    - How could those differences affect the methodology?
    - Are additional sensitivity studies required?
    - Should additional single failure scenarios be considered?
    - Are analyses of limiting scenarios, effects of equipment failures, etc. applicable for the specific plant Design?
    - Can analyses be made while maintaining compliance with both the intent and literal definition of the methodology?

Differences in the plant configurations and licensing bases could invalidate the application of a particular methodology. The existence of these differences does not preclude the application of a new methodology to a Facility; however, differences must be identified, understood and documented. If evaluation determines the differences to be material to the Authority approval basis for the method, then the method cannot be considered approved for the intended application.

c. Examples

The following example illustrates the implementation of this criterion:

The PSAR states that a damping value of 0.5 percent is used in the seismic analysis of Safety-related piping. The Licensee wishes to change this value to 2 percent to re-analyse the seismic loads for the piping. Using a higher damping value to represent the response of the piping to the acceleration from the postulated earthquake in the analysis would result in lower calculated stresses because the increased damping reduces the loads.

Since this analysis was used in establishing the seismic Design bases for the piping, and since this is a change to an element of the method that is not conservative and is not essentially the same, this change would require prior Authority approval under this criterion.

On the other hand, had the Authority approved an alternate method of seismic analysis that allowed 2 percent damping provided certain other assumptions were made, and the Licensee used the complete set of assumptions to perform its analysis, then the 2 percent damping under these circumstances would not be a departure because this method of evaluation is considered "approved by the Authority for the intended application."

9. The modification results in a departure from or non-conformance with the Management System and organisational arrangements as described in the application documents

When modifications to any management system and organisational arrangements are made, which may result in significant nuclear Safety implications, those changes shall be approved by the Authority before implementation of change. Any change to the application documents (i.e. Licensee Quality Assurance Manual, QA-MAN-111-01) shall be evaluated against the acceptable methods and guidance provided in FANR-RG-002 (Reference 2) for implementing the requirements specified in the Authority regulation FANR-REG-01 (Reference 1).

Example: The erection, installation, modification, or inspection of SSCs to the approved NQA-1 standards deviates from the management system arrangements described in application documents.

Organisational changes shall be evaluated and classified according to their importance to Safety and each change shall be justified.

The implementation of such a change should be planned, controlled, communicated, monitored, tracked and recorded to ensure that Safety is not compromised. Documentation of the organisational change shall be maintained as Quality Assurance Records subject to the Authority inspection. Recordkeeping and retention requirements shall adhere to those stated in Article (5) (5) and Article (8).

A proposed organisational change can be categorised as “Minor Organisational Change” which does not require Authority approval or “Major Organisational Change“, which does require Authority approval in accordance with its Safety significance.

Safety significance is mainly linked to the extent to which a proposed change and the potential consequences of the change have an impact on nuclear Safety or quality.

Minor organisational change:

A change to the organisational structure or resources, which will not have a negative impact on the capability of the organisation to maintain Safety and compliance with the Authority Regulations.

Example: Changes to organisation structure or responsibilities that do not impact nuclear Safety, quality, or the functioning of key functional areas.

Major organisational change:

A change to the organisational structure or resources, which could represent a change to compliance with the Authority regulations or Licence conditions and/ or may reduce the capability or effectiveness of the Licensee's management of Safety.

Examples:

- Organisation change that could seriously reduce the Authority's confidence in the Licensee's oversight and assurance of nuclear Safety or in the Licensee's licensing function.
- A change to a key position within the Licensee's organisation
- Transfer of significant work scope for a key functional area affecting nuclear Safety or quality to a contractor

Disposition of Safety Significance Evaluations

Article (7)

There are two possible conclusions to a Safety significance evaluation:

1. The proposed modification may be implemented without prior Authority approval.
2. The proposed modification requires prior Authority approval.

A modification is considered "implemented" when it is incorporated in the Facility under Construction. Thus, the Licensee may Design and plan a modification prior to receiving Authority approval to the extent that these preliminary activities do not themselves require prior Authority approval.

For proposed activities that are determined to require prior Authority approval, there are three possible options:

1. Cancel the planned change.
2. Re-Design the proposed modification so that it may proceed without prior Authority approval.
3. Apply for and obtain Authority approval prior to implementing the modification. Technical and licensing evaluations performed for such modifications may be used as part of the basis for approval requests.

It is important to remember that determining that a proposed modification requires prior Authority approval does not determine whether it is safe. In fact, a proposed modification that requires prior Authority approval may significantly enhance overall plant Safety at the expense of a small adverse impact in a specific area. It is the responsibility of the Licensee to assure that proposed modifications are safe.

Documentation and Reporting

Article (8)

The following documentation and record-keeping are required for modifications that require evaluation against the Safety significance evaluation criteria (i.e. the modification “screens in”) and are determined to not require prior Authority approval:

1. The records of modifications must include a written evaluation (e.g. Safety significance evaluation) which provides the bases for the determination that the modification does not require Authority approval.
2. The Licensee shall submit a report containing a brief description of any modifications for which a Safety significance evaluation was performed including a summary of the evaluation of each. A report must be submitted at intervals not to exceed 6 months.
3. The records of modifications in the Facility must be retained for the life of the Facility.

The above requirements refer to those modifications that were evaluated against the Safety significance evaluation criteria (because, for example, they affect the Facility as described in the PSAR or other application documents), not to those modifications that were screened out. Documentation and record-keeping for modifications that screen out is subject to the requirements in Article (5)(5). Similarly, documentation is not required for modifications that are cancelled or that are determined to require prior Authority approval and are implemented via the Authority approval or Licence amendment request process.

1. Documenting Safety significance evaluations

In performing a Safety significance evaluation of a proposed modification, the Licensee must address all of the Safety significance evaluation criteria to determine if prior Authority approval is required. Although the conclusion in each criterion may be simply "yes," "no," or "not applicable," there must be an accompanying explanation providing adequate basis for the conclusion. These explanations should be complete in the sense that another knowledgeable reviewer could draw the same conclusion. Restatement of the criteria in a negative sense or making simple statements of conclusion is not sufficient and should be avoided. It is recognised, however, that for certain very simple activities, a statement of the conclusion with identification of references consulted to support the conclusion would be adequate and the Safety significance evaluation could be very brief.

The importance of the documentation is emphasised by the fact that experience and engineering knowledge (other than models and experimental data) are often relied upon in determining whether evaluation criteria are met. Thus the basis for the engineering judgement and the logic used in the determination should be documented to the extent practicable and to a degree commensurate with the Safety significance and complexity of the modification. This type of documentation is of particular importance in areas where no established consensus methods are available, such as for software reliability, or the use of commercial-grade hardware and software where full documentation of the Design process is not available.

Since an important goal of the Safety significance evaluation is completeness, the items considered by the evaluator must be clearly stated. Each Safety significance evaluation is unique. Although each applicable criterion must be addressed, the questions and considerations listed throughout this guidance document to assist evaluating the criteria are not requirements for all evaluations. Some evaluations may require that none of these questions be addressed while others will require additional considerations beyond those addressed in this guidance.

When preparing Safety significance evaluations, the Licensee may combine responses to individual criteria or reference other portions of the evaluation.

As discussed in Article (5), the Licensee may elect to use screening criteria to limit the number of modifications for which written Safety significance evaluations are carried out. A documentation basis should be maintained for determination of modifications against the screening criteria. Retention period requirements for this documentation are provided in Article (5)(5).

2. Reporting to the Authority

A summary of Safety significance evaluations for modifications implemented without requiring Authority approval must be provided to the Authority. Modifications that were screened out, cancelled or implemented via Authority approval or Licence amendment need not be included in this report. The reporting requirement is every six months.

References

Article (9)

1. FANR Regulation, FANR-REG-01, “Regulation for Management Systems for Nuclear Facilities”
2. FANR Regulatory Guide, FANR-RG-002, “Application of Management Systems for Nuclear Facilities”
3. IAEA Safety Standards for protecting people and the environment “The Management System for Nuclear Installations”, 2009, IAEA Safety Guide No. GS-G-3.5.
4. Letter FANR-NSD-ENEC-COR-00215-2013, 28 FEB 2013
5. Letter FANR-NSD-ENEC-COR-00100-2014, 27 JAN 2014,
6. United States Nuclear Regulatory Commission Regulatory Guide RG 1.187, “Guidance for implementation of 10 CFR 50.59, Changes, Tests, and Experiments”
7. FANR Regulation, FANR-REG-08, “Physical Protection for Nuclear Materials and Nuclear Facilities”
8. FANR Regulation, FANR-REG-16, “Regulation for Operational Safety including Commissioning”
9. FANR Regulation, FANR-REG-04, “Regulation for Radiation Dose Limits and Optimisation of Radiation Protection for Nuclear Facilities”

APPENDIX 1 - Safety significance evaluation Process