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Federal Authority for Nuclear Regulation

United Arab Emirates

Draft Regulatory Guide

Significance Evaluations for Modifications of Nuclear Facilities during Operation (FANR-RG-029)

Version 0
Public Review

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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 purpose of this regulatory guide, the following terms have the meanings set forth below. Other capitalised terms used but not defined herein shall have the meanings 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):

Additional Protocol	This refers to the Protocol Additional to the Safeguards Agreement. The Additional Protocol was ratified by Federal Decree No. 63 of 2010 and entered into force on 20 December 2010 and reproduced in the International Atomic Energy Agency (IAEA) Information Circular INFCIRC/622/Add.1.
Corporate Governance	A term encompassing the Licensee's joint venture arrangements and agreements, financial instruments and arrangements including insurance, civil liability for nuclear damages, and the Decommissioning trust fund.
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	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.
Design Information Questionnaire	A questionnaire used to submit Design information about the Nuclear Facility to the IAEA by the UAE.

Emergency Plan	A description of the concept, policy and objectives of operations for the response to an Emergency, and of the structure, authorities and responsibilities for a systematic, coordinated and effective response. The Emergency Plan serves as the basis for the development of other plans, procedures and checklists.
Facility Attachment	See **Subsidiary Arrangements**.
Final Safety Analysis Report	A document required by FANR Regulation for an Application for a Licence to operate a Nuclear Facility (FANR REG-14) to support an application for a Licence to Operate a Nuclear Power Plant.
General Design Criteria	This criteria establishes the minimum requirements for the principal Design criteria for the water-cooled nuclear power plants similar in Design and location to nuclear power plants for which a Construction Licence has been issued by the Authority.
Items Important to Safety	These are items that are important to Safety and/ or could lead to radiation exposure of the site personnel or members of the public should the item have a malfunction. Such items include the following: • Structures, Systems and Components that prevent anticipated operational occurrences from leading to Accident conditions. • Features that are provided to mitigate the consequences of malfunction or failure of Structures, Systems and Components.
Organisational Arrangements	A term encompassing the Licensee's Management System, Quality Assurance programme; organisational structure; and Corporate Governance areas, as described in the application documents.
Probabilistic Risk Assessment	A comprehensive, structured approach to identifying failure scenarios constituting a conceptual and mathematical tool for deriving numerical estimates of risk. Level 1 includes 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.
Safety Analysis Report	The detailed demonstration of the Safety, security and safeguards of a Nuclear Facility presented in the form of an integrated report that presents the necessary and sufficient information in support of the Licence application for authorisation of any Regulated Activities requested.

Safety Analysis	Evaluation of the potential hazards associated with the Operation of a facility or the conduct of an activity.
Safety Evaluation Report	The regulatory review and assessment of the Construction Licence application and the operating Licence application, which is presented in the form of an integrated report that summarises the review and assessment performed by or for the regulatory body and provides a clear conclusion about the Safety of the authorised activity.
Structures, Systems and Components	A general term encompassing all the elements of a Facility or Activity, which contributes to protection and Safety except Organisational Arrangements. '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'.
Subsidiary Arrangements	The document containing the technical and administrative procedures for specifying how the provisions laid down in the Safeguards Agreement are to be applied. Subsidiary Arrangements to the Safeguards Agreement consist of a 'general part', which is applicable to all common nuclear activities of the UAE, and of a Facility Attachment prepared for each Facility in the UAE and describing arrangements specific to that Facility.

Objective

Article (2)

This regulatory guide sets forth the Authority's guidance to the Licensee of a Nuclear Facility in determining if a proposed modification related to Safety or safeguards requires prior approval by the Authority before its implementation. This regulatory guide aims to provide guidance on Licence Condition 4 (Operation Licence), and supports Article (17) of FANR Regulation for Management Systems for Nuclear Facilities (FANR-REG-01) and Article (13) of FANR Regulation on Operational Safety including Commissioning (FANR-REG16).

Purpose and Scope

Article (3)

1. This regulatory guide applies only to Nuclear Facilities that are in Operation. The purpose of the guide is to provide guidance for the process and criteria to be used by the Licensees of Nuclear Facilities during operation in determining, based on a significance evaluation, if a proposed modification requires prior approval by the Authority before its implementation.
2. This scope of the regulatory guide includes the following:
    a) Applicability and screening to determine if a significance evaluation is required - as defined in Article (4) of this regulatory guide.
    b) Evaluation criteria to determine if approval must be obtained from the Authority.
    c) Documenting and reporting to the Authority modifications to be implemented under the significance evaluation process and records.
3. The process flow for the functions mentioned in this article can be found in Appendix 1.

Terminology

Article (4)

1. This article describes the key terms applicable to this regulatory guide.
2. The term *significance evaluation* is the documented evaluation against the criteria specified in the following articles of this regulatory guide:
    a) Article (8) paragraphs 18 and 19 for modifications related to the Structures, Systems and Components of a Nuclear Facility during Operation.
    b) Article (9) paragraphs 10 to 18 for modifications related to the Organisational Arrangements.
    c) Article (10) paragraphs 7 and 8 for modifications related to the Emergency Plan.
    d) Article (11) for modifications related to the Safeguards Arrangements.

    In order to determine if a proposed modification requires prior approval by the Authority before its implementation.
3. Only changes to Structures, Systems and Components and/ or Organisational Arrangements, and/ or the

Emergency Plan, or Safeguards Arrangements of the Nuclear Facility that have significant Safety implications require evaluation and reporting to the Authority.

4. The term *modification* relates to a change, an addition, or a removal from either the Structures, Systems and Components, the Organisational Arrangement, documents, or the standards referenced to (or submitted in the Operation Licence application), which affect: (i) a Design function, (ii) a method of performing or controlling the function, (iii) an evaluation that demonstrates how intended functions will be accomplished, or (iv) the Quality Assurance programme submitted previously to and accepted by the Authority.

5. Additions and/ or removals can adversely impact the bases for the acceptability of the Design function and Operation. Thus, the term *modification* includes changes to an existing provision as mentioned in the Operation Licence application documentation as follows:

   a) Structures, Systems and Components (i.e. the Design requirements, analysis methodology, assumptions, Design parameters or applicable standards as well as additions and/ or removals (i.e. physical removals, abandonment, or non-reliance on a system to meet a requirement of the Structures, Systems and Components of the Nuclear Facility).
   b) Organisational Arrangements (i.e. the Licensee's Management System, Quality Assurance Programme, organisational structure and Corporate Governance areas).
   c) Emergency Plan.
   d) Safeguards arrangements (i.e. the arrangements, procedures and measures).

6. Terms that are relevant to *modification* on the Structures, Systems and Components of a Nuclear Facility during Operation can be found in this article. Further discussion of terms relating to *modification* can be found in articles (8), (9), (10) and (11) of this regulatory guide.

7. The term *Design function* covers a function of Structures, Systems and Components that is credited in the Safety Analysis, or that supports or impacts upon a function of a Structure, System and Component credited in Safety Analysis. This may include (i) functions performed by Safety-related Structures, Systems and Components or non-Safety-related Structures, Systems and Components, and (ii) functions of non-Safety-related Structures, Systems and Components that may initiate a plant transient or Accident, if performed.

8. *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.

9. The method of performing or controlling a function is how a *Design function* is accomplished as credited in the Safety Analysis 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.

10. An evaluation should demonstrate that intended function(s) will be accomplished. For example, a

thermodynamic calculation that demonstrates that the Emergency core cooling system has sufficient heat removal capacity to respond to a postulated Accident.

11. The following changes or activities are not considered *modifications*:

    a) The restoration of a Structures, Systems and Component to its 'as-designed' condition e.g. replacement of a component with a similar component that meets the original Design specifications.

    b) Editorial changes to documents and/or procedures..

12. The term *temporary changes* to the facility or procedures such as jumpering terminals, lifting leads, placing temporary lead shielding on pipes and equipment, and use of temporary blocks, bypasses, scaffolding and supports, are made to facilitate a range of plant activities and are subject to screening to determine if prior approval from the Authority is required.

13. Other *temporary changes* to the facility or procedures that are not associated with Maintenance are subject to screening in the same manner as permanent changes to determine if prior approval from the Authority is required.

14. *Temporary changes* associated with Maintenance activities should be assessed and approved by the Licensee's management. Screening of such activities is not required provided that *temporary changes* are removed (i.e. affected Structures, Systems and Components must be restored to their normal, 'as-designed' condition) at the conclusion of the Maintenance activity.

15. The departure from a method of evaluation described in the application documents will require changing a part of the method described in the application documents and supporting documentation unless the Authority has previously approved that method for the intended application. Specific guidance on how to make this decision can be found in Article (8) of this regulatory guide.

16. A departure from the Management System and Organisational Arrangements described in the application documents means a change to the interacting elements (i.e. the Management System) to establish policies, processes, programmes and changes to the organisation that affect or influence Nuclear Safety or safeguards. Specific guidance can be found in Article (9) of this regulatory guide.

17. The term *facility* as described in the application documents will cover the following:

    a) The Structures, Systems and Components including the Design and performance requirements for such Structures, Systems and Components described in the application documents, and the evaluations or methods of evaluation included in the application documents for such Structures, Systems and Components that demonstrate how their intended function(s) will be accomplished.
    b) The Organisational Arrangements.
    c) The controlled provisions and methods of safeguards.
    d) Facilities identified for the on-site Emergency Plan.
    e) The nuclear power plant as described in the Final Safety Analysis Report.

18. The term *procedure* as described in the application documents will cover information related to the Operation and control of Structures, Systems and Components, the Organisational Arrangements, Emergency Plan and safeguards.

19. The term *programme* will cover a planned, coordinated group of activities, processes and /or procedures that are required to comply with a specific requirement of the Authority, or allows for compliance with the said requirement.

Application Documents

Article (5)

The documents including the Final Safety Analysis Report referenced in (and/ or submitted with) the Licensee's application for the Construction Licence and Operation Licence of a Nuclear Facility and the additional information submitted by the Licensee to support the request for implementing the *modification*.

Screening Process

Article (6)

1. Screening is the part of the process that determines whether a *significance evaluation* is required prior to implementing a proposed *modification* i.e. the *modification* 'screen-in'. It is applicable to *modifications* that involve changes to the Structures, Systems and Components or Organisational Arrangements, or Emergency Plan, or safeguards arrangements described in the application documents. Engineering, Design, Quality Assurance and other technical information concerning the *modification* should be used to assess whether the *modification* requires screening. Screening is applicable to *modifications* that result in a change, addition or removal, which affect the following:

    a) A Design function of a Structure, System and Component.

    b) A method of (or a procedure on) performing or controlling the *Design function*.

    c) Radiation Doses to workers, the general public or the environment.

    d) An evaluation to demonstrate how intended *Design functions* will be accomplished, or the Quality Assurance programme submitted previously to (and accepted by) the Authority.

    e) The Management System (including any Level 0 main processes or Level 1 sub-processes or *programmes*) directly impacting the Structures, Systems and Components or Operation of the Nuclear Facility.

    f) The Licensee's organisational structure, or the Corporate Governance areas described in the application documents including:

        I. The Licensee's joint venture arrangements and agreements.

        II. Financial instruments and arrangements including insurance.

        III. Civil liability for nuclear damages.

        IV. The Decommissioning trust fund.

g) The effectiveness of the Emergency Plan.

h) The latest Design Information Questionnaires submitted to the Authority.

i) Approved physical inventory taking, and *procedures* on Nuclear Material accountancy and control.

j) Safeguards organizational structure.

2. The Licensee may determine the applicability of the *significance evaluation* by performing screening activities based on the guidance in Article 6 of this regulatory guide. Once it has been determined that screening is applicable, the screening is performed by qualified personnel to determine if the *modification* should be evaluated against the *significance evaluation* criteria.

3. Activities that are 'screened-out' from *significance evaluations* should be documented as discussed in Article (12) paragraphs 11 to 13 of this regulatory guide. Activities that 'screen out' may require nonetheless application document information to be updated.

Description of the Methodology of the Evaluation Process

Article (7)

1. Screening is the part of the process that determines whether a *significance evaluation* is required prior to implementing a proposed *modification*. Evaluation is the part of the process, which determines for *modifications* that 'screen in', whether a *modification* must be submitted to the Authority for approval. More information about screening for proposed *modifications* can be found in the following articles of this regulatory guide:

   a) Article (8) for *modifications* related to the Structures, Systems and Components of a Nuclear Facility during Operation.
   b) Article (9) for *modifications* related to Organisational Arrangements.
   c) Article (10) for *modifications* related to the Emergency Plan.
   d) Article (11) for *modifications* related to the safeguards arrangements.

2. Once it has been determined that a *modification* requires a *significance evaluation*, the written evaluation must address the applicable criteria found in the following articles of this regulatory guide:

   a) Article (8) paragraphs 18 and 19 for *modifications* related to the Structures, Systems and Components of Nuclear Facilities during Operation.
   b) Article (9) paragraphs 10 to 18 for *modifications* related to the Organisational Arrangements.
   c) Article (10) paragraphs 7 and 8 for *modifications* related to the Emergency Plan.
   d) Article (11) for *modifications* related to the safeguards arrangements.

3. The process for the *significance evaluation* process can be found in Appendix 1.

4. These criteria are used to evaluate the effects of proposed *modifications* on the Operation of the Nuclear Facility. If any of the above 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 adequately documented in line with Article (12) of this regulatory guide.
5. Screening and *significance evaluations* are not required under the following circumstances:

    a) The *modification* requires a Licence amendment.
    b) The *modification* requires the Authority's approval as stipulated by applicable Laws, or regulations issued by the Authority, or a Licence condition.
    c) The Licensee decides to submit a request to the Authority for approval of a *modification*.

Modification on the Structures, Systems and Components of a Nuclear Facility during Operation

Article (8)

Screening Process

1. In order to determine how a proposed *modification* affects a *Design function*, or 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 Structures, Systems and Components and the proposed change is essential. Only proposed *modifications* based on supporting engineering and technical information that would result in an adverse effect (e.g. a decrease in capability or a reduction in the level of compliance with standards or requirements) need to be evaluated against *significance evaluation* criteria. A decision on whether adverse effects exist should be based on both direct and indirect effects of the *modification*. A *significance evaluation* would be required under the following circumstances:

    a) The *modification* decreases the ability of the Structures, Systems and Components to perform its required Safety functions under stated conditions for a specified period of time.
    b) The *modification* affects existing safety margins, redundancy, diversity or Defence-in-Depth, or the integrity of any of the fission product barriers.
    c) The *modification* adds or deletes an automatic or manual *Design function* of the Structures, Systems and Components .
    d) The *modification* converts a feature that was automatic to manual or vice-versa.
    e) The *modification* introduces a previously un-reviewed system interaction.
    f) The *modification* adversely affects the ability or response time to perform required actions, e.g. alters equipment access or adds steps necessary to perform tasks.
    g) The *modification* degrades the seismic or environmental qualification of the Structures, Systems and Components.
    h) The *modification* introduces previously un-reviewed effects on other units at a multiple unit site.

i) The *modification* results in a departure from a method of evaluation used to establish the Design bases or in the Safety Analysis.

j) For *modifications* affecting Structures, Systems and Components, and procedures that are not described in the Final Safety Analysis Report or other application documents, the *modification* has a direct or indirect adverse effect on the Safety or Design analysis described in the Final Safety Analysis Report or other application documents.

2. A safety evaluation is required for changes that adversely affect *Design functions*, methods used to perform or control *Design functions*, or evaluations that demonstrate that intended *Design functions* will be accomplished. Changes that have none of these effects, or have positive effects, may be 'screened out' because only adverse changes have a potential to increase the likelihood of malfunctions, increase consequences, create the new Accidents, or otherwise meet the safety evaluation criteria.

3. Structures, Systems and Components may have preventive as well as a mitigating Design function. Adverse changes to either must be 'screened in'. Thus, a change that decreases the reliability of a function whose failure could initiate an Accident would be considered as to adversely affect a Design function, and would be deemed to 'screen in'. In this regard, changes that would relax the manner in which code requirements are met for certain Structures, Systems and Components should be screened for adverse effects on *Design function*. Similarly, changes that would result in a new type of Accident or malfunction would be 'screened in'.

4. If a change has both positive and adverse effects, the change should be screened. The Safety evaluation should focus on the adverse effects.

5. The screening process is not concerned with the magnitude of identified adverse effects. Any change that adversely affects an application document, which describes Design function, a method of performing or controlling Design functions, or an evaluation that demonstrates that intended Design functions are accomplished, is 'screened in'. The magnitude of the adverse effect (e.g. is the minimal increase standard met?) is the focus of the Safety evaluation process.

6. The decision of whether or not to screen is made based on the engineering/ technical information supporting the change. Technical/ engineering information (e.g. Design evaluations) that demonstrate changes have no adverse effect on application documents describing *Design functions*, methods of performing or controlling *Design functions*, or evaluations that demonstrate that intended *Design functions* are accomplished, may be used as a basis for 'screening out' the change. If the effect of a change is such that an existing Safety Analysis would no longer be bounding and therefore Safety Analyses as described in application documents must be carried out again to demonstrate that the change meets all required Safety functions and Design requirements, the change is considered as adverse and must be screened in.

7. Changes that entail the update of a Safety Analysis to reflect improved performance, capacity, timing, which results from a change (beneficial effects on *Design functions*) that are not considered adverse, do not need to be 'screened in' even though the change calls for the Safety Analysis to be updated.

8. The following examples illustrate the screening process for the *significance evaluations* as applied to changes of Structures, Systems and Components:

a) The change that improves the closure time of the Main Control Room isolation dampers reduces the calculated Dose to Operators, and application documents Dose consequence analyses are

to be updated as a result. In this case, the Dose analyses are being revised to reflect the lower Dose for the Main Control Room, not to demonstrate that the requirements of the General Design Criteria continue to be met. This case would screen out. A change that would adversely affect the *Design function* of the dampers (post-Accident isolation of the Main Control Room) and increase the existing calculated Dose to Operators would be considered adverse and would 'screen in'. In this case, the Dose analyses must be re-run to ensure that the requirements of the General Design Criteria continue to be met. The revised analyses would be used in support of the Safety evaluation to determine if the increase exceeds the minimal standard and requires a Safety justification.

b) The change to a diesel generator starting relay that delays the diesel generator start time from 20 seconds to 25 seconds. The Design function as described in the application documents relating to Accident analyses is for the diesel generator to start within 25 seconds. This change would 'screen out' because it is apparent that the change will not adversely affect the diesel generator's *Design function* in the Accident analyses. However, a change that would delay the diesel generator start time to 30 seconds would 'screen in' because the change adversely effects the *Design function* (to start in 25 seconds). Such a change would 'screen in' even if technical/ engineering information supporting the change includes revised Safety Analysis that demonstrates all required Safety functions supported by the diesel generator, e.g. core heat removal, containment isolation, containment cooling are satisfied and that applicable Dose limits continue to be met. While this change may be acceptable with respect to the performance of required Safety functions and meeting Design requirements, the analyses necessary to demonstrate acceptability are beyond the scope/ intent of the Safety evaluation process screening reviews. Thus a Safety evaluation would be required.

Screening changes to the Facility not described in the application documents

9. Screening to determine that a *significance evaluation* is required is straightforward when a *modification* affects a *Design function* of a Structure, System and Component, a method of performing or controlling a Design function, or an evaluation that demonstrates how intended *Design functions* will be accomplished as described in the application documents. However, a Facility also contains many Structures, Systems and Components not described in the application documents. These can be components, sub-components or even entire systems including non-Safety related systems with supporting functions to Safety-related Structures, Systems and Components. Changes affecting Structures, Systems and Components or procedures that are not explicitly described in the application documents can have the potential to affect other Structures, Systems and Components' *Design functions* that are described in the application documents, thus these changes may require screening and a *significance evaluation*. In such cases, the approach to determine whether a *modification* involves a change to the Facility as described in the application documents, is to consider the impact of the *modification* on all the Structures, Systems and Components in the application documents i.e. to consider all the Structures, Systems and Components that have an interface with the system being modified. If for the larger Structures, Systems and Components the change affects application documents, which described a *Design function*, a method of performing or controlling the Design function, or an evaluation demonstrating how the intended Design functions will be accomplished, then screening and *significance evaluation* is required. 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.

10. 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 Structures, Systems and Components (whether or not described in the application documents) can affect the application documents through indirect or secondary effects, which describes the *Design function* of Structures, Systems and Components

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

    a) 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 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 the emergency diesel generator. If the Licensee concludes that the change would not affect the application documents' description of the Design function of the circuit or emergency diesel generator, then this would form the basis for screening out the change, and no *significance evaluation* would be required.

12. If an activity/ condition is determined to be neither, then it is deemed to 'screen out' and may be implemented without further evaluation under the Safety evaluation process. Activities that are 'screened out' from further evaluation should be documented as discussed in Article (12) paragraphs 11 to 13 of this regulatory guide.

Screening changes to procedures as described in the application documents

13. Changes to technical procedures are deemed to be 'screened in' (i.e. require a *significance evaluation*) if the change affects how the Structures, Systems and Components' *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 do not affect how the Design functions of a Structure, System and Component are carried out or controlled (as described in the application documents) would be deemed to 'screen out'.

14. For purposes of the Safety evaluation screening process, changes that fundamentally alter (replace) the existing means of performing or controlling Design functions should be conservatively treated as adverse and 'screened in'. Such changes include replacement of automatic action by manual action (or vice versa), changes to the man-machine interface, changing a valve from 'locked closed' to 'administratively closed', and similar changes.

15. The following example illustrates the screening process for *significance evaluations* as applied to proposed procedure changes:

    a) The Final Safety Analysis Report 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 Final Safety Analysis Report. 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 be deemed to 'screen in' and require a *significance evaluation* to be carried out.

b) Emergency operating procedures include Operator actions and response times associated with response to Design basis events, which are described in the application documents, but also address Operator actions for severe accident scenarios that are outside the Design basis and not described in the Safety Analysis Report. A change would be deemed to 'screen out' at this step if the change was to those procedures or parts of procedures dealing with Operator actions during severe Accidents.

c) If the description in the application documents of the Nuclear Reactor start-up procedure contains eight fundamental sequences, the Licensee's decision to eliminate one of the sequences would be deemed to 'screen in'. On the other hand, if the Licensee consolidated the eight fundamental sequences and it did not affect the method of controlling or performing Nuclear Reactor start-up, the change would be deemed to 'screen out'.

Screening changes to methods of evaluation used for the application documents

16. Methods of evaluation included in the application documents to demonstrate how intended Structures, Systems and Components' *Design functions* are accomplished are considered part of the 'Facility-as-described-in-the-application-documents'. Thus the use of new or revised methods of evaluation is considered to be a change under FANR-RG-029 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 *significance evaluation* to determine if prior approval from the Authority is required.

17. The following examples illustrate the screening of changes to the method of evaluation:

a) The Final Safety Analysis Report identifies the name of the computer code used to carry out containment performance analyses with no further discussion of the methods used within the code to carry out those analyses. Changes to the computer code may be 'screened out' provided that the changes do not invalidate the results of the analysis reported in the application documents, and its application is within the constraints and limits identified in the associated topical report and Safety Evaluation Report. A change that goes beyond restrictions on the use of the method would be considered adverse and evaluated under the Safety evaluation process to determine if a Safety justification is required.

b) The application documents describe the methods used for atmospheric heat transfer and containment pressure response calculations contained within the CONTEMPT-LT computer code. The code is also used for developing long-term temperature profiles (post-recirculation phase of loss-of-coolant accidents) for environmental qualification through modelling of the residual heat removal system. Neither this application of the code nor the analysis method is discussed in the application documents. A revision to the CONTEMPT code to incorporate more dynamic modelling of the residual heat removal system's transfer of heat to the ultimate heat sink would be deemed to 'screen out' because this application of the code is not described in the application documents as being used in the Safety Analysis, or to establish the Design bases. However, changes to the CONTEMPT-LT code that affect the atmospheric heat transfer or containment pressure predictions may not 'screen out' (as the application documents describes this application in the Safety Analysis), and will require a Safety evaluation.

c) The steam line break mass and energy release calculations were originally performed at a power level of 105% of the nominal power (plus uncertainties) in order to allow margin for a future power up-rate. The Licensee later decides that it would not pursue the power up-rate and wishes to use the margin to address other equipment qualification issues. The steam line break mass and energy release calculations were re-analysed using the same methodology at 100% power (plus uncertainties). This change would be deemed to 'screen out' as a method change because the proposed activity/ condition involved a change to an input parameter (i.e. the percentage of power) and not a method change. This change should be screened according to Article (8) paragraphs 20 to 26 of this regulatory guide to determine if it constitutes a change to the facility as described in the application documents that requires evaluation under the Safety evaluation process.

d) Due to fuel management changes, core physics parameters change for a particular reload cycle. The application documents describe how the core physics parameters are to be calculated to explicitly allow the use of either 2-D or 3-D modelling for the analysis. A change to add or remove discretionary conservatism via the use of 3-D methods instead of 2-D methods or vice-versa would be deemed to 'screen out' because the change is within the terms and conditions of the Final Safety Analysis Report.

Significance Evaluation Process

18. Once it has been determined that a *modification* requires a *significance evaluation*, the written evaluation must address the applicable criteria of the Safety evaluation process in Article (8) paragraphs 20 to 93 of this regulatory guide. These criteria are used to evaluate the effects of proposed modifications involving changes to the Structures, Systems and Components, methods of analysis, methods of testing or other processes or activities associated with the Operation of the Nuclear Facility.

19. If any of the below mentioned criteria are met, the Licensee must apply to the Authority for approval prior to implement the *modification*. The evaluation against each criterion should be appropriately documented in line with Article (12) of this regulatory guide.

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

20. If the modification results in an increase in the frequency of occurrence of an Accident or transient previously evaluated in the application documents, the first step to address this criterion is to identify the Accidents that have been evaluated in the application documents, which are affected by the proposed *modification*. Then a decision should be made as to whether the frequency of these Accidents occurring would be more than minimally increased.

21. Accidents and transients have been divided into categories based upon a qualitative assessment of frequency. For example, standards of the American National Standard Institute (ANSI 51.1) define the following categories for plant conditions for most pressurised water reactors:

a) Normal Operations: these are expected frequently or regularly in the course of power Operation, refuelling, Maintenance or manoeuvring.

b) Incidents of Moderate Frequency: these ae defined as any incident that is expected per plant during a calendar year.

c) Infrequent Incidents: these refer to any incident that is expected per plant during plant lifetime.

d) Limiting Faults: these are expected to occur but could release significant amounts of Radioactive Material thus requiring protection by Design.

22. 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.

23. 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 decision 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 may be used to evaluate a proposed *modification* in a quantitative sense. It should be emphasised that Probabilistic Risk Assessments are just one of the tools to evaluate the effect of proposed *modifications*, and their use is not required to perform *significance evaluations*.

24. Reasonable engineering practices, engineering judgement and Probabilistic Risk Assessment techniques, as appropriate, should be used to determine whether the frequency of occurrence of an Accident or transient would more than minimally increase 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 to determine what constitutes a 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.

25. The following are examples where there is not more than a minimal increase in the frequency of occurrence of an Accident:

a) 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 to determine 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).

b) The proposed activity meets the requirements previously accepted by FANR as well as the Design, material, and construction standards applicable to the Structures, Systems and Components being modified. If the proposed activity would not meet applicable requirements and standards, the change is considered to involve more than a minimal increase in the frequency of occurrence of an Accident, and a Safety justification is required.

c) The change in frequency of occurrence of an Accident is calculated to support the evaluation of the proposed activity, and one of the two criteria:

i. The increase in the pre-change Accident or transient frequency does not exceed 10 percent.

ii. The resultant frequency of occurrence remains below the applicable plant-specific threshold (below 1E-6).

26. If the proposed activity would not meet either of the above criteria, the change is considered to involve more than a minimal increase in the frequency of occurrence of an Accident, and a Safety justification is required.

The modification results in an increase in the likelihood of occurrence of a malfunction of Safety systems and Safety related items (Structures, Systems and Components that are important to Safety) previously evaluated in the application documents

27. In reference to a *modification* that results in an increase in the likelihood of there being a malfunction of Safety systems and Safety-related items (i.e. Structures, Systems and Components that are important to Safety), which were previously evaluated in the application documents, this criterion refers to the failure of Structures, Systems and Components to perform their intended Design functions. 'Safety systems' refers to systems that are important to Safety, which are provided to ensure the safe shutdown of the Nuclear Reactor or the residual heat removal from the Nuclear Reactor core, or to limit the consequences of anticipated operational occurrences and Design Basis Accidents. A 'Safety-related item' is an item, which is important to Safety but does not form part of a Safety system. The cause and mode of a malfunction should be taken into account to determine whether there is a change in the likelihood of a malfunction. The effect or result of a malfunction should be taken into account to determine whether a malfunction with a different result is involved in Article (8) paragraphs 52 to 58.

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

29. Direct effects are those where the proposed *modification* affects the Structures, Systems and Components (e.g. a motor change on a pump). Indirect effects are those where the proposed *modification* affects one Structure, System and Component, and this particular Structure, System and Component affects the capability of another Structure, System and Component to perform its *Design function* as described in the application documents. Indirect effects also include the effects of proposed *modifications* on the *Design functions* of Structures, Systems and Components as found in the Safety Analysis. The Safety Analysis assumes certain *Design functions* of Structures, Systems and Components in demonstrating the adequacy of the Design. Thus, certain *Design functions* or Design parameters, while not specifically identified in the Safety Analysis, are credited in an indirect sense.

30. After determining the effect of the proposed *modification* on the Structures, Systems and Components that are important to Safety, a decision can be made on whether the likelihood of a malfunction of such Structures, Systems and Components has increased by more than a minimal amount. A 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.

31. 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 failure modes and effects' analyses as described in existing application documents. 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*. 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.

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

33. 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 a Safety system or Safety-related item:

    a) 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.

34. *Modifications* that would reduce system/ equipment redundancy, diversity, separation or independence would require prior approval from the Authority 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.

35. Examples below illustrate cases where there would not be more than a minimal increase in the likelihood of occurrence of a malfunction of a Structure, System and Component that is important to safety.

    a) The change involves installing additional equipment or devices (e.g. cabling, manual valves, protective features) provided that all applicable Design and functional requirements (including applicable codes, standards, etc.) continue to be met. For example, adding protective devices to breakers or installing an additional drain line (with

appropriate isolation capability) would not cause a more than minimal increase in the likelihood of malfunction.

b) The change involves substitution of one type of component for another of similar function provided that 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.

c) The change involves a new or modified Operator action that supports a Design function credited in the Safety Analyses provided that:

I. The action (including required completion time) is reflected in plant procedures and Operator training programmes.

II. One has demonstrated that the action can be completed in the time required considering the aggregate affects such as workload or environmental conditions, which are expected to exist when the action is required.

III. The evaluation of the change considers the ability to recover from credible errors in performance of manual actions, and the expected time required to make such a recovery.

IV. The evaluation considers the effect of the change on plant systems.

36. Examples below illustrate cases where there would be more than a minimal increase in the likelihood of there being a malfunction of a Structure, System and Component that is important to Safety.

a) The change would cause Design stresses to exceed their code allowable or other applicable stress or deformation limit (if any) including vendor-specified stress limits for pump casings that ensure pump functionality.

b) The change would reduce system/equipment redundancy, diversity, separation, or independence.

c) The change would (permanently) substitute manual action for automatic action for performing *Design functions* as described in application documents.

The modification results in a change in the consequences and /or a reduction in safety margin of an Accident previously evaluated in the application documents

37. In relation to the criterion, *the modification results in a change in the consequences and/ or a reduction in the Safety margin 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 more than a minimal increase in consequences, it must be

recognised that the objective is the protection of public health and Safety as well as maintaining the Safety margin as documented in the application documents. The Safety margin is the difference between the calculated results against the regulatory acceptance criterion. For example, the calculated peak clad temperature against the regulatory allowable value represents the Safety margin for the Accident under consideration. That is, it represents the Safety envelope accepted by the Authority and any reduction represents a degradation to Safety. Therefore, an increase in consequences must involve an increase in radiological Doses to the public, on-site personnel, or to control room Operators as well a reduction in the Safety margin. Changes in barrier performance or other outcomes of the proposed activity that do not result in increased radiological Dose to the public, on-site personnel, or to control room Operators are addressed under the other criteria on *significance evaluations* as found in Article (8) paragraphs 59 to 70 of this regulatory guide.

38. *Modifications* affecting on-site or off-site Dose consequences, or a reduction of the existing Safety margin will require prior Authority approval.

39. The consequences from any Accident included in the application documents need to be evaluated. The Accidents include those typically covered in Chapters 6, 15, and 19 of the Final Safety Analysis Report, 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 *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' (i.e. ALARA) through formal Licensee Radiation Protection programmes.

40. FANR Regulation for Radiation Dose Limits and Optimisation of Radiation Protection for Nuclear Facilities (FANR-REG-04) establishes requirements for protection against radiation during normal operations and Decommissioning. *Significance evaluations* of Accident Dose consequence criteria and evaluation guidance are not applicable to proposed activities governed by the requirements of FANR-REG- 04.

41. For a given Accident, calculated Dose values and the existing Safety margin for that Accident would be identified in the application documents. The revised consequences from a proposed *modification* is defined to be no more than minimal if (i) the increase is less than or equal to 10 percent of the difference between the current calculated Dose value and the regulatory guidance value or (ii) the reduced Safety margin is less than 10% of the existing margin.

42. If a proposed *modification* would result in more than a minimal change from the existing calculated consequences for any Accident, then the *modification* would require prior Authority approval.

43. In order to determine 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 and/ or existing Safety margin affected as a direct result of the proposed *modification*. Examples of questions that assist in this decision are:

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

    b) Will the proposed *modification* alter assumptions previously made in evaluating the radiological consequences of an Accident described in the application documents?

c) Will the proposed *modification* play a direct role in mitigating the radiological consequences of an Accident described in the application documents?

44. The next step is to quantify the effects of the *modification* on either the increased radiological consequences or the reduced Safety margin of any of the Accidents evaluated in the application documents.

45. Revise and document the analysis taking into account the proposed *modification* and determine if more than a minimal change of 10% has occurred as described above.

The modification results in more than a minimal increase in the consequences of a malfunction of a Structure, System and Component important to Safety previously evaluated in the application documents

46. As per paragraphs 37 to 45 above, changes in the consequence of the *modification* is quantified. In relation to the criterion, *the modification results in more than a minimal increase in the consequences of a malfunction of a Structure, System and Component important to Safety previously evaluated in the application documents*: if the *modification* results in more than a minimal increase or a reduction in the Safety margin in the consequence of any Accident described in the application documents, the Authority's approval is required to implement the *modification*.

The modification creates a possibility for "an Accident of a different type" than any previously evaluated in the application documents

47. In relation to the criterion, *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 referred to in this criterion is 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.

48. 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'.

49. The possibility of Accidents of a different type is limited to Accidents 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 described 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 so 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 sample Accidents could already be discussed in the application documents.

50. Here is an example of an Accident of a different type:

    a) A proposal to build a new railway track next to the station can potentially create an Accident of a different type not evaluated in the application documents if the train will transport new hazardous cargo that was not analysed in the application documents. The operating units may be exposed to the hazardous substance or toxic gases not previously evaluated in the application documents due to a train derailment or explosion.

51. When 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'.

The modification creates a possibility for a malfunction of a Structure, System and Component Important to Safety with a different result than any previously evaluated in the application documents

52. In relation to the criteria, *the modification creates a possibility for a malfunction of a Structure, System and Component important to safety with a different result than any previously evaluated in the application documents*: malfunctions of Structures, Systems and Components 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 examples illustrates this point:

    a) 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 (i.e. the failure of the pump to run) was previously evaluated and bounded then a malfunction with a different result has not been created.

    b) If a feedwater control system is being upgraded from an analogue to a digital system, new components may be added that could fail in ways other than the components in the original Design. Provided the end result of the component or sub-system failure is the same as (or is bounded by) the results of malfunctions currently described in the application documents (i.e. failure to maximum demand, failure to minimum demand, failure 'as-is', etc.), then this upgrade would not create a malfunction with a different result.

53. 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.

54. 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.

55. 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.

56. In evaluating a proposed *modification* against this criterion, the types and results of failure modes of Structures, Systems and Components 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 in line with any failure modes and effects analysis described in the application documents whilst taking into account that certain proposed activities may require a new failure modes and effects analysis 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. 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.

57. 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 can be identified.

58. Comparing the two lists can provide the answer to the criterion. 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. Here is an example:

    a) The *modification* involves the installation of a pipe or component in a new area. A pipe break in this area was not analysed previously in the application documents. Such accident may result in an accident with a different results.

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

59. In relation to the criterion, *the modification results in a Design basis limit for a fission product barrier as described in the application documents being exceeded or altered*: *significance evaluations* under the criterion focus on the fission product barriers (i.e. fuel cladding, reactor coolant system 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:

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

60. 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:

    a) The parameter is fundamental to the barrier's integrity. Design basis limits for fission product barriers establish the reference bounds for the Design of the barriers. They are the limiting values for parameters that directly determine the performance of a fission product barrier i.e. the 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.

61. 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 basis parameters/ limits that ensure fission product barrier integrity. For example, auxiliary feedwater Design flow is a subordinate parameter for purposes of this evaluation, not a Design basis parameter/ limit. The acceptability of a reduction in the auxiliary feedwater Design flow would be determined based on its effect on the limits of the Design basis for the reactor coolant system (e.g. reactor coolant system pressure).

    a) 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.

    b) The limit is identified in the application documents. They may be located in a vendor’s topical report that is incorporated by reference in the application documents.

62. 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.

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

Barrier	Design Basis Parameter	Typical Design Basis Limit
Fuel Cladding	Departure from Nucleate Boiling Ratio (DNBR)	Value corresponding to the 95/95 Departure from Nucleate Boiling (DNB) criterion for a given Departure from Nucleate Boiling (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 a specific Accident
Containment	Pressure	Containment Design pressure

Table 1: Examples of Fission Barrier Limits

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

    a) Licensees of pressurised water reactors may use a 100% pressuriser level as a limiting parameter to ensure reactor coolant system integrity for some Accident sequences

    b) A peak containment temperature may be established in the application documents as an independent limit for ensuring the integrity of the containment.

65. 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.

66. 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 *significance evaluations*. Alternatively, the effects of a proposed *modification* could be evaluated first to determine if the change affects Design basis parameters for fission product barriers. The results of these two approaches are equivalent provided that the guidance is followed for *exceeded or altered* as described below (i.e. paragraph 67). In all cases, the direct and indirect effects of proposed *modifications* must be included in the evaluation.

67. A specific proposed *modification* requires prior approval from the Authority 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 has changed.

68. The effect of the proposed *modification* includes both direct and indirect effects. Extending the maximum fuel burn-up limits until the fuel rod’s internal gas pressure exceeds the Design basis limit is a direct effect that would require the Authority’s 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 reactor coolant system to the steam generators. That effect could increase the reactor coolant system temperature, which would raise the pressure and pressuriser level of the reactor coolant system. The *significance evaluations* of this change would focus on whether the Design basis limit associated with the pressure of the reactor coolant system for that Accident sequence would be exceeded.

69. 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 Departure from the Nucleate Boiling Ratio (DNBR) value from the value corresponding to the 95/95 criterion for a given Departure from the Nucleate Boiling (DNB) correlation perhaps as a result of a new fuel Design being implemented; a new correlation or a new value for the 95/95 Departure from the Nucleate Boiling (DNB) criterion with the same fuel type would be evaluated below. Another example is re-Designing sections of the reactor coolant system boundary to no longer comply with the code of Construction. These are infrequent activities affecting key elements of the

Defence-in-Depth approach. As such, no distinction has been made between a conservative and non-conservative change in these limits. In contrast with these examples, altering the auxiliary feedwater Design flow or other subordinate parameter/ limit is not subject to the 'may not be altered' criterion because the auxiliary feedwater Design flow is not a Design basis limit for fission product barrier integrity.

70. 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 *significance evaluations* against this criterion are 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 or additional analysis 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.

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

71. In relation to the criterion, *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. In cases where the analytical methodology was considered to be an important part of the conclusion that the Facility met the required Design basis, such analytical methods would have been described in the application documents and been approved by the Authority after having undergone various reviews during the licensing process.

72. As *significance evaluations* provide a process to determine if prior approval from the Authority 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 *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.

73. If the proposed *modification* does not involve a change to a method of evaluation, then the *significance evaluations* should reflect that this criterion is not applicable. If the *modification* involves only a change to a method of evaluation, then the *significance evaluations* should reflect that change in the frequency of occurrence in accordance with Article (8) paragraphs 20 to 70 above.

74. The first step to applying this criterion (i.e. Article (8) paragraph 71) 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 (8) paragraphs 16 to 17.

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

    a) Changes to any element of analysis methodology that yield results that are not conservative or not essentially the same as the results from the analysis of record.

b) Use of new or different methods of evaluation that are not previously approved by the Authority for the intended application.

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

a) A departure from methods of evaluation that are not described, outlined or summarised in the application documents; such changes may have been deemed 'screened out' as discussed in Article (8) paragraphs 1 to 8.

b) The 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 (i) based on sound engineering practice, (ii) appropriate for the intended application, and (iii) within the limits of the applicable Safety Evaluation Report. The basis for such determination should be documented in the Licensee's evaluation against this criterion.

c) 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 Safety Evaluation Report.

77. The following provides guidance on:

a) Making changes to one or more elements of an existing method of evaluation used to establish the Design basis or in the Safety Analysis.

b) Adopting an entirely new method of evaluation to replace an existing one.

c) Examples illustrating the implementation of this criterion.

(a) Guidance for changing one or more elements of a method of evaluation

78. The Licensee can make changes to methods of evaluation where the results are 'conservative' or are not important with respect to the demonstrations of performance that the analysis provides. 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

79. 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 *significance evaluation*. Such departures require prior approval from the Authority of the revised method. Analytical results obtained by changing any element of a method are not conservative in relation to the previous results if they are closer to Design basis limits or Safety Analysis 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 non-conservative change when applying this criterionIn other words, the revised method is not conservative if it predicts more severe conditions given the same set of input. This results in a reduction in the Safety margin and thus would require the Authority's approval.

80. 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 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"

81. The Licensee may change one or more element of a method of evaluation such that results move in the conservative direction without prior approval from the Authority 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 calculation 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 approval from the Authority.

82. In order to determine whether a new analysis result would be considered 'essentially the same' as the previous result, the revised method can be benchmarked against the existing one, or it 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 to determine whether two methods yield results that are 'essentially the same'.

(b) Guidance for changing from one method of evaluation to another

83. The Licensee can 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, limits and conditions for its use are satisfied.

84. It is incumbent upon the user of a new methodology to ensure that all conditions and limits under which the method received the Authority's 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 approval from the Authority. Methods that have been otherwise accepted as part of another plant's licensing basis (Shin Kori 3&4) are still subject to the Authority's approval. The Licensee may continue to seek plant-specific approval to use new methods of evaluation.

85. When considering the application of a methodology, it is necessary to adopt the methodology and apply it in line with applicable terms, limits and conditions. Mixing attributes of new and existing methodologies is considered a revision to a methodology and must be evaluated as such per the guidance in bullet (a) above.

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

86. The following questions highlight important considerations to determine 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 approval from the Authority:

    a) Is the application of the methodology consistent with the Licensee's licensing basis?
    b) Will the methodology supersede a methodology addressed by other regulations or the plant's technical specifications or severe Accidents Operation Licence condtions?
    c) Is the methodology consistent with relevant industry standards?

87. 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 approval from the Authority 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.

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

88. 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.

89. 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:

    a) How could those differences affect the methodology?

    b) Are additional sensitivity studies required?

    c) Should additional single failure scenarios be considered?

    d) Are analyses of limiting scenarios, effects of equipment failures, etc. applicable for the specific plant Design?

    e) Can analyses be made while maintaining compliance with both the intent and literal definition of the methodology?

90. Differences in the plant configurations and licensing basis 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's approval basis for the method, then the method cannot be considered approved for the intended application.

91. The following example illustrates the implementation of this criterion: the Final Safety Analysis Report 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 to establish the seismic Design basis for the piping, and since this is a change to an element of the method that is not conservative and not 'essentially the same', this change would require prior approval from the Authority under this criterion (i.e. Article (8) paragraph 71). If the Authority had approved an alternate method of seismic analysis that allowed 2 percent damping provided that 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'.

Disposition of the Evaluation

92. There are two possible conclusions to a *significance evaluation*:

    a) The proposed *modification* may be implemented without prior approval from the Authority.

    b) The proposed *modification* requires prior approval from the Authority.

93. A *modification* is considered to be 'implemented' when it is incorporated in the Facility. Thus, the Licensee may design and plan a *modification* prior to receiving approval from the Authority to the extent that these preliminary activities do not themselves require prior approval from the Authority.

94. For proposed activities that require prior approval from the Authority, there are three possible options:

    a) Cancel the proposed *modification*.

    b) Re-design the proposed *modification* so that it may proceed without prior approval from the Authority.

    c) Apply for and obtain approval from the Authority prior to implementing the *modification*. Technical and licensing evaluations performed for such *modifications* may be used as part of the basis for approval requests.

95. It is important to remember that determining if a proposed *modification* requires prior approval from the Authority does not determine that it is safe. In fact, a proposed *modification* that requires prior approval from the Authority may significantly enhance overall plant Safety but result in a small adverse impact in a specific area. It is the responsibility of the Licensee to ensure that proposed *modifications* are safe.

Documentation and Reporting

96. For information on documentation and reporting requirements, see Article (12) of this regulatory guide.

Modifications to the Organisational Arrangements as described in the Application Documents Article (9)

Description and Overview

1. Performing the screening and subsequent significance evaluation for modifications to Structures, Systems and Components in Nuclear Facilities as described in Article (8) of this regulatory guide follows a well-understood process used by nuclear regulators and Licensees in multiple countries. However, for the screening and significance evaluation of Organisational Arrangements (as explained below), there is limited practical guidance available. (The International Atomic Energy Agency (IAEA) provides only limited, general guidance.)
2. This Article provides guidance for the process and criteria to be used by the Licensees of Nuclear Facilities during operations to determine if a proposed *modification* to the Organisational Arrangements described in the application documents requires prior approval by the Authority before its implementation. Specifically, screening, and in some cases evaluation, is applicable to *modifications* that result in a change, addition, or removal that affects:
    a) The Management System including any Level 0 main processes or Level 1 sub-processes or programmes directly impacting the Structures, Systems and Components or Operation of the Nuclear Facility.
    b) The Quality Assurance programme.
    c) The Licensee's organisational structure, or Corporate Governance areas described in the application documents such as:
        I. The Licensee's joint venture arrangements and agreements.
        II. Financial instruments and arrangements including insurance.
        III. Civil liability for nuclear damages.
        IV. The Decommissioning trust fund.

Screening and Evaluation

3. Screening is the part of the process that determines whether a *significance evaluation* is required prior to implementing a proposed *modification*, i.e. the modification 'screens-in'. Evaluation is the part of the process, which determines for *modifications* that 'screen-in', whether a *modification* must be submitted for the Authority's approval. This is similar to the process for Structures, Systems and Components described in Article 8 of this regulatory guide.
4. Article 9, however, is different from Article 8. In Article 9, *modifications* to the Quality Assurance programme and organisational structure should undergo screening and evaluation. The other areas of Organisational Arrangements (Level 0 and Level 1 processes, programmes and Corporate Governance) require no screening or evaluation because any *modifications* in these areas must be submitted to the Authority for approval. No analysis is necessary. This is explained further in each area. Appendix 3 Screening and Evaluation Flowchart for Organisational Arrangements illustrates this approach.

5. Where it is required as part of the two-step process, the *significance evaluation* needs to reflect the potential Nuclear Safety impact of *modifications*. Under the two-step process, all changes can undergo initial screening in which the potential Safety impact is assessed, the level of analysis needed is determined, and decisions not to carry out a more detailed assessment (for changes that have little or no Safety impact) are documented.

Screening Process Overview

6. In order to determine how a proposed *modification* affects the Organisational Arrangements, a complete understanding of the proposed change is essential. Screening must be carried out by qualified personnel.
7. In the two-step process, the Licensee determines the need for a *significance evaluation* by carrying out screening activities based on the guidance and examples discussed in each area. Activities that do not meet these criteria are said to 'screen out' from further review i.e. may be implemented without a *significance evaluation* and would not require the Authority's approval. Documentation and record-keeping requirements for screening are described in Article (12) of this regulatory guide. Activities that are deemed to 'screen out' may nonetheless require information in the application documents to be updated.
8. The screening process is straightforward for Corporate Governance, Level 0 main processes and Level 1 sub-processes, and programmes. If there is a change from what was submitted in application documents (other than minor editorial revisions that do not change the meaning or intent) then the change should be submitted to the Authority for approval. An analysis would be necessary to explain to the Authority the reason for the change, but no analysis or evaluation is needed to determine if the change should be reported since it is simply a 'yes' or 'no' decision. A record should be maintained of revisions as per Article (12) of this regulatory guide.
9. In the Quality Assurance programme and the Licensee's organisational structure, proposed *modifications* that might have an adverse effect such as a decrease in capability or a reduction in the level of compliance with standards or requirements, needs to be evaluated against the criteria in a *significance evaluation*. *Modifications* that could have an adverse impact would be deemed to 'screen in'.

Significance Evaluation Process Overview

10. For those areas of Organisational Arrangements that require the two-step process, a *significance evaluation* determines if a proposed *modification* requires prior approval from the Authority before its implementation. *Significance evaluations* should be applied to any *modification* that has been 'screened in'. This includes any *modification* that could potentially have a significant impact on Nuclear Safety.

11. Once it has been determined that a *modification* requires a *significance evaluation*, the written evaluation must address the applicable IAEA criteria listed below in paragraphs 12 and 13. Such criteria are used to evaluate the effects of proposed *modifications* on the Operation of the Nuclear Facility.

The modification potentially results in a major reduction in the standards of Nuclear Safety (i.e. a major Nuclear Safety impact) with the potential for on-site and off-site impact

12. In relation to the criterion, *the modification potentially results in a major reduction in the standards of Nuclear Safety (i.e. a major Nuclear Safety impact) with the potential for on-site and off-site impact*: This *modification* must be submitted to the Authority for approval. Examples include (but are not limited to):

    a) Wide-ranging company or site changes that have the potential to affect the validity of (or basis on which) the nuclear site Licence was granted.

    b) Changes involving more than one business unit, division or site.

    c) Large-scale downsizing or outsourcing of a significant function in relation to Nuclear Safety.

The modification potentially results in a significant reduction in the standards of Nuclear Safety (i.e. a significant Nuclear Safety impact) with the potential to affect large parts of (or the whole) site

13. In relation to the criterion, *the modification potentially results in a significant reduction in the standards of Nuclear Safety (i.e. a significant Nuclear Safety impact) with the potential to affect large parts of (or the whole) site*: This *modification* must be submitted to the Authority for approval. Examples include but are not limited to:

    a) Changes that affect people within a whole Facility.

    b) Changes that affect a whole department or impact Safety-related functions, roles and responsibilities of staff.

    c) Changes that affect several levels of management.

    d) A significant reduction in the size of a team that has a Safety role such as Nuclear Performance Improvement (NPI).

    e) Changes resulting in a significant transfer of key Safety accountabilities and responsibilities such as those associated with control room Operator duties.

    f) Changes to staff shift patterns that impacts shift operating personnel.

The modification potentially results in a minor reduction in the standards of Nuclear Safety (minor Nuclear Safety impact) with the potential to affect a single plant, department or business unit

14. In relation to the criterion, *the modification potentially results in a minor reduction in the standards of Nuclear Safety (minor Nuclear Safety impact) with the potential to affect a single plant, department or business unit*: It is not required to report this type of *modification* to the Authority. Examples include (but are not limited to):

    a) *Modifications* that affect staff (only) within a process area that impacts Safety.

    b) *Modifications* that affect a small group of staff such as part of a department.

    c) Small reductions in the size of a team.

d) Transfer of responsibilities between units or departments.

The modification has <u>negligible or no impact</u> on Nuclear Safety

15. In relation to the criterion, if *the modification has negligible or no impact on Nuclear Safety*, it is not required to report the *modification* to the Authority. Examples include (but are not limited to):

    a) Changes to organisational responsibilities that do not lead to a significant increase in the workload of any line manager or group of staff.

    b) A reduction in the size of a team that has little or no Safety role.

    c) Departure or reassignment of staff after completion of a project.

16. When performing the *significance evaluation*, some *modifications* may fall partially under more than one area. In these situations, a conservative approach should be taken, and the change at the higher level should be taken into account.

17. The impact from changes to Organisational Arrangements are not always obvious. The magnitude of the impact in the standards of Nuclear Safety must be evaluated case by case using a systematic approach. A full account of any operational experience must also be taken into consideration. Below are some examples of changes to Organisational Arrangements which impacted Safety in a detrimental way when those changes have been poorly implemented. The Licensee should take these examples into consideration during their evaluation of changes.

    a) **The *modification* aims to reduce costs thereby improving financial performance.** The drive to reduce costs could result in inadequate resources being made available to maintain all the components of the plant at a high level of reliability. Although these decisions could lead to short-term improvements in the financial state of the company, long-term Safety could suffer.

    b) **The *modification* involves downsizing and/ or 're-engineering' of the companies involved with plant operations.** This *modification* could result in understaffing and a lack of competent staff. Outsourcing could lead to difficulties in maintaining the availability of the necessary expertise in contractors and to an overreliance on external sources of expertise, which cannot be guaranteed in the long-term. The reduction of management levels could result in inadequate supervision or oversight of staff work.

    c) **The *modification* affects available resources for training and retraining staff.** Cost reduction programmes could lead to reduced resources being made available for training and retraining staff. This can lead to instances where the qualifications of staff needed to assess the significance of Design changes or to maintain key pieces of equipment are inadequate.

    d) ***Modifications* to procurement policies.** The reduction of spare parts inventory arising from this type of change may result in shortcuts being taken in Maintenance particularly where there is significant pressure to keep outage times short.

    e) **Downstream effects of *modifications* on staff values and Safety culture.** The impact of changes to Organisational Arrangements are sometimes difficult to assess, and management should consider the potentially negative effect of a change on staff morale and plant Safety culture as part of their evaluation. Changes that are seen as threats to individuals or their Safety

values can have an adverse effect on their state of mind, commitment to the organisation and contribution to Safety culture.

Those attributes of a good Safety culture (e.g. reporting of near-misses, maintaining a challenging and questioning attitude, and working in teams to identify and achieve improvement opportunities) can be early casualties if individuals feel that their values are no longer congruent with those of the organisation. For example, Safety engineers may be less inclined to press for a fully acceptable Safety case for a Design change as they have traditionally done if a company's changes to the Organisational Arrangements lead to a perception that cost reduction is more highly valued than Safety.

Management System Modifications

18. The Management System consists of Level 0 main processes, level 1 sub-processes, and programmes. A clear line of traceability is required for any changes to the application documents that were submitted and reviewed by the Authority as part of the Operation Licence application. Therefore any *modification* to a Level 0 main process, Level 1 sub-process or a programme should be submitted to the Authority for approval. No evaluation is required to decide if a report is to be submitted. All three are subject to the one-step process and require that any change be submitted to the Authority for approval.
19. Minor editorial changes that have no impact on the meaning can be submitted as a change without any elaboration other than specifying that the changes are editorial only and do not change the meaning ascribed to them in the application documents. Other changes must be submitted for approval prior to implementation with a full justification for those changes.
20. The report to the Authority should specifically state whether the revised programme description and process description document(s) depart significantly from what the Authority had previously reviewed and accepted. Examples of *modifications* that are not merely editorial in nature include (but are not limited to):

    a) Any significant departure from (or non-conformance with) the previous revision in areas such as (but not limited to) objectives, regulations and which regulatory guides of the US Nuclear Regulatory Commission are followed.

    b) Changes to a programme with direct impact on the performance of Structures, Systems and Components (i.e. Maintenance rule) as discussed in Article 30 of FANR Regulation for Operational Safety including Commissioning (FANR-REG-16). In this example, if the change deviates from the Maintenance rule programme description in the application documents, the change would need to be reported.

    c) Changes to a WM003, WM004, WM005, WM009 (i.e. Perform Maintenance Process Description) as discussed in Article 30 of FANR-REG-16. If the objectives of the Perform Maintenance Process Description are changed to delete the scope of work for Predictive Maintenance, that would be deemed non-compliance with Article 30 of FANR-REG-16, and the change would need to be reported.

QA Programme Modifications

21. Modifications to the Quality Assurance programme are subject to the two-step process of screening and, if required, evaluation to determine if the *modifications* should be submitted to the Authority for approval.
22. After the Quality Assurance programme as described in Licence application documents has been accepted by the Authority, any proposed *modifications* should be analysed to determine their consequences for safe Operation, and proposals should be submitted to the Authority, if required, for approval or review before implementation. Examples of *modifications* that would be deemed to 'screen in' include:

    a) The Nawah Quality Assurance Programme Manual previously accepted by the Authority (is changed to a different standard than ASME NQA-1:1994 (with 1995 Addenda).

    b) A change that deletes incoming inspection Quality Assurance requirements from the Nawah Quality Assurance Programme Manual.

    c) A change to the requirement for storage of non-permanent records that provide evidence of activities affecting quality.

Organisational Structure Modifications

23. Modifications to the Licensee's Organisational Structure are subject to the two-step process of screening and, if required, evaluation, to determine if the *modifications* should be submitted to the Authority for approval.
24. After the operating organisation structure as described in Licence application documents has been accepted by the Authority, any proposed *modifications* including changes to numbers of staff and Safety related positions should be analysed to determine their consequences for safe Operation, and proposals should be submitted to the Authority, if required, for approval or review before implementation.
25. An example of a more specific screening checklist to manage *modifications* to the organisational structure is presented in the table below. If the answer is 'yes' to any position listed in the table below under heading (A), and/ or the change is of a type listed in the table below under heading (B), then there may be potentially significant Safety impacts and a more detailed assessment is required, i.e. the *modification* is deemed to 'screen in'. The checklist below is only an example. The Licensee should adapt the screening checklist to its specific Organisational Arrangements.

(A) Does the change have a potential Safety impact on the functions mentioned below? Select 'yes' or 'no'.	Yes	No
Main Control Room staff		

Line supervisor or manager		
Maintenance staff		
Radiation Protection supervisor		
Radiation Protection staff		
Licensing manager		
Technical support staff		
(B) Will the change affect any of the following? Select 'yes' or 'no'.	Yes	No
Reduction in the number of job positions		
Reduction in the number of persons in those positions		
Significant increase in duties		
Significant change in responsibilities		
Changes to lines of reporting		
Changes to hierarchical structure of an organisation		

Table 2: Checklist

Corporate Governance Modifications

26. Corporate Governance, as used in this regulatory guide, includes the following:

a) Licensee's joint venture arrangements and agreements.

b) Financial instruments and arrangements including insurance.

c) Civil liability for nuclear damages.

d) Decommissioning trust fund.

27. The one-step process is applied for all Corporate Governance issues. Any changes to these subjects from what is provided in the application documents are required to be submitted to the Authority for approval. Minor editorial changes that have no impact on the meaning can be submitted as a change without the need to elaborate other than noting that the changes are editorial only and do not change the meaning ascribed to them in the application documents. Other changes must be submitted to the Authority for approval prior to implementation with a full justification for those changes.

28. Screening is not required if a requirement to report the *modification* already exists. For example:

a) The *modification* requires an amendment to the Licence.

b) The *modification* requires the Authority's approval as stipulated by applicable laws or regulations or a Licence condition.

c) The Licensee decides to submit a request to the Authority for approval of a *modification* and forego the screening process.

Disposition of the Evaluation

29. *Modifications* identified in the one-step process discussed previously require approval from the Authority prior to implementation. The Licensee should provide the Authority with a request for approval that explains the *modification*, the reasons for the *modification*, and the resulting implications of the change.

30. *Modifications* identified in the two-step process result in either a determination that the changes need to be assessed for significance, or, there is a Safety significance, which requires an evaluation.

There are two possible conclusions to a *significance evaluation*:

a) The proposed *modification* may be implemented without prior approval from the Authority.

b) The proposed *modification* requires prior approval from the Authority.

31. If the screening and evaluation criteria is met, the Licensee must apply to the Authority for approval prior to implementing the *modification*. The evaluation against this criterion should be appropriately documented and provide the *significance evaluation* criteria as well as offer guidance and examples to evaluate the proposed *modifications*.

32. Determining a proposed *modification* requires prior approval from the Authority but does not in itself define if it is safe. A proposed *modification* that requires prior approval from the Authority may significantly enhance overall plant Safety at the expense of a small adverse impact in a specific area. Similarly, the improvement of plant Safety in a specific area could create negative overall consequences. It is the responsibility of the Licensee to evaluate *modifications* completely in order to ensure they are safe.

33. A *modification* is considered to be implemented when it is incorporated in the Facility or approved for use. Thus, the Licensee may design and plan a *modification* prior to receiving approval from the Authority to the extent that these preliminary activities do not themselves require prior approval from the Authority.

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

    a) Cancel the proposed *modification*.

    b) Revise the proposed *modification* so that it may proceed without prior approval from the Authority.

    c) Apply for (and obtain) approval from the Authority prior to implementing the *modification*. Technical and licensing evaluations performed for such *modifications* may be used as part of the basis for approval requests.

Documentation and Reporting

35. For information on documentation and reporting requirements, see Article (12) of this regulatory guide.

Modifications to On-Site Emergency Plan for Nuclear Facilities
Article (10)

1. The Licensee may make *modifications* to its Emergency Plan without the Authority's approval only if the Licensee performs and retains the analysis documentation demonstrating that the *modifications* do not reduce the effectiveness of the plan, and the plan as modified continues to meet the requirements of FANR Regulation on Emergency Preparedness for Nuclear Facilities (FANR-REG-12) and FANR Regulation on the Requirements for Off-site Emergency Plans for Nuclear Facilities (FANR-REG-15). The *modification* process starts once a Licensee makes a *modification* to its Emergency Plan.
2. If another *modification* process controls the proposed *modification*, then you should put the other *modification* process into place. If the proposed *modification* is subject to one or more *modification* processes, compliance with all of the applicable *modification* processes is required. For example, a *modification* to the radiation monitoring system described in the application documents that is subject to a technical specification and that affects an Emergency Action Level (EAL) threshold could be subject to other *modification* processes.
3. This review process provides an acceptable method to screen, evaluate and submit *modifications* to the Authority for approval, and document the *modification* analysis.

Screening Modification

4. The Licensee should screen all proposed *modifications* to the Emergency Plan and changes to arrangements to determine whether a *significance evaluation* in line with Article (10) paragraphs 7 and 8 of this regulatory guide are necessary and whether another formal *modification* process identified in this regulatory guide is applicable. The purpose of this screening is not to decide how the proposed *modification* could reduce effectiveness but instead whether a *significance evaluation* is necessary. The Licensee should screen each proposed *modification* separately and reserve the treatment of *modifications* collectively for the following:

    a) Repetitive identical *modification*.

    b) Editorial or typographical *modifications* such as formatting, paragraph numbering, spelling, or punctuation that do not alter intent.

    c) Conforming modification.

    d) Two or more elements that are interdependent e.g. a *modification* to one element compensates for a *modification* to another element.

5. The screening *modification* that is deemed to 'screen out' and does not required further evaluation:

    a) The *modification* is editorial or typographical such as formatting, paragraph numbering, spelling, or punctuation that do not alter intent.

b) The *modification* does not involve any of the requirements on Emergency Preparedness in FANR-REG-12.

6. The Licensee should document this screening if it concludes that an evaluation is not necessary.

Significance Evaluation Process

7. The Licensee must evaluate proposed *modifications* to the Emergency Plan and changes to arrangements, which the above screening process in steps 4 through 6 of this Article did not determine whether the *modification* reduces the effectiveness of the Emergency Plan. The Licensee should submit to the Authority for approval any *modifications* that will reduce the effectiveness of the Emergency Plan before implementing those *modifications*.

8. The significance evaluation process should address the items listed below.

a) Identify the individual proposed *modifications* to be evaluated. Each proposed *modification* should be evaluated separately. The treatment of *modifications* collectively should be reserved for the following:

i. Repeated identical m*odifications*.

ii. Editorial or typographical *modifications* such as formatting, paragraph numbering, spelling, or punctuation that does not alter intent.

iii. Conforming *modifications*.

iv. Two or more elements that are interdependent e.g. a *modification* to one element compensates for a *modification* to another element.

b) For each proposed *modification*, determining the licensing basis for each existing 'programme element' that is being modified should take into account the following when performing an evaluation:

i. Regulatory requirements: the requirements of FANR-REG-12.

ii. Licence, Licence conditions and License amendments: the Facility's Licence may contain Emergency Preparedness commitments and requirements that are binding on the Licensee.

iii. Final Safety Analysis Report (application documents): requirements of Chapter 13.3 Emergency Planning.

c) Identify the Emergency Preparedness requirements affected by each proposed *modification*. Recognise that a proposed *modification* can affect more than one Emergency Preparedness requirement.

d) Evaluate whether each proposed *modification* would reduce the capability to execute Emergency Preparedness requirements.

e) Compare the Emergency Plan approved by the Authority with the *modifications* being considered to evaluate the Licensee's capability to continue to meet the Emergency Preparedness requirements. In other words, compare the Licensee's commitment in the current Emergency Plan approved by the Authority with what would be the commitment after the plan is modified. Plant reconfigurations enabled by other *modification* processes do not factor into this comparison. This is a 'yes' or 'no' decision; the *modification* would reduce the effectiveness of the Emergency Plan or it would not. There are no degrees of reduction; there is no 'minor' reduction). It is inappropriate for a Licensee to conclude that certain commitments made in the approved plan approved by the Authority are no longer required and to then compare the Emergency Plan as modified to this conclusion rather than the Authority-approved plan.

f) Maintain the level of rigor and thoroughness in the Licensee's evaluations in line with the scope of the proposed *modifications*. The Authority may consider Enforcement Action for any evaluations that are of inadequate scope and extent to reasonably assess the effect of the proposed *modification* on the effectiveness of the Emergency Plan.

g) Arrange a pre-application phone call with the Authority to discuss the proposed *modification* when the Licensee is unsure whether the proposed *modifications* continue to meet the Emergency Preparedness requirements. Ask the Authority to clarify the regulatory positions in this regulatory guide. Note that pre-application conference calls do not relieve the Licensee of its responsibility to determine whether the *modification* continues to meet the Emergency Preparedness requirements.

h) The Authority expects the Licensee to evaluate all alternative approaches as it would any proposed *modification* to determine whether the proposed approach reduces the effectiveness of the Emergency Plan.

i) The *modifications* to a Licensee's Emergency Plan that reduce the effectiveness of the plan may not be implemented without prior approval from the Authority. A Licensee who endeavours to make such a *modification* shall submit a request to the Authority for approval.

Disposition of Evaluation

9. The Licensee is required to submit a request to the Authority for prior approval of a *modification* that it believes will reduce the effectiveness of its Emergency Plan. In addition to the reporting requirements of Article 12, the application must include all Emergency Plan pages affected by the *modification* and a forwarding letter identifying the *modification(s)*, the reason for the *modification(s)*, and the Licensee's basis for concluding that its Emergency Plan, as revised, continues to meet the requirements of FANR-REG-12 and applicable requirements of FANR-REG-15.

Documentation of modification

10. The Licensee shall retain a record of each *modification* to the Emergency Plan and changes to arrangements made without prior approval from the Authority for a period of three years from the date of the *modification*. This record should explicitly identify each *modification* made and the basis for the Licensees conclusion that the *modification* would not require prior approval from the Authority. All conclusions should be supported by justifiable, rationale statements e.g. The proposed *modification* does not affect the Emergency Preparedness requirement because….'. The depth of rationale will vary according to the scope and nature of the *modification*; a simple check-list is generally not acceptable because it cannot represent what the reviewer considered nor can it explain the reviewer's basis for the conclusion.

11. The Licensee is required to submit a report on each *modification* including a summary of its analysis within 30 days after the *modification* has been implemented.

12. The Licensee is required to retain the Emergency Plan and each *modification* for which it has obtained prior approval from the Authority as a record until the Authority terminates the Licence for the Nuclear Facility. Although the Licensee is not required to maintain records of *modifications* made without prior approval from the Authority beyond three years, a lack of documentation on such *modifications* does not absolve the Licensee from having to justify any *modification* that is subsequently questioned on how it affects the Licensee's Emergency Plan. As such, a Licensee may find it prudent to save all Emergency Plan *modification* documentation to facilitate the resolution of such issues.

Modifications to Safeguards Arrangements
Article (11)

1. Managing *modifications* related to the regulatory field of safeguards is important to satisfy the United Arab Emirates' international nuclear non-proliferation obligations mainly with the International Atomic Energy Agency (IAEA). The requirements for managing *modifications* and involving the Authority in safeguards-relevant *modifications* stem from the FANR Regulation for the System of Accounting for and Control of Nuclear Material and Application of Additional Protocol (FANR-REG-10), the Safeguards Agreement including Subsidiary Arrangements (General Part and Facility Attachment(s)), and the Additional Protocol.
2. Managing *modifications* should be considered in terms of three categories: plant, procedures and people.
3. Plant: this category concerns physical changes to the Design or Operation of the Nuclear Facility (the term 'Facility' or 'Facilities' is used in Article 11 of this regulatory guide as defined in Article 1 of FANR-REG-10), or to the form, type use or Storage arrangements of Nuclear Material (as defined in Article 1 of FANR-REG-10). All Facilities require Design information to be provided in accordance with Article 18 of FANR-REG-10. Design information is requested by the Authority in the format of a Design Information Questionnaire (DIQ) as specified by the IAEA for different types of Facility. In considering plant *modifications*, the Licensee of a Facility should do the following:
    a) Inform the Authority pursuant to Article 18(2) of FANR-REG-10 as soon as the decision is made to modify the Facility, and before any *modifications* are made to aspects of the Facility (i.e. the plant) that would impact on the correctness and completeness of the latest Design Information Questionnaire submitted to the Authority, or on other information previously submitted to the Authority. The Licensee should be aware of the Facility Attachment document and the requirements for informing the Authority on *modifications* that may impact on the IAEA's

safeguards approach, or the ability of the IAEA or the Authority to verify Nuclear Material. Licensees of Facilities should ensure that their procedures (see paragraphs 4 (Procedures)) below on Nuclear Material accountancy and control, and physical inventory taking) reflect the relevant Facility Attachment requirements concerning *modifications*.

b) Apply for and receive written authorisation from the Authority before any plant *modifications* or activities that may impact on safeguards equipment (e.g. power supply or data connections of IAEA cameras/ seals and associated supporting systems for containment and surveillance) – see Article 6 (1)c of FANR-REG-10. Such application should be made to the Authority before any planned *modifications* or activities.

c) Notify the Authority before any changes to approved locations by the Licensee where Nuclear Material is used or stored – see Article 9 (1)c of FANR-REG-10. Such changes should also be reflected in the Design Information Questionnaire within the timescales specified in Article 18(3) of FANR-REG-10 or within twenty working days when specifically requested by the Authority to meet the UAE's safeguards obligations.

d) Notify the Authority in advance of any type of *modification* or change that may affect IAEA access or the Authority's safeguards inspectors or equipment for verification purposes.

4. Procedures: procedures for physical inventory taking and nuclear material accountancy and control must be submitted to the Authority for approval as part of the licensing process (see Article 5(3) of FANR-REG-10). The Licensee must notify the Authority in writing about any changes in the approved safeguards procedures. The Licensee should apply and receive written approval from the Authority for any changes proposed by the Licensee to the approved safeguards procedures, which may affect the application of the safeguards' obligations, the physical inventory taking of Nuclear Material or Nuclear Material accountancy and control.

5. People: the Licensee should designate a person who is responsible for the management of the system of Nuclear Material Accountancy and Control, and compliance with FANR-REG-10 (see Article 9(1) of FANR-REG-10). Any changes to the designated persons, deputies or other nominated contact persons should be notified to the Authority at the same time as new appointments or changes to appointments are made.

6. Licensees of Facilities should always seek guidance from the Authority when unsure of whether a particular *modification* is likely to impact on safeguards implementation. Licensees of Facilities are encouraged to meet the Authority on a regular basis to discuss safeguards implementation and any plans or thoughts concerning future changes.

Documentation and Reporting

Article (12)

1. The following documentation and record-keeping are required for *modifications* that require evaluation against the *significance evaluation* criteria (i.e. the *modification* is deemed to 'screen in') and are determined through *significance evaluation* to not require prior approval from the Authority:

a) The records of *modifications* must include a written evaluation (e.g. significance evaluation), which provides the bases for the conclusion that the *modification* does not require the Authority's approval.

b) The Licensee must submit a report containing a brief description of any *modifications* for which a *significance evaluation* was performed, including a summary of the evaluation of each mod.

The report must be submitted at intervals not to exceed six months.

c) The records of *modifications* in the Facility must be retained for the life of the Facility.

Documenting significance evaluations

2. In performing a *significance evaluation* of a proposed *modification*, the Licensee must address all of the *significance evaluation* criteria to determine if prior approval from the Authority is required. Although the conclusion in each criterion may be simply a 'yes', a 'no', or a 'not applicable', there must be an accompanying explanation that provides an adequate basis for the conclusion. These explanations should be complete in the sense that another knowledgeable reviewer could draw the same conclusion. Re-stating the criteria in a negative sense or making simple statements of conclusion is not sufficient and should be avoided. For certain basic activities, it would be adequate to identify the references in the conclusion to support it, and the *significance evaluation* could be brief.
3. The importance of the documentation is emphasised by the fact that experience and engineering knowledge/ judgement (other than models and experimental data) are often relied upon to determine 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 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.
4. Since an important goal of the *significance evaluation* is completeness, the items considered by the evaluator must be clearly stated. Each 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.
5. When preparing *significance evaluations*, the Licensee may combine responses to individual criteria or reference other parts of the evaluation.
6. As discussed in Article (6) of this regulatory guide, the Licensee may elect to use screening criteria to limit the number of *modifications* for which written *significance evaluations* are carried out. A documentation basis should be maintained for the determination of *modifications* against the screening criteria. Retention period requirements for this documentation are provided below.

Documentation and record-keeping for modifications that are "screened out"

7. 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 an Inspection by the Authority. Documentation of screening for *modifications* that 'screen out' shall be retained as permanent records.
8. The basis for the screening conclusion should be documented to a degree commensurate with the

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 *significance evaluation* has been performed or for *modifications* that were never implemented.

9. Documentation of the screening process is not required for *modifications* that are cancelled or that are determined to require prior approval from the Authority and are implemented via the Authority's approval or Licence amendment request process.

Reporting to the Authority

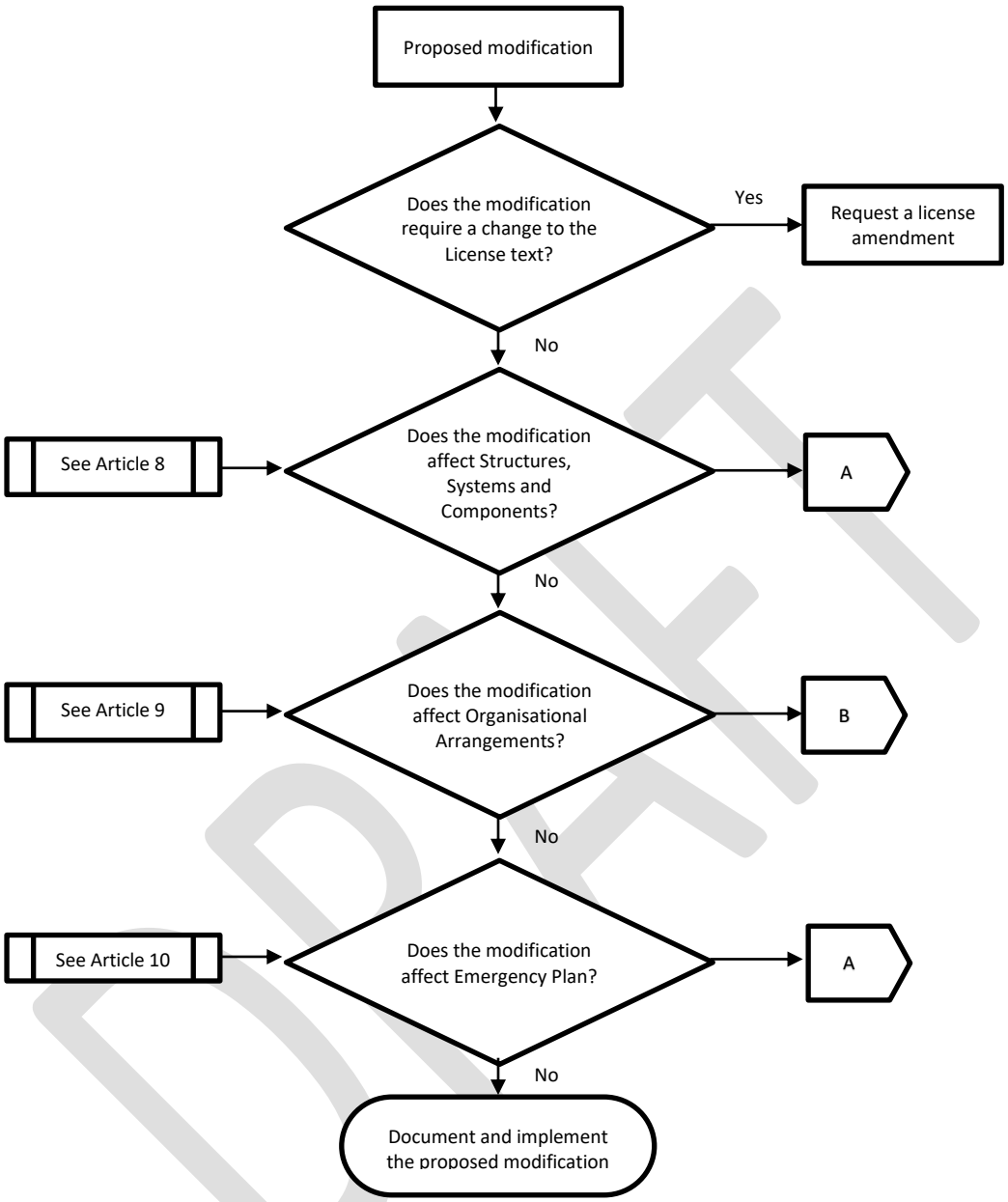
10. A summary of *significance evaluations* must be provided to the Authority every six months for *modifications* implemented without requiring approval. *Modifications* that were deemed to 'screen out', cancelled or implemented via the Authority's approval or a Licence amendment need not be included in this report.

References

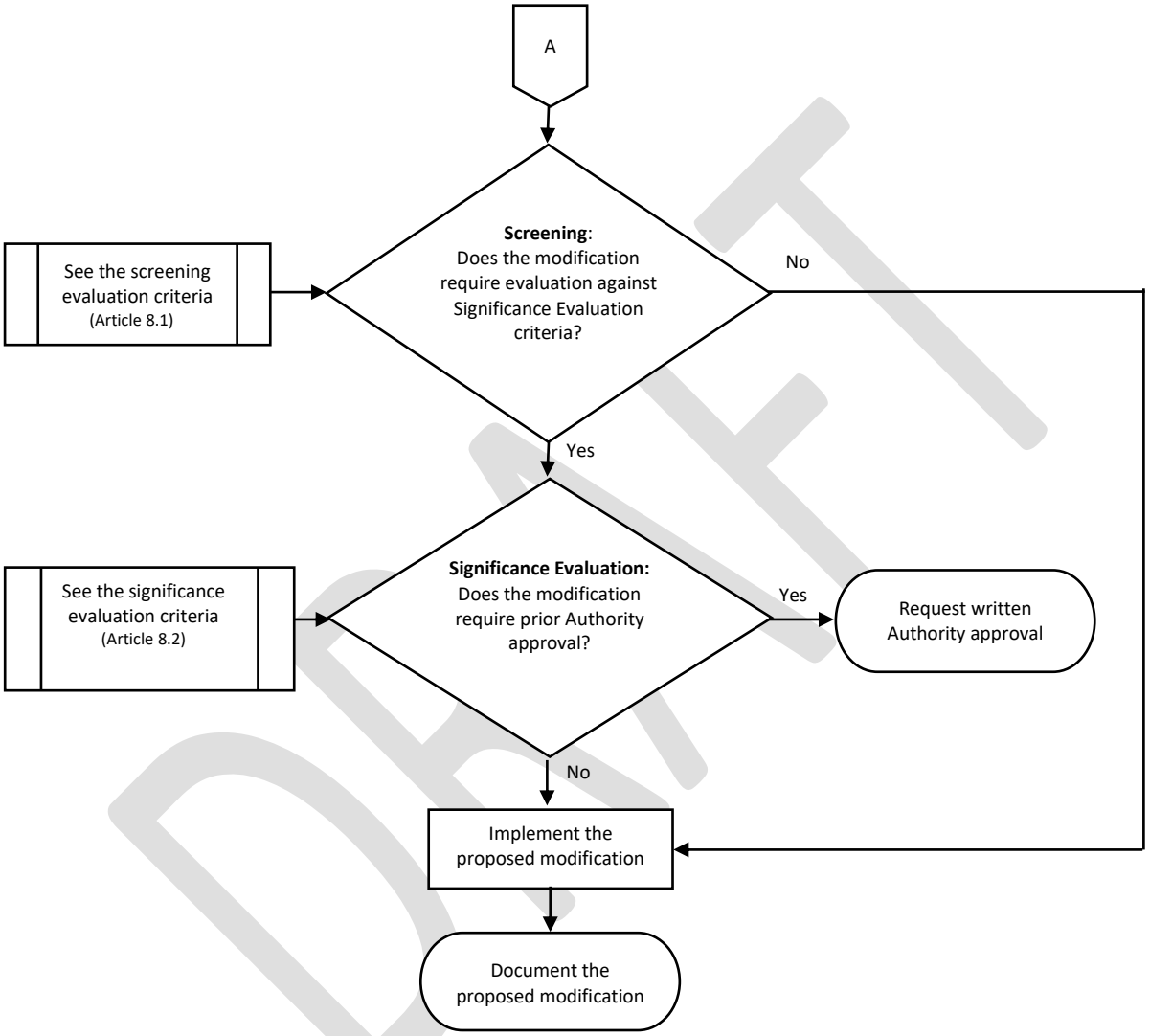
Article (13)

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, Safety Guide No. GS-G-3.5, 2009
4. FANR Regulation FANR-REG-16, “Regulation for Operational Safety including Commissioning”
5. FANR Regulation, FANR-REG-04, “Regulation for Radiation Dose Limits and Optimisation of Radiation Protection for Nuclear Facilities”
6. FANR Regulation, FANR-REG-12, “Regulation for Emergency Preparedness for Nuclear Facilities”
7. FANR Regulation, FANR-REG-15, “Regulation for Requirements for Off-site Emergency Plans for Nuclear Facilities”

APPENDIX 1 - Significance Evaluation Process



APPENDIX 2 - Significance Evaluation Process for Structures, Systems and Components



APPENDIX 3 - Screening and Evaluation Process for Organisational Arrangements